CASA Regulatory Subgroup
Land Committee

The November 12, 2015 meeting is a Conference Call held concurrently with the CASA Regulatory Water Committee

Dial-in Number: (712) 432-1212
Meeting ID: 637-929-852#

Committee Meeting
10:30 AM – 12:30 PM

Next Meeting – December 10, 2015
Annual Luncheon and Holiday Gift Exchange
Boy Scout Council
San Leandro, CA
# CASA Biosolids Land Committee Agenda

**November 12, 2015**

**Conference Call**

**10:30 AM – 12:30 PM**

## Topics

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<tr>
<th>1. County Updates</th>
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<tr>
<td>Kern County Litigation Update</td>
<td>G. Kester, Diane Gilbert</td>
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<td>Ordinance Status</td>
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<td>G. Kester/L. Baroldi/D. Gilbert/T. Meregillano</td>
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<tr>
<th>2. State Regulatory/Legislation/Initiatives</th>
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<tbody>
<tr>
<td>CalRecycle Regs: Exemption Co-Digestion</td>
<td>G. Kester</td>
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<td>FOG &lt;pH5 co-digestion at POTW – SWQCB Response</td>
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<td>Short Lived Climate Pollutant Reduction Strategy and Excess Digester Capacity Survey</td>
<td>G. Kester</td>
<td>CASA Letter</td>
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<td>CDFA Healthy Soils Initiative - Fire Ravaged Lands and Mine Reclamation</td>
<td>G. Kester</td>
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<th>3. Federal Regulatory/Legislation/Initiatives</th>
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<tbody>
<tr>
<td>Hazardous Waste Pharmaceuticals Proposed Rule</td>
<td>T. Meregillano</td>
<td>Fed Register</td>
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<tr>
<td>EPA Finalizes Rule to Modernize Clean Water Act Reporting</td>
<td>G. Kester</td>
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<td>Other EPA updates i.e. Arsenic/503</td>
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<th>4. Biosolids Research/Innovative Technologies</th>
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<td>UC Davis – Endocrine Disrupting Compounds (EDC) Research</td>
<td>G. Kester</td>
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<td>WERF Ebola Update Meeting</td>
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<td>WERF Rare Earth Element Research</td>
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<td>Cerium Salts for P control</td>
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<th>5. Regional Facilities Updates</th>
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<td>M. Copeland</td>
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<th>6. Industry Association Updates</th>
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<td>CWEA</td>
<td>J. Hay</td>
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### CASA Biosolids Land Committee Agenda

**November 12, 2015**  
**Conference Call**  
**10:30 AM – 12:30 PM**

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<tr>
<th>Topics</th>
<th>Lead Person</th>
<th>Attachments</th>
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<tr>
<td>SCAP</td>
<td>T. Meregillano/D. Gilbert</td>
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<td>A. Chakrabarti</td>
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<td>CVCWA</td>
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Dear Chairman Nichols and Board Members:

The California Wastewater Climate Change Group (CWCCG) and California Association of Sanitation Agencies (CASA) appreciate the opportunity to comment on the Draft Short Lived Climate Pollutant (SLCP) Reduction Strategy (Draft Strategy). We especially look forward to proactively working with the Air Resources Board (ARB) and related agencies to collaborate as partners in achieving the shared vision and goals of this strategy. The CWCCG and CASA are statewide groups of municipalities that collect and treat over 90 percent of municipal wastewater in California, many of whom also provide recycled water services and actively participate in the beneficial use of biosolids and biogas. Our joint mission is to address climate change policies, initiatives, and opportunities through a unified voice advocating for wastewater community perspectives. Our members are focused on helping the State achieve its multiple mandates and goals by 2030 and beyond, including:

- Reducing carbon dioxide equivalent emissions to 40% below 1990 levels
- Providing 50% of the State’s energy needs from renewable sources
- Reducing carbon intensity of transportation fuel used in the State by 10 percent
- Effectively eliminating organic waste disposal in landfills
- Increasing soil carbon under the Healthy Soils Initiative and Forest Carbon Plan
- Reducing SLCP emissions (specifically, methane emissions 40% below 2013 levels)

CWCCG and CASA agree with ARB that publicly owned (wastewater) treatment works (POTWs) are part of the solution. In addition to providing the essential public service of cleaning water and treating biosolids, the wastewater sector can maximize resource recovery from a wide array of waste streams and potential end-products. POTWs can do this while reducing the release of SLCPs and by maximizing the use of existing infrastructure (i.e., anaerobic digesters, power generating units, and biosolids treatment facilities).

We estimate that the wastewater sector has existing excess capacity to co-digest up to 75% of the food waste and FOG currently being landfilled. The acceptance of hauled-in organic waste such as fats, oils and grease (FOG), food waste (source separated), vegetative...
food waste (cannery, food processing, etc.), and others for anaerobic digestion at POTWs is a steadily increasing practice, and an important management option for this valuable waste stream.

Similarly, the receipt of some types of green waste for co-composting with biosolids is a common means of managing biosolids and is an increasing practice. Therefore, POTWs can receive a large fraction of diverted organic waste from landfills using existing infrastructure. **We are working to determine the excess capacity for green waste at existing biosolids compost facilities and will provide that as soon as possible.**

The following comments on the Draft Strategy are organized by category. Specific comments and suggested text changes to the Draft Strategy are provided in Appendix A.

**Funding Allocation**

CalRecycle and the California Department of Food and Agriculture (CDFA) estimate that $100 million over the next five years are needed to build the necessary infrastructure in the waste sector to meet the landfill organic diversion goals. We believe this number to be too low, and in fact, waste industry representatives have estimated that the real number will be between $1 and $2 billion by 2020. This number includes new composting and anaerobic digestion facilities, however, it does not include what is needed for POTWs to modify their infrastructure to accept diverted organic waste. This indicates that there is a very significant funding gap if the Draft Strategy goals are to be met. We recommend that ARB prioritize cap-and-trade revenues toward this infrastructure, especially the funding for POTWs that are willing to utilize their excess digester capacity to accept diverted organic waste. These types of projects are cost effective when compared to building new anaerobic digestion facilities, and will kick-start the management of organic waste sooner than new infrastructure projects.

**Making Use of Existing Capacity and Biogas Utilization**

The ARB correctly pointed out POTWs are part of the solution in reducing SLCPs. Achieving significant reductions in SLCPs will require substantial investments in the form of incentives and direct funding. To help ARB understand the potential role POTWs can play in efforts to reduce SLCPs, CASA has prepared a preliminary estimate of existing excess capacity at municipal wastewater treatment plants for which food waste and FOG diverted from landfills could be accepted for co-digestion. **We estimate that municipal wastewater treatment plants have capacity in existing digesters to accept up to 75% and possibly more of the food waste/FOG currently being landfilled.** Of course, other factors will help determine the practical reality of being able to accept this fraction of food waste; including operational limitations, adequate funding to ensure cost-effectiveness, capacity which may be claimed by increased flow from connected users, and effective high level support for the recycling of resulting biosolids. This estimate does not yet include the compostable fraction of the organic waste (which includes woody waste and some yard waste). CASA is currently collecting data for estimating the excess capacity for the compostable fraction of the solid waste stream at existing biosolids composting facilities. Our intent is to provide ARB with a refined estimate of the funding needed to achieve this potential. CASA and the wastewater community look forward to working with you all to maximize the opportunity and in achieving our shared objectives.
We concur with the Draft Strategy that opportunities exist to optimize investments and co-locate infrastructure or utilize existing infrastructure, especially excess digestion capacity that exists at many wastewater treatment plants. It will be essential for California to work collaboratively “to overcome obstacles to financing and developing projects that use organic waste streams.” We would like to participate in the suggested work group effort to identify and address the obstacles/barriers, as well as the incentives that will be needed to transform both markets and infrastructure to support the State’s vision. We believe a proactive approach developed collaboratively with incentives will advance our shared goals much more effectively than through regulatory mandates as is suggested in the Draft Strategy. We therefore strongly request the deletion of the suggested regulatory approach of requiring POTWs to take diverted organics in recognition that it does not address the real challenge facing the State. The issue is not the willingness of POTWs to accept organic waste streams but the timely creation of the infrastructure and markets needed to make this enterprise successful.

We are concerned about the conclusion offered on Page 55 of the Draft Strategy that states, “As many of the State’s wastewater treatment plants undergo renovation or reconstruction over the next 15 years...” We are not aware that this is true, and so would appreciate having the opportunity to review the data ARB is relying upon to make this assertion along with the suggestion that methane gas from wastewater treatment plants may not be effectively utilized currently.

POTWs that produce biosolids as part of the treatment process typically manage those solids in anaerobic digesters and capture the methane which is managed through some form of beneficial use with less than 10% of it being flared. In cases where much of the captured methane is used beneficially, its use typically results in 40 to 70 percent of a POTW’s power and heating demand being met. In some cases, this can exceed the power demand to operate the treatment plant and excess power can be sold. By generating and using power on-site, the facility can save on the cost of purchased power or natural gas by displacing the use of fossil fuel with on-site renewable power generation. It is the additional capacity within these digesters that provides the POTW community the immediate opportunity to help divert organic materials from landfills and assist the State in meeting its SLCP goals.

**Biosolids/Digestate Utilization**

Similarly, biosolids management at individual POTWs is a cost/benefit decision. While most biosolids are beneficially recycled to agricultural land, there are opportunities to expand composting and other uses of these materials. However, currently there are numerous county ordinances (not based on sound science or public policy) that limit the use of biosolids in unincorporated parts of those counties. As the Draft Strategy underscores, development of the markets that support beneficial use of biosolids is vital and the State will need to provide strong support at all levels of government, as well as funding, to ensure such markets are enabled and promoted.

The Draft Strategy also states that we need to build market certainty and value for compost and other soil amendment products to secure financing for projects that utilize organic waste, and subsequently reduce emissions of SLCPs. Biosolids used as soil amendments from anaerobic digesters at California POTWs significantly improve soil health, increase crop yields, reduce the need for irrigation because of their high water holding capacity, sequester carbon long term in the soil, and avoid the use of fossil fuel based inorganic nitrogen fertilizer (i.e., nearly a quarter of a gallon of fossil fuel is required for every pound of inorganic nitrogen produced). Collaboration among state agencies, wastewater agencies, and
local governments will help quantify the benefits of using compost and biosolids for fire and other reclamation projects, soil remediation, water conservation, and other beneficial uses.

Efforts to increase composting and anaerobic digestion— and capture the diverse benefits from doing so—can be promoted by showing an accounting of the benefits of using compost and other soil amendments that come from these processes. ARB is coordinating with CDFA and other agencies working on the Healthy Soils Initiative to quantify the benefits of using compost and other soil amendments.

We strongly encourage ARB to work with the Water Boards and CASA to include biosolids and biosolids compost in building healthy soils and understanding the significant body of research already conducted which demonstrates the plethora of benefits from their land application.

In summary, POTWs are capable of contributing toward multiple statewide goals utilizing approaches that optimize use of incentive funds while maximizing air quality, climate, soil, and water quality co-benefits. POTWs can:

- Significantly reduce emissions of methane by maximizing the use of existing anaerobic digesters and compost facilities through the receipt and management of hauled-in organic waste for co-digestion and co-composting.
- Sequester carbon in soil through the application of biosolids to agricultural land, thereby avoiding use of fossil fuel-intense inorganic fertilizer while improving soil health, crop yields, and water holding capacity.
- Increase the productive use of the captured methane through power generation, on-site heating needs, pipeline injection, or conversion to transportation fuel.
- Directly use biosolids to reclaim fire ravaged land and reduce the potential severity of future wild fires (the primary source of black carbon).

Support and funding are needed to advance these practices (which constitute the “low hanging” fruit in the reduction of SLCPs), as well as advancing research on emerging technologies (e.g., through demonstration projects and/or pilot programs). We strongly recommend allocation of cap-and-trade auction proceeds and additional incentives to fund POTW projects. We also agree that the State needs to build market certainty and value for energy, fuel, soil amendment, and other products resulting from composting and anaerobic digestion facilities.

The Draft Strategy states that a more thorough accounting of costs and benefits will be presented in the proposed Strategy by December. CWCCG and CASA would like to work with ARB on this and provide information that can be used in the economic analysis for both the Draft Strategy and in the 2016 Scoping Plan update.
Again, CWCCG and CASA appreciate the opportunity to provide comments on the Draft Strategy and look forward to working with ARB and other agencies moving forward. Please contact us if you have any questions at (916) 446-0388 or via email at gkester@casaweb.org and sdeslauriers@carollo.com. We welcome the opportunity to further discuss the wastewater community’s position in helping ARB proactively reduce SLCP emissions to achieve the commendable State goals and mandates for 2020, 2030, and 2050.

Sincerely,

Greg Kester                        Sarah A. Deslauriers, P.E.
CASA Director of Renewable Resource Programs  CWCCG Program Manager

cc:   Mary Nichols - Chair, ARB
      Scott Smithline – Director, CalRecycle
      Wade Crowfoot, Martha Guzman-Aceves, Graciela Castillo-Krings – Governor Brown’s Office
      Ryan McCarthy, Mike Tollstrup - ARB
      Evan Johnson, Bob Horowitz, Tim Hall - CalRecycle
      Fran Spivy-Weber, Felicia Marcus, DeeDee D’Adamo, Tom Howard, Scott Couch, Annalisa Kihara,
      Johnny Gonzales - Water Boards
      Ashley Conrad-Saydah - CalEPA
      Jamie Ormond, Commissioner Sandoval - CPUC
      Rob Oglesby - CEC
      Karen Ross – Secretary, CDFA
      Jenny Lester Moffitt – Deputy Secretary, CDFA
      Julia Levin – Executive Director, BAC
      Bobbi Larson – Executive Director, CASA
APPENDIX A

Specific comments and suggested text changes to the Draft Strategy are provided below. Additions are underlined and deletions are struck through.

Page 39:

CWCCG/CASA agree with the conclusion that POTWs emit only small amounts of methane. Figure 5 shows "wastewater" as contributing 4 percent to the state's total methane emissions in 2013. However, if the same "wastewater" sources that were considered in the 2012 inventory (presented in the 2014 Scoping Plan Update), are also considered in Figure 5 of this Draft Strategy for the 2013 inventory, then nearly 50 percent of the "wastewater" methane emissions are related to industrial wastewater systems, and another 25% are related to septic systems not owned or operated by POTWs. CWCCG/CASA recommend separating septic system emissions from the estimate of "wastewater" related emissions (consistent with how these emissions are treated in the U.S. Inventory) and further noting the percentage of industrial wastewater versus POTW (or domestic) wastewater related emissions. The same argument applies to Figure 6 showing the percent breakdown of 2030 methane emissions sources assuming existing measures. This will improve ARB's inventory by providing a more accurate accounting of emissions from POTWs, and demonstrate how little methane emissions are actually emitted from these sources.

Page 54:

The first paragraph under the Wastewater Treatment, Industrial, and Other Sources section states, "California's 250 wastewater treatment plants are designed to remove contaminants from wastewater, primarily from household sewage." While this is true when referencing municipal wastewater treatment plants, "wastewater" in Figures 5 and 6 are likely including septic tank and industrial wastewater related emissions as well. We recommend making a consistent reference to "wastewater" throughout the Draft Strategy and clarify when speaking only of household (or domestic) wastewater as in this section of the Draft Strategy.

We recommend the following edits to the Wastewater Treatment, Industrial, and Other Sources section:

"Wastewater treatment, industrial operations, rice cultivation, and other sources of organic waste account for about 9 percent of the State's methane inventory. California's approximately 250 major municipal wastewater treatment plants are designed to remove contaminants from wastewater, primarily from household sewage. Treatment of wastewater typically relies on physical, chemical, and biological processes to remove contaminants and produce environmentally-safe, treated wastewater (or recycled water treated effluent) and biosolids. A typical by-product of sewage treatment is a semi-solid slurry or sludge that undergoes further treatment before being suitable for disposal or land application. Most municipal wastewater sources contain organic constituents which are treated anaerobically. This treatment process produces methane.

Anaerobic digestion is a typical part of the wastewater treatment process employed at many POTWs across the state. More than 90 percent of municipal wastewater flow in California is treated at POTWs that have anaerobic digestion as the solids treatment process. The anaerobic digestion process produces biogas (which includes methane). Methane emissions can be
avoided by either treating the wastewater and the associated sludge under aerobic conditions (composting), or by capturing methane released under anaerobic conditions (anaerobic digestion). Technologies are available to capture and use the methane generated by anaerobic digestion; these facilities is captured and used for on-site heating needs, or as a source of renewable power or transportation fuel to benefit California's climate and energy goals. This power production generally provides between 40 and 70 percent of the POTW's energy needs (and in some cases 100%), significantly reducing demand from the grid and offsetting the need for fossil-fuel based power with a renewable energy source. In rare circumstances, biogas can be flared. Approximately 150 of the State's wastewater treatment plants, which treat over 90 percent of total wastewater flow, currently use anaerobic digestion in their treatment process. About 110 of these plants use some or all of the captured methane to generate electricity.

Many municipal wastewater treatment plants have large amounts of spare capacity to potentially take in additional sources of organic waste for anaerobic digestion. These facilities can co-digest materials such as food waste, fats, oils and grease from food and other high-strength organic wastes. Many of the largest treatment plants are located close to population centers and could obtain and utilize significant amounts of food and other suitable organic waste streams from adjacent cities and towns. As such, municipal wastewater facilities provide an opportunity to help divert organic wastes from landfills and use them to produce renewable electricity, fuels, and soil amendments. These facilities can be designed to co-digest materials such as fats, oils and grease from food and other organic wastes.

Diverting these organic materials into municipal wastewater digestion systems can support the capture and reduction of methane emissions from regional organic sources, further boost the beneficial use of methane gas at municipal wastewater treatment plants, and reduce flaring or non-contained releases of methane to the atmosphere. These facilities can also be designed to produce agricultural “biosolids,” which when composted can be used to help sequester soil carbon, and reduce the use of fossil-fuel based fertilizers, and improve soil health and crop yields.

As many of the State’s wastewater treatment plants undergo renovation or reconstruction over the next 15 years, ARB will work with the State Water Resources Control Board, Regional Water Quality Control Boards, and others to assess the feasibility and benefits of actions to require capturing and effectively utilizing methane generated from wastewater treatment. Programs based on collaboration with State agencies and that rely on financial incentives and/or regulatory actions could be implemented to ensure that new and existing municipal wastewater treatment plants in California maximize use of excess capacity by accepting food waste and FOG for co-digestion and effectively utilize fully implement captured methane capture systems (potentially to produce on-site renewable electricity, satisfy on-site heating needs, transportation fuel, or pipeline biogas), and as well as beneficially recycling biosolids maximize digestion of regional organic materials. The potential actions could be tailored to each municipal wastewater treatment plant based on size or capacity, and other factors such as potential for co-digestion expansion or location of stand-alone digesters located at municipal wastewater treatment plants, proximity of co-digestion waste streams, and regional air quality standards and rules. The Water Boards could develop permit terms and other regulatory tools to support the program while achieving water supply, water quality, and related co-benefits. CalRecycle could require or incentivize landfill operators to divert organics, and to municipal wastewater...
treatment plants would be a potential recipient for some components of the organic waste stream (following pre-processing).

Many wastewater treatment plants are permitted to combust burn digester biogas through flaring and are classified as industrial facilities. Capturing the biogas to produce electricity, such as through a combined heat and power (CHP) system may result in re-classifying the facility’s purpose as “electricity generation” and subject the plant to more onerous emission compliance and abatement equipment rules, even though the change in criteria pollutant emissions are minimal. In addition, the beneficial use of methane generated at municipal wastewater treatment facilities faces many of the same hurdles faced by dairy digesters and waste treatment management facilities. State agencies will work collaboratively to address these barriers, as they are for those hindering other productive uses of California’s waste streams, in the dairy and landfill sectors, as well.

Coupled with improved monitoring to detect and fix leaks and fugitive emissions, as described for the oil and gas sector, California aims to reduce fugitive methane emissions from wastewater, industrial, and other sources by 40 percent below current levels (2013) by 2030."

We recommend the following edits to the second paragraph on page 67:

"Local agencies also play a role in utilizing methane beneficially reduction at wastewater treatment plants. Many local agencies water districts own and operate wastewater treatment facilities and are implementing strategies to reduce methane emissions from wastewater treatment operations, such as capturing methane for use in fuel cells for on-site energy production. Local strategies to improve management and utilization of organic waste throughout the State may also have the ability to help reduce methane emissions throughout the agricultural and wastewater treatment sectors. Wastewater treatment plants offer a tremendous opportunity to divert organics from landfills and utilize them for producing energy or fuel and soil amendments. Many treatment plants are located near population centers and could potentially utilize significant amounts of food and other organic waste streams that come from cities and towns. Collaboration amongst local and regional agencies, such as solid waste management and wastewater agencies, is the key to success."
Environmental Protection Agency

Management Standards for Hazardous Waste Pharmaceuticals; Proposed Rule
Environmental Protection Agency

40 CFR Parts 261, 262, 266, 268, and 273

[EPA-HQ-RCRA-2007-0932; FRL-9924-08-OSWER]

RIN 2050–AG39

Management Standards for Hazardous Waste Pharmaceuticals

Agency: Environmental Protection Agency (EPA).

Action: Proposed rule.

Summary: Some pharmaceuticals are regulated as hazardous waste under the Resource Conservation and Recovery Act (RCRA) when discarded. Healthcare facilities that generate hazardous waste pharmaceuticals as well as associated facilities have reported difficulties complying with the Subtitle C hazardous waste regulations for a number of reasons. First, healthcare workers, whose primary focus is to provide care for patients, are not knowledgeable about the RCRA hazardous waste regulations, but are often involved in the implementation of the regulations. Second, a healthcare facility can have thousands of items in its formulary, making it difficult to ascertain which ones are hazardous wastes when disposed. Third, some active pharmaceutical ingredients are listed as acute hazardous wastes, which are regulated in small amounts. To facilitate compliance and to respond to these concerns, the U.S. Environmental Protection Agency (EPA or the Agency) is proposing to revise the regulations to improve the management and disposal of hazardous waste pharmaceuticals and tailor them to address the specific issues that hospitals, pharmacies and other healthcare-related facilities face. The revisions are also intended to clarify the regulation of the reverse distribution mechanism used by healthcare facilities for the management of unused and/or expired pharmaceuticals.

Dates: Comments must be received on or before November 24, 2015.

Addresses: Submit your comments, identified by Docket ID No. EPA–HQ–RCRA–2007–0932, to the Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit http://www2.epa.gov/dockets/commenting-epa-dockets.

For further information contact: Kristin Fitzgerald, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: 703–308–8286; email address: fitzgerald.kristin@epa.gov or Josh Smeraldi, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: 703–308–0441; email address: smeraldi.josh@epa.gov.

Supplementary Information:

I. General Information

Does this action apply to me?

This is a proposed rule. If finalized, this rule would apply to healthcare facilities, pharmaceutical reverse distributors, and owners or operators of treatment, storage, and disposal facilities engaged in the management of hazardous waste pharmaceuticals. The list of NAICS codes for the potentially affected entities, other than RCRA treatment, storage and disposal facilities (TSDFs), are presented in Table 1. More detailed information on the potentially affected entities is presented in Section V.A and Section V.B.1 of this preamble.

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<th>TABLE 1—NAICS Codes of Entities Potentially Affected by This Final Rule—Healthcare Facilities and Pharmaceutical Reverse Distributors</th>
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This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities potentially impacted by this action. This table lists examples of the types of entities of which EPA is aware that could potentially be affected by this action. Other types of entities not listed could also be affected. To determine whether your entity, company, business, organization, etc. is affected by this action, you should examine the applicability criteria in this rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding FOR FURTHER INFORMATION CONTACT section of this document.

Preamble Outline

I. Statutory Authority

II. List of Abbreviations and Acronyms

III. Summary of the Proposed Rule

IV. Background

...
A. What is the history of hazardous waste pharmaceutical management under RCRA?
B. What are the rationale and goals for this proposed rule?
C. What was the 2008 pharmaceutical universal waste proposal?
D. EPA’s Office of Inspector General Report
V. Detailed Discussion of the Proposed Rule
A. What terms are defined in this proposed rule?
B. What is the scope of this proposed rule?
C. What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals?
D. How does this proposed rule address healthcare facilities that accumulate potentially creditable hazardous waste pharmaceuticals prior to shipment to pharmaceutical reverse distributors?
E. What are the proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?
F. What are the proposed standards for shipping hazardous waste pharmaceuticals?
G. What are the proposed standards for pharmaceutical reverse distributors?
VI. Implementation and Enforcement
A. Healthcare Facilities
B. Pharmaceutical Reverse Distributors
C. Healthcare Facilities and Pharmaceutical Reverse Distributors
D. State Enforcement Activities and Interpretations
VII. Request for Comment on EPA’s Efforts To Identify Additional Pharmaceuticals as Hazardous Wastes
VIII. Request for Comment on EPA’s Efforts To Amend the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075)
A. Background
B. Basis for Original Listing
C. Rationale for EPA’s Efforts To Amend the P075 Listing
D. Two Possible Approaches for Amending the P075 Listing
E. Request for Comments
IX. State Authorization
A. Applicability of Rules in Authorized States
B. Effect on State Authorization
C. Effect on State Authorization in States That Have Added Pharmaceuticals to the Universal Waste Program
X. Adding and Reserving Part 266, Subpart Q
XI. Summary of the Regulatory Impact Analysis
XII. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Paperwork Reduction Act (PRA)
C. Regulatory Flexibility Small Business Analysis
D. Unfunded Mandates Reform Act (UMRA)
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
H. Executive Order 12298: Federal Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act (NTTAA)
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
I. Statutory Authority
II. List of Abbreviations and Acronyms
AARP American Association of Retired Persons
AEA Atomic Energy Act
API Active Pharmaceutical Ingredient
BDAT Best Demonstrated Available Technology
CERCLA Comprehensive Environmental Response, Compensation and Liability Act
CESQG Conditionally Exempt Small Quantity Generator
CFR Code of Federal Regulations
CSA Controlled Substances Act
CWA Clean Water Act
DEA Drug Enforcement Administration
DHHS Department of Health and Human Services
DOE Department of Energy
DOT Department of Transportation
EPA Environmental Protection Agency
EO Executive Order
FDA U.S. Food and Drug Administration
FR Federal Register
HIPAA Health Insurance Portability and Accountability Act
HSWA Hazardous and Solid Waste Amendments
LQG Large Quantity Generator
LQUWH Large Quantity Universal Waste Handler
LTCP Long-term Care Facility
MTCP Long-term Care Pharmacy
MSWLF Municipal Solid Waste Landfill
NIOSH National Institute for Occupational Safety and Health
NPRM Notice of Proposed Rulemaking
NRC Nuclear Regulatory Commission
OIG Office of Inspector General
OMB Office of Management and Budget
ONDCE Office of National Drug Control Policy
OSHA U.S. Department of Labor’s Occupational Safety and Health Administration
OSWER Office of Solid Waste and Emergency Response
OSWI Other Solid Waste Incinerators
OTC Over-the-counter
POTW Publicly Owned Treatment Works
RCRA Resource Conservation and Recovery Act
RQ Reportable Quantity
SQG Small Quantity Generator
SQUWH Small Quantity Universal Waste Handler
SWDA Solid Waste Disposal Act
TC Toxicity Characteristic
TCLP Toxicity Characteristic Leaching Procedure
TSDF Treatment, Storage and Disposal Facility
III. Summary of the Proposed Rule
EPA is proposing to add a subpart P under 40 CFR part 266. Part 266 is entitled, “Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities.” This new subpart P is a tailored, sector-specific regulatory framework for managing hazardous waste pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors. If finalized, healthcare facilities that are currently small quantity generators (SQGs) or large quantity generators (LQGs) and all pharmaceutical reverse distributors, regardless of their RCRA generator category, will be required to manage their hazardous waste pharmaceuticals under subpart P of 40 CFR part 266, instead of 40 CFR part 262. That is, the proposed standards are not an optional alternative to managing hazardous waste pharmaceuticals under 40 CFR part 262; they are mandatory standards.
Briefly, healthcare facilities will have different management standards for their non-creditable and creditable hazardous waste pharmaceuticals. Non-creditable hazardous waste pharmaceuticals (i.e., those that are not expected to be eligible to receive manufacturer’s credit) will be managed on-site similar to how they would have been under a previous proposal for managing these wastes: The 2008 Universal Waste proposal for pharmaceutical waste (73 FR 73520; December 2, 2008). When shipped off-site, they must be transported as hazardous wastes, including the use of the hazardous waste manifest, and sent to a RCRA interim status or permitted facility. On the other hand, healthcare facilities will continue to be allowed to send potentially creditable hazardous waste pharmaceuticals to pharmaceutical reverse distributors for processing manufacturers’ credit. In response to comments received on the Universal Waste proposal, EPA is proposing standards to ensure the safe and secure delivery of the creditable
hazardous waste pharmaceuticals to pharmaceutical reverse distributors.

EPA is also proposing standards for the accumulation of the creditable hazardous waste pharmaceuticals at pharmaceutical reverse distributors. Like healthcare facilities, pharmaceutical reverse distributors will not be regulated under 40 CFR part 262 as hazardous waste generators, nor will they be regulated under 40 CFR parts 264, 265 and 270 as treatment, storage, and disposal facilities (TSDFs). Rather, the proposal establishes a new category of hazardous waste entity, called pharmaceutical reverse distributors. The proposed standards for pharmaceutical reverse distributors are, in many respects, similar to the LQGs standards, with supplementary standards added to respond to commenters’ concerns.

For both healthcare facilities and reverse distributors, EPA is proposing to prohibit facilities from disposing of hazardous waste pharmaceuticals down the toilet or drain (i.e., flushed or sewered). Further, EPA proposes that hazardous waste pharmaceuticals managed under subpart P will not be counted toward calculating the site’s generator category. Additionally, EPA is proposing a conditional exemption for hazardous waste pharmaceuticals that are also DEA controlled substances.

Finally, EPA is proposing management standards for hazardous waste pharmaceutical residues remaining in containers.

IV. Background

A. What is the history of hazardous waste pharmaceutical management under RCRA?

1. What Is the Resource Conservation and Recovery Act?

The Resource Conservation and Recovery Act governs the management and disposal of hazardous wastes. Under Subtitle C of RCRA, EPA has established a comprehensive set of regulations for hazardous waste management, generation, transportation, treatment, storage, and disposal. EPA can authorize an individual state hazardous waste program to operate in lieu of the federal program provided the authorized state’s program is at least as stringent as, and consistent with, the federal program. However, EPA maintains oversight of the authorized state’s hazardous waste program and the authority to take independent enforcement actions. RCRA regulates pharmaceutical wastes that meet a listing of hazardous waste or exhibit one or more characteristics of hazardous waste. Accordingly, hospitals, pharmacies, reverse distributors and other healthcare-related establishments that generate hazardous wastes, including hazardous waste pharmaceuticals, are required to manage and dispose of their hazardous wastes in accordance with applicable federal, state, and/or local environmental regulations.

2. What are the current standards for generators of hazardous waste?

Currently, there are no RCRA Subtitle C regulations that focus specifically on the management of hazardous wastes from hospitals, pharmacies, reverse distributors and other healthcare-related facilities. Rather, healthcare facilities are currently required to comply with the same RCRA hazardous waste regulations as many other industries that generate hazardous waste. While the RCRA Subtitle C program has requirements for all aspects of hazardous waste management, including those generating (referred to as “generators” by RCRA), transporting, storing, treating, and disposing of hazardous wastes, it is the generator requirements found under 40 CFR part 262 that will typically be most pertinent to healthcare-related facilities.

Under the federal RCRA regulations, the standards for hazardous waste generators are divided into three categories—LQGs, SQGs, and Conditionally Exempt Small Quantity Generators (CESQGs) depending upon the total amount of hazardous waste a facility generates per calendar month. It is the facility’s generator category that determines the applicable RCRA hazardous waste management requirements with which the generator must comply. A generator that generates a solid waste is required by §262.11 to determine whether such waste meets the definition of RCRA hazardous waste. If the waste meets the RCRA definition of a hazardous waste, then the generator must manage the waste in accordance with the regulations that apply to its hazardous waste generator category (see §261.5 and 40 CFR part 262 for the generator regulations). In particular:

- Facilities qualify as LQGs if in a calendar month they generate 1,000 kg or more of hazardous waste or more than 1 kg of acute hazardous waste (i.e., P-listed waste), or more than 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§261.31 or 261.33(e). Federal regulations for LQGs include, but are not limited to the following: Obtaining an EPA Identification number; a 90-day limit for accumulating hazardous waste on-site (with relevant standards for the accumulation of hazardous waste) without having to obtain a RCRA permit or comply with the interim status standards, provided that they comply with the conditions for exemption set forth in §262.34(a) such as management and labeling standards specific to the type of accumulation unit (e.g., container, tank); RCRA training of personnel; contingency planning; manifesting and recordkeeping and reporting (biennial report).

- Facilities qualify as SQGs if in a calendar month they generate more than 100 kg but less than 1,000 kg of hazardous waste. SQGs are subject to fewer requirements than LQGs and are subject to fewer regulations for hazardous waste management, generation, transportation, treatment, storage, and disposal. EPA can authorize an individual state hazardous waste program to operate in lieu of the federal program provided the authorized state’s program is at least as stringent as, and consistent with, the federal program. However, EPA maintains oversight of the authorized state’s hazardous waste program and the authority to take independent enforcement actions. RCRA regulates pharmaceutical wastes that meet a listing of hazardous waste or exhibit one or more characteristics of hazardous waste. Accordingly, hospitals, pharmacies, reverse distributors and other healthcare-related establishments that generate hazardous wastes, including hazardous waste pharmaceuticals, are required to manage and dispose of their hazardous wastes in accordance with applicable federal, state, and/or local environmental regulations.

- Facilities qualify as CESQGs if in a calendar month they generate less than 100 kg but more than 1 kg of acute hazardous waste (i.e., P-listed waste), or more than 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§261.31–33. CESQGs are subject to fewer requirements than LQGs and are subject to fewer regulations for hazardous waste management, generation, transportation, treatment, storage, and disposal. EPA can authorize an individual state hazardous waste program to operate in lieu of the federal program provided the authorized state’s program is at least as stringent as, and consistent with, the federal program. However, EPA maintains oversight of the authorized state’s hazardous waste program and the authority to take independent enforcement actions. RCRA regulates pharmaceutical wastes that meet a listing of hazardous waste or exhibit one or more characteristics of hazardous waste. Accordingly, hospitals, pharmacies, reverse distributors and other healthcare-related establishments that generate hazardous wastes, including hazardous waste pharmaceuticals, are required to manage and dispose of their hazardous wastes in accordance with applicable federal, state, and/or local environmental regulations.

1. RCRA also governs the disposal of non-hazardous solid wastes; however, state and/or local environmental regulatory agencies predominantly administer the regulations pertaining to the management of non-hazardous wastes.


3. For more information on hazardous waste generators, please see: http://www.epa.gov/waste/hazard/generation/index.htm.

4. See 40 CFR 261.2 for the definition of solid waste.

5. The waste determination process includes determining if the waste is specifically excluded or exempted from the RCRA hazardous waste regulations. If not, then the entity must determine if the waste is listed by EPA under the F-, K-, P- or U-lists of hazardous wastes (§§261.31–33). If the waste is not listed, then it must be determined if the waste exhibits a characteristic of a hazardous waste: ignitability, corrosivity, reactivity, or toxicity (§§261.21–24).
Finally, under the household hazardous waste exemption in §261.4(b)(1), hazardous wastes generated by households are not subject to the RCRA hazardous waste regulations. This exemption from the Subtitle C requirements extends to any household wastes collected during community-oriented take-back programs or events, as long as these collected household hazardous wastes are managed separately from regulated hazardous wastes. However, while collected household hazardous wastes are not regulated under the federal standards, more stringent state standards may apply.

3. Are pharmaceuticals considered hazardous wastes under RCRA?

A portion of the pharmaceuticals currently on the market meets RCRA’s definition of hazardous waste when discarded. As previously explained, it is the responsibility of the generator of a solid waste to determine if the waste is hazardous; this includes solid wastes that are pharmaceuticals. If the pharmaceutical waste meets RCRA’s definition of hazardous waste, then the generator must manage it in accordance with all applicable federal, state, and/or local environmental regulations. A pharmaceutical is considered a hazardous waste under RCRA in one of two ways. First, a discarded pharmaceutical can be a listed hazardous waste if it is a commercial chemical product that is listed under RCRA’s P- or U-list, and the pharmaceutical has not been used for its intended purpose (§261.33(e) and (f), respectively). A few examples of pharmaceuticals that are considered P-listed wastes when discarded are arsenic trioxide (P012), smoking cessation products with nicotine as the sole active ingredient (P075), and pharmaceuticals with greater than 0.3% warfarin (and salts) as the sole active ingredient, such as Coumadin (P001). Some examples of pharmaceuticals that are considered U-listed wastes are: Cyclophosphamide (U058), mitomycin C (U010), streptozotocin (U206) and warfarin and salts (≤0.3%) as the sole active ingredient.

Second, if the discarded pharmaceutical is not on the P- or U-list, then the pharmaceutical may be a hazardous waste if it exhibits one or more of the hazardous waste characteristics. Under the federal requirements (§261.21–24), a waste is a characteristic hazardous waste if it is ignitable (D001), corrosive (D002), reactive (D003) or toxic (D004–D043). A number of pharmaceuticals are prepared in alcohol, which may cause the waste to be hazardous due to ignitability (D001), even if the active pharmaceutical ingredient itself is not considered hazardous waste. The Regulatory Impact Analysis for this proposed rule includes a list of pharmaceuticals that, to our knowledge, are hazardous waste when discarded, although this list should not be considered exhaustive (see the docket for this proposed rule EPA–HQ–RCRA–2007–0932).

Since the hazardous waste rules were initially promulgated, EPA has issued several clarifications regarding the regulatory status of certain commercial chemical products on the P- and U-lists, and these clarifications have affected the regulatory status of some active pharmaceutical ingredients. For example, EPA recently clarified that phentermine hydrochloride and other phentermine salts are not included within the scope of the P046 (phentermine) listing. Similarly, EPA has also clarified that epinephrine salts are not included in the epinephrine listing (P042). In addition, medicinal nitroglycerin typically is not considered P081 since the medicinal form of this compound generally does not exhibit the characteristic of reactivity for which nitroglycerin was originally listed. Furthermore, in a 1998 memo, EPA clarified that the U034 listing includes both anhydrous chloride and chloral hydrate. And in a 2010 memo, EPA stated that unused nicotine patches, gums and lozenges are finished dosage forms of nicotine and therefore are regulated as P075 when discarded.

Finally, EPA has developed a “Hazardous Waste Pharmaceuticals Wiki” as a platform to facilitate the sharing of expertise among the healthcare industry and other stakeholders in order to help make accurate hazardous waste determinations for waste pharmaceuticals and increase compliance with the hazardous waste regulations. The Hazardous Waste Pharmaceuticals Wiki will also help users find guidance documents, state-specific information, and manufacturers’ information. The Hazardous Waste Pharmaceuticals Wiki can be viewed at: http://hwpharms.wikispaces.com. EPA encourages healthcare stakeholders to use the Wiki to share information regarding federal hazardous waste
pharmaceuticals, as well as state-only hazardous waste pharmaceuticals. 17

B. What are the rationale and goals for this proposed rule?

1. Sector-Based Approach

The impetus behind this proposal is to address the various concerns raised by stakeholders regarding the difficulty in implementing the Subtitle C hazardous waste regulations for the management of hazardous waste pharmaceuticals generated at healthcare facilities. EPA has met with various stakeholders to learn about compliance challenges, and it has received input from stakeholders through more formal mechanisms. For instance, when EPA solicited stakeholder input in response to Executive Order 13563 (Improving Regulation and Regulatory Review), retailers submitted comments detailing compliance challenges with hazardous waste pharmaceuticals in their stores. 18 Further, EPA’s Office of Inspector General (OIG) published a report citing the need to clarify how hazardous waste pharmaceuticals are regulated (for more information on both of these reports, see the next section). These two reports and input from healthcare (and associated) facilities identified a number of ways in which a healthcare facility differs from a manufacturing facility when it comes to applying the RCRA Subtitle C program for generating and managing hazardous waste.

First, in the healthcare setting, many hazardous waste pharmaceuticals are generated unpredictably and in relatively small quantities by a number of different employees across the facility. This situation differs from a manufacturing facility where fewer employees in a few locations generate comparatively much larger volumes of a smaller range of hazardous wastes.

Second, under the current hazardous waste regulatory scheme, healthcare workers, whose primary focus is to provide care for patients, are typically responsible for making hazardous waste determinations since they are at the point of generation (e.g., a patient’s bedside). Yet, healthcare workers, such as nurses and doctors, do not typically have the expertise to make hazardous waste determinations.

Third, a healthcare facility can have thousands of items in its formulary at any one time and these may vary over time. In addition, pharmaceutical waste comes in many different forms, such as pills, patches, lozenges, gums, creams, and liquids, and are delivered by a variety of devices, such as nebulizers, intravenous (IV) tubing, syringes, etc. The combination of having thousands of different pharmaceutical products and little expertise in hazardous waste regulations makes it difficult for healthcare workers to make appropriate hazardous waste determinations when pharmaceuticals are disposed. This situation differs from manufacturing, where fewer, more predictable waste streams are generated.

Fourth, several of the hazardous waste pharmaceuticals that are generated by healthcare facilities are P-listed acute hazardous wastes (see § 261.33(e)), which are regulated at much smaller amounts. If a facility generates more than 1 kg of acute hazardous waste per calendar month or accumulates that amount at any time, it is regulated as an LQG. In addition to the pharmaceuticals, residues within pharmaceutical containers that contained P-listed commercial chemical products must be managed as acute hazardous waste even if the pharmaceutical was fully dispensed, 19 unless the container is RCRA-empty (e.g., by triple-rinsing the container). Triple rinsing can be impractical with certain medical devices, such as syringes and paper cups, so healthcare facilities often end up managing these containers as hazardous waste, which can result in the facilities being subject to the most stringently regulated generator category (i.e., LQG). 20 To facilitate compliance among healthcare facilities and to respond to these concerns, EPA is proposing a new set of sector-specific regulations to improve the management and disposal of hazardous waste pharmaceuticals at healthcare facilities. This proposed rule also intends to clarify the regulatory status of a major practice used by healthcare facilities for management of unused and/or expired pharmaceuticals, known as reverse distribution (see Sections V.D.1 and V.G).

In addition to improving compliance and responding to stakeholder concerns, the Agency has two additional goals for this proposal. The first is to reduce the amount of pharmaceuticals that are disposed of “down the drain.” This is presently an allowable and common disposal practice among healthcare facilities (as long as the pharmaceutical waste is not ignitable (see the Clean Water Act regulations of 40 CFR 403.5(b)(1)) and provided certain conditions are met (see the Clean Water Act regulations of 40 CFR 403.12(p)). Studies have found that many healthcare facilities, particularly long-term-care facilities, are using drain disposal as a routine disposal method for pharmaceutical waste. Although pharmaceuticals are also entering the environment through excretion, 21 reducing sewer disposal is one mechanism to help reduce the environmental loading of pharmaceuticals into our Nation’s waters. For more information about sewer disposal and pharmaceuticals in water, see Section V.E.1.

The second goal is to address the overlap between EPA’s RCRA hazardous waste regulations and the controlled substances regulations of the Drug Enforcement Administration (DEA). Stakeholders have indicated that hazardous waste pharmaceuticals that are also controlled substances are stringently regulated and expensive to dispose of in accordance with both sets of requirements when sent for incineration. In addition, stakeholders have indicated that those regulated hazardous waste pharmaceuticals that are also controlled substances are most likely to be sewer disposed to avoid the costs of compliant incineration. EPA expects that comments on this proposed rule, as this is an unnecessary burden for healthcare facilities and revised requirements will help to reduce sewer disposal.

2. Executive Order 13563 for the Retrospective Review of Existing Regulations

On January 18, 2011, President Obama issued Executive Order 13563, which directed all federal agencies to perform periodic retrospective reviews of existing regulations to determine whether any should be modified.

17 Anyone may view the Wiki. Those in the healthcare community who wish to contribute content or edit the Wiki can register by sending an email to hpr@epa.gov.
19 P-listed hazardous waste residues in containers are themselves considered P-listed hazardous wastes (see § 261.33(c)), unless the container is considered “RCRA empty” either by undergoing triple-rinsing with an appropriate solvent; or cleaning with a method that has been proven in scientific literature or tests conducted by the generator to achieve equivalent removal (see § 261.7(b)(3)).
20 On November 4, 2011, ORCR issued a memo to the Regional RCRA Division Directors highlighting three acceptable approaches, beyond triple-rinsing containers, that healthcare facilities can employ when managing P-listed container residues. Please see: Memo from Suzanne Rudzinski to RCRA Division Directors, RCRA Online #14827 (http://yosemite.epa.gov/osw/rcra.nsf/ 0c994248c239947e85256d090071175f/57B21F2FE33735128525795F00610F0F/$file/ 14827.pdf).
streamlined, expanded, or repealed. EPA made its preliminary plan available for public review and comment during the spring of 2011 and released the final version of the plan in August 2011.

During the public comment process, EPA received requests to clarify and make more effective the hazardous waste regulations as they pertain to discarded retail products, including pharmaceutical wastes. In response to this specific issue, EPA agreed to review data and information currently in its possession as part of the development for a rulemaking to address pharmaceutical waste management issues. This Notice of Proposed Rulemaking provides notice that EPA has completed its review and has satisfied this part of its obligation for retail hazardous waste pharmaceutical management issues.

3. Retail Notice of Data Availability

EPA published a Notice of Data Availability (NODA) for the Retail Sector on February 14, 2014 (79 FR 8926), in which the Agency requested, among other things, comment on a series of topics related to retail operations in order to better understand the issues retail stores/establishments face in complying with RCRA regulations. Many retail commenters mentioned that because nicotine is an acute hazardous waste (P075), they are considered LQGs when they discard more than 1 kg per month of unused nicotine-containing products (e.g., e-cigarettes and smoking cessation products such as gums, patches and lozenges). Retailers discard these products mainly because they are either expired or they are returned by customers and the retailer does not restock them due to safety concerns. In comments to the NODA, retailers urged the EPA to provide them some regulatory relief with regard to nicotine-containing products. See Section VIII of this preamble for a discussion of EPA’s potential future efforts to amend the acute hazardous waste listing for nicotine and salts (P075).

C. What was the 2008 Pharmaceutical Universal Waste proposal?

1. The 2008 Proposal To Add Hazardous Waste Pharmaceuticals to the Federal Universal Waste Program

On December 2, 2008, EPA proposed to add hazardous waste pharmaceuticals to the existing federal universal waste program, which would have provided a streamlined approach to facilitate the proper management and disposal of hazardous waste pharmaceuticals generated at pharmacies, hospitals, reverse distributors, and other healthcare-related facilities. Specifically, under the universal waste program, handlers and transporters who generate or manage items designated as a universal waste are subject to the management standards under part 273, rather than the full RCRA subtitle C hazardous waste regulations. Universal waste handlers include universal waste generators and collection facilities. The regulations distinguish between “large quantity handlers of universal waste” (or those who handle more than 5,000 kilograms of total universal waste at any one time) and “small quantity handlers of universal waste” (or those who hand less than 5,000 kilograms of total universal waste at any one time). The streamlined requirements for all types of universal waste include modified requirements for storage, labeling and marking, preparing the waste for shipment off-site, employee training, response to releases and notification. Transporters of universal waste are also subject to less stringent requirements than the full RCRA subtitle C hazardous waste transportation regulations. However, the primary difference between the universal waste transportation requirements and full RCRA subtitle C requirements is that no hazardous waste manifest is required for the transport of universal waste.

Destination facilities under the universal waste program are those facilities that treat, store, dispose of, or recycle universal wastes. Universal waste destination facilities are subject to all currently applicable requirements for hazardous waste treatment, storage, and disposal facilities (TSDFs), including the requirement to obtain a RCRA permit for such activities. (See 73 FR 73520, December 2, 2008, for a more detailed discussion of the proposed universal waste program for pharmaceutical wastes.)

2. What were the public comments to the 2008 Pharmaceutical Universal Waste proposal?

EPA received approximately 100 public comments on the 2008 proposal to add hazardous waste pharmaceuticals to the universal waste program. Generally, public commenters supported the Agency’s desire to address the issue of hazardous waste pharmaceutical management. However, although there were several aspects of the proposal that were well supported (e.g., training requirements, accumulation times, and hazardous waste pharmaceuticals not being counted towards the generator category), public commenters expressed concern over the lack of notification and tracking requirements for small quantity handlers of universal waste and the reduced notification and tracking requirements for large quantity handlers. As a result, commenters, including state environmental regulatory agencies, expressed concern that they would not be informed of hazardous waste pharmaceutical generation, management, and transportation in their regulatory jurisdictions. Furthermore, public commenters expressed concern that because the universal waste program does not require a hazardous waste manifest or another tracking mechanism, the hazardous waste pharmaceuticals could be vulnerable to diversion. Public commenters argued that hazardous waste pharmaceuticals are different from the other federal universal wastes (batteries, mercury-containing equipment, lamps, and pesticides) in that the pharmaceuticals, as well as their containers, still retain considerable value upon disposal and can be easily diverted for illicit purposes. Therefore, tracking requirements beyond the requirements included in the current universal waste program were considered necessary by the majority of the public commenters.

In addition to the public comments about the strengths and weaknesses of using the universal waste program to address the disposal of hazardous waste pharmaceuticals, EPA received other comments expressing concern with the proposal, including the following: The point of generation of hazardous waste pharmaceuticals as it pertains to reverse distribution; the management of
containers that contain hazardous waste pharmaceutical residues; the variability in the land disposal restriction (LDR) treatment standards for hazardous waste pharmaceuticals; the overlap of EPA and DEA regulations for the management of hazardous waste pharmaceuticals that are also controlled substances; and the lack of activity to add pharmaceutical wastes to the hazardous waste listings. The Agency provides additional discussion on these specific comments within this preamble.

3. Why is EPA not finalizing the 2008 Pharmaceutical Universal Waste proposal?

Based on the adverse comments received on the 2008 Pharmaceutical Universal Waste proposal regarding the lack of notification and tracking requirements for small quantity universal waste handlers, the reduced notification and tracking requirements for large quantity universal waste handlers, as well as the other issues raised in public comments, the Agency has decided to not finalize the proposal to add hazardous waste pharmaceuticals to the Universal Waste program. In fact, EPA has concluded that the universal waste program is not appropriate for managing hazardous waste pharmaceuticals because, among other things, we are unable to adequately address the notification and tracking concerns raised by the public comments within the Universal Waste program. Under the Universal Waste regulations, there are eight factors to consider when determining whether it is appropriate to add a new hazardous waste or category of hazardous waste to the Universal Waste program (§ 273.81). A hazardous waste does not need to meet every factor in order to be added to the Universal Waste program. Rather, the Agency’s decision is “based on the weight of evidence showing that regulation under part 273 is appropriate for the waste or category of waste, will improve management practices for the waste or category of waste, and will improve implementation of the hazardous waste program” (§ 273.80(c)).

The Agency has concluded based on the comments received that the weight of evidence does not show that regulation under the Universal Waste program is appropriate for hazardous waste pharmaceuticals. Specifically, we find the Universal Waste program to be lacking with regard to the factor in § 273.81(e), which states that the risk posed by the waste being considered for universality is relatively low compared to other hazardous wastes and that the management standards would be protective of human health and the environment during accumulation and transport. Although we continue to believe that potentially creditable pharmaceuticals en route to reverse distributors pose a low risk for leaks and other releases to the environment, commenters urged us to consider the unique risk posed by the accumulation and transport of hazardous waste pharmaceuticals: the risk of diversion. Although it is rare that a hazardous waste is so valuable that it is sought for abuse or sale on the black market, EPA believes that the diversion of hazardous waste pharmaceuticals for illicit use is a risk to human health.

The Universal Waste program does not include sufficient tracking requirements to address the potential for diversion. Under part 273, tracking is not required for shipments by small quantity handlers of universal waste; certain tracking of shipments is required only for large quantity handlers of universal waste and destination facilities. More importantly, these basic tracking requirements consist only of recordkeeping of shipments sent and received and no tracking is required to ensure delivery. Commenters noted that these tracking requirements are not sufficient given the high value of many of the unused pharmaceuticals en route to reverse distribution and the potential for diversion.

Accordingly, the Agency is proposing to amend § 273.80 to state that hazardous waste pharmaceuticals may not be added as a category of hazardous waste for management under the Universal Waste program. See Section IX State Authorization of the preamble for a discussion on the effect on the two states that have adopted pharmaceuticals under the Universal Waste program (Michigan and Florida).

By proposing a new set of management standards outside the confines of the Universal Waste program, it allows us greater flexibility in addressing the tracking of such shipments, as well as additional pharmaceutical waste management issues raised by stakeholders, such as drain disposal, container residues, pharmaceutical reverse distribution, and the overlap with DEA regulation. This new action will address the original stakeholder concerns that resulted in the 2008 Pharmaceutical Universal Waste proposal, as well as the comments received on that proposal.

To reiterate, EPA is not adding hazardous waste pharmaceuticals to the federal Universal Waste program. Rather, we are issuing sector-specific regulations for the management of hazardous waste pharmaceuticals by healthcare facilities and pharmaceutical reverse distributors. If finalized, these regulations will be codified in 40 CFR part 266, separate from both the generator regulations (40 CFR part 262) and the Universal Waste program (40 CFR part 273). This new proposed rulemaking will pertain to those waste pharmaceuticals that meet the current definition of a CRRA hazardous waste and are generated by healthcare-related facilities and managed by pharmaceutical reverse distributors, as defined by this proposal. Finally, as this current proposal is a direct result of the comments received on the December 2, 2008, Pharmaceutical Universal Waste proposal, the Agency considers the 2008 Pharmaceutical Universal Waste proposal obsolete. Therefore, EPA is withdrawing the Universal Waste proposal for pharmaceutical waste, and does not seek comment on any provisions of the 2008 Pharmaceutical Universal Waste proposal or the current Universal Waste program. The Agency will only be accepting comments from the public on the provisions of this new proposed rulemaking.

D. EPA’s Office of Inspector General Report

On May 25, 2012, the EPA’s Office of Inspector General (OIG) issued the report, “EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal” (Report No. 12-P-0508). The OIG reviewed EPA’s process for identifying and listing pharmaceuticals as hazardous wastes. Because of this review, the OIG provided the following recommendations to the Assistant Administrator for the Office of Solid Waste and Emergency Response (OSWER):

(1) Identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

(2) Establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

(3) Develop a nationally consistent outreach and compliance assistance plan to help states address challenges that healthcare facilities, and others as needed, have in complying with RCRA regulations for managing HWPs (hazardous waste pharmaceuticals) (Report No. 12-P-0508).

As detailed in OSWER’s response to OIG, this proposal fulfills our obligation.

27 For a copy of the report, please see: http://www.epa.gov/oig/reports/2012/20120525-12-P-0508.pdf or see the docket for this proposed rule: EPA–HQ–RCRA–2007–0032.
for addressing the third recommendation. EPA does not address the OIG’s first two recommendations as part of this proposed rulemaking; however, in Section VII of this preamble, we solicit comment on our ongoing efforts to identify additional pharmaceuticals as hazardous wastes.

V. Detailed Discussion of the Proposed Rule

EPA is proposing an entirely new set of regulations (40 CFR part 266, subpart P) for managing hazardous waste pharmaceuticals at both healthcare facilities and pharmaceutical reverse distributors. This section discusses in detail the major features of the proposal. The Agency also presents other options that it is considering or were considered in developing the proposed rule. EPA welcomes comments on all aspects of this proposed rule, and on options under consideration. Throughout this section, EPA requests comments on specific options and on specific issues, but comments are welcome on all provisions of this proposal.

A. What terms are defined in this proposed rule?

All the definitions that appear in this proposal are for the purposes of 40 CFR part 266, subpart P only. Therefore, the definitions are relevant only to healthcare facilities and pharmaceutical reverse distributors that are subject to these proposed standards. For the purposes of this regulation, the Agency is proposing and soliciting public comment on the following terms and their definitions presented below: “evaluated hazardous waste pharmaceutical,” “hazardous waste pharmaceutical,” “healthcare facility,” “household waste pharmaceutical,” “long-term care facility,” “non-creditable hazardous waste pharmaceutical,” “non-hazardous waste pharmaceutical,” “non-pharmaceutical hazardous waste,” “pharmaceutical,” “pharmaceutical reverse distributor,” and “potentially creditable hazardous waste pharmaceutical.” Although the proposed definitions appear in alphabetical order in the regulations, we have chosen to discuss the proposed definitions in a different order in the preamble.

1. What is the proposed definition of “pharmaceutical”?

This proposed rule defines “pharmaceutical” as any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act (FD&C Act), prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from the spills of pharmaceuticals.

This proposed definition of “pharmaceutical” is intended to include all dose forms, including, but not limited to tablets, capsules, medicinal gums or lozenges, medicinal liquids, ointments and lotions, intravenous (IV) or other compounded solutions, chemotherapy pharmaceuticals, vaccines, allergenic, medicinal shampoos, and any delivery device, including medicinal dermal patches, with the primary purpose to deliver or dispense the pharmaceutical. As a rule of thumb, if an over-the-counter product is required by the FDA to include “Drug Facts” on the label, it would be considered a pharmaceutical for the purposes of this rule. EPA asks for comment to identify additional types or forms of pharmaceuticals that are not adequately captured by the definition.

EPA previously proposed to define the term “pharmaceutical” in the December 2008 Pharmaceutical Universal Waste proposal to mean “any chemical product, vaccine or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or allergenic), not containing a radioactive component, that is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or injury in man or other animals; or any chemical product, vaccine, or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine, or allergenic), not containing a radioactive component, that is intended to affect the structure or function of the body in man or other animals. This definition includes products such as transdermal patches, and oral delivery devices such as gums or lozenges. This definition does not include sharps or other infectious or biohazard waste, dental amalgains, medical devices not used for delivering or dispensing purposes, equipment, contaminated personal protective equipment or contaminated cleaning materials.” This definition was adapted from FD&C Act’s definition for “drug” 21 U.S.C. 321(g).

Based on the comments received in response to the Pharmaceutical Universal Waste proposal, the Agency is continuing to rely primarily on the FD&C Act’s definition for “drug” for the definition of pharmaceutical in this proposal and has preserved most of the definition proposed in the previous proposal. However, EPA is proposing to expand on its previous proposed definition of pharmaceutical based on stakeholder input. In particular, stakeholders requested that the Agency take a broad view in delineating what items are included in the definition of pharmaceutical so that the proposed standards apply broadly. Stakeholders indicated a preference for managing more items under the new standards than trying to determine how to apply the existing RCRA framework to pharmaceutical related items. Thus, the proposed definition of pharmaceutical no longer excludes pharmaceuticals with a radioactive component and includes items not specifically recognized by the U.S. Food and Drug Administration (FDA) as drugs, such as dietary supplements and pharmaceutical residues in containers (including delivery devices), personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from spills of pharmaceuticals.

EPA’s decision to include dietary supplements under this rulemaking’s proposed definition of hazardous waste pharmaceutical reflects our interest in promoting a management scheme for all types of pharmaceuticals, and is based upon our understanding that dietary supplements are commonly found in various healthcare settings because they are recommended or prescribed by healthcare providers to patients. Further, retail pharmacies routinely sell vitamins and other medicinal minerals and supplements.

When EPA uses the term “dietary supplements” in our proposed definition of “pharmaceutical,” EPA is referencing the definition for dietary supplement used by the FDA, as amended by the Dietary Supplement Health and Education Act of 1994 (21 U.S.C. 321ff). EPA understands that...
the FDA does not recognize dietary ingredients or dietary supplements as "drugs." Rather, it categorizes such items under the general umbrella of foods and therefore, does not review them before being marketed. For the purposes of this proposed rule, however, EPA recognizes that healthcare facilities may benefit from managing dietary supplements along with other drugs under the regulatory scheme being proposed, and thus, is including it in the proposed definition of pharmaceutical. Although dietary supplements would be considered pharmaceuticals under this proposed definition, only the dietary supplements that meet the definition of hazardous waste (e.g., exhibits the toxicity characteristic for metal content) would be regulated under part 266, subpart P as hazardous waste pharmaceuticals (see the definition of "hazardous waste pharmaceutical"). We seek public comment on the Agency’s decision to recognize dietary supplements as pharmaceuticals under this regulation.

The Agency also is clarifying that its proposed definition includes any items containing pharmaceutical residuals, such as dispensing bottles, IV bags and tubing, vials, unit dose packages, and delivery devices, such as syringes and patches. In addition, EPA is proposing that items contaminated with or containing residual pharmaceuticals, such as personal protective equipment containing trace amounts of pharmaceutical residuals or lab spill clean-up materials (including loose tablets accumulated during pharmacy floor sweepings) also meet this proposed definition of pharmaceutical. However, this proposed definition does not include sharps (e.g., needles from IV bags or syringes). Used sharps, such as needles or syringes with needles, are not included under the proposed rule because sharps are considered medical wastes, presently regulated at the state and local level. In addition, sharps pose both an unreasonable physical danger and biohazard danger so have not been included in the definition of pharmaceutical under this proposed rule.

OSHA’s Technical Manual incorporates a recommendation from the American Society of Hospital Pharmacists that “all syringes and needles used in the course of preparation be placed in "sharps" containers for disposal without being crushed, clipped, or capped.” Further, as discussed in Section V.E.3.c of this preamble, EPA is proposing to conditionally exclude the residues of hazardous waste pharmaceuticals remaining in fully dispensed syringes from RCRA regulation. However, EPA is concerned about the possibility that some syringes may be disposed of in sharps containers that may contain significant amounts of undispensed pharmaceutical. EPA seeks comment on the prevalence of this situation.

The Agency solicits public comment on the proposed definition of "pharmaceutical" in its entirety, and particularly on EPA’s decision to incorporate dietary supplements and items containing pharmaceutical residuals as part of the definition of pharmaceutical.

2. What is the proposed definition of a “hazardous waste pharmaceutical”? This proposed rule defines “hazardous waste pharmaceutical” as a pharmaceutical that is a solid waste, as defined in §261.2, and is listed in part 261, subpart D, or exhibits one or more characteristics identified in part 261, subpart C. See Section IV.A.3. of this preamble for a discussion of pharmaceuticals that may be listed or characteristic hazardous wastes.

The Agency is proposing to define the term “hazardous waste pharmaceutical” in order to clarify its intent that only pharmaceuticals (as defined in this proposal) that meet the definition of hazardous waste when disposed or discarded need to be managed under these proposed management standards. This means that any pharmaceutical waste that meets the definition of hazardous waste is a hazardous waste pharmaceutical for the purposes of this rule. For example, the prescription pharmaceutical warfarin (brand name Coumadin) is a listed hazardous waste and when discarded meets the definition of a hazardous waste pharmaceutical. EPA requests public comment on the proposed definition for “hazardous waste pharmaceutical.” The Agency also solicits information on whether any dietary supplements currently on the market meet or potentially could meet RCRA’s definition of a hazardous waste.

3. What is the proposed definition of a “potentially creditable hazardous waste pharmaceutical”? In order to distinguish hazardous waste pharmaceuticals that are transported to RCRA treatment, storage and disposal facilities (TSDFs) from those hazardous waste pharmaceuticals being returned by a healthcare facility to a pharmaceutical reverse distributor for a determination or verification of manufacturer’s credit, the Agency is proposing a definition for “potentially creditable hazardous waste pharmaceutical.”

The proposed rule defines “potentially creditable hazardous waste pharmaceutical” to mean a hazardous waste pharmaceutical that has the potential to receive manufacturer’s credit and is (1) unused or un-administered; and (2) unexpired or less than one year past expiration date.

The term does not include “evaluated hazardous waste pharmaceuticals,” residues of pharmaceuticals remaining in containers, contaminated personal protective equipment, and clean-up material from the spills of pharmaceuticals.

Whether a pharmaceutical is eligible for manufacturer’s credit is determined solely by the manufacturer’s return policy. Based on comments received for the 2008 Universal Waste proposed rule and through discussions with various stakeholders, the Agency understands that the return policies of manufacturers change regularly. As a result, pharmacies are not always aware if a particular pharmaceutical will be creditable at the time that it is pulled from the shelves. However, the Agency also understands that there are instances where it is well known that a pharmaceutical will not be creditable. Examples of these instances include the following: if the pharmaceutical has been removed from the original container and re-packaged for dispensing purposes; if an attempt was made to administer a pharmaceutical, but the patient refused to take it; if the hazardous waste pharmaceutical was generated during patient care; if the pharmacy receives a return of a dispensed pharmaceutical for which...
they had already received compensation by a third-party payer; or if the pharmaceutical is more than one year past its expiration date. In these instances, as well as others, the healthcare facility knows that it will not receive manufacturer’s credit. It is the Agency’s intent for the proposed definition of potentially creditable hazardous waste pharmaceuticals to allow the return of hazardous waste pharmaceuticals to reverse distributors for the determination of credit. It is not the Agency’s intent, however, for reverse distributors to serve in the capacity as TSDFs when it is well known that the manufacturer will not give credit for those hazardous waste pharmaceuticals.

Also, based on communication with stakeholders and the public comments received on the 2008 Universal Pharmaceutical Waste proposal, EPA understands that pharmaceutical manufacturers’ policies often allow for credit to be received on the return of ‘‘partials.’’ Partials is a term used in the industry to refer to opened containers that have had some contents removed. Under the proposed definition, the Agency would consider partials to be potentially creditable hazardous waste pharmaceuticals.

The Agency is soliciting comment on the proposed definition of ‘‘potentially creditable hazardous waste pharmaceutical’’ and whether the definition is broad enough to encompass the various types of hazardous waste pharmaceuticals that are shipped to reverse distributors for manufacturer’s credit, while also ensuring that non-creditable hazardous waste pharmaceuticals are not inappropriately shipped to reverse distributors solely for waste management purposes. Finally, the Agency is seeking comment on additional situations where it is well known that a returned pharmaceutical will or will not receive manufacturer’s credit.

4. What is the proposed definition of ‘‘non-creditable hazardous waste pharmaceutical’’?

As discussed previously, there are instances when it is well known that credit will not be received for certain hazardous waste pharmaceuticals. In order to distinguish hazardous waste pharmaceuticals that have the potential for credit from those that have no expectation of receiving credit, the Agency is proposing to define the term ‘‘non-creditable hazardous waste pharmaceutical.’’ The proposed definition of a ‘‘non-creditable hazardous waste pharmaceutical’’ is a hazardous waste pharmaceutical that is not expected to be eligible for manufacturer’s credit. Examples include, but are not limited to: if the pharmaceutical has been removed from the original container and re-packaged for dispensing purposes; if an attempt was made to administer a pharmaceutical, but the patient refused to take it; if the hazardous waste pharmaceutical was generated during patient care; if the pharmacy receives a return of a dispensed pharmaceutical for which they had already received compensation by a third-party payer (e.g., health insurance company); or if the pharmaceutical is more than one year past its expiration date. EPA requests comment on the proposed definition and seeks additional examples of hazardous waste pharmaceuticals that have no expectation of receiving manufacturer’s credit.

5. What is the proposed definition of ‘‘evaluated hazardous waste pharmaceutical’’?

After potentially creditable hazardous waste pharmaceuticals arrive at a pharmaceutical reverse distributor, they are evaluated to determine whether they are eligible for manufacturer’s credit, or whether they need to be transferred to another pharmaceutical reverse distributor for additional verification of manufacturer’s credit. Hazardous waste pharmaceuticals that need to be transferred to another pharmaceutical reverse distributor for additional verification of manufacturer’s credit will continue to be considered potentially creditable hazardous waste pharmaceuticals. EPA is proposing that hazardous waste pharmaceuticals for which manufacturer’s credit has been issued (and no further verification of credit is required), as well as those that have been deemed non-creditable, be referred to as ‘‘evaluated hazardous waste pharmaceuticals.’’ EPA is proposing to define ‘‘evaluated hazardous waste pharmaceutical’’ as a hazardous waste pharmaceutical that was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a pharmaceutical reverse distributor to establish whether it is eligible for manufacturer’s credit and will not be sent to another pharmaceutical reverse distributor for further evaluation or verification. It is important to define this term since the proposed management and shipping standards for potentially creditable hazardous waste pharmaceuticals differ from the proposed management and shipping standards for evaluated hazardous waste pharmaceuticals. For a discussion of the proposed management and shipping standards for potentially creditable hazardous waste pharmaceuticals, see Section V.F.2. For a discussion of the proposed management and shipping standards for evaluated hazardous waste pharmaceuticals, see Section V.F.1.b.

6. What is the proposed definition of ‘‘household waste pharmaceutical’’?

We are proposing to define the term ‘‘household waste pharmaceutical’’ as a solid waste, as defined in § 261.2, that also meets the definition of pharmaceutical, as defined in this proposed rule, but is not a hazardous waste because it is exempt from RCRA Subtitle C regulation by the household waste exclusion in § 261.4(b)(1). We are proposing this term to distinguish this type of waste pharmaceutical from the hazardous waste pharmaceuticals that are proposed to be regulated under this new subpart. This proposed rule does not apply to pharmaceutical waste that is exempt due to the household waste exclusion.

7. What is the proposed definition of ‘‘non-hazardous waste pharmaceutical’’?

We are proposing to define the term ‘‘non-hazardous waste pharmaceutical.’’ While hazardous waste pharmaceuticals are proposed to be regulated under this new subpart, non-hazardous waste pharmaceuticals will not be regulated under this new subpart, nor the RCRA Subtitle C hazardous waste regulations. The Agency is proposing to include this definition since we believe it important to delineate what is and is not regulated under this new subpart. We propose to define the term ‘‘non-hazardous waste pharmaceutical’’ to mean a pharmaceutical that is a solid waste, as defined in § 261.2, but that is not a listed hazardous waste and does not exhibit any characteristics of hazardous waste (i.e., ignitable, corrosive, reactive, toxic).

8. What is the proposed definition of ‘‘non-pharmaceutical hazardous waste’’?

Like the previous definition, we are proposing a definition for non-pharmaceutical hazardous waste to help us delineate what is and what is not regulated under this new subpart. We are proposing to define the term ‘‘non-pharmaceutical hazardous waste’’ as a solid waste, as defined in § 261.2, that is either a listed hazardous waste or exhibits one or more characteristics of hazardous waste, but does not meet the definition of a pharmaceutical, as proposed under this new subpart. The management of non-pharmaceutical hazardous wastes is not regulated under this subpart; rather generators of non-
pharmaceutical hazardous wastes, including healthcare facilities and reverse distributors, remain subject to the existing Subtitle C hazardous waste regulations for the management of those hazardous wastes. Examples of non-pharmaceutical hazardous wastes that healthcare facilities may generate include cleaning solutions, solvents, and laboratory wastes. Some hazardous wastes exist in pharmaceutical form and non-pharmaceutical form. For example, warfarin, nicotine, and lindane were all originally listed as hazardous waste because they were pesticides, not medicines. If these products are not intended for human or animal use, they would be considered non-pharmaceutical hazardous wastes and remain subject to the existing RCRA hazardous waste regulations, not part 266, subpart P.

9. What is the proposed definition of a “healthcare facility”? These proposed regulations differ from those in the Pharmaceutical Universal Waste proposal in that they apply based not only on the type of hazardous waste generated, but also on the sector generating the waste. Accordingly, EPA is proposing a definition for “healthcare facility” so that it is clear to whom these proposed regulations apply. This proposed definition is adapted from the definition of “health care” that the Department of Health and Human Services (DHHS) promulgated as a result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 CFR part 160.103). Thus, for the purposes of these proposed regulations, EPA is proposing that “healthcare facility” means any person that (1) provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal that affects the structure or function of the human or animal body; or (2) sells or dispenses over-the-counter or prescription pharmaceuticals. This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians’ offices, optical and dental providers, chiropRACTORS, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and

hospitals. Thus, these proposed regulations will be applicable to any healthcare facility for human or animal which generates hazardous waste pharmaceuticals on its premises.

EPA proposes to include coroners in the definition of a healthcare facility despite the fact that the services coroners provide occur after life. Coroners will often inventory, and then dispose of, any pharmaceuticals that may be found at the scene of a death. A common method of disposal is sewer. In order to reduce the sewer disposal practices of coroners, and to provide the same management options that are available to other healthcare facilities, EPA has decided to include “coroners” within the definition of healthcare facility, although the Agency solicits comment on including coroners within the definition of healthcare facility. Under the proposed definition, healthcare facilities include locations that sell pharmaceuticals over the internet, through other distribution mechanisms. A pharmacy does not necessarily have to have a “brick and mortar” or “store front” presence to be considered a healthcare facility for the purposes of this proposed rule. The proposed definition of a “healthcare facility” also applies to entities that engage in drug compounding. In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. The proposed definition of “healthcare facility” applies to state-licensed pharmacies, Federal facilities, and licensed physicians that compound drugs in accordance with section 503A of the FD&C Act, and to outsourcing facilities that compound drugs in accordance with section 503B of the FD&C Act. The Agency is soliciting comment on the proposed definition of “healthcare facility,” including whether it is appropriate to consider these compounding as healthcare facilities within the scope of this proposed rule. The proposed definition of “healthcare facility” does not apply to pharmaceutical manufacturers and their representatives, wholesalers, or any other entity that is involved in the manufacturing, processing or wholesale distribution of over-the-counter or prescription pharmaceuticals, unless they meet the definition of a “reverse distributor” as discussed in this section and in Section V.G. The purpose for these sector-based regulations is to address the various issues that healthcare facilities and reverse distributors face when managing hazardous waste pharmaceuticals. As noted previously, the Agency does not anticipate that manufacturing facilities, which predictably generate a known range of hazardous wastes, face the same issues as healthcare facilities.

10. What is the proposed definition of a “long-term care facility”? The term “long-term care facility” does not have a standardized, industry definition. EPA is, therefore, proposing the following definition for “long-term care facility” (LTCF): a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, assisted living, hospices, nursing homes, skilled nursing facilities, and the assisted living and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, and the independent living portions of continuing care retirement communities. The included facilities are licensed care facilities that are more similar to hospitals than to standard residences. Although group homes may be licensed care facilities, they are typically very small (under 10 beds). Independent living communities are not licensed care facilities, but rather are residences made up of individual units such as townhomes or apartments. Finally, private residences with visiting nurses are not considered long-term care facilities. EPA requests public comment on the proposed definition of long-term care facility, and the inclusion of assisted living facilities, skilled nursing facilities and other LTCFs that administer their residents’ pharmaceuticals as an integral part of their services within the definition of “healthcare facility.” The DEA’s definition of “long term care facility” is “a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients” (21 CFR 1300.01). EPA’s definition is more descriptive, and includes a list—which not

The Agency also needs to clarify the difference between what is defined as a pharmaceutical reverse distributor for the purposes of these proposed regulations and how DEA regulations define "reverse distribute." The recently amended DEA regulatory definition of "reverse distribute" is to "acquire controlled substances from another registrant or law enforcement for the purposes of: (1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer’s behalf; or (2) Destruction (21 CFR 1300.01).39

Under DEA’s definition, a reverse distributor does not necessarily process pharmaceuticals for the purpose of determining manufacturer’s credit; rather, their main function under DEA’s definition is to destroy the controlled substances. Under EPA’s proposed definition, however, a pharmaceutical reverse distributor is defined more broadly as a facility that can accept potentially creditable pharmaceuticals for the purposes of determining manufacturer’s credit. These potentially creditable pharmaceuticals may or may not be identified as controlled substances by DEA.40 Therefore, a DEA-registered reverse distributor may or may not meet EPA’s definition of a pharmaceutical reverse distributor and vice versa. For example, a pharmaceutical reverse distributor that accepts controlled substances (that are also hazardous wastes) for the sole purpose of destruction (e.g., incineration) would be regulated as a DEA-registered reverse distributor and as a RCRA TSDF, and not as a pharmaceutical reverse distributor under the RCRA hazardous waste regulations. Conversely, a pharmaceutical reverse distributor that processes pharmaceuticals for manufacturer’s credit, but is not a DEA registrant and therefore, cannot accept controlled substances, would meet the RCRA pharmaceutical reverse distributor definition, but not DEA’s reverse distributor definition. However, EPA has heard from stakeholders that many, if not all, entities that facilitate manufacturer’s credit are also DEA-registered reverse distributors. Therefore, such pharmaceutical reverse distributors would meet both EPA’s proposed definition of pharmaceutical reverse distributor, as well as the DEA’s definition of reverse distributor. Lastly, we would note that EPA’s definition for reverse distribution does not alter or supersede the requirements of the Controlled Substances Act and DEA regulations.

In addition, the Department of Transportation’s Pipeline and Hazardous Materials Safety Administration (PHMSA) has defined the closely related term, “reverse logistics,” in a recent proposed rulemaking.41 The EPA has been coordinating with the PHMSA to ensure that our rules are compatible, even if the definitions differ. It is important to note that, when finalized, the PHMSA rule will not supersede EPA’s RCRA Subtitle C regulations for when something is considered a solid or hazardous waste or how a hazardous waste must be managed.

The Agency solicits public comment on its proposed definition of a “pharmaceutical reverse distributor.” Specifically, EPA asks for comment on whether the definition of “pharmaceutical reverse distributor” captures the universe of facilities acting as reverse distributors for pharmaceuticals. In addition, the Agency asks for comment regarding the intersection of DEA and EPA’s definitions.

B. What is the scope of this proposed rule?

1. What facilities are subject to this rulemaking?

a. Healthcare facilities. The Agency is proposing that healthcare facilities that are currently considered either SQGs or LQGs will be required to manage all hazardous waste pharmaceuticals generated at their facilities in accordance with the standards proposed in this document. In other words, these management standards will apply to any healthcare facility that generates (or accumulates) more than 100 kg of hazardous waste per calendar month or more than 1 kg of acute hazardous waste per calendar month (e.g., P-listed hazardous waste) or more than 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31, or 261.33(e) per calendar month. All healthcare facilities

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37 As noted in the definition of “potentially creditable hazardous waste pharmaceutical,” credit is provided for those pharmaceuticals that are less than one year past the expiration date.

38 Through the return of pharmaceuticals by a pharmacy for manufacturer’s credit, manufacturers are able to maintain control of the pharmaceutical up to the point of its disposal, thereby, decreasing the risk of diversion of the pharmaceutical.

39 On September 9, 2014, DEA finalized new definitions for “reverse distribute” and “reverse distributor.” Please see 79 FR 53520. The term “reverse distributor” is defined as “a person registered with the Administration [DEA] as a reverse distributor.”

40 In order for a reverse distributor to be able to accept controlled substances, the reverse distributor must be a DEA registrant. See 21 CFR part 1308 for a complete list of controlled substances.

41 79 FR 46748; August 11, 2014. The PHMSA’s proposed definition of reverse logistics “is the process of moving goods from their final destination for the purpose of capturing value, recall, replacement, proper disposal, or similar reason.”
that meet these applicability criteria will be subject to the same set of standards for the management of their hazardous waste pharmaceuticals. That is, subpart P is not optional for healthcare facilities that generate above the CESQG monthly quantity limits (see Section V.B.1.c. of the preamble for a discussion of what regulations apply to CESQGs). EPA is proposing to make subpart P mandatory to promote national consistency, a goal championed by stakeholder comments as well as EPA. In addition, having one set of standards applicable to pharmaceutical waste will be less confusing to the regulated community, which should lead to better compliance. The stringency of the subpart P management standards for hazardous waste pharmaceuticals do not change if a healthcare facility generates more hazardous waste pharmaceuticals from one month to another. The generator categories—that is, LQG, SQG, and CESQG—under the part 262 RCRA requirements will only be relevant for the healthcare facilities’ non-pharmaceutical hazardous waste because non-pharmaceutical hazardous waste remain subject to the 40 CFR part 262 generator regulations (see Section VI. Implementation and Enforcement for further discussion).

b. Long-term care facilities subject to this rule. Long-term care facilities are included within the proposed definition of healthcare facility. Further, EPA is proposing to change its policy regarding the management of hazardous waste and hazardous waste pharmaceuticals generated on the premises of long-term care facilities. Under current federal RCRA interpretation (see 73 FR 73525, December 2, 2008), hazardous wastes (including pharmaceuticals) generated on the premises of a long-term care facility can fall under two categories: (1) RCRA Subtitle C hazardous waste or (2) household hazardous waste that is exempt from RCRA Subtitle C regulation. As explained in the preamble to the proposal to add pharmaceuticals to the Universal Waste program, “the [long-term care] facility itself may generate hazardous wastes as a result of its central management of pharmaceuticals in its pharmacy or pharmacy-like area. These hazardous pharmaceutical wastes would be subject to the RCRA hazardous waste generator regulations since the pharmaceuticals are under the control of the facility, and thus, the resulting wastes are generated by that facility. However, patients and residents in long-term care facilities may generate hazardous wastes. Those pharmaceuticals that are under the control of the patient or resident of the long-term care facility, when discarded, would be subject to RCRA’s household hazardous waste exclusion (§ 261.4(b)(1)). Hazardous pharmaceutical wastes generated by the resident are excluded from regulation because they are considered to be derived from a household” (see December 2, 2008; 73 FR 73525).

The Agency is now providing notice that it intends to revise this interpretation. Specifically, hazardous waste (including pharmaceuticals) generated at long-term care facilities will no longer be considered exempt as household hazardous waste. It will be regulated as hazardous waste, subject to the appropriate RCRA Subtitle C management standards, including the standards being proposed. The Agency is revising its interpretation with regard to hazardous wastes generated at long-term care facilities based on a reevaluation of how such facilities operate. Specifically, in order for hazardous waste to qualify for the household hazardous waste exemption of § 261.4(b)(1), it must meet two criteria: (1) The hazardous waste must be generated by individuals on the premises of a household, and (2) the hazardous waste must be composed primarily of materials found in the wastes generated by consumers in their homes. EPA now believes that hazardous waste generated at long-term care facilities, even when those pharmaceuticals are under the control of the patient or resident, does not meet either criterion for the household hazardous waste exemption.

First, a long-term care facility is more akin to a hospital than it is a typical residence and EPA does not consider hospitals to be households. Long-term care facilities are licensed, residential care settings that offer their residents a range of services, many of which are centered on administering medications and providing healthcare by various professional healthcare providers, such as medical technicians, nurse’s aides, nurses, and doctors. Other services provided involve assistance in performing activities of daily living, such as bathing, and eating. A 2012 American Association of Retired Person (AARP) Public Policy Institute report indicates that “residents take an average of seven or eight different prescriptions and two OTC [over-the-counter] medications daily.” This number is larger than what we would expect a typical household to generate. This distinction about volume of waste is analogous to the distinction that EPA has made in the past about contractor or do-it-yourself waste from

2012-AARP_ppi LTC pdf or see the docket for this proposed rulemaking (EPA-HQ-RCRA-2007-0032).

2009 Overview of Assisted Living: a collaborative research project of AAHSA, ASHA, ALFA, NCAL & NIC.

43 Ibid.

44 Net weight (without packaging) of types of pharmaceuticals wastes, including those that are RCRA hazardous, non-RCRA hazardous, DEA controlled, prescription and over-the-counter. Memo from Lillian Gonzalez, Colorado Department of Public Health and Environment to Kristin Fitzgerald, EPA; January 9, 2013, see the docket for this proposed rulemaking (EPA-HQ-RCRA-2007-0032).

Based on another report prepared as a collaborative project of the American Association of Homes and Services for the Aging (AAHSA), American Seniors Housing Association (ASHA), Assisted Living Federation of America (ALFA), National Center for Assisted Living (NCAL) and National Investment Center for the Seniors Housing and Care Industry (NIC), there is an average of 54 units (e.g., rooms) for all types of assisted living/dementia care properties. Unlike other multiple dwellings, approximately 8 percent of these facilities store medications in a central location and 89 percent administer medications to their residents. Given that long-term care facilities are licensed settings for the care of their residents and routinely provide healthcare services, we believe that long-term care facilities more closely resemble hospitals than typical residences.

Second, the hazardous wastes generated by long-term care facilities do not meet the second criteria for the waste to be considered household hazardous waste. This is primarily due to the quantity of pharmaceuticals wastes that are often generated on the premises of long-term care facilities when compared to a typical residence. For example, the Colorado Department of Public Health and Environment estimates that a 100-bed nursing home might expect to generate approximately 120 to 336 pounds of pharmaceutical waste per year. In addition, long-term care facilities, such as assisted living facilities and nursing homes, generate a greater variety of hazardous waste pharmaceuticals and a greater quantity of hazardous waste than a typical household generates. The AARP Public Policy Institute report indicates that "residents take an average of seven or eight different prescriptions and two OTC [over-the-counter] medications daily." This number is larger than what we would expect a typical household to generate. This distinction about volume of waste is analogous to the distinction that EPA has made in the past about contractor or do-it-yourself waste from
households: waste from “routine residential maintenance” is exempt as household hazardous waste, while waste from “building construction, renovation, demolition” is not exempt. Therefore, EPA is providing notice that if this rule is finalized, long-term care facilities may no longer use the household hazardous waste exemption. If this rule is finalized, long-term care facilities would need to manage their hazardous waste pharmaceuticals in accordance with the applicable RCRA hazardous waste generator requirements in §261.5 (for CESQGs) or part 262 (for SQGs and LQGs). However, even though long-term care facilities will no longer be considered eligible to use the household hazardous waste exemption, our data show that only 28% of long-term care facilities generate hazardous waste pharmaceuticals, and of those, 85% are small enough to be considered CESQGs of hazardous waste (regulated under §261.5) and therefore not subject to part 266, subpart P (except the sewer ban). The Agency seeks comment on whether this proposed change to consider long-term care facilities to be healthcare facilities instead of households is appropriate. We also seek comment on the extent to which long-term care facilities will pass the cost of compliance onto its customers. Until this rule is finalized, the current interpretation from the Universal Waste Preamble will stand regarding hazardous waste from long-term care facilities.

c. Conditionally exempt small quantity generators (CESQGs). As discussed in the Background Section (Section IV.A.2), CESQGs are subject to a limited set of federal RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in §261.5. This proposed rulemaking will preserve this current regulatory structure for the most part; therefore, healthcare facilities that generate hazardous waste pharmaceuticals and qualify as CESQGs, will maintain their conditional exemption under §261.5 and will not be subject to most aspects of this proposal. However, as part of this rulemaking, EPA is proposing a ban on sewer disposal of hazardous waste pharmaceuticals by all healthcare facilities and reverse distributors. EPA is proposing that the sewer ban would apply to all healthcare facilities, including CESQG healthcare facilities. Please see Section V.E.1 of this preamble for a more detailed discussion on this proposed sewer prohibition. EPA asks for comment on whether the proposed healthcare facility standards, in addition to the sewer ban, should apply to CESQG healthcare facilities.

EPA is proposing one additional change for CESQGs in order to allow them to continue to send their potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor. Currently, under §261.5, CESQGs are limited in where they may send their hazardous waste for treatment and disposal (see §261.5(f)(3)(i)-(vii) for acute hazardous waste and §261.5(g)(3)(i)-(vii) for hazardous waste). However, in §266.504(a) we are proposing to allow CESQGs to send their potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor. Without this change, CESQGs would be required to send all their hazardous waste pharmaceuticals, including those that are potentially creditable, to one of the types of facilities in §261.5, which does not include a pharmaceutical reverse distributor. Although we are proposing to make this change within part 266, subpart P, we request comment on whether stakeholders would prefer this change to be made within §261.5 instead. CESQGs will still be required to send their non-pharmaceutical hazardous waste and their non-creditable hazardous waste pharmaceuticals to one of the types of facilities listed in §261.5.

In addition, it has been suggested that EPA seek comment on providing a rebuttable presumption that LTCFs with fewer than 10-beds are assumed to be CESQGs and thus would not be required to count the amount of hazardous waste generated each month. Under this presumption, they would be subject to all the requirements for CESQGs as described elsewhere in this proposal, including the requirement not to sewer hazardous waste pharmaceuticals. Therefore, we seek comment on this rebuttable presumption and specifically whether the 10-bed cut off is appropriate or whether there are other criteria EPA should take into account. Further, EPA asks for comments to submit data to support a 10-bed cut off to show that LTCFs with fewer than 10-beds are generally CESQGs. Alternatively, if comments wish to support a different cut-off for the rebuttable assumption, EPA also asks that the commenters submit information/data to support their suggested cut-off.

d. Pharmaceutical reverse distributors. EPA is proposing that pharmaceutical reverse distributors, including pharmaceutical manufacturers, which accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals are subject to this rule. Pharmaceutical reverse distributors are only subject to this proposed rule for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals; if a reverse distributor also treats and/or disposes of hazardous waste pharmaceuticals, it is subject to the applicable RCRA Subtitle C TSDF regulations, including the requirement to have a permit or interim status. Stakeholders have indicated a strong preference for EPA to clarify how pharmaceutical reverse distributors are regulated under RCRA, as states have applied varied hazardous waste regulatory approaches to pharmaceutical reverse distributors. EPA is proposing specific standards in 40 CFR part 266, subpart P for pharmaceutical reverse distributors (as defined in this proposed rule) that incorporate various generator standards, as well as some TSDF standards. See Section V.G for more information.

2. To what facilities does this rule not apply?

a. Pharmaceutical manufacturers. EPA does not intend for these proposed regulations to apply to hazardous waste pharmaceuticals that are generated by pharmaceutical manufacturers or wholesalers. Pharmaceutical manufacturers and wholesalers do not face the same challenges that healthcare facilities experience when managing hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals in accordance with the federal RCRA subtitile C requirements (for an explanation of the challenges healthcare facilities face, see discussion in section IV.B.1 of the preamble). These entities (i.e., manufacturers and wholesalers) generate hazardous waste pharmaceuticals that are more predictable and the staff have the
necessary expertise to determine which pharmaceutical waste is hazardous waste. However, as mentioned previously, when any facility, including a pharmaceutical manufacturer, meets the definition found in this proposal for a “pharmaceutical reverse distributor,” it would be subject to the proposed regulations for pharmaceutical reverse distributors with respect to those operations.

b. Households. The Agency would like to emphasize that the regulatory requirements in this proposed rule do not apply to households or to household pharmaceutical collection and take-back events and programs. (For information regarding collection programs, see Section V.E.2.) Pharmaceuticals that are unwanted by consumers (households) are not regulated as hazardous waste and are generally considered municipal solid wastes. While a small percentage of these household waste pharmaceuticals meet the definition of hazardous waste under RCRA, the federal RCRA hazardous waste regulations include an exclusion for all hazardous wastes generated by households (see the “household hazardous waste” exclusion at §261.4(b)(1)). Thus household waste pharmaceuticals—like other household hazardous wastes—are not subject to the federal RCRA hazardous waste regulations.

EPA excluded household wastes because the legislative history of RCRA indicated an intent to exclude such wastes, though not because they necessarily pose no hazard. Some household products, including pharmaceuticals, contain ignitable, corrosive, reactive, or toxic ingredients. As a result, for household hazardous waste collected at a take-back event or program, the Agency has historically recommended that communities operating the collection programs manage the collected household hazardous wastes as hazardous waste, even though it is not required by RCRA. Furthermore, the Agency has recently recommended that collected household waste pharmaceuticals be incinerated—preferably at a permitted hazardous waste incinerator, but when that is not feasible, at a large or small municipal waste combustor.

The Agency believes that this practice is already common among collection programs since one goal of many collection programs is to divert pharmaceuticals from municipal landfills. Nevertheless, the Agency is proposing to make this recommendation a requirement for collected household waste pharmaceuticals in §266.506. The Agency seeks comment on changing this recommendation to a requirement for pharmaceutical collection programs.

The Agency recommends that, whenever possible, households utilize pharmaceutical take-back events as the disposal option for their unwanted pharmaceuticals. For consumers without access to a pharmaceutical take-back event, FDA provides information on the disposal of unused pharmaceuticals and step-by-step guidance for disposing of pharmaceuticals in the household trash. For more information on the safe disposal of household pharmaceuticals, please see: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicinesafely/EnsuringSafeUseOfMedicines/SafeDisposalofMedicines/ucm186187.htm.

3. Which hazardous wastes are addressed by this proposed rule?

a. Hazardous waste pharmaceuticals. If finalized, these regulations will only pertain to those pharmaceutical wastes that are RCRA hazardous wastes generated by healthcare facilities or managed by pharmaceutical reverse distributors. Under this rulemaking, EPA is not proposing to add additional pharmaceuticals to the hazardous waste listings or to expand the hazardous waste characteristics to include additional pharmaceuticals. See Section VII of the preamble, Request for Comment on EPA’s Efforts to Identify Additional Pharmaceuticals as Hazardous Waste, for a discussion of possible future actions by EPA to regulate additional pharmaceuticals as hazardous waste.

b. How does this proposal affect hazardous waste pharmaceuticals that are also regulated by other federal or state regulations? The management, transportation, treatment, storage and disposal of hazardous waste pharmaceuticals are regulated under RCRA Subtitle C. However, hazardous waste pharmaceuticals may also be subject to a number of other statutes and implementing regulations administered by state or other federal agencies. Examples include pharmaceuticals that are subject to the Controlled Substances Act and DEA regulations; infectious pharmaceutical wastes that are subject to state and local medical waste regulations; and pharmaceuticals with a radioactive component that are subject to the Atomic Energy Act (AEA). These potentially overlapping requirements make the appropriate management of pharmaceutical wastes a complex matter. The following discusses the impact of this proposed rule on various dually regulated hazardous waste pharmaceuticals.

i. Hazardous waste pharmaceuticals that are also controlled substances. Under current regulations, any healthcare facility generating or managing a RCRA hazardous waste pharmaceutical that is also a controlled substance listed in Schedule II–V must comply with the RCRA hazardous waste requirements, as well as the requirements of the Controlled Substances Act and DEA regulations. Recently revised DEA regulations to implement the Secure and Responsible Drug Disposal Act of 2010 require that controlled substances be destroyed so that they are “non-retrievable.” In the preamble to both the proposed and final rules, DEA has stated that flushing alone will not meet DEA’s new non-retrievable standard. Stakeholders have told EPA that it is expensive and difficult to incinerate controlled substances that are also hazardous wastes under both DEA and EPA regulatory schemes. As a result, healthcare facilities with hazardous waste pharmaceuticals that are also controlled substances have often sewered on-site in order to avoid the expense of complying with dual regulations that would apply if they were incinerated. Due to difficulties associated with managing these hazardous waste pharmaceuticals that are also controlled substances, the Agency is proposing to conditionally exempt from RCRA regulatory requirements those pharmaceuticals that are both a RCRA hazardous waste and a DEA controlled substance, provided the hazardous waste pharmaceuticals that are also DEA controlled substances are combusted at a permitted or interim...
status hazardous waste incinerator, or a permitted municipal solid waste incinerator. A more detailed discussion of this exemption is found in Section V.E.2 of this proposal, Conditional Exemption for Hazardous Waste Pharmaceuticals that are also Controlled Substances.

ii. Hazardous waste pharmaceuticals that are also medical wastes. There are instances when a hazardous waste pharmaceutical will also exhibit a biological hazard. The healthcare industry often refers to pharmaceutical wastes that are both RCRA hazardous and a biological hazard as “dual wastes,” and such wastes must be managed in accordance with RCRA and state and/or local medical waste regulations. As a result, the healthcare facility must send these dual wastes to a hazardous waste treatment, storage and disposal facility that is also permitted to accept medical wastes. Some examples of dual wastes include un-administered syringes containing hazardous waste pharmaceuticals (e.g., physostigmine) or IV bags containing residues of a hazardous waste pharmaceutical that are attached to the tubing and needles used to administer the pharmaceutical. The RCRA hazardous waste pharmaceutical portion of these “dual” wastes are included within these proposed management standards so that healthcare facilities can obtain the benefits of this proposal, while ensuring the hazardous waste portion of the waste is managed appropriately and ultimately delivered to RCRA-permitted TSDFs. In addition, healthcare facilities must still manage the biological hazard in accordance with state and/or local medical waste requirements. EPA notes that autoclaving is not an acceptable method of treating hazardous wastes that are also medical waste. In addition, as discussed in Section V.E.3.c of this preamble, EPA is proposing to conditionally exclude the residues of hazardous waste pharmaceuticals remaining in fully dispensed syringes from RCRA regulation.

iii. Hazardous waste pharmaceuticals that contain a radioactive component. Hazardous waste pharmaceuticals that also contain a radioactive component subject to the Atomic Energy Act of 1954 (AEA) (i.e., “mixed waste”) are regulated by multiple agencies. The hazardous waste component is regulated under EPA or the authorized state RCRA programs, while either the Nuclear Regulatory Commission (NRC) or the Department of Energy (DOE) regulates the radioactive component of the waste under the AEA.57 Healthcare facilities would be able to use this rule (if finalized) to comply with the hazardous waste component for hazardous waste pharmaceuticals. Although we do not believe that anything in this proposal is inconsistent with the AEA, § 1006(a) of RCRA states that if the RCRA requirements are inconsistent with the AEA requirements, then the RCRA requirements do not apply. Therefore, if a healthcare facility that manages hazardous waste pharmaceuticals encounters specific RCRA requirements that are inconsistent with specific AEA requirements, only the AEA requirements would apply.

As is discussed in the Joint NRC/EPA Guidance on Testing Requirements for Mixed Radioactive and Hazardous Waste (62 FR 62079, 62085; November 20, 1997), an inconsistency occurs when compliance with one statute or set of regulations would necessarily cause non-compliance with the other statute or set of regulations. Relief from the regulatory inconsistency would be provided by the AEA requirement overriding the specific RCRA requirement. It is important to note, however, that the determination of an inconsistency would relieve the healthcare facility only from compliance with the specific RCRA requirement(s) that is deemed inconsistent with the AEA requirement(s); it would still be required to comply with all of the other hazardous waste pharmaceutical management standards.

4. Management of Wastes Generated at Healthcare Facilities That Are Not Included in the Scope of this Proposed Rule

Wastes that are not included in the scope of this proposed rule include non-hazardous wastes or non-pharmaceutical hazardous wastes. Pharmaceutical wastes that are not listed or characteristic hazardous wastes under RCRA Subtitle C may nonetheless pose some risks to public health and the environment. These wastes are discussed further below.

a. How should non-hazardous waste pharmaceutical be disposed? A large portion of the pharmaceutical wastes generated at healthcare facilities will not meet the definition of a RCRA hazardous waste under RCRA Subtitle C. This proposal, therefore, does not require that healthcare facilities manage these waste pharmaceuticals under the RCRA subtitle C hazardous waste regulations, including this proposed rule. However, a healthcare facility may choose to manage its solid and hazardous waste pharmaceuticals together (as hazardous waste pharmaceuticals) under these new proposed regulations. Because all healthcare facilities operating under this subpart are regulated in the same way regardless of quantity of pharmaceutical hazardous waste generated, managing non-hazardous waste pharmaceuticals as hazardous waste under this subpart would not affect the facility’s hazardous waste generator category. While not regulated by the federal RCRA hazardous waste requirements, non-hazardous waste pharmaceuticals are still considered solid wastes under the federal regulations and must be managed in accordance with applicable federal, state and/or local regulatory requirements.

If a healthcare facility decides to segregate its hazardous and non-hazardous pharmaceuticals, EPA recommends that healthcare facilities follow the best management practices (BMPs) outlined in the “Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States” (Practice Greenhealth, Revised August 2008)58 for the management, treatment, storage and disposal of non-hazardous waste pharmaceuticals. The following summarizes the recommended BMPs found in the Blueprint for various categories of pharmaceutical wastes, including those wastes that possess hazardous waste-like qualities yet are not regulated as hazardous waste under RCRA Subtitle C. Recommended BMPs for healthcare facilities managing non-hazardous waste pharmaceuticals possessing hazardous waste-like qualities. Currently, most pharmaceuticals are not regulated as RCRA hazardous wastes when discarded by healthcare facilities. These “non-RCRA-hazardous” pharmaceuticals can be divided into two categories: those that possess hazardous waste-like qualities and those that do not. As outlined in the Blueprint, there are pharmaceuticals that possess hazardous waste-like qualities, but for various reasons, are not regulated by the RCRA Subtitle C hazardous waste regulations. The Agency supports the Blueprint’s

57 The NRC regulates radioactive wastes generated by commercial or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

58 Published in 2006, the development of the original Blueprint was funded by the Office of Solid Waste and Emergency Response and managed by EPA Region 1. The 2008 revision of the Blueprint was funded by the Healthcare Environmental Resource Center. http://practicegreenhealth.org/sites/default/files/upload-files/pharmwasteblueprint.pdf
recommendation of hazardous waste incineration as the BMP for healthcare facilities and pharmaceutical reverse distributors discarding pharmaceuticals that may possess hazardous waste-like qualities, but are not regulated as RCRA hazardous waste. This recommendation would apply to pharmaceuticals with more than one active ingredient listed on the P- or U-lists, \(^{50}\) chemotherapy agents characterized as bulk wastes, \(^{60}\) pharmaceuticals which meet the NIOSH Hazardous Drug Criteria, \(^{61}\) pharmaceuticals listed in Appendix VI of the OSHA Technical Manual, \(^{62}\) pharmaceuticals with LD50s \(\leq 50\) mg/kg, pharmaceuticals that are carcinogenic or endocrine disrupting compounds, and vitamin/mineral preparations containing heavy metals.

ii. **Recommended best management practices for other non-hazardous pharmaceutical wastes (i.e., those not possessing hazardous waste-like qualities).** As far as other non-hazardous waste pharmaceuticals (i.e., those not possessing hazardous waste-like qualities), the disposal of non-hazardous waste pharmaceuticals at healthcare facilities via drain disposal is strongly discouraged and not recommended by EPA. Therefore, EPA endorses the Blueprint’s recommendation of municipal solid waste or medical waste incineration for any non-hazardous waste pharmaceuticals, even when they do not possess hazardous waste-like qualities. The potential risk remains for active pharmaceutical ingredients (APIs) to be released into the environment if municipal solid waste landfills or medical waste autoclaves are used for the purposes of pharmaceutical waste treatment and disposal. For example, autoclaves are designed to kill pathogens and do not achieve the temperatures required to destroy most APIs during the autoclaving process. As a result, there is the potential for wastewater containing APIs to be generated and discharged into the sewer. In addition, some limited studies have shown APIs present in landfill leachate collected in municipal solid waste landfill leachate systems.\(^{63}\)\(^\text{64}\) Typically, the collected landfill leachate is subsequently sent to wastewater treatment plants for treatment, but their treatment technologies are not designed to remove all APIs from the wastewater (See Section V.E.1 for more information regarding severing and APIs).

b. **Non-pharmaceutical hazardous wastes.** These proposed regulations will only pertain to hazardous waste pharmaceuticals. Therefore, other types of hazardous wastes generated at healthcare facilities that do not meet the definition of a hazardous waste pharmaceutical cannot be managed in accordance with these proposed regulations. For example, hazardous wastes generated in hospital laboratories or during cleaning and maintenance of the facility are not considered hazardous waste pharmaceuticals and are not included within the scope of this proposal. The generation of non-pharmaceutical hazardous wastes is often more routine and does not trigger the same concerns that healthcare facilities experience when managing hazardous waste pharmaceuticals.

After a healthcare facility determines it is subject to this proposed rule and manages its hazardous waste pharmaceuticals under part 266, subpart P, it is no longer required to count the hazardous waste pharmaceuticals that it generates towards its generator category. As a result, the healthcare facility may experience a change in RCRA generator category for its non-pharmaceutical hazardous waste. For example, a healthcare facility may shift from being an LGQ to a SQG or even CESQG by not counting its hazardous waste pharmaceuticals toward its generator category, especially when acute hazardous waste pharmaceuticals such as warfarin (brand name: Coumadin) no longer need to be counted. A shift in generator category, should it occur, would allow a healthcare facility to manage its non-pharmaceutical hazardous waste, such as hazardous waste from laboratories, according to the reduced generator requirements. It is important to note that only when a healthcare facility is managing its hazardous waste pharmaceuticals under the new proposed subpart does it have the benefit of not counting them towards its generator category (see Section VI. Implementation and Enforcement for further discussion).

C. What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals?

This section discusses the proposed management standards for healthcare facilities (except CESQGs) that manage non-creditable hazardous waste pharmaceuticals, which include the following:

1. Notification requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
2. Personnel training requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
3. Making a hazardous waste determinations for non-creditable hazardous waste pharmaceuticals;
4. Elimination of central accumulation area and satellite accumulation area requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
5. Container standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
6. Labeling standards on containers for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
7. Accumulation time limits for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
8. Land disposal restrictions for non-creditable hazardous waste pharmaceuticals;
9. Procedures for shipping non-creditable hazardous waste pharmaceuticals off-site from healthcare facilities;
10. Procedures for managing rejected waste shipments of non-creditable hazardous waste pharmaceuticals from healthcare facilities;
11. Reporting requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
12. Recordkeeping requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
(14) special requirements for long-term care facilities managing non-
creditable hazardous waste pharmaceuticals;
(15) conditions for healthcare facilities that accept hazardous waste pharmaceuticals from off-site CESQGs; and
(16) a prohibition of sewering hazardous waste pharmaceuticals for all healthcare facilities; (see section V.E.1. of the preamble, Sewer Disposal Prohibition.

The proposed management standards discussed in this section only apply to hazardous waste pharmaceuticals that are non-creditable hazardous waste pharmaceuticals (i.e., they are destined for a RCRA permitted or interim status TSDF). They do not apply to those hazardous waste pharmaceuticals that meet the definition of a “potentially creditable hazardous waste pharmaceutical.” Please refer to Section V.D for the proposed healthcare facility management standards for potentially creditable hazardous waste pharmaceuticals that are transported to reverse distributors for the processing of manufacturer’s credit.

1. Notification Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

In order to address commenters’ concerns from the 2008 Pharmaceutical Universal Waste proposal that regulatory agencies are unaware of hazardous waste pharmaceutical management activities, EPA is proposing to require that a healthcare facility that does not qualify as a CESQG to submit a one-time notification as a “healthcare facility” to the appropriate EPA Regional Administrator. Healthcare facilities subject to 40 CFR part 266, subpart P will have to submit notification even if the healthcare facility has previously obtained an EPA identification number. The required notification will enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals subject to the 40 CFR part 266, subpart P requirements. In addition, having this information allows EPA and state environmental regulatory agencies to track healthcare facilities for enforcement and inspection purposes, ensuring the hazardous waste pharmaceuticals are managed in accordance with the regulations.

At any point a healthcare facility’s hazardous waste pharmaceutical generation may decrease due to waste minimization efforts or other reasons, causing the facility to legitimately decrease its total monthly hazardous waste generation enough to qualify as a CESQG. In this case, if the healthcare facility plans to withdraw from the 40 CFR part 266, subpart P requirements due to qualifying as a CESQG, it will be required to re-notify EPA of its choice to withdraw.

Alternatively, if a healthcare facility determines that it is a CESQG, but does not want to keep track of the amount of hazardous waste generated and whether it is above or below the CESQG threshold limit, it can choose to operate under this proposed rule. By choosing to operate under this proposed rule, the CESQG healthcare facility must comply with all of the requirements and must submit the one-time notification that it is operating under 40 CFR part 266, subpart P. Healthcare facilities that are not CESQGs, however, are required to operate under 40 CFR part 266, subpart P for the management of their hazardous waste pharmaceuticals.

The Agency is proposing that this notification occur via the RCRA Subtitle C Site Identification Form (EPA Form 8700–12; or Site Identification Form). EPA believes that notification via the Site Identification Form is the preferred approach for notification purposes for several reasons. First, both state environmental regulatory agencies and hazardous waste generators are familiar with the form, as it is the form currently used by hazardous waste generators to notify regulators of their RCRA Subtitle C activities. Second, as stated previously, the use of the Site Identification Form will allow for EPA and state regulatory agencies to monitor the healthcare facilities utilizing the new regulatory requirements. Lastly, public comments received on previous EPA actions (e.g., Academic Laboratories Rulemaking (73 FR 72912; December 1, 2008)) have indicated that notification via the Site Identification Form is the notification approach typically preferred by the regulated community. We are proposing that healthcare facilities can submit their notification as part of the Biennial Report, if the healthcare facility will be required to submit a Biennial Report due to its non-pharmaceutical hazardous waste. Otherwise, healthcare facilities are required to notify within 60 days of this new subpart becoming effective, or within 60 days of becoming subject to this new subpart.

If this notification requirement is finalized, the Site Identification Form will be modified by EPA in a separate action. Specifically, the Agency intends to amend the Site Identification Form by adding a section to the form for a healthcare facility to indicate the type of entity it is (e.g., a hospital, a doctor’s office, a veterinary clinic, a pharmacy, an assisted living facility, etc.) and to indicate that it generates hazardous waste pharmaceuticals. The healthcare facility will no longer be required to identify on the Site Identification Form the specific types of hazardous waste pharmaceuticals it generates. The Agency also intends to add a checkbox to the section in order to allow a healthcare facility to indicate that its generator category is changing to a CESQG and it is no longer managing its hazardous waste pharmaceuticals according to 40 CFR part 266, subpart P.

The Agency does not anticipate that this proposed notification requirement will place any undue economic burden upon healthcare facilities or the environmental regulatory agencies that process these notifications (see the Regulatory Impact Analysis for the proposed rule in the rulemaking docket EPA–HQ–RCRA–2007–0932). In fact, under these proposed regulations, healthcare facilities would no longer need to count the hazardous waste pharmaceuticals managed under 40 CFR part 266, subpart P towards a healthcare facility’s generator category. As a result, EPA anticipates that many healthcare facilities will change their generator category to either a SQG or CESQG for their other, non-pharmaceutical hazardous wastes. So while the notification requirement ensures that the environmental regulatory agencies are informed of all hazardous waste pharmaceutical management activities subject to the 40 CFR part 266, subpart P requirements in their jurisdictions, the fact that some healthcare facilities will no longer qualify as LQGs will reduce the number of healthcare facilities in the LQG universe. Because LQGs are inspected more frequently than SQGs or CESQGs, EPA expects this could result in an overall decrease in burden for both.
the healthcare facilities and the environmental regulatory agencies.

The Agency is soliciting comment on the notification requirement for healthcare facilities, the method of notification via the Site Identification Form, and whether this notification requirement will result in any undue burden to either healthcare facilities or state environmental regulatory agencies.

2. Personnel Training Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Under the current RCRA Subtitle C regulations, an LQG healthcare facility must provide RCRA training to its healthcare workers involved in the generation and/or management of hazardous waste. Under §262.34(a)(4), LQGs are required to comply with the personnel training requirements for interim status TSDFs (which are found in §263.16). These personnel training requirements should either include either classroom instruction or on-the-job training in RCRA and state that the facility must maintain training documents and records for each trained staff person. On the other hand, under current regulation, healthcare facilities that are SQGs must meet a performance-based standard when training their healthcare workers. This entails ensuring “that all employees are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies” (§262.34(f)(5)(iii)). For comparative purposes, healthcare facilities that are considered CESQGs do not have any personnel training requirements under the current federal regulations.

Similarly, generators, including healthcare facilities, are not required to provide RCRA training to personnel that only work in satellite accumulation areas regulated under §262.34(c). However, healthcare personnel that are involved in the generation of pharmaceutical waste must be familiar enough with the pharmaceuticals with which they are working to know when they have generated a hazardous waste so that it will be managed in accordance with the RCRA regulations.

EPA believes that the LQG RCRA training requirement is excessive for healthcare workers who sporadically generate hazardous waste pharmaceuticals at healthcare facilities, but believe it is necessary to have some familiarity with the dangers that hazardous waste pharmaceuticals can pose. Therefore, the Agency is proposing healthcare facility-specific personnel training requirements that are akin to the training requirements for SQGs and small quantity universal waste handlers. Specifically, healthcare facilities managing their hazardous waste pharmaceuticals in accordance with the proposed healthcare facility standards must inform all employees that handle or have responsibility for generating and/or managing hazardous waste pharmaceuticals of the proper handling and emergency procedures appropriate to their responsibilities during normal facility operations and emergencies. This training information can be disseminated through verbal communication or through distribution of pamphlets or other documentation. However, a healthcare facility that is an LQG due to its non-pharmaceutical hazardous wastes may choose to continue to use its existing training program as an LQG so as not to have different training programs and that would be acceptable, as well.

The Agency solicits comments on the personnel training requirements proposed in this document for healthcare facilities managing hazardous waste pharmaceuticals. Specifically, the Agency is seeking comment regarding the appropriateness of these personnel training requirements and if these requirements will be sufficient for communicating key procedures to healthcare workers that generate and/or manage hazardous waste pharmaceuticals.

EPA is seeking comment on whether documentation of training is necessary in order to verify compliance with the training requirement. Based on the comments received, we may include a requirement in the final rule for documenting and retaining records of healthcare personnel training. Finally, the Agency wants to reiterate that these proposed personnel training requirements only apply to staff generating and/or managing hazardous waste pharmaceuticals. The training requirements of 40 CFR part 262 will continue to apply to staff generating and/or managing other types of hazardous wastes at the healthcare facility.


Similar to the current RCRA Subtitle C generator requirements, healthcare facilities will still be required to make a hazardous waste determination on pharmaceutical wastes prior to managing them under the proposed cradle-to-grave standards. Therefore, when a healthcare facility generates a solid waste pharmaceutical, the healthcare facility must determine if the pharmaceutical waste is listed in 40 CFR part 261, subpart D and if it exhibits one or more of the four characteristics of hazardous waste identified in 40 CFR part 261, subpart C. However, unlike the existing generator requirements, the healthcare facility does not need to identify the specific waste codes applying to the pharmaceutical wastes. If the pharmaceutical waste is determined to be a hazardous waste, then the healthcare facility must manage the hazardous waste pharmaceuticals in accordance with these proposed requirements instead of 40 CFR part 262. Pharmaceutical wastes not meeting the definition of a hazardous waste (i.e., non-hazardous waste pharmaceuticals) must be managed in compliance with applicable federal, state and local regulations.

EPA understands that healthcare facilities utilize various approaches when making hazardous waste determinations. For example, healthcare facilities may hire contractors to review their formularies and identify those pharmaceuticals that are hazardous wastes when discarded. These facilities may then identify hazardous waste pharmaceuticals at the pharmacy level, marking these pharmaceuticals with a special label so that healthcare personnel know how to properly dispose of the pharmaceutical when it becomes a waste. Other healthcare facilities may instruct personnel to dispose of all pharmaceutical wastes into one RCRA hazardous waste collection container. These facilities may then choose to manage all of the contents of the container as hazardous waste or they may choose to sort the hazardous waste portion from the non-hazardous waste pharmaceutical portion in the central accumulation area. Due to the various ways that healthcare facilities make the hazardous waste determination, the Agency is not proposing that a specific approach be utilized when making the determination, only that the facility performs the waste determination. However, healthcare facilities may choose to manage all of their pharmaceutical wastes as hazardous, and thus, if a healthcare facility chooses this approach, they would not need to make individual hazardous waste determinations, but would have made a generic decision that all of their waste pharmaceuticals are hazardous and manage them as hazardous waste pharmaceuticals in accordance with the proposed requirements in 40 CFR part 266, subpart P.
4. No Central Accumulation Area and Satellite Accumulation Area Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Hazardous waste pharmaceuticals are generated at numerous locations across a healthcare facility. Under the current RCRA Subtitle C requirements, each location at the healthcare facility with a RCRA hazardous waste receptacle for the disposal of hazardous waste pharmaceuticals is considered a satellite accumulation area and is subject to volume accumulation limits and other requirements. Of particular concern regarding the satellite accumulation requirements for healthcare facilities is the one quart accumulation limit for acute hazardous wastes (i.e., P-listed wastes). Under the December 2008 Pharmaceutical Universal Waste proposal, no accumulation areas, central or satellite, were proposed to be established for hazardous waste pharmaceuticals. This proposed approach was consistent with the current federal universal waste program, since facilities are not required to designate a special centralized area for the accumulation of universal wastes nor are they required to have satellite accumulation areas for universal wastes. Nevertheless, EPA understands that facilities that handle universal wastes will often accumulate their universal wastes within their 90- or 180-day hazardous waste accumulation areas. 

For the reasons articulated in the Pharmaceutical Universal Waste proposal, the Agency has decided that a healthcare facility accumulating hazardous waste pharmaceuticals will not be subject to the satellite accumulation area regulations or the central accumulation area regulations (also sometimes called less than 90- or 180-day areas), but rather to the proposed accumulation time limits and container standards. A healthcare facility may choose to accumulate hazardous waste pharmaceuticals within its 90- or 180-day central accumulation area if it has one established for its other hazardous wastes as long as it maintains compliance with the proposed accumulation time limit and container requirements of 40 CFR part 266.

The Agency notes that even if the hazardous waste pharmaceuticals are accumulated in a 90- or 180-day central accumulation area, these hazardous waste pharmaceuticals are not subject to the 90- or 180-day requirements. EPA solicits public comment on its decision to not require hazardous waste pharmaceutical-specific central and satellite accumulation area requirements.


The container standards discussed in this section apply to those containers used by healthcare facilities to accumulate, store and transport non-creditable hazardous waste pharmaceuticals. First, we would note that due to the relatively small quantities of hazardous waste pharmaceuticals that are typically accumulated and stored at a healthcare facility, the Agency understands that other types of waste management units, such as tanks, are not used for the management of waste pharmaceuticals. Therefore, we are only proposing standards for containers. However, the Agency solicits comment as to whether other types of waste management units are also used by healthcare facilities to accumulate and store hazardous waste pharmaceuticals and whether EPA should establish technical standards for other types of waste management units.

The Agency is proposing to require that healthcare facilities pack hazardous waste pharmaceuticals into containers that are structurally sound and that are compatible with the hazardous waste pharmaceuticals that will be contained within them. EPA intends this requirement to mean that containers used for holding hazardous waste pharmaceuticals must be in good condition, with no severe rusting, apparent structural defects, or deterioration. Containers also must not have any evidence of leakage, spillage or damage that could result in the release of waste under reasonably foreseeable circumstances. Furthermore, the Agency is proposing to require that incompatible wastes not be placed in the same container, unless the co-mingling of incompatible hazardous wastes is conducted in such a way that it does not have the potential to (1) generate extreme heat or pressure, fire or explosion, or violent reaction; (2) produce uncontrollable toxic mists; (3) produce uncontrollable flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions; (4) damage the structural integrity of the facility or container containing the hazardous waste pharmaceuticals; or (5) through other like means threaten human health or environment. For example, the majority of a healthcare facility’s non-creditable hazardous waste pharmaceuticals are likely organic in nature, and thus, compatible with each other and can be accumulated together, especially since they will most likely be incinerated once they are transported to a TSDF. However, some non-creditable hazardous waste pharmaceuticals, such as metal bearing wastes not containing sufficient organics, are prohibited from being incinerated (e.g., P012, arsenic trioxide). The hazardous waste pharmaceuticals that cannot be incinerated must be accumulated separately from organic wastes destined for incineration.

The Agency believes that these technical standards, like similar technical standards that EPA has promulgated in §265.17 for interim status TSDFs, would ensure that hazardous waste pharmaceuticals are properly managed and would not be released into the environment, while at the same time providing flexibility to the healthcare facility in selecting those containers that are most appropriate for their situation.

In addition to the proposed container standards, the Agency is also proposing that accumulation containers for hazardous waste pharmaceuticals be secured in a manner that prevents unauthorized access to the contents in order to prevent the pilfering of hazardous waste pharmaceuticals or inadvertent exposures to them. As we have noted previously, hazardous waste pharmaceuticals still retain considerable value and can easily be diverted for illicit purposes. To ensure this does not occur, we believe it is important to propose a requirement that would prevent the unauthorized access to the contents of these containers. EPA intends this requirement to be performance-based and does not intend to propose prescriptive regulatory requirements for this standard. The Agency believes that healthcare facilities can choose to utilize containers that have built-in mechanisms to prevent access to their contents or can choose to store containers in locked storage lockers, closets or rooms where the public does not have access to the containers or their contents.
The Agency is seeking comment on the appropriateness of the proposed container management standards. In addition, the EPA is soliciting comment on the proposed requirement for ensuring that the hazardous waste pharmaceuticals contained in collection containers remain secure.


During the period of accumulation and storage, the Agency is proposing that containers of hazardous waste pharmaceuticals be marked with the words “Hazardous Waste Pharmaceuticals.” The Agency is not proposing to require that the hazardous waste numbers (often referred to as hazardous waste codes) of the container’s contents be listed on the label. The personnel at healthcare facilities that typically generate the hazardous waste pharmaceuticals will be healthcare workers (e.g., nurses). Healthcare workers are not usually intimately familiar with RCRA and its regulations and are primarily focused on patients and their health. In addition, while a healthcare facility may have an environmental compliance manager or environmental consultant that is knowledgeable about RCRA and its regulations and can make hazardous waste determinations, this individual cannot be present to assign a hazardous waste code and label the collection receptacle each time a pharmaceutical waste is generated. For these reasons, EPA does not believe it is necessary to require individual waste codes on the hazardous waste pharmaceutical collection container at the healthcare facility. The Agency is soliciting comment on the appropriateness of the proposed general labeling requirement. The Agency also requests comment on security concerns regarding having the word “pharmaceutical” marked on the containers.

7. Accumulation Time Limits for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Several hazardous waste pharmaceuticals are P-listed, acute hazardous wastes (e.g., nicotine, warfarin, etc.). Under current regulations, if a generator generates more than 1 kg of acute hazardous waste per calendar month or accumulates more than 1 kg of acute hazardous waste at any time, the generator is regulated as an LQC. Due to this low generation/accumulation threshold associated with P-listed wastes, healthcare facilities are often LQGs. However, while healthcare facilities can generate enough P-listed waste to become LQGs, they often do not generate sufficient amounts of hazardous waste pharmaceuticals within the allowed accumulation period of 90 days to make off-site shipments using a hazardous waste transporter cost-effective.

Under the 2008 Pharmaceutical Universal Waste proposal, universal waste handlers would have had one year for accumulation of its hazardous waste pharmaceuticals in order to facilitate proper treatment and disposal. Commenters on the 2008 Universal Waste proposed rule indicated support for the one-year accumulation time limit. Thus, the Agency is proposing to allow healthcare facilities to accumulate hazardous waste pharmaceuticals for up to one year, without having interim status or a RCRA permit. As with Universal Waste, one year is an appropriate timeframe because it strikes a balance between allowing healthcare facilities enough time to accumulate amounts of hazardous waste pharmaceuticals to make it economically viable for transporting their hazardous waste pharmaceuticals off-site while ensuring that the hazardous wastes are not accumulated beyond the one year storage limit under the land disposal restrictions programs (see §268.50).

Healthcare facilities will have various approaches to demonstrate the length of time that hazardous waste pharmaceuticals are accumulated onsite. For example, a healthcare facility can choose to mark the container label with the date that accumulation first began, maintain an inventory system that identifies dates when the hazardous waste pharmaceuticals were first accumulated, identify in the central accumulation area the earliest date that a hazardous waste pharmaceutical became a waste, or any other method that clearly demonstrates the length of time that the hazardous waste pharmaceutical has been accumulated from the date it became a hazardous waste. The Agency assumes that any accumulation for up to one year is for the purpose of facilitating proper treatment and disposal. EPA proposes to require that any healthcare facility needing a longer accumulation time for any unforeseen circumstances beyond the control of the healthcare facility...
while most of the hazardous waste pharmaceuticals are likely organic in nature and will be incinerated, some of their hazardous waste pharmaceuticals may not be suitable for incineration and therefore must be segregated from the organic wastes. The pharmaceutical hazardous wastes not suitable for incineration include characteristic metal wastes prohibited from being combusted because of the dilution prohibition of § 268.3(c), as well as the listed wastes U151 (mercury), U205 (selenium sulfide), and P012 (arsenic trioxide), unless they contain greater than 1% total organic carbon. In order to comply with the LDRs, healthcare facilities will need to segregate these wastes from the organic pharmaceutical hazardous wastes so that they can be properly treated by the TSDF. The Agency seeks comment on whether it is necessary to incorporate into the regulations a requirement to segregate these wastes and whether additional labeling requirements are necessary to identify the hazardous waste pharmaceuticals that are not suitable for incineration.

Tables 2 through 4 list the hazardous waste pharmaceuticals with their hazardous waste codes and their LDR treatment standards.
<table>
<thead>
<tr>
<th>Waste Code</th>
<th>Description</th>
<th>Non-Wastewater Treatment Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>D001</td>
<td>Ignitable</td>
<td>DEACT and UTS or RORGS or CMBST</td>
</tr>
<tr>
<td></td>
<td>Ignitable All D001, except high TOC D001</td>
<td>261.21(a)(1)</td>
</tr>
<tr>
<td></td>
<td>Ignitable High TOC D001 based on 261.21(a)(1)</td>
<td>RORGS or CMBST or POLYM</td>
</tr>
<tr>
<td>D002</td>
<td>Corrosivity</td>
<td>DEACT and UTS</td>
</tr>
<tr>
<td>D004 *</td>
<td>Arsenic</td>
<td>5.0 mg/L TCLP and UTS</td>
</tr>
<tr>
<td>D005 *</td>
<td>Barium</td>
<td>21 mg/L TCLP and UTS</td>
</tr>
<tr>
<td>D006 *</td>
<td>Cadmium</td>
<td>0.11 mg/L TCLP and UTS</td>
</tr>
<tr>
<td>D007 *</td>
<td>Chromium</td>
<td>0.60 mg/L TCLP and UTS</td>
</tr>
<tr>
<td>D008 *</td>
<td>Lead</td>
<td>0.75 mg/L TCLP and UTS</td>
</tr>
<tr>
<td>D009*</td>
<td>Mercury</td>
<td>IMERC or RMERC</td>
</tr>
<tr>
<td></td>
<td>Mercury ≥260 mg/kg total Hg (high mercury organics)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mercury &lt; 260 mg/kg total Hg &amp; are not residues from RMERC (low mercury)</td>
<td>0.025 mg/L TCLP and UTS</td>
</tr>
<tr>
<td>D010 *</td>
<td>Selenium</td>
<td>5.7 mg/L TCLP and UTS</td>
</tr>
<tr>
<td>D011 *</td>
<td>Silver</td>
<td>0.14 mg/L TCLP and UTS</td>
</tr>
<tr>
<td>D013</td>
<td>Lindane</td>
<td>IMERC or RMERC</td>
</tr>
<tr>
<td></td>
<td>Lindane alpha-BHC</td>
<td>0.066 mg/kg and UTS</td>
</tr>
<tr>
<td></td>
<td>Lindane beta-BHC</td>
<td>0.066 mg/kg and UTS</td>
</tr>
<tr>
<td></td>
<td>Lindane delta-BHC</td>
<td>0.066 mg/kg and UTS</td>
</tr>
<tr>
<td></td>
<td>Lindane gamma-BHC</td>
<td>0.066 mg/kg and UTS</td>
</tr>
<tr>
<td>D022</td>
<td>Chloroform</td>
<td>6.0 mg/kg and UTS</td>
</tr>
</tbody>
</table>
Table 3: P-listed Hazardous Waste Pharmaceuticals

<table>
<thead>
<tr>
<th>Waste Code</th>
<th>Description</th>
<th>Non-Wastewater Treatment Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>P001</td>
<td>Warfarin (concentration &gt; 0.3%)</td>
<td>CMBST</td>
</tr>
<tr>
<td>P012 *</td>
<td>Arsenic trioxide</td>
<td>5.0 mg/L TCLP</td>
</tr>
<tr>
<td>P042</td>
<td>Epinephrine</td>
<td>CMBST</td>
</tr>
<tr>
<td>P046</td>
<td>Phentermine</td>
<td>CMBST</td>
</tr>
<tr>
<td>P075</td>
<td>Nicotine</td>
<td>CMBST</td>
</tr>
<tr>
<td>P081</td>
<td>Nitroglycerin</td>
<td>CMBST</td>
</tr>
<tr>
<td>P188</td>
<td>Physostigmine salicylate</td>
<td>1.4 mg/kg or CMBST</td>
</tr>
<tr>
<td>P204</td>
<td>Physostigmine</td>
<td>1.4 mg/kg or CMBST</td>
</tr>
</tbody>
</table>

*Waste code may not be treated by combustion unless the waste meets one of the criteria in § 268.3(c) (e.g., has >1% total organic carbon)

BOLD indicates that the waste is an organic waste with a concentration-based treatment standard

UTS = Universal Treatment Standards in § 268.48

Table 4: U-listed Hazardous Waste Pharmaceuticals

<table>
<thead>
<tr>
<th>Waste Code</th>
<th>Description</th>
<th>Non-Wastewater Treatment Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>U010</td>
<td>Mitomycin</td>
<td>CMBST</td>
</tr>
<tr>
<td>U015</td>
<td>Azaserine</td>
<td>CMBST</td>
</tr>
<tr>
<td>U034</td>
<td>Chloral hydrate</td>
<td>CMBST</td>
</tr>
<tr>
<td>U035</td>
<td>Chlorambucil</td>
<td>CMBST</td>
</tr>
<tr>
<td>U044</td>
<td>Chloroform</td>
<td>6.0 mg/kg</td>
</tr>
<tr>
<td>U058</td>
<td>Cyclophosphamide</td>
<td>CMBST</td>
</tr>
<tr>
<td>U059</td>
<td>Daunomycin</td>
<td>CMBST</td>
</tr>
<tr>
<td>U075</td>
<td>Dichlorodifluoromethane</td>
<td>7.2 mg/kg</td>
</tr>
</tbody>
</table>

*Waste code may not be treated by combustion unless the waste meets one of the criteria in § 268.3(c) (e.g., has >1% total organic carbon)
The organic hazardous waste pharmaceuticals (other than arsenic trioxide) may all be incinerated at RCRA permitted or interim status hazardous waste combustors. As noted in Tables 2–4, most of the organic wastes have a specified treatment standard of combustion (CMBST). The remaining seven organics (lindane, chloroform, m-cresol, dichlorodifluoro methane, trichloromonofluoromethane, phenacetin and phenol) have numerical treatment standards, such that no particular treatment technology is specified or required in order to achieve the numerical treatment standards. While these wastes may be incinerated, the incinerator residue (ash) must be analyzed for these seven organic constituents to demonstrate compliance with the LDR treatment standards before that ash can be disposed.

As mentioned earlier, because this proposed rule does not require that healthcare facilities label their waste with the hazardous waste codes, the TSDF must always analyze the incinerator ash for these seven constituents—lindane, chloroform, m-cresol, dichlorodifluoro methane, trichloromonofluoromethane, phenacetin, and phenol—according to their waste analysis plan, as they could possibly be present in any shipment of organic hazardous waste pharmaceuticals.

*a. Alternative treatment standards considered.* In their comments to the 2008 Universal Waste proposal, Environmental Technology Council (ETC) suggested revising the treatment standards for the organic hazardous waste pharmaceuticals that have numerical treatment standards to the specified treatment standard of

<table>
<thead>
<tr>
<th>Waste Code</th>
<th>Description</th>
<th>Non-Wastewater Treatment Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>U089</td>
<td>Diethylstilbestrol</td>
<td>CMBST</td>
</tr>
<tr>
<td>U121</td>
<td>Trichloromonofluoromethane</td>
<td>30 mg/kg</td>
</tr>
<tr>
<td>U122</td>
<td>Formaldehyde</td>
<td>CMBST</td>
</tr>
<tr>
<td>U129</td>
<td>Lindane</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lindane alpha-BHC</td>
<td>0.066 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Lindane beta-BHC</td>
<td>0.066 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Lindane delta-BHC</td>
<td>0.066 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Lindane gamma-BHC</td>
<td>0.066 mg/kg</td>
</tr>
<tr>
<td>U132</td>
<td>Hexachlorophene</td>
<td>CMBST</td>
</tr>
<tr>
<td>U150</td>
<td>Melphalan</td>
<td>CMBST</td>
</tr>
<tr>
<td>U151*</td>
<td>Mercury</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mercury ≥260 mg/kg total Hg (high mercury organics)</td>
<td>IMERC or RMERC</td>
</tr>
<tr>
<td></td>
<td>Mercury &lt; 260 mg/kg total Hg &amp; are not residues from RMERC (low mercury)</td>
<td>0.025 mg/L TCLP and UTS</td>
</tr>
<tr>
<td>U182</td>
<td>Paraldehyde</td>
<td>CMBST</td>
</tr>
<tr>
<td>U187</td>
<td>Phenacetin</td>
<td>16 mg/kg</td>
</tr>
<tr>
<td>U188</td>
<td>Phenol</td>
<td>6.2 mg/kg</td>
</tr>
<tr>
<td>U200</td>
<td>Reserpine</td>
<td>CMBST</td>
</tr>
<tr>
<td>U201</td>
<td>Resorcinol</td>
<td>CMBST</td>
</tr>
<tr>
<td>U205*</td>
<td>Selenium sulfide</td>
<td>5.7 mg/L TCLP</td>
</tr>
<tr>
<td>U206</td>
<td>Streptozotocin</td>
<td>CMBST</td>
</tr>
<tr>
<td>U237</td>
<td>Uradic mustard</td>
<td>CMBST</td>
</tr>
<tr>
<td>U248</td>
<td>Warfarin</td>
<td>(Concentration ≤ 0.3%)</td>
</tr>
</tbody>
</table>

*Waste code may not be treated by combustion unless the waste meets one of the criteria in § 268.3(c) (e.g., has >1% total organic carbon)

**BOLD** indicates that the waste is an organic waste with a concentration-based treatment standard

**UTS = Universal Treatment Standards in § 268.48**
impermissible dilution (see § 268.3(c)) and therefore is an allowable form of treatment.

Emissions from combustion units that burn hazardous waste are regulated under RCRA and the Clean Air Act (CAA). The implementing regulations under these statutory authorities include emission limits for new and existing combustion units for mercury, semi-volatile metals (cadmium and lead), low volatility metals (arsenic, beryllium, and chromium), particulate matter, chlorinated dioxins and furans, other toxic organic compounds, hydrogen chloride and chlorine. The regulations also require that when and how combustion sources must comply with the emission standards and operating requirements. (2) Prescribe detailed monitoring requirements to show continuous compliance with the emission standards, and (3) prescribe performance testing requirements to demonstrate compliance with the emission standards (see 40 CFR part 63, subpart EEE).

To ensure continuous compliance with the emission limits, hazardous waste combustors are required to establish limits on (1) the feedrate of metals (including mercury), chlorine, and (for some types of hazardous waste combustors) ash; (2) combustor operating parameters such as minimum combustion chamber temperature; and (3) operating parameters of the air pollution control device. For mercury, continuous compliance requirements would generally include a limit on the total feedrate of mercury in all feedstreams to the combustion unit, limits on the operation of a wet scrubber (depending on the species of mercury in the combustion gases, wet scrubbers can be efficient at removing mercury), and operating limits on the activated carbon injection or carbon bed system, if such systems are used.

In addition, RCRA directs permitting authorities to impose additional terms and conditions on a site-specific basis as may be necessary to protect human health and the environment (see § 270.32(b)). Thus, if the mercury emission limits specified previously are not protective in an individual instance, the permit writer will establish permit limits that are protective.

Nevertheless, EPA is aware that some stakeholders are concerned about the risks associated with incinerating mercury-bearing hazardous wastes and we encourage healthcare facilities and pharmaceutical reverse distributors to consider the use of treatment technologies other than incineration for meeting the numeric treatment standards for mercury-bearing hazardous waste pharmaceuticals. Thimerosal-containing pharmaceuticals are expected to be non-wastewaters as defined by § 268.2, because they have more than 1% total organic carbon. For low mercury non-wastewaters, the numeric treatment standard can be achieved by stabilization/solidification, either with or without subsequent encapsulation.75

9. Shipments of Non-Creditable Hazardous Waste Pharmaceuticals Off-site From Healthcare Facilities

The Agency is proposing to maintain the current RCRA Subtitle C tracking requirement by requiring that a hazardous waste manifest be prepared for each off-site shipment of non-creditable hazardous waste pharmaceuticals from healthcare facilities. Accordingly, each off-site shipment of hazardous waste pharmaceuticals must be transported to an interim status or permitted TSDF via a hazardous waste transporter. However, the Agency is proposing that for hazardous waste pharmaceuticals shipped by healthcare facilities, the RCRA hazardous waste codes do not need to be listed on the manifest. This is intended to accommodate the fact that healthcare providers generating the hazardous waste pharmaceuticals are generally unfamiliar with RCRA and are focused on providing healthcare to patients. One function of the hazardous waste codes is to determine the appropriate hazardous waste treatment standards under the land disposal restrictions (part 268). However, virtually all hazardous waste pharmaceuticals sent for off-site treatment are sent to hazardous waste incinerators, even when the treatment standard does not require incineration. The fact that EPA is proposing not to require hazardous waste codes for shipping hazardous waste pharmaceuticals is not intended to alter or impact any Department of Transportation (DOT) requirements for the shipment of these hazardous wastes. For a more detailed discussion of these proposed requirements, as well as the basis for these requirements, please see Section V.F.1 of this document.

73 See comment number 0125 in the docket for this rulemaking. EPA–HQ–RCRA–2007–0932.

74 Combustors that burn hazardous waste include the following types of combustion units: Incinerators, cement kilns, lightweight aggregate kilns, industrial boilers and process heaters, and hydrochloric acid production furnaces.

75 EPA is not aware of any testing done to demonstrate the effectiveness of this treatment method specifically for thimerosal-containing hazardous wastes, so vendors performing such treatment may need to do treatability studies to identify optimal use of stabilization/solidification treatment technologies.
10. Rejected Shipment From Healthcare Facilities of Non-creditable Hazardous Waste Pharmaceuticals

In rare circumstances, a healthcare facility may send its non-creditable hazardous waste pharmaceuticals to a designated facility that is unable to manage the hazardous waste. For such situations, we are proposing that healthcare facilities follow the same procedures listed in 40 CFR part 262 (see § 262.23(f)). Specifically, if a designated facility is unable to accept the hazardous waste pharmaceuticals, and it returns the hazardous waste pharmaceuticals to the healthcare facility, the healthcare facility must sign the manifest that was used to return the shipment, provide the transporter a copy of the manifest, send a copy of the manifest within thirty days to the designated facility that returned the shipment and retain a copy of the manifest for three years from the date of delivery of the returned shipment. EPA believes that it is appropriate to continue current practices for rejected shipments that are part of the generator regulations of 40 CFR part 262 because rejected shipments are relatively rare and the procedures currently used for rejected shipments is relatively straightforward. In addition, healthcare facilities should be familiar with these procedures already.

11. Reporting Requirements for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals

The Agency is proposing that healthcare facilities managing non-creditable hazardous waste pharmaceuticals have reporting requirements similar to SQGs s regulated under 40 CFR part 262—that is, the exception reporting requirement under § 262.44(b) and the additional reporting requirement under § 262.44(c). In addition, we are proposing that healthcare facilities that are LQGs would no longer be required to include their hazardous waste pharmaceuticals on their biennial report (BR). Each of these reporting requirements for healthcare facilities is discussed below.

First, as part of the current RCRA Subtitle C generator requirements, healthcare facilities that are LQGs must submit a BR to the Regional Administrator by March 1st of every even numbered year (see § 262.41). Among other requirements, the BR must include a description (EPA hazardous waste number and DOT hazard class) and quantity of each hazardous waste shipped off-site to a TSDF during each odd numbered year. If a healthcare facility is an LQG due to its non-pharmaceutical hazardous waste, it will continue to be required to submit a BR. However, it need not include its hazardous waste pharmaceuticals in its BR. As discussed previously, the Agency is no longer requiring healthcare facilities to count hazardous waste pharmaceuticals when determining their generator category. Instead, all healthcare facilities, with the exception of CESQGs, will be subject to this proposed rule. The Agency has determined that it does not need the information to be included in the BR because this proposed rule will bring a consistent approach to managing pharmaceutical hazardous wastes. Nevertheless, the Agency is soliciting public comment on whether the Agency should require healthcare facilities— that is, all healthcare facilities subject to the 40 CFR part 266, subpart P requirements—to submit a BR, and if so, the type of information that should be included.

Second, the Agency is proposing that healthcare facilities follow the same reporting procedures for exception reporting that generators operating under the 40 CFR part 262 must follow. We are proposing to incorporate the generator exception reporting procedures in this new subpart. Specifically, if a healthcare facility does not receive a copy of the hazardous waste manifest from the designated facility within 60 days, the healthcare facility must submit to the EPA Regional Administrator a copy of the manifest with a statement that the healthcare facility did not receive confirmation of the hazardous waste pharmaceuticals’ delivery along with an explanation of the efforts taken to locate the hazardous waste pharmaceuticals and the results of those efforts. Likewise, if a shipment of hazardous waste pharmaceuticals from a healthcare facility is rejected by the designated facility and it is shipped to an alternate facility and if the healthcare facility does not receive a signed copy of the hazardous waste manifest from the alternate facility within 60 days, it must submit to the EPA Regional Administrator a copy of the hazardous waste manifest with a statement that the healthcare facility did not receive confirmation of the hazardous waste pharmaceuticals’ delivery along with an explanation of the efforts taken to locate the hazardous waste pharmaceuticals and the results of those efforts. Again, the Agency believes it is advantageous to use established procedures that should be familiar to healthcare facilities, especially given that rejected shipments are relatively rare.

Finally, the Agency proposes that the Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of hazardous waste pharmaceuticals. This is already the case for generators operating under the 40 CFR part 262 requirements. As with 40 CFR part 262, it is a codification of statutory authority under §§ 2002(a) and 3002(a)(6) that provides the Agency some flexibility in what reports may be required. The Agency solicits public comment on the proposed reporting requirements for healthcare facilities managing their hazardous waste pharmaceuticals in accordance with the standards proposed in this document.

12. Recordkeeping Requirements for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals

The Agency is proposing that healthcare facilities managing non-creditable hazardous waste pharmaceuticals maintain records similar to the records that must be kept by generators regulated under 40 CFR part 262 (see § 262.40). Specifically, healthcare facilities must keep a signed copy of each hazardous waste manifest as a record for three years from the date that the non-creditable hazardous waste pharmaceutical was accepted by the initial hazardous waste transporter. If the healthcare facility is required to file an exception report because it does not receive a signed copy of the manifest from the designated facility within 60 days of the date that the hazardous waste pharmaceutical was accepted by the initial transporter, then the healthcare facility must keep a copy of the each exception report for a period of at least three years from the due date of the report. In addition, EPA is proposing that a healthcare facility must keep records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals regarding which pharmaceuticals are hazardous wastes for three years from the date of the test, analysis, or other determination.

76 § 262.40 requires that generators keep a copy of each BR for a period of at least three years from the due date of the report. However, since we are not requiring a healthcare facility to include its hazardous waste pharmaceuticals on its a BR, the Agency is also not including in subpart P a requirement that a BR be kept at the healthcare facility. If healthcare facility must submit a BR due to its non-pharmaceutical hazardous waste, the § 262.40 recordkeeping requirements will apply (see the discussion under Requirement for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals for the Agency’s basis of not requiring healthcare facilities to include hazardous waste pharmaceuticals on the BR.)
The Agency is also proposing that any of the retention periods be extended during the course of enforcement actions against any activity associated with hazardous waste pharmaceutical management or as requested by the Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action. The Agency solicits public comment on the proposed recordkeeping requirements for healthcare facilities managing their non-creditable hazardous waste pharmaceuticals in accordance with the standards proposed in this document.


For hazardous waste pharmaceuticals generated and managed by healthcare facilities under the proposed standards, the Agency is proposing basic release response procedures, including the requirement that healthcare facilities immediately contain all releases of, and other residues from, hazardous waste pharmaceuticals. In addition, this proposal would require healthcare facilities to determine whether any material, residue, or debris resulting from the release is or contains a hazardous waste pharmaceutical and, if so, to manage it under the management standards for hazardous waste pharmaceuticals proposed in this document. These proposed release response procedures are the same as those under the Universal Waste program (see § 273.17 for small quantity universal waste handlers, and § 273.37 for large quantity universal waste handlers). Commenters to the 1993 proposed rule that established the Universal Waste program overwhelmingly supported the release response measures (60 FR 25528; May 11, 1995). Thus, we believe it is appropriate to include it in this proposal.

Any releases of hazardous waste pharmaceuticals not cleaned up immediately would generally constitute illegal disposal, which may result in further action by EPA or an authorized state under RCRA. In addition, hazardous wastes under RCRA are included in the definition of hazardous substances for purposes of the Comprehensive Environmental Response Compensation, and Liability Act (CERCLA) (see CERCLA Section 101(14)) 77. Thus, any releases into the environment of hazardous substances above the reportable quantity (RQ) thresholds must be reported under CERCLA (see CERCLA Section 103). That is, since hazardous waste pharmaceuticals are hazardous wastes and, hazardous substances under CERCLA, reporting for hazardous waste pharmaceutical releases is required when RQs are exceeded (see 40 CFR 302.4 for a list of RQs and hazardous substances). Such reports provide notification to the Agency (through the National Response Center) concerning releases into the environment and help inform whether EPA should take action, if necessary, under either RCRA or CERCLA.

The Agency solicits comment regarding the proposed standard for the response to releases of hazardous waste pharmaceuticals at healthcare facilities.

14. Long-Term Care Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Long-term care facilities differ in one respect from other types of healthcare facilities subject to these proposed standards. Unlike hospitals, who own the pharmaceuticals they dispense to patients, many of the hazardous waste pharmaceuticals generated at long-term care facilities belong to the residents of the facility. That is, the pharmaceuticals are dispensed under the patient’s name. However, as previously discussed in this preamble, EPA is proposing to no longer allow hazardous waste pharmaceuticals generated at long-term care facilities (as defined under this proposed regulation) to be eligible for the household hazardous waste exemption. As a result, long-term care facilities must manage all hazardous waste pharmaceuticals generated on-site, regardless of ownership, in accordance with these same proposed management standards for healthcare facilities. EPA understands that while long-term care facilities often maintain each individual’s pharmaceuticals in a centralized location, such as a pharmaceutical cart, there are instances where some individuals may keep and self-administer their own pharmaceuticals. EPA is proposing that the long-term care facilities collect and manage all hazardous waste pharmaceuticals generated at their facilities in accordance with these proposed requirements. This requirement means that in addition to the hazardous waste pharmaceuticals kept in the centralized location, long-term care facilities will need to collect all other hazardous waste pharmaceuticals from individuals that self-administer these pharmaceuticals and manage them in accordance with these proposed standards, which, among other things, prohibits the sewer ing of hazardous waste pharmaceuticals. The Agency solicits comment on the extent to which long-term care facilities keep an inventory of the pharmaceuticals that individuals self-administer, as this would facilitate the collection of the hazardous waste pharmaceuticals for proper disposal.

Although long-term care facilities would not be required under this rule to collect non-hazardous waste pharmaceuticals, or hazardous waste pharmaceuticals from the independent living portion of a continuing care facility, EPA recommends that long-term care facilities collect all waste pharmaceuticals to ensure proper management, avoid flushing, and minimize the potential for accidental poisonings, misuse or abuse. As discussed later in this preamble, DEA regulations govern the management of controlled substances and the implications of that rule and this proposed rule for long-term care facilities.78 Also discussed later in more detail, EPA is proposing to exempt from RCRA those hazardous waste pharmaceuticals that are also controlled substances, provided they are combusted at a permitted or interim status hazardous waste incinerator or permitted municipal solid waste incinerator and managed in compliance with applicable DEA regulations (see Section V.E.2 of the preamble for a detailed discussion of the exemption).

The Agency solicits comment regarding this requirement, and specifically requests comment on the various approaches that long-term care facilities use, or could use in collecting hazardous waste pharmaceuticals from individuals that self-administer their pharmaceuticals.

15. Healthcare Facilities That Accept Hazardous Waste Pharmaceuticals From Off-Site Conditionally Exempt Small Quantity Generators (CESQGs) 79

Typically, hazardous waste pharmaceuticals from healthcare facilities are transported either to a reverse distributor, if it is potentially creditable,80 or to a permitted or interim

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78 DEA’s final rule for disposal of controlled substances: 79 FR 53520; September 9, 2104.
79 Unlike other sub-sections of Section V.C., which discusses the proposed standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals, this sub-section addresses both non-creditable and creditable hazardous waste pharmaceuticals.
80 Potentially creditable hazardous waste pharmaceuticals include pharmaceuticals that are: (1) Unused or un-administered, (2) unexpired or...
status hazardous waste TSDF. However, stakeholders have informed EPA that in some cases, hazardous waste pharmaceuticals are transported to another healthcare facility. We are aware of at least two situations in which this is occurring. First, patients at long-term care facilities who receive their pharmaceuticals from an off-site long-term care pharmacy sometimes return their unused pharmaceuticals to the long-term care pharmacy.86 Upon return, the long-term care pharmacy sorts through the returned pharmaceuticals to determine whether they will be disposed or restocked for reuse. Due to many factors, such as Medicare regulations and the cost of the pharmaceutical as compared to the cost of repackaging and restocking, only a small fraction of the returned pharmaceuticals are restocked for potential reuse. One long-term care pharmacy estimated that approximately 10 percent of the pharmaceuticals it sends to long-term care facilities come back as returns.87 Some portion of the returns would be considered hazardous waste pharmaceuticals when discarded.88 In the second situation, the Army has established off-post health clinics to provide easier access to healthcare for military personnel, including veterans. The pharmacies at the off-post clinics receive their pharmaceutical products via couriers that deliver the pharmaceuticals from the on-post, main pharmacy. The off-post pharmacies also return their unused pharmaceuticals to the on-post, main pharmacy via courier.

EPA data indicate that the majority of long-term care facilities are CESQGs89 and the Army has informed EPA that their off-post clinics are generally CESQGs, as well.90 The existing CESQG regulations do not allow a generator to send its hazardous waste off-site to another hazardous waste generator, unless the receiving generator is also one of the seven types of facilities listed in § 261.5(f)(3) for acute hazardous waste or § 261.5(g)(3) for hazardous waste, including municipal and non-municipal non-hazardous solid waste landfills. The Agency does not think that disposal in landfills is the best option for hazardous waste pharmaceuticals. Limited studies have shown active pharmaceutical ingredients are present in landfill leachate that is collected in municipal solid waste landfill leachate collection systems.91 Landfill leachate is then typically transported to a wastewater treatment plant for treatment; however, active pharmaceutical ingredients can pass through the treatment system and into our Nation’s waters.

EPA thinks it would be preferable to allow healthcare facilities that are CESQGs to send their hazardous waste pharmaceuticals to another healthcare facility, rather than putting them in a landfill. If pharmaceutical waste is landfilled, the Agency would consider landfill leachate a hazardous waste, since leachate that is collected in municipal solid waste landfill leachate collection systems is considered hazardous waste. EPA’s proposed requirements that the majority of long-term care facilities are CESQGs and the Army has informed EPA that their off-post clinics are generally CESQGs, as well.90 The Agency has proposed an exception to these requirements.

D. How does this proposed rule address healthcare facilities that accumulate potentially creditable hazardous waste pharmaceuticals prior to shipment to pharmaceutical reverse distributors?

1. Potentially Creditable Hazardous Waste Pharmaceuticals are Not Products

One difference between this proposal and the 2006 Pharmaceutical Universal Waste proposal is the proposed interpretation of how RCRA applies to pharmaceuticals that are returned to reverse distributors to obtain manufacturers’ credit. Two previous agency policy memos set out EPA’s existing understanding of the status of these “creditable” pharmaceuticals. The healthcare facilities that are SQGs and LQGs must comply with the requirements proposed in 40 CFR part 266 subpart P.
first, a letter to Merck Sharp & Dohme in 1981, explained that pharmaceuticals sent for credit may be reclaimed and are not wastes since the decision to discard a particular material does not occur until after the product has been returned to the manufacturing plant. 90 The second, a letter to BFI Pharmaceutical Services, Inc. in 1991 states, “to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered as wastes until a determination has been made to discard them.” 91 In addition to these letters, EPA's 2008 Pharmaceutical Universal Waste proposal stated, “Because unused or expired pharmaceuticals are returned (via the reverse distributor) for creditable manufacturer's credit, they still have potential value to the pharmacy or hospital and are thus not considered wastes.” 92

In this action, we are proposing to modify EPA's position regarding the waste status of creditable pharmaceuticals. Because we understand that many participants in this sector have relied on the interpretations in the two letters and the 2008 Pharmaceutical Universal Waste preamble, we are providing notice of a change in EPA's position and providing an opportunity for public comment. Until this rule is final and effective, however, EPA's previous interpretations will continue to be in effect.

In terms of the concept that returned pharmaceuticals have value and are not waste, EPA confirms the general rule under RCRA that materials that are discarded are solid wastes, regardless of the economics of the system in which those discarded materials are handled. Therefore, the fact that a material may have monetary value (e.g., through a manufacturer's credit) does not determine whether that material is a solid waste. Rather, the “decision point” on whether a pharmaceutical is a solid waste is when it has been discarded, or the decision has been made to discard the material. That is, a discarded pharmaceutical may retain value in the reverse distribution system, but still be considered a solid waste.

Additionally, the economic value of hazardous waste can be one important consideration in determining whether a hazardous waste is legitimately recycled (see, for example, the discussion of Useful Economic Information in the 2008 Definition of Solid Waste final rule, 73 FR 84706–07, October 30, 2008) and therefore excluded from being a solid waste. The definition of legitimate recycling is codified at 40 CFR 260.43 and is discussed in the 2015 Definition of Solid Waste final rule (80 FR 1694, January 13, 2015).

Commenters to the 2008 Pharmaceutical Universal Waste proposal, the 2014 Retail Notice of Data Availability (NODA), stakeholders, and pharmaceutical reverse distributors themselves have informed EPA that pharmaceuticals transported to reverse distributors to receive credit are rarely, if ever, repurposed, recycled, or reused. One commenter wrote, “. . . EPA’s belief that reverse distributors first arrange to transport and receive the drugs, and then determine whether the drugs are useful products or wastes, is pure fiction.” 93 Another commenter wrote, “. . . the vast majority of the returned pharmaceuticals are to be collected for disposal or destruction once credit has been given.” 94 A third commenter wrote, “. . . drugs sent through reverse distribution are not reused or recycled due to economic and safety reasons.” 95 Regulations pertaining to the repurposing of pharmaceuticals vary by state, as they are established by each state's Board of Pharmacy. However, stakeholders have overwhelmingly declared that state Boards of Pharmacy only allow pharmaceuticals to be repurposed under very narrow circumstances—that is, when a specific set of conditions are followed to ensure the viability and integrity of the pharmaceutical. The set of conditions vary by state; however, states have some restrictions in common when it comes to repurposing drugs.

According to the National Conference of State Legislatures (NCSL), “Virtually all [state] laws include some restrictions designed to assure purity, safety and freshness of the products. Unless otherwise noted, all programs require:

- All donated drugs must not be expired and must have a verified future expiration date.
- Controlled substances, defined by the federal Drug Enforcement Administration (DEA) usually be excluded and prohibited.
- A state-licensed pharmacist or pharmacy to be part of the verification and distribution process.
- Each patient who is to receive a drug must have a valid prescription form in his/her own name.” 96

Thus, in most, if not all cases, pharmaceuticals that are transported back to a reverse distributor for credit are discarded by the reverse distributor. 97 For that reason, the decision to send a pharmaceutical to a reverse distributor is essentially a decision to discard the pharmaceutical.

Therefore, EPA is proposing to reinterpret its position such that the decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical. As a result, once the decision is made to send a hazardous waste pharmaceutical to a reverse distributor, it is a solid waste at the healthcare facility. In this document, EPA is proposing to define the term “potentially creditable hazardous waste pharmaceutical.” A portion of the potentially creditable pharmaceuticals at healthcare facilities that are transported to reverse distributors will likely meet the definition of hazardous waste. Of the set of pharmaceuticals that are hazardous wastes, only “potentially creditable” hazardous waste pharmaceuticals may be transported to a reverse distributor for manufacturer’s credit (see definition Section V.A.3).

The Agency notes that the management standards discussed below pertain only to potentially creditable hazardous waste pharmaceuticals that are managed via reverse distribution and do not apply to the reverse distribution or reverse logistics systems that may exist for other consumer products. In addition to the standards discussed in this section, EPA is proposing standards for shipping potentially creditable hazardous waste pharmaceuticals to pharmaceutical reverse distributors as well as associated recordkeeping (see Section V.F.2. of the preamble).

2. Hazardous Waste Determination for Potentially Creditable Hazardous Waste Pharmaceuticals

As with non-creditable hazardous waste pharmaceuticals discussed

91 Any facility, including a pharmaceutical manufacturer engaged in processing pharmaceutical hazardous waste for facilitation or verification of manufacturer’s credit would be considered a pharmaceutical reverse distributor under the proposed rule with respect to those operations, and would be subject to the proposed regulations for pharmaceutical reverse distributors. 

previously, a healthcare facility must determine which potentially creditable pharmaceuticals are listed or characteristic hazardous wastes, in order to determine which potentially creditable pharmaceuticals are subject to regulation under this subpart. Potentially creditable hazardous waste pharmaceuticals must be managed under this subpart, while pharmaceuticals that do not meet the definition of hazardous waste but are potentially creditable, do not have to be managed under this subpart. However, a healthcare facility may choose to manage all of its potentially creditable pharmaceuticals (both hazardous and non-hazardous) as potentially creditable hazardous waste pharmaceuticals while accumulating on-site and when shipping off-site. If a healthcare facility chooses this approach, it would not need to make individual hazardous waste determinations, but would have made a generic decision that all of their potentially creditable waste pharmaceuticals are hazardous and manage them as potentially creditable hazardous waste pharmaceuticals in accordance with the proposed requirements in 40 CFR part 266, subpart P.

3. Accumulation Time, Container Management, and Labeling for Potentially Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities

Typically, EPA requires specific management standards for containers that hold hazardous waste. However, potentially creditable hazardous waste pharmaceuticals appear to pose lower environmental risk of release than patient care hazardous waste pharmaceuticals or traditional industrial hazardous waste. The risk of release is lower for several reasons. First, potentially creditable hazardous waste pharmaceuticals are prepared for shipment to a reverse distributor are usually in their original containers as well as outer packaging, providing two layers of protection from leaks or spills. Second, potentially creditable hazardous waste pharmaceuticals are typically generated in the pharmacy area of a healthcare facility where there is restricted access, creating a layer of security for these pharmaceuticals. Third, EPA has been informed that it is common practice at healthcare facilities for potentially creditable pharmaceuticals that are destined for a reverse distributor to be taken from the shelves of the pharmacy periodically and promptly boxed for off-site shipment. EPA anticipates that this relatively quick timing is largely driven by the economic value of the manufacturer’s credit for the returned pharmaceuticals. Therefore, because of the lower risk these pharmaceuticals pose, EPA is not proposing specific management standards for healthcare facilities that accumulate containers of potentially creditable hazardous waste pharmaceuticals. For the same reasons, we also are not proposing a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals. EPA requests comment on the assumption that healthcare facilities promptly remove potentially creditable hazardous waste pharmaceuticals from pharmacy shelves and send them to reverse distributors. EPA asks for comment on whether the expectation of credit provides sufficient incentive to ensure that the hazardous waste pharmaceuticals will be managed appropriately or whether it is necessary to establish management standards and/or a maximum time limit for the accumulation of potentially creditable hazardous waste pharmaceuticals prior to off-site shipment. In the 2008 Pharmaceutical Universal Waste proposal, EPA specifically solicited comment on whether stakeholders have knowledge of problems with mixing incompatible pharmaceuticals during accumulation. In response, one commenter indicated that there were no issues encountered with the compatibility of pharmaceuticals during storage. Therefore, a 2011 article by Charlotte Smith states, “oxidizers, acids, and bases also are incompatible, but they occur infrequently as finished dosage forms.” It is important to note that the accumulation of some potentially creditable hazardous waste pharmaceuticals, such as liquids and aerosols, may pose more of a risk than solid pills due to possible spillage or leakage. However, EPA believes that the small quantities in which the liquid and aerosol potentially creditable hazardous waste pharmaceuticals are generated, along with the DOT packaging requirements (49 CFR parts 173, 178, and 180), would likely obviate these risks. In addition, to further mitigate the potential for spillage or leakages, as a best management practice, EPA encourages healthcare facilities to place the original containers and packaging containing liquids and aerosols

EPA also is proposing not to require specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals, while they accumulate on-site. EPA does not want to deter the practice of co-mingling potentially creditable hazardous waste pharmaceuticals with potentially creditable non-hazardous waste pharmaceuticals since both are typically transported to a reverse distributor together. In addition, due to concerns regarding diversion of pharmaceuticals, EPA believes that it is safer not to call attention to the fact that these containers hold pharmaceuticals. Unlike floor waste or patient care pharmaceutical waste, or most hazardous waste, the hazardous waste pharmaceuticals returned to a reverse distributor often have high street value that makes them susceptible to diversion. Thus, EPA is not proposing to require a label for potentially creditable hazardous waste pharmaceuticals during accumulation at a healthcare facility. The Agency seeks comment on its proposal not to require specific accumulation, container management or labeling standards for potentially creditable hazardous waste pharmaceuticals that will be transported to a reverse distributor, including no specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals on-site prior to shipment off-site.

E. What are the proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?

1. Sewer Disposal Prohibition

a. Regulatory background on the domestic sewage exclusion. Under RCRA and the Subtitle C hazardous wastes regulations, if a material is not a solid waste, then it cannot be considered a hazardous waste. Under § 261.4(a)(1)(ii) of the RCRA regulations, “Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment” is not a solid waste for purposes of Subtitle C regulation. This exclusion was finalized by EPA on May 19, 1980, based on the reasoning that “Mixsed waste streams that pass through sewer systems to publicly-owned treatment works (POTW’s) will be subject to controls under the Clean
Water Act. The Agency’s construction grants program provides financial assistance for the proper treatment of these wastes. In addition, the Agency’s pretreatment program provides a basis for EPA and the local communities to ensure that users of sewer and treatment systems do not dump wastes in the system that will present environmental problems” (45 FR 33097).

In 1984, Congress enacted the Hazardous and Solid Waste Amendments (HSWA) to the Solid Waste Disposal Act (SWDA), as amended under existing Federal law or regulated in a manner sufficient to protect human health and the environment; and (2) based on the report, revise the existing regulations that are necessary to “ensure that substances . . . which pass through a sewer system to a publicly owned treatment works are adequately controlled to protect human health and the environment.”

EPA submitted its Report to Congress on February 7, 1986 (Domestic Sewage Study). Subsequent to the Report to Congress, EPA issued an advance notice of proposed rulemaking (ANPR) on August 22, 1986 (51 FR 30166); a response to comments on the ANPR on June 22, 1987 (52 FR 23477); a notice of proposed rulemaking (NPR) on November 23, 1988 (53 FR 47632); and a final rule on July 24, 1990 (55 FR 30002). That final rule prohibits the discharge of pollutants which create a fire or explosion hazard in the POTW, which includes, but is not limited to, wastestreams with a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Celsius using the test methods specified in 40 CFR 260.1.21” (55 FR 30008). Although the exclusion for mixtures of domestic sewage and other wastes is found under the RCRA regulations in § 261.4(a)(1)(ii), the sewer ban of liquid ignitable hazardous wastes (i.e., with the hazardous waste code D001) was established under 40 CFR 403.5(b)(1), which is under the Clean Water Act (CWA). The Agency seeks comment on whether it would be helpful to incorporate in 40 CFR 261.4(a)(1)(ii), a cross-reference to the CWA regulations prohibiting the sequestration of liquid ignitable hazardous wastes.

b. Prevalence of flushing in lieu of hazardous waste management. In the preamble to the July 1990 final rule, EPA stated its intent “to carefully review the effect of this rule and promulgate in the future any additional regulations that experience reveals are necessary to improve control over hazardous waste and other industrial user discharges to POTWs” (55 FR 30004). Since then, studies have found that many healthcare facilities, particularly long-term care facilities, use drain disposal as a routine disposal method for pharmaceutical wastes in lieu of collection and shipment off-site for management. For example, • A 2008 study of 59 long-term care facilities showed that 46 percent of the long-term care facilities dispose of their pharmaceuticals by dumping them down the drain.101

• A 2003 King County, Washington survey of healthcare facilities showed that the vast majority of liquids, and nearly half of the pills, were disposed of down the drain.102

• In a study by The Albany Medical Center, funded by an EPA Pollution Prevention Grant, the author states, “up to now, toilet wasting has been the common practice for drug wasting by patient care staff.”103

• In a detailed study about the waste management practices within the healthcare industry, EPA’s Office of Water also found that sequestering of waste pharmaceuticals was common practice.104

• EPA staff from the Office of Research and Development (ORD) have published numerous articles on the subject of active pharmaceutical ingredients (APIs) in the environment. One such paper states that “unit-packaged pills are probably not frequently disposed via toilets, whereas liquids are probably routinely poured down drains.” although the authors acknowledge that “gaining an understanding of the types and quantities of APIs introduced directly and purposefully to the environment by


105 Ruhoy and Daughton; Beyond the medicine cabinet: An analysis of where and why medications accumulate; Environment International 34(2008) 1157–1169.


The pharmaceuticals entering the environment, through flushing or other means, are having a negative effect on aquatic ecosystems and on fish and animal populations. The Regulatory Impact Analysis for this proposed rulemaking summarizes the scientific literature with regard to ecological effects (see the Regulatory Impact Analysis in the docket for this proposed rule EPA–HQ–RCRA–2007–0932). The scientific research with regard to human health effects due to pharmaceuticals in the environment is still ongoing. Nevertheless, the important features and risks of the problem can be summarized as follows: 109

(1) Pharmaceuticals are intrinsically bioactive compounds; therefore, they are potentially able to impact living systems.

(2) There is a continuous and worldwide increase in their use and, thus, on their subsequent input into the environment.

(3) Many of the hundreds of frequently prescribed pharmaceuticals are known for targeted effects and adverse off-target side effects, a problem that can be exacerbated by interactive effects during therapy involving coadministration.

b. Banning sewer disposal of hazardous waste pharmaceuticals. Given the demonstrated negative ecological effects and the potential for negative human health effects, EPA is proposing to impose a sewer ban on all hazardous waste pharmaceuticals managed by healthcare facilities and pharmaceutical reverse distributors that are subject to this proposed rule—that is, they are prohibited from disposing of pharmaceuticals that are listed hazardous waste and/or exhibit one or more of the four hazardous waste characteristics (i.e., ignitability, corrosivity, reactivity, or toxicity) by putting them down a drain (e.g., sink, toilet, or floor drain).

In addition, while healthcare facilities that are CESQGs are generally not subject to this proposed rule, EPA is proposing that the sewer ban of hazardous waste pharmaceuticals also apply to healthcare facilities that are CESQGs. The vast majority of healthcare facilities are CESQGs (84 percent). Some particular types of healthcare facilities have an even larger proportion of CESQGs: Over 94 percent of dental offices are CESQGs, and 94 percent of continuing care retirement communities are CESQGs (see the Regulatory Impact Analysis in the docket for this proposed rule EPA–HQ–RCRA–2007–0932).

EPA is concerned that these smaller healthcare facilities are more likely to dispose of their hazardous waste pharmaceuticals via the sewer. EPA estimates that there are more than 145,000 healthcare facilities that are CESQGs. Given this large number, the combined impact of sewer disposal by healthcare facilities that are CESQGs has an even greater potential to provide a substantial impact on the environment, as well as human health.

EPA solicits comment on EPA’s proposal to ban the sewer disposal of hazardous waste pharmaceuticals at all healthcare facilities, including healthcare facilities that are CESQGs that generate such wastes. As part of its solicitation of comments, the Agency especially requests comment on the risk–risk tradeoffs inherent in prohibiting sewer disposal which extends the life cycle of pharmaceutical waste, resulting in additional opportunities for diversion and increasing the possibility of inadvertent exposures for certain workers (and possibly even patients or visitors) as a tradeoff for a reduction in aquatic risks. EPA also solicits comment on whether the ban on sewer disposal should be limited to those healthcare facilities that are currently LQGs and SQGs, and not extended to CESQGs.

Under 40 CFR 403.12(p) of the CWA regulations, industrial users that discharge a substance to a POTW that, if otherwise disposed of, would be a hazardous waste, must notify in writing the POTW, the EPA Regional Waste Management Division Director and State hazardous waste authorities. POTWs should be made aware that under this proposal, if made final, the notifications they receive from healthcare facilities will no longer include hazardous waste pharmaceuticals since the healthcare facilities will be prohibited from sewer disposal of hazardous waste pharmaceuticals. We note that EPA’s proposed ban on sewer disposal of hazardous waste pharmaceuticals is consistent with other federal and state actions. For example, the Drug Enforcement Administration (DEA) has finalized new regulations to implement the Secure and Responsible Drug Disposal Act of 2010 (September 9, 2014; 79 FR 53520). DEA’s new regulations require a “non-retrievable” method of destruction of controlled substances. The preambles to DEA’s proposed and final rules state that flushing does not meet the non-retrievable standard for destruction.110

According to the preamble of the DEA final rule, DEA received 20 comments supporting their position against flushing controlled substances.111 The comments supporting the prohibition against sewerage came from states, regional and local hazardous waste management programs, recycling associations, non-governmental organizations (NGOs), trade associations and environmental organizations. Many of these commenters noted that wastewater treatment systems do not flush away many of the medications that are flushed into the sewers and requested that DEA clearly state in the regulatory language, not just preamble, that sewerering is not allowable as a means of destruction.

In addition, three states and the District of Columbia have taken action to limit the sewer disposal of pharmaceuticals and a third has introduced a bill. In 2009, Illinois passed the Safe Pharmaceutical Disposal Act, which prohibits healthcare facilities from flushing any unused medications into public sewers or septic systems.112 In 2012, New Jersey passed a similar law that prohibits healthcare facilities from discharging prescription medications into public sewers or septic systems.113

In 2002, California banned the use of lindane in pharmaceuticals after it found that lindane was adversely impacting wastewater quality. The authors of the paper “Outcomes of the California Ban on Pharmaceutical Lindane: Clinical and Ecologic Impacts” state that “This is the first time that a pharmaceutical has been outlawed to protect water quality.”114 After researching and documenting environmental benefits of the ban, the authors conclude, “This ban serves as a model for governing bodies considering limits on the use of lindane or other pharmaceuticals.” And the District of Columbia has promulgated municipal regulations, effective January 1, 2011, that prohibits healthcare facilities from flushing pharmaceutical products.115 The Connecticut legislature has also considered a bill to ban the discharge of medication into public or private waste water collection systems or septic


110 Proposed rule: December 21, 2012; 77 FR 75784 (see page 75803) and Final rule: September 9, 2014; 79 FR 53520 (see page 53548).

111 September 9, 2014; 79 FR 53520 (see page 53548).

112 Illinois Public Act 096–0221.

113 Nicknamed Bateman’s Law, after Senator Christopher “Kip” Bateman (R-Somerset) that sponsored the legislation.


115 Title 22–B Chapter 5 Safe Disposal of Unused Pharmaceuticals in Health Care Facilities.
systems, although it has not yet become law.\footnote{State of Connecticut General Assembly, January Session 2013, Raised Bill No. 6439. An Act Concerning the Disposal and Collection of Unused Medication.}

Finally, we would note that although the sewer ban is limited to pharmaceuticals that are RCRA hazardous wastes, EPA strongly recommends as a best management practice to not sewer any waste pharmaceutical (i.e., hazardous or non-hazardous), except when sewerage is specifically directed by FDA guidance (as noted on pharmaceutical packaging).\footnote{http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM337803.pdf.}

For household pharmaceutical waste, we refer the public to the guidelines developed by the U.S. Office of National Drug Control Policy (ONDCP), the FDA, and EPA for the disposal of unwanted household pharmaceuticals. In summary, these guidelines are as follows:

1. Use a drug take-back event or program, when available;
2. Dispose in household trash, after mixing the unwanted medicines with an undesirable substance such as kitty litter or coffee grounds and placing in a sealed container; and
3. Only if the drug label specifically instructs you to, flush the unwanted medicine down the toilet.\footnote{http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM337803.pdf.}

2. Conditional Exemption for Hazardous Waste Pharmaceuticals That Are Also Controlled Substances

When a pharmaceutical that is discarded is both a hazardous waste and a controlled substance, its management and disposal is regulated under both the RCRA Subtitle C hazardous waste regulations, which is under EPA’s or the authorized state’s purview, and the Controlled Substances Act (CSA) and its implementing regulations, which is under DEA’s purview. EPA understands that only a handful of pharmaceuticals are in common usage that are both hazardous waste and controlled substances and therefore subject to dual regulation by both EPA and the DEA. These are identified in Table 5:

<table>
<thead>
<tr>
<th>Name of Drug</th>
<th>Other Name(s)</th>
<th>Medical Uses</th>
<th>RCRA HW Code</th>
<th>DEA CS Schedule</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloral; chloral hydrate</td>
<td>Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes</td>
<td>Sedative</td>
<td>U034 toxic</td>
<td>IV</td>
<td>Used in hospital pediatric units; common ingredient in vet anesthetics</td>
</tr>
<tr>
<td>Fentanyl sublingual spray</td>
<td>Subsys</td>
<td>Analgesic</td>
<td>D001 ignitable</td>
<td>II</td>
<td>Ignitable due to alcohol content</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>Besseral-S, Donnatal, Luminal,</td>
<td>Anticonvulsant</td>
<td>D001 ignitable</td>
<td>IV</td>
<td>Ignitable due to alcohol content</td>
</tr>
<tr>
<td>Testosterone gels</td>
<td>Androgep, Fortesta, Testim</td>
<td>Hormone</td>
<td>D001 ignitable</td>
<td>III</td>
<td>Ignitable due to gel base</td>
</tr>
<tr>
<td>Valium injectable</td>
<td>Diazepam</td>
<td>Anti-anxiety</td>
<td>D001 ignitable</td>
<td>IV</td>
<td>Ignitable due to alcohol content</td>
</tr>
</tbody>
</table>

Chloral hydrate, U034, is the only dually regulated hazardous waste/controlled substance that is a listed hazardous waste. It is listed for toxicity (note that EPA’s U034 listing includes chloral hydrate, see memo dated April 6, 1998: Brandes to Knauss, RCRA Online #14175). On the other hand, the remaining four dually regulated hazardous wastes/controlled substances in common use are considered hazardous because they exhibit the characteristic of ignitibility (D001). However, the active ingredient is not ignitable, but these particular forms of the pharmaceuticals are ignitable because they are prepared in ignitable solutions, such as alcohol.

EPA is aware of three additional hazardous waste pharmaceuticals that are DEA controlled substances, but it is our understanding that they are no longer in common usage, although there may be legacy supplies remaining in healthcare facilities. See Table 6.


Similarly, as noted in Table 7, phentermine is a controlled substance, but the medical form is a phentermine salt, and the salts are no longer considered to be within the scope of the P046 listing (see memo dated February 17, 2012; from Devlin to RCRA Division Directors, RCRA Online #14831).

Table 6: DEA Controlled Substances & RCRA Hazardous Wastes Pharmaceuticals that Are Not in Common Use

<table>
<thead>
<tr>
<th>Name of Drug</th>
<th>Other Name(s)</th>
<th>Medical Uses</th>
<th>RCRA HW Code</th>
<th>DEA CS Schedule</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraldehyde</td>
<td>1,3,5-Trioxane, 2,4,6-trimethyl-; Paral</td>
<td>Anticonvulsant</td>
<td>U182 toxic</td>
<td>IV</td>
<td>No longer in common use</td>
</tr>
<tr>
<td>Paregoric</td>
<td>camphorated tincture of opium</td>
<td>Analgesic, expectorant, antidiarrheal</td>
<td>D001 ignitable</td>
<td>III</td>
<td>No longer in common use</td>
</tr>
<tr>
<td>Opium Tincture</td>
<td>Laudanum</td>
<td>Analgesic, antidiarrheal</td>
<td>D001 ignitable</td>
<td>II</td>
<td>No longer in common use</td>
</tr>
</tbody>
</table>

Table 7: Pharmaceuticals that are DEA Controlled Substances & RCRA Hazardous Wastes Salt(s) No Longer Considered Hazardous Waste

<table>
<thead>
<tr>
<th>Name of Drug</th>
<th>Other Name(s)</th>
<th>Medical Uses</th>
<th>RCRA HW Code</th>
<th>DEA CS Schedule</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phentermine</td>
<td>alpha, alpha-Dimethylphenethylamine; Benzeneethanamine, alpha,alphadimethyl-; Adipex-P, Atti Plex P, Fastin, Ionamin, Kraftobese, Panshape M, Obe-Nix, Pentercot, Phentride, Pro-Fast, Raphtre, Supramine, Tara-8, Termene, Termine, Zantryl</td>
<td>Appetite suppressant</td>
<td>P046 Acutely toxic</td>
<td>IV</td>
<td>If in salt form, it does not meet the P046 listing and medical dosage forms are salts</td>
</tr>
</tbody>
</table>

EPA requests comment on whether these are, indeed, the only pharmaceuticals in common usage that are regulated both as DEA controlled substances, and when discarded, RCRA hazardous waste.

Common practices that healthcare facilities have used in the past in order to comply with the DEA regulations for destroying controlled substances include sewer ing and incineration. However, DEA’s new regulation requires that controlled substances must be destroyed, such that they are “non-retrievable.” As discussed previously, the preambles for DEA’s proposed and final rules state that flushing will not meet their new non-retrievable standard, a position which EPA fully supports. However, EPA is concerned that flushing will continue to be used by healthcare facilities for eliminating their controlled substances. In part, this concern is due to a 2009 EPA report which concluded, “controlled substances are the pharmaceuticals most commonly poured down the drain, especially the partially-used IVs containing controlled substances.”

In addition, stakeholders have informed EPA that it is expensive and difficult to manage controlled substances that are also hazardous wastes under both DEA and EPA regulatory schemes and therefore the unintended consequence is that they are often sewered on-site in order to avoid the expense of complying with dual regulation en route to incineration.

EPA wants to eliminate the flushing of pharmaceuticals in order to reduce potential environmental contamination. Sewering hazardous wastes that are ignitable (D001) is already banned and EPA is now proposing to eliminate the sewer of all other hazardous waste pharmaceuticals.\textsuperscript{120} To eliminate duplicative regulation and thereby further reduce the incidence of flushing, EPA is proposing to conditionally exempt from RCRA Subtitle C regulation those hazardous wastes that are also DEA controlled substances. Specifically, EPA is proposing that hazardous wastes that are also controlled substances will be exempt from all RCRA Subtitle C requirements, including 40 CFR part 266, subpart P, provided they meet two conditions: (1) They are combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln), and (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances.

The first condition is to ensure that the controlled substances are destroyed in an environmentally protective manner by a high-temperature combustor, such as a large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln). The majority of the hazardous wastes that are also controlled substances are hazardous because they exhibit the characteristic of ignitability. The best demonstrated available technology (BDAT) developed for ignitable hazardous waste under the LDRs includes combustion (see § 268.40). In addition, although chloral hydrate (U034) is listed because of its toxicity, its BDAT is also combustion. Therefore, in an effort to eliminate the sewer of these dually regulated hazardous wastes/controlled substances, and because combustion of these pharmaceuticals is a suitable technology for destruction, EPA is proposing to allow the few hazardous wastes pharmaceuticals that are also controlled substances to be combusted at municipal solid waste combustors, although as noted previously, a hazardous waste incinerator (permitted or interim status) would also be allowed.

We realize that DEA may allow a technology other than combustion to be used to destroy controlled substances. However, if the RCRA hazardous pharmaceuticals that are DEA controlled substances are exempt from RCRA, the other destruction technologies may lack environmental controls and permits. Therefore, combustion of the hazardous wastes/controlled substances, which requires permitting, operating and monitoring standards, is a condition of the exemption. EPA requests comment on whether there are additional technologies that would be appropriate to include for the destruction of hazardous waste pharmaceuticals that are also controlled substances. Under this proposal, if DEA allows a technology other than incineration for the destruction of controlled substances, it would be allowed only for DEA controlled substances, but not for those that are also RCRA hazardous wastes.

The second condition is to ensure that dually regulated hazardous wastes/controlled substances are managed under another rigorous regulatory program since they will not be managed in accordance with the RCRA Subtitle C regulations. Although developed for different reasons, both EPA’s hazardous waste and DEA’s controlled substance regulatory programs are designed to track the regulated material from cradle to grave. DEA regulations have requirements similar to EPA’s hazardous waste manifest. In particular, in order to ship a schedule II controlled substance, a DEA registrant must submit a DEA Form 222 to the supplier of the schedule II controlled substance. The DEA Form 222 is a numerically controlled form issued by the DEA to authorized registrants, containing certain pre-printed information. The supplier must indicate on the DEA Form 222, the quantity of packages shipped and the date the packages were shipped. Like a hazardous waste manifest, a copy of Form 222 must accompany the shipment and it must be kept by both the supplier and purchaser for at least two years (copies of manifests must be kept for three years). Suppliers and distributors may utilize the electronic version of the DEA Form 222, which requires the same information and retention period. Similarly, DEA Schedule III, IV and V controlled substances must be accompanied by an invoice, which also must include a detailed inventory of the contents shipped. A copy of the invoice must also be retained by the supplier and purchaser of the controlled substances for a period of two years. EPA believes that the DEA tracking and shipping requirements are sufficient to act in lieu of the RCRA hazardous waste manifest and hazardous waste transporter requirements. EPA requests comment on this assessment.

DEA has previously stated that controlled substance “pharmaceutical wastage” may be disposed of in accordance with applicable federal, state, and local laws, regulations, and healthcare facility policies, to include sewer or putting down the drain.\textsuperscript{121} The term “pharmaceutical wastage” refers to leftover, unadministered pharmaceuticals (“e.g., some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized”\textsuperscript{122}). EPA is proposing that the few hazardous waste pharmaceuticals that are also controlled substances would be exempt from RCRA, but only on the condition that they are incinerated at a permitted hazardous waste or municipal solid waste incinerator and managed in accordance with DEA regulations. As a result, if pharmaceutical wastage is both hazardous waste and controlled substance it would not be allowed to be sewer; it would have to be incinerated. Prior to incineration, the pharmaceutical wastage would be exempt from RCRA and could be collected in a container at the healthcare facility. As an alternative, we request comment on whether to allow the sewer of the pharmaceutical wastage for the five hazardous wastes that are also controlled substances. We are concerned, however, that this alternative approach will lead to the sewer of all pharmaceutical wastage as healthcare providers are unlikely to keep track of which hazardous waste pharmaceuticals are allowed to be sewer and which are not. We request comment on these approaches for pharmaceutical wastage and request data on the impact on healthcare facilities of not allowing pharmaceutical wastage to be sewer.

\textsuperscript{120} See 40 CFR 403.5 for specific pretreatment prohibitions.


\textsuperscript{122} Ibid.
two exceptions. First, hazardous waste pharmaceuticals that are also controlled substances will not be subject to RCRA, provided they meet two conditions: (1) They are combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln), and (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances. Second, as discussed previously, EPA estimates that only 28% of long-term care facilities generate hazardous waste pharmaceuticals and of those, 85% generate small enough quantities of hazardous waste that they will qualify as CESQGs and will be subject to the reduced regulatory requirements of 40 CFR 261.5, and only the sewer ban provision of this new subpart.123

DEA’s new regulations to implement the Secure and Responsible Drug Disposal Act of 2010 are expected to help alleviate the problem that long-term care facilities face when discarding controlled substances. DEA’s new regulations allow retail pharmacies and hospital/clinics with an on-site pharmacy that are DEA registrants to modify their registrations and become “collectors” to place collection receptacles at long-term care facilities (or at the retail pharmacy or hospital/clinic with an on-site pharmacy) for the collection of controlled substances from ultimate users (i.e., consumers).

Under the new DEA regulations, long-term care facilities have three options, two of which are new, for managing their patients’ controlled substances. First, if a DEA registered retail pharmacy or hospital/clinic with an on-site pharmacy places a collection container at a long-term care facility, the staff from the long-term care facility may place the patients’ controlled substances in the collection receptacles. Second, although long-term care facilities will not be able to conduct collection events for their patients’ controlled substances for mail-back programs, they will be allowed to assist patients who choose to use a mail-back program for their own controlled substances, on an individual-by-individual basis. And third, law enforcement will continue to be allowed to pick up patients’ controlled substances for disposal. With these changes to DEA’s regulation, long-term care facilities can now dispose of patients’ controlled substances in a more environmentally protective way.

Because we are proposing that hazardous waste pharmaceuticals that are also controlled substances are conditionally exempt from RCRA, these wastestreams may also be managed in any of these three ways allowed by DEA, provided the waste is managed to meet the conditions of the RCRA conditional exemption.

The new DEA regulations do not mandate the placement of collection receptacles or patient participation in mail-back programs or take-back events. However, if long-term care facilities are prohibited from disposing of pharmaceuticals down the toilet or drain under RCRA (and as a method of destruction under DEA regulations), then the only way for patients at long-term care facilities to lawfully dispose of DEA controlled substances that are also RCRA hazardous wastes would be through participation in one of DEA’s collection methods. Long-term care facilities are allowed to place patients’ hazardous waste pharmaceuticals that are controlled substances in the DEA collection receptacles; the other hazardous waste pharmaceuticals generated by long-term care facilities must be managed under the proposed RCRA management standards for healthcare facilities. However, we note that if the long-term care facility is a CESQG, we are proposing as an acceptable method of disposal of the long-term care facility’s hazardous waste pharmaceuticals would be to place them in a DEA collection receptacle, even if they are not controlled substances (see § 266.504(b)). DEA already allows controlled substances to be co-mingled with non-controlled substances. Therefore, EPA believes it is consistent to allow CESQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA collection receptacles with controlled substances. EPA believes that management of CESQGs’ hazardous wastes as DEA controlled substances is preferable to management as municipal solid waste because it provides greater protection to patients, visitors and workers at long-term care facilities to have the hazardous waste pharmaceuticals in DEA collection receptacles rather than in the regular trash. See Table 8 for a summary of the intersection of RCRA and DEA regulations for the disposal of hazardous waste pharmaceuticals at long-term care facilities:

<table>
<thead>
<tr>
<th>Types of pharmaceutical waste at long-term care facilities</th>
<th>Regulatory requirements</th>
<th>DEA Authorized collection methods allowed for patients’ pharmaceuticals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous Waste Pharmaceuticals that are also Controlled Substances.</td>
<td>Conditionally exempt from RCRA ...........................................................................</td>
<td>Yes.</td>
</tr>
<tr>
<td>Hazardous Waste Pharmaceuticals that are not Controlled Substances.</td>
<td>..................................................................................................................................</td>
<td></td>
</tr>
<tr>
<td>if LTCF is a CESQG .........................................................................................</td>
<td>261.5 and sewer ban .........................................................................................</td>
<td>Yes.</td>
</tr>
<tr>
<td>if LTCF is not a CESQG ................................................................................</td>
<td>Part 266, subpart P .........................................................................................</td>
<td>No.</td>
</tr>
</tbody>
</table>

**Table 8—RCRA & DEA Regulations at Long-Term Care Facilities**

*b. Household hazardous waste collected in DEA authorized collection receptacles.* In response to questions that EPA has received since the DEA rule was published, we are taking this opportunity to clarify the current RCRA regulatory status of the pharmaceuticals collected in DEA authorized collection receptacles. DEA’s regulations allow the co-mingling of controlled substances and non-controlled substances in its collection receptacles. In some instances, the pharmaceuticals that are collected by retail pharmacies and law enforcement in DEA authorized collection receptacles may contain pharmaceuticals that are RCRA hazardous waste. However, as household wastes, these hazardous waste pharmaceuticals would be excluded from regulation by

123 See the docket for this rulemaking for data about long-term care facilities which was developed using data in the economic analysis: EPA–HQ–RCRA–2007–0932.
§ 261.4(b)(1) because the exclusion applies even when the household hazardous wastes are collected. It is important to note that in order to maintain the exclusion, a retail pharmacy (or other DEA authorized collector pharmacy) can use the DEA authorized collection receptacle to collect waste generated only at households and brought to the store for collection. The hazardous waste generated by the retail pharmacy and store, including hazardous waste pharmaceuticals, are not excluded household wastes under RCRA and may not be placed in the DEA authorized receptacle.124 Furthermore, states generally regulate non-hazardous waste and they may have licensing or permitting requirements for the collection of solid waste. Because EPA would like to see the use of DEA authorized collection receptacles become widespread, we encourage states to streamline any requirements that may create a barrier to the use of the collection receptacles.

Under this proposal, pharmaceuticals collected in DEA authorized collection receptacles will continue to be excluded from regulation as household hazardous waste, with some conditions. The Agency has a long-standing recommendation that household hazardous waste collection programs manage the collected waste as hazardous waste. We strongly believe that if a program goes to the expense of collecting the waste, including waste pharmaceuticals, it should manage the waste as hazardous waste, rather than manage it as municipal solid waste, which the household could do absent the collection program. However, the current household waste exemption does not require an entity that hosts a household hazardous waste collection event to manage the collected waste as hazardous waste. Typically, the parties conducting household hazardous waste collection events have been government entities—municipalities and counties. It is relatively new that retail pharmacies and others are becoming interested in performing this function. To encourage this practice, while at the same time ensuring that collection programs are managing the collected waste properly, we are proposing that pharmaceuticals that are household hazardous waste (i.e., “household waste pharmaceuticals”) and are collected in DEA authorized collection receptacles where they may be co-mingled 125 with controlled substances continue to be excluded from RCRA regulation, provided they are:

1. Composted at a municipal solid waste or hazardous waste combustor, and
2. Managed in accordance with all applicable DEA regulations (see § 266.506(a)(2)). The Agency solicits comments on all these provisions.

On a separate, but related matter, EPA has received a number of inquiries about the exemption in the Clean Air Act regulations for Other Solid Waste Incinerator (OSWI) “units that combust contraband or prohibited goods” (see the exemption at 40 CFR 60.2887(p) for new OSWIs and 40 CFR 60.2993(p) for existing OSWIs). As indicated in a previous guidance memo, EPA does not consider pharmaceuticals, voluntarily collected from ultimate users in a take-back program, to be contraband or prohibited goods.126 Likewise, EPA will not consider pharmaceuticals that are voluntarily dropped off at collection receptacles to be contraband or prohibited goods. Therefore, the OSWI exemption does not apply and law enforcement may not destroy voluntarily collected pharmaceuticals in the same way that it is allowed to destroy contraband or prohibited goods.

3. Management of Residues in Pharmaceutical Containers

a. Regulatory background. Over the years, EPA has received numerous inquiries regarding the regulatory status of various types of containers that once held pharmaceuticals that are considered hazardous waste when discarded because of the hazardous waste residue in the containers. Stakeholders have been particularly concerned about containers that once held pharmaceuticals that are on the “P-list” of acutely hazardous commercial chemical products in § 261.33(e) because a generator becomes an LQG if it generates more than 1 kg of acute hazardous waste per calendar month or accumulates more than 1 kg of acute hazardous waste at any time.127 The current regulatory status of acute and non-acute commercial chemical product residues remaining in a container are specifically addressed in § 261.33:

The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded . . .

c. Any residue remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is empty as defined in § 261.7(b). [emphasis added]

According to § 261.7(b)(1), there are two ways a container that held a non-acute hazardous waste can be considered “empty”:

A container or an inner liner removed from a container that has held any hazardous waste, except a waste that is a compressed gas or that is identified as an acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter is empty if:

(i) All wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, e.g., pouring, pumping, aspirating, and
(ii) No more than 2.5 centimeters (one inch) of residue remain on the bottom of the container or inner liner, or
(iii) (A) No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size; or
(B) No more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size.

Therefore, if the container that held the non-acute hazardous waste pharmaceutical does not have its contents removed by a commonly employed practice and either has one inch or less of residue remaining or has 3 percent or less by weight of the total capacity of the container remaining,128 then the container is not considered “RCRA empty,” even though the pharmaceutical may have been fully dispensed. If the container is not “RCRA empty,” then the residues are regulated as hazardous waste (since the residues are within the container, the container must be managed as hazardous waste, as well, even if it is not itself hazardous waste). On the other hand, if the contents of the container have been removed by a commonly employed

124 DEA regulations also prohibits retail pharmacy stock/inventory from being placed in the collection receptacle or mail-back envelopes (see 21 CFR 1317.05(a)).

125 DEA does not prohibit co-mingling of controlled substances with non-controlled substances provided they are all then managed as controlled substances.

126 Rudzinski to RCRA Division Directors, September 26, 2012. RCRA Online #14833 http://yosemite.epa.gov/owm/rcra.nsf/0/994246c239947e8556d89061175f cb11db86f1d4 b1685257afe005e58ce/OpenDocument.

127 Additionally, acute hazardous wastes are included on the F-list of § 261.31; however none of those acute hazardous wastes are pharmaceuticals.

128 We are assuming that containers that hold pharmaceuticals are in containers less than 119 gallons in size.
practice and either have one inch or less of residue remaining, or 3 percent or less of weight of the total capacity of the container remaining, then the container is considered “RCRA empty,” and may be managed as non-hazardous waste.

Likewise, according to § 261.7(b)(3), there are three ways that a container that held an acute hazardous waste can be considered “empty”:

A container or an inner liner removed from a container that has held an acute hazardous waste listed in §§ 261.31 or 261.33(e) is “empty” if:

(i) The entire container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;

(ii) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or

(iii) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed.

Therefore, if the container that held the P-listed pharmaceutical is not triple rinsed, or cleaned by another method that has been demonstrated to achieve equivalent removal, or had the inner liner removed, the container is not considered “RCRA empty,” even though the pharmaceutical may have been fully dispensed. If the container is not “RCRA empty,” then the residues are regulated as acute hazardous waste.

In November 2011, EPA issued guidance about containers that once held P-listed pharmaceuticals that provides three possible regulatory approaches for generators:

(1) Count only the weight of the residue toward generator category

(2) Demonstrate an equivalent removal method to render containers RCRA empty

(3) In the case of warfarin, show that the concentration in the residue is below the P-listed concentration.

This guidance was intended as a short-term solution that worked within the confines of the existing RCRA hazardous waste regulations and EPA indicated at the time that a more comprehensive solution would require notice and public comment that occurs during a rulemaking. We are proposing to amend the regulations that pertain to containers that once held pharmaceuticals that are RCRA hazardous wastes. We are proposing different regulatory solutions for different types of containers found in healthcare settings. Specifically, we address the following three types of containers:

(a) Single-unit dose containers

(b) Unit-dose containers

(c) Unit-dose dispensing bottles and vials

We are proposing that the removal of the pharmaceutical ingredient in the packaging of four different P-listed pharmaceuticals has been demonstrated to achieve equivalent to rendering the container “RCRA empty.” Therefore, for containers that once held non-acute hazardous wastes, it will not be necessary to measure the remaining contents, and for containers that once held acute hazardous wastes, it will not be necessary to triple-rinse the containers or demonstrate an equivalent removal method. Rather, if the contents of the container have been fully dispensed by removing all pharmaceuticals that can be removed using the practices commonly employed to remove materials from that type of container, the residues (and therefore the container) may be disposed of as non-hazardous waste.

We are proposing this conditional exemption for two reasons. First, we want to eliminate the sewerage of pharmaceuticals. We are particularly concerned that in a healthcare setting, when containers are triple rinsed, the rinsate will be poured down the drain which is not a good environmental practice. We think it is important that the residues be managed in a more controlled manner—such as municipal solid waste management—rather than poured down the drain. Second, although the “empty container” regulations of §261.7 apply to all sizes of containers, they were developed with larger, industrial-sized containers in mind. For the most part, the containers that hold pharmaceuticals range in size from a few milliliters (e.g., packaging for nicotine gum, paper cups used to dispense pharmaceuticals to in-patients) to a liter (e.g., bottles that hold bulk quantities of pills). In rare circumstances, containers with pharmaceuticals are as large as two or three liters (e.g., powders that are reconstituted with water). This differs significantly from the 55-gallon drums that are typically used in other sectors that generate hazardous waste.

Consequently, the amount of residues in the containers was anticipated to be much more substantial than is the case for containers typically used for pharmaceuticals.

EPA has received data from three stakeholders demonstrating that there is very little residue remaining in fully dispensed containers of pharmaceuticals. In addition, EPA’s ORD conducted similar research. The results from each of the four sources are summarized below: the full results are included in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).

i. Consulting Firm. One stakeholder, with a hazardous medical materials consulting firm, provided some laboratory testing. They had the residues from single-unit dose packaging of four different P-listed pharmaceuticals tested using gas chromatography/mass spectrometry (GC/MS) and high performance liquid chromatography/ultraviolet detector (HPLC/UV). The amount of active pharmaceutical ingredient in the residues remaining in containers was quantified and the results from containers that had been triple rinsed were compared with containers that had not been triple rinsed. For the containers that were triple rinsed, the active ingredient in the residues was non-detect in all cases. For the containers that were not triple rinsed, the highest level detected was 35.8 μg (or 0.0358 mg). The laboratory results submitted to EPA are summarized in Table 9; the full laboratory results are included in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

129 Rudzinski to RCRA Division Directors, November 11, 2011, RCRA Online #14827.
Table 9: Active Pharmaceutical Ingredient in Residues in Single-Unit Dose Packaging

<table>
<thead>
<tr>
<th>Drug (packaging type)</th>
<th>HW Code</th>
<th>Active pharmaceutical ingredient in Triple-Rinsed Packaging (µg)</th>
<th>Active pharmaceutical ingredient in Non-Triple-Rinsed Packaging (µg)</th>
<th>Reporting Limit (µg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine gum* (blister pack)</td>
<td>P075</td>
<td>ND</td>
<td>ND</td>
<td>0.00005</td>
</tr>
<tr>
<td>Nicotine patch* (single use packet)</td>
<td>P075</td>
<td>ND</td>
<td>35.8</td>
<td>0.00005</td>
</tr>
<tr>
<td>Warfarin** (blister pack)</td>
<td>P001</td>
<td>ND</td>
<td>6.4</td>
<td>5.0</td>
</tr>
<tr>
<td>Physostigmine** (ampoule)</td>
<td>P204</td>
<td>ND</td>
<td>ND</td>
<td>100</td>
</tr>
</tbody>
</table>

*Method EPA 8720B  
**HPLC/UV  
ND = non-detect

ii. Large Retailer. The second stakeholder that submitted data to EPA was a large retailer. Their data provide the weight of active pharmaceutical ingredient residues remaining in bulk containers (i.e., 100-count) of various dosage strengths of warfarin. The residues were quantified using HPLC–UV/Vis (high performance liquid chromatography/ultraviolet/visible light detector). The data are summarized in Table 10; the full results submitted to EPA are included in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).

Table 10: Warfarin Residues in 100-Count Dispensing Bottles

<table>
<thead>
<tr>
<th>Warfarin Dose</th>
<th>Number of Bottles Tested</th>
<th>Total Warfarin Residue in all Containers (mg)</th>
<th>Average Warfarin Residue/Bottle (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low (1 - 3 mg)</td>
<td>17</td>
<td>2,638</td>
<td>0.155</td>
</tr>
<tr>
<td>Medium (5 - 7.5 mg)</td>
<td>18</td>
<td>12,820</td>
<td>0.712</td>
</tr>
<tr>
<td>High (10 mg)</td>
<td>18</td>
<td>21,530</td>
<td>1.196</td>
</tr>
</tbody>
</table>

The results from each of the first two stakeholders reflect only the weight of the active pharmaceutical ingredient, not the full weight of the hazardous waste residues. Since it is the Agency’s position that it is the full weight of the hazardous waste residues and not just the weight of the active pharmaceutical ingredients that must be counted in determining generator status, we have used the results to calculate the weight of the total residues. In the retailer’s case, they have informed EPA that a typical pill with a 10 mg dose of Coumadin (brand name of warfarin) weighs 200 mg. The active ingredient represents 10 mg, or 5% of the weight of the pill, while 190 mg, or 95% of the weight of the pill, consists of ingredients other than the active ingredient. As indicated in Table 10, the average weight of warfarin residue remaining in a fully dispensed bottle of the high dose of warfarin (10 mg) is 1.196 mg. If we assume that the residue in the container has the same proportions of ingredients (i.e., 5% of the residue is warfarin and 95% of the residue are other ingredients), then there would be an average of 23.92 mg of total hazardous waste residue remaining in a 100-count bottle of 10 mg pills of warfarin. The amount of hazardous waste residue remaining in a 100-count bottle of pills is very small compared with the residue that would remain in a 55-gallon drum, which is what the regulations for container residues envisaged.

iii. Riverside County. The third stakeholder that provided data to EPA was the Riverside County Department of Environmental Health, Hazardous Materials Management Branch. The county received a grant from the California Certified Unified Program Agency (CUPA) Forum Board to conduct a study of residues remaining in pharmaceutical containers. Researchers at the University of California, Riverside (UCR) conducted the study and provided their results in a report to Riverside County entitled, Residue Analysis of P-Listed Pharmaceutical Containers for Warfarin and Nicotine. The results are summarized below, but UCR’s full results are in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).\(^{130}\)

The intent of the study was to investigate the third regulatory approach suggested in the November 2011 memo discussed previously. That

\(^{130}\) See Exhibit 2 of the CUPA Forum Board Trust Fund Grant Report submitted by the Riverside County Department of Environmental Health at the conclusion of the grant.
is, the study investigated whether the concentration of warfarin in the residues of warfarin pill bottles was greater than 0.3% and therefore met the listing criteria for P001 or whether the residues were at or below 0.3% and therefore met the listing criteria for U248. Although nicotine is not a concentration-based P-listing, packaging from nicotine-containing products were also investigated to determine total remaining residues.

The researchers collected a total of 59 samples containers, including 44 sample containers that had held warfarin pills but had been fully dispensed and another 15 sample containers from nicotine-containing products. The samples included warfarin and nicotine from several manufacturers, in a range of dose strengths and in various container types. The residues were solvent-extracted and then dried by rotary evaporation to determine the total weight of residues. Subsequently, the residues were re-dissolved in methanol and analyzed using HPLC to determine the concentration of the active pharmaceutical within the residues.

The majority of warfarin containers were plastic bottles, but some containers were blister packs and three samples were 30-pill blister packs, sometimes referred to as a “bingo card.” The results indicate that the concentration of the active pharmaceutical ingredient warfarin in the residues in plastic bottles was usually over the 0.3% concentration. However, the concentration of warfarin in the residues on blister packs, including the 30-pack blister pack, was consistently below 0.3%. Overall, in the majority of cases, the warfarin within the residues was present at a high enough concentration to be considered P001 (33 of 44 samples, 75 percent of the samples).

However, the results also confirm the results from the first two stakeholders. That is, the total weight of residues remaining in the containers after they were emptied of the warfarin pills is negligible. For the plastic bottles, the total weight of residue ranged from 4.3–82.3 mg. For the single-dose blister packs, the total weight of residue ranged from 3.5–7.6 mg. And for the 30-pack blister pack, the total weight ranged from 134.8–273 mg. Taking the smallest amount of residue of 3.5 mg, it would take close to 300,000 containers per month to exceed the 1 kg threshold to be an LQG. Even on the conservative side, taking the largest amount of residue of 273 mg, it would take close to 4000 containers per month to exceed the 1 kg threshold to be an LQG.

The results for nicotine residues were similar. For containers of gum and patches, the weight of total residues ranged from 9–111.2 mg, although the two containers of liquid nicotine solution contained more residues—1301 and 1616 mg. Although nicotine is not a concentration-based listing, it is worth noting that the active pharmaceutical ingredient of nicotine in the residues was below the quantifiable limit of 1.5 \( \mu g/ml \) in 8 of the 15 samples and for the other 7 samples, the concentration of nicotine ranged from 0.01–0.09%.

iv. EPA’s Office of Research and Development. Finally, EPA’s ORD conducted an analysis to evaluate whether simply removing a drug from the container is equivalent to triple rinsing the container. ORD’s results are summarized in Table 11, but the Final Project Report containing the full results is in the docket for this proposed rulemaking (EPA—HQ—RCRA—2007–0932). ORD analyzed three different P-listed pharmaceuticals: Warfarin, nicotine and physostigmine salicylate. Table 11 lists the 18 different combinations of active pharmaceutical ingredients, form, dosage strengths and packaging combinations that ORD analyzed.

<table>
<thead>
<tr>
<th>Active pharmaceutical ingredient</th>
<th>Manufacturer/Brand name</th>
<th>Form</th>
<th>Dosage</th>
<th>Packaging type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warfarin</td>
<td>Taro Pharmaceutical Industries, Ltd.</td>
<td>Tablet</td>
<td>1 mg</td>
<td>Plastic bottle.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tablet</td>
<td>5 mg</td>
<td>Plastic bottle.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tablet</td>
<td>10 mg</td>
<td>Plastic bottle.</td>
</tr>
<tr>
<td></td>
<td>Upsher-Smith/Jantoven</td>
<td>Tablet</td>
<td>2 mg</td>
<td>Single-dose blister pack.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tablet</td>
<td>1 mg</td>
<td>Single-dose blister pack.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tablet</td>
<td>10 mg</td>
<td>Single-dose blister pack.</td>
</tr>
<tr>
<td>Nicotine</td>
<td>GlaxoSmithKline/Nicorette</td>
<td>Gum</td>
<td>2 mg</td>
<td>Single-dose blister pack.</td>
</tr>
<tr>
<td></td>
<td>Rugby Laboratories</td>
<td>Gum</td>
<td>4 mg</td>
<td>Single-dose blister pack.</td>
</tr>
<tr>
<td></td>
<td>GlaxoSmithKline/Nicorette</td>
<td>Lozenge</td>
<td>2 mg</td>
<td>Single-dose blister pack.</td>
</tr>
<tr>
<td></td>
<td>Habitrol</td>
<td>Patch</td>
<td>7 mg</td>
<td>Peel-off plastic.</td>
</tr>
<tr>
<td></td>
<td>Rugby Laboratories</td>
<td>Patch</td>
<td>14 mg</td>
<td>Peel-off plastic.</td>
</tr>
<tr>
<td></td>
<td>Pfizer/Nicotrol</td>
<td>Spray</td>
<td>21 mg</td>
<td>Peel-off plastic.</td>
</tr>
<tr>
<td></td>
<td>Akron Inc.</td>
<td>Liquid</td>
<td>1 mg/ml</td>
<td>Glass ampoule.</td>
</tr>
<tr>
<td>Physostigmine Salicylate.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

All combinations in Table 11 were analyzed in triplicate using the following three-step approach:

(1) After removing the tablets, gum, lozenges, etc from the containers, the amount of total residuals remaining in the container was determined using a sensitive balance to weigh the container before and after triple rinsing.

(2) The “maximum possible weight of residual drug/total residual/container” was calculated for each compound and packaging combination. This calculated result was used to infer a theoretical upper limit for the amount of active pharmaceutical compound in the total residue remaining in the container, and

(3) Thermal gravimetric analysis (TGA) was used to qualitatively evaluate the presence of active pharmaceutical ingredient in the residuals removed from the containers before and after triple-rinsing.

With respect to the weight of the remaining residuals in the containers, ORD’s results are similar to the results...
from the first three sources. That is, the weight of the total residuals remaining in the packaging of P-listed pharmaceuticals is minimal. For single-dose blister packs, lozenge vials and the peel-off plastic from nicotine patches the weight of the residuals was negligible and within the range of error of the balance, but all results were below 0.0002 grams. For plastic containers that held tablets, the weight of residuals were higher, but still very low, ranging from 0.0152–0.0157 grams. For containers that held liquids, the weight of residuals was the highest, but still very low, ranging from 0.0472 grams for glass vials of nicotine spray, to 0.0651 grams for glass ampoules that held liquid phystostigmine salicylate. The residuals in the nicotine inhaler were not experimentally determined; rather, the manufacturer (Pfizer) states on the packaging that the 10 mg cartridge delivers a 4 mg dose, so the residuals are assumed to be 6 mg (or 0.006 grams).\(^{131}\)

Unlike the quantitative results from the HPLC analyses from outside stakeholders, the results from the TGA are qualitative only. That is, the TGA was only intended to evaluate the presence of the API and compare the results from containers that had been triple rinsed with those that had not been triple rinsed. Using TGA, the API was not detected in the residuals, with one exception: The liquid nasal spray (note that TGA was not used on the nicotine inhaler residuals). In most cases, the TGA detected other, unspecified ingredients in the residuals, but not the active pharmaceutical ingredient on the P-list. The total weight of the residues was well under a gram and the active pharmaceutical ingredient is a small proportion of the total weight of the tablet, gum, etc. As a result, with the exception of the nicotine nasal spray, the TGA was not sensitive enough to detect the presence of the active pharmaceutical ingredient, regardless of whether the container had been triple rinsed or not.

EPA is aware that there are certain limitations with the data from the four sources. For instance, in the case of the consulting firm, no replicate samples were tested. In the case of the retailer, only warfarin residues were tested. However, given the size of the containers involved and the nominal quantities of residues involved, the Agency is proposing to allow the residues in single-unit dose containers/ packaging and dispensing bottles, vials and ampules that once held pharmaceuticals to be managed as non-hazardous waste pharmaceuticals provided the pharmaceutical product has been fully dispensed (e.g., all pills have been removed). EPA is soliciting comment on whether these studies are representative of the spectrum of formulations and containers that might be encountered.

Finally, we note that the Agency is concerned about the potential for diversion of the pharmaceutical containers that may occur when the pharmaceutical residuals and containers are discarded in the municipal waste stream. In such instances, we are concerned that the containers could be diverted from the municipal waste stream and used for illicit purposes, such as packaging counterfeit pharmaceuticals. Therefore, EPA is proposing that “RCRA empty” pharmaceutical containers that are original pharmaceutical packages (and therefore are susceptible to diversion) should be destroyed prior to placing them in the trash. These types of containers would include dispensing bottles, vials or ampules typically used in pharmacies, but would not include paper or plastic cups, or blister packs used for dispensing singles doses to patients. The means of destruction could include crushing or shredding the container. We do not believe that simply defacing the label would be sufficient to avoid diversion, since labels could be replaced if the container is intact.

We request comment on these proposed provisions, including whether it is necessary to limit the size of the dispensing bottle to which this provision would apply. In our observation, EPA has rarely seen pharmaceutical dispensing bottles that are larger than 1000-count, which are approximately 1 liter in size. EPA requests comment on whether larger containers are used for dispensing pharmaceuticals and, if so, which pharmaceuticals they are used for and what RCRA hazardous waste codes apply. We also seek comment as to whether “RCRA empty” pharmaceutical containers that are the original pharmaceutical packages should be destroyed prior to placing them in the trash.

c. Dispensed syringes. With regard to dispensed syringes, EPA is proposing a conditional exemption for syringes that have been used to administer pharmaceuticals that are listed or characteristic hazardous waste when discarded. The residues remaining in a dispensed syringe would not be regulated as hazardous waste provided the syringe has been used to administer a pharmaceutical to a patient and the syringe is placed in a sharps container (if appropriate) and is managed in accordance with all applicable state and federal medical waste regulations. This would apply to syringes used to administer pharmaceuticals that are P- or U-listed, or exhibit a hazardous waste characteristic.

EPA issued guidance regarding the regulatory status of residues in syringes in December 1994\(^{132}\) and April 2008.\(^{133}\) In the December 1994 RCRA/Superfund Hotline Q&A about whether epinephrine in a discarded syringe would be P042, EPA stated, “Drug residues often remain in a dispensing instrument after the instrument is used to administer medication. EPA considers such residues remaining in a dispensing instrument to have been used for their intended purpose. The epinephrine remaining in the syringe, therefore, is not a commercial chemical product and not a P042 hazardous waste. The epinephrine could be a RCRA hazardous waste, however, if it exhibits a characteristic of hazardous waste.”\(^{134}\)

In the April 2008 memo, EPA clarified that the 1994 interpretation extends to other P- and U-listed pharmaceuticals that have been used to administer the pharmaceutical by syringe. This proposed conditional exemption for syringes, in large part, would maintain the existing interpretation. The primary difference is that under the proposed conditional exemption, healthcare facilities would not be required to determine if the residues in the syringes meet a listing description or exhibit a hazardous waste characteristic.

\(^{131}\) Optimizing drug dose is a major factor in improving the sustainability of healthcare. The prescriber needs to be cognizant that prescribed treatments can have unanticipated, collateral impacts that reach far beyond the healthcare setting. See: Daughton and Ruhoy, Lower-dose prescribing: Minimizing “side effects” of pharmaceuticals on society and the environment; Sci Total Environ, 443(2013), pp. 324–336, which presents a critical examination of the multi-faceted potential role of drug dose in reducing the ambient levels of APIs in the environment and in reducing the incidence of drug wastage, which ultimately necessitates disposal of leftovers. (http://sciedirect.com/science/article/pii/S0048969712019279)

\(^{132}\) December 1994, RCRA Online #13718 http://yosemite.epa.gov/ows/rcra.nsf/0c99424b2c39947e65256d690671175f/1C1D6E964A6AB685256D70F069BCDC2/$file/13718.pdf.

\(^{133}\) Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788 http://yosemite.epa.gov/ows/rcra.nsf/0c99424b2c39947e65256d690671175f/6A5DEDFF2FBA24F6652574B400054B4AF/$file/14788.pdf.

\(^{134}\) Note that since this Q&A was issued, EPA issued guidance indicating that epinephrine salts are not included in the scope of the P042 listing and therefore, most, if not all, medical applications of epinephrine are not P042 (October 15, 2007; RCRA Online #14778).
EPA believes this conditional exemption is important to minimize the potential for exposures to healthcare workers, which can happen if they are accidentally stuck with a needle. Typically, sharps containers are more readily available to a medical practitioner than a hazardous waste container. Therefore, the used syringe will be discarded more quickly into a sharps container and there will be less opportunity for accidental sticks to occur en route to disposing the sharp. However, we also note that syringes in sharps containers are typically autoclaved prior to disposal. EPA is concerned that the residues remaining in the syringes could be aerosolized during autoclaving and inadvertently expose workers to the aerosolized hazardous waste residues, posing risks (via pulmonary exposure) to those present during venting of the autoclave. Research suggests that autoclaving may even increase the toxicity of certain drugs. EPA seeks comment on the extent of risks associated with autoclaving hazardous waste residues leftover in syringes and whether it is necessary to place a limit on the volume of residue or the volume of the syringe to which this conditional exemption would apply or whether any other conditions would be appropriate. For instance, stakeholders have informed us that they will squirt the residues remaining in a syringe onto a gauze pad prior to placing the syringe in the sharps container. Then, if the residues on the gauze pad are hazardous waste, the gauze pad is managed as hazardous waste, while allowing the syringe to be fully dispensed before placing it in the sharps container. In EPA’s view, this method of managing excess residues is preferred over another practice that is commonly used: The disposal of excess residues down the drain.

d. Other containers, including delivery devices. With regard to other containers, including delivery devices, EPA is proposing that the residues remaining in unused or used containers (such as IV bags and tubing, inhalers, aerosols, or ointment, gels, or creams) would be regulated as hazardous waste if the residues are a P- or U-listed hazardous waste or exhibit a hazardous waste characteristic. In some cases, such as with IV bags, the volume of hazardous waste is much larger than with residues contained in syringes or unit-dose containers. Stakeholders have stated that it is common practice for the leftover contents of IV bags and tubing to be emptied into a sink, which is a practice we are striving to eliminate. It is extremely difficult to determine how much residue remains in tubes of ointment, gel or cream. In the case of aerosols, it would be inadvisable to remove the contents of the container. Since hazardous waste pharmaceuticals managed under this proposed rule would not be counted towards a facility’s generator category, managing these residues and containers as hazardous waste under proposed 40 CFR part 266, subpart P should not pose the same burden that generators currently face with keeping track of the monthly amount of residues in containers that are not “RCRA empty.” Further, comments on the 2008 Pharmaceutical Universal Waste proposal indicated that stakeholders prefer clear distinctions in regulating the hazardous waste from healthcare facilities and this proposed standard for container residues responds to that comment. EPA seeks comment on whether these proposed provisions address stakeholder concerns, while protecting human health and the environment.

F. What are the proposed standards for shipping hazardous waste pharmaceuticals?

1. Shipping Standards for Non-Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals to Treatment, Storage, and Disposal Facilities

a. Shipping Standards for Non-Creditable Hazardous Waste Pharmaceuticals From Healthcare Facilities to TSDFs

Typically, hazardous waste pharmaceuticals generated in a healthcare facility fall into two categories: (1) Non-creditable (e.g., patient care) hazardous waste pharmaceuticals and (2) potentially creditable hazardous waste pharmaceuticals. This section discusses the proposed requirements for shipping of non-creditable, patient care/floor hazardous waste pharmaceuticals. For information regarding the shipment of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and pharmaceutical reverse distributors, see Section V.F.2 of the preamble.

Generally, patient care/floor hazardous waste pharmaceuticals differ from potentially creditable hazardous waste pharmaceuticals in that they have been partially administered and often are not in their original packaging. In addition, patient care/floor hazardous waste pharmaceuticals cannot receive manufacturer’s credit and therefore may not be shipped to a reverse distributor. EPA is proposing that patient care/floor hazardous waste pharmaceuticals generated at healthcare facilities, when shipped off-site, must be shipped to a designated facility (i.e., an interim status or permitted hazardous waste TSDF), as currently required (unless the healthcare facility has interim status or a RCRA permit to store or treat hazardous waste). Specifically, EPA proposes that non-creditable hazardous waste pharmaceuticals must continue to comply with the existing pre-transport requirements for packaging, labeling and marking, and that the non-creditable hazardous waste pharmaceuticals must continue to be shipped using a hazardous waste transporter and tracked with a hazardous waste manifest. However, to avoid unnecessarily burdening the healthcare facility staff, who are unfamiliar with RCRA, EPA proposes that the hazardous waste numbers (often called hazardous waste codes) are not required to be entered into the hazardous waste manifest for non-creditable hazardous waste pharmaceuticals. In lieu of hazardous waste codes, EPA is proposing that the words, “hazardous waste pharmaceuticals” must be entered in the “special handling and additional information” box on the manifest (box # 14). All existing RCRA recordkeeping requirements regarding hazardous waste manifesting continue to apply, (see Section V.C.12), as well as all applicable DOT shipping requirements. EPA requests comment on this proposed approach for manifesting non-creditable hazardous waste pharmaceuticals from a healthcare facility.

b. Shipping Standards for Evaluated Hazardous Waste Pharmaceuticals From Pharmaceutical Reverse Distributors to TSDFs

For pharmaceutical reverse distributors, once potentially creditable hazardous waste pharmaceuticals have been deemed non-creditable or credit has been issued and they do not require any additional verification of credit, EPA is proposing that the hazardous waste pharmaceuticals be referred to as “evaluated hazardous waste pharmaceuticals.” As with shipping non-creditable hazardous waste pharmaceuticals, when evaluated hazardous waste pharmaceuticals are shipped off-site, EPA is proposing that they must be shipped in accordance

135 Daughton CG, Drugs and the Environment: Stewardship & Sustainability, National Exposure Research Laboratory, Environmental Sciences Division, U.S. EPA, Las Vegas, NV; NERL–LV–ES Division, 10/08, EPA/600/R–10/106; September 2010 (http://www.epa.gov/nerlled1/bios/daughton/APM200-2010.pdf)
with the existing pre-transport requirements for packaging, labeling and marking, and that evaluated hazardous waste pharmaceuticals must be shipped via a hazardous waste transporter using a hazardous waste manifest to a designated facility. This continues current practices under existing regulations for this type of hazardous waste pharmaceutical and does not represent an increase in burden. EPA believes that use of a hazardous waste manifest and a hazardous waste transporter are appropriate at this point for two reasons. First, once credit for the hazardous waste pharmaceuticals has been issued and verified, the potential for mismanagement is greater. This is because the pharmaceuticals have lost their value and will cost the reverse distributor money to dispose. Second, TSDFs are accustomed to receiving hazardous waste via a hazardous waste transporter with a hazardous waste manifest and it would place administrative and compliance burdens on the receiving TSDF to accept shipments of hazardous waste with alternative tracking.

EPA is proposing that the pharmaceutical reverse distributor list the appropriate hazardous waste codes on the manifest (even though the healthcare facility is not required to provide such information to the reverse distributor). Hazardous waste pharmaceuticals received by pharmaceutical reverse distributors are in their original packaging with their label, so the information to determine the appropriate hazardous waste codes should be readily available. Also, reverse distributors are currently required to include hazardous waste codes on the manifest and it is expected that they have the necessary expertise in the management of these hazardous wastes that healthcare workers lack. As described in Section V.G.3 (pharmaceutical reverse distributor management standards), reverse distributors must keep copies of hazardous waste manifest forms for three years from the date of shipment. EPA requests comment regarding the proposed manifest and transportation requirements for non-creditable hazardous waste pharmaceuticals from healthcare facilities and evaluated hazardous waste pharmaceuticals from pharmaceutical reverse distributors.

c. Importing/Exporting Non-Creditable or Evaluated Hazardous Waste Pharmaceuticals

Under the existing regulations, a healthcare facility or pharmaceutical reverse distributor may not import hazardous waste pharmaceuticals unless it has a RCRA permit or interim status that allows it to accept hazardous waste from off-site and complies with the requirements for importing hazardous waste in 40 CFR part 262, subpart F. This proposal does not change the regulations as they apply to the import of non-creditable or evaluated hazardous waste pharmaceuticals. Likewise, under existing regulations, a healthcare facility or pharmaceutical reverse distributor may not export (non-creditable or evaluated) hazardous waste pharmaceuticals unless it complies with requirements for exporting hazardous waste in 40 CFR part 262, subpart E. This proposal also does not change the regulations as they apply to the export of (non-creditable or evaluated) hazardous waste pharmaceuticals. 

EPA requests comment on the likelihood that non-creditable hazardous waste pharmaceuticals that are shipped from a healthcare facility to a domestic TSDF, would then be exported to a TSDF in a foreign country. In addition, EPA does not anticipate that hazardous waste pharmaceuticals would be destined for transboundary shipments for purposes of recovery operations and therefore potentially subject to 40 CFR part 262, subpart H; however, we also request comment on whether this is the case.

2. Shipping Standards for Potentially Creditable Hazardous Waste Pharmaceuticals

This section discusses the proposed requirements for shipping potentially creditable hazardous waste pharmaceuticals from healthcare facilities to pharmaceutical reverse distributors and between pharmaceutical reverse distributors. The return of potentially creditable pharmaceuticals (hazardous and non-hazardous) to reverse distributors can involve multiple shipping steps before the pharmaceuticals are transported for ultimate treatment and disposal. In comments on the 2008 Pharmaceutical Universal Waste proposal and in response to EPA’s request for information, pharmaceutical reverse distributors explained various scenarios that require extra shipping steps. For example, a healthcare facility typically sends pharmaceuticals to the reverse distributor with which it has a contract. However, some manufacturers will only provide manufacturer’s credit after the pharmaceuticals have been returned to the reverse distributor with which the manufacturer has a contract. Thus, if the reverse distributor with which the healthcare facility has a contract differs from the reverse distributor with which the manufacturer has a contract, then the healthcare facility’s reverse distributor must send the pharmaceuticals on to the manufacturer’s reverse distributor for the manufacturer’s credit to be given to the healthcare facility. In some cases, a pharmaceutical manufacturer may require the reverse distributor to ship the returned pharmaceuticals to the manufacturer so that the manufacturer itself can verify pharmaceutical amounts and credits. The estimate of the amount of pharmaceuticals transported from reverse distributors to manufacturers for verification varies. Based on our request for information, reverse distributors have indicated that the percent of potentially creditable pharmaceuticals transported to manufacturers ranged from an estimated 25 percent to 93 percent, depending on the contractual agreement between the reverse distributor and the manufacturer. Both of the scenarios described previously happen routinely and are part of the business of returning pharmaceuticals to reverse distributors (including manufacturers) for manufacturer’s credit.

As explained in Section V.D.1, EPA is proposing that pharmaceuticals transported to pharmaceutical reverse distributors for credit are solid wastes, some of which will also be considered hazardous wastes. Under the current RCRA Subtitle C regulations, hazardous waste, including hazardous waste pharmaceuticals must be manifested to a permitted or interim status TSDF and shipped using a hazardous waste transporter to ensure the cradle-to-grave system of RCRA is maintained. However, compared to other hazardous wastes, EPA believes that the risk of environmental release posed by most potentially creditable hazardous wastes pharmaceuticals during accumulation and transport are relatively low. The risk is low because of the form and packaging of most potentially creditable hazardous waste pharmaceuticals, which are typically small, individually packaged doses (such as with many tablets and capsules) or small vials.
These small volumes of individually wrapped or packaged pharmaceuticals, when aggregated in a larger container, are unlikely to spill or be released into the environment since they are essentially double-packed when transported to a reverse distributor. 138 Potentially creditable hazardous waste pharmaceuticals that are in liquid and aerosol forms may pose more of a risk during accumulation and transport due to possible spillage or leakage, but the small quantities in which they are generated, along with the DOT packaging requirements of 49 CFR parts 173, 178, and 180, would likely mitigate this risk (see EPA’s recommendation regarding liquids and aerosols in Section V.D.2.). Further, the 2008 Pharmaceutical Universal Waste proposal specifically sought comment regarding the risks of transportation of hazardous waste pharmaceuticals and no commenters identified environmental risks.

Due to the low risk of release to the environment described previously, EPA is proposing to allow potentially creditable hazardous waste pharmaceuticals to be shipped without a hazardous waste manifest and without the use of hazardous waste transporters. However, this exemption from manifesting and use of hazardous wastes transporters only applies if the healthcare facility is sending potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor, or if a pharmaceutical reverse distributor is sending potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor. Further, DOT shipping requirements continue to apply to shipments of potentially creditable hazardous waste pharmaceuticals.

In lieu of requiring a hazardous waste manifest and the use of hazardous waste transporters, EPA is proposing an alternate type of tracking for potentially creditable hazardous waste pharmaceuticals—with two requirements. First, for each shipment, healthcare facilities and pharmaceutical reverse distributors must provide in writing (via letter or electronic communication), advance notice of the shipment to the pharmaceutical reverse distributor. Second, for each shipment, the receiving pharmaceutical reverse distributors must provide confirmation to the healthcare facility or pharmaceutical reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived. One way to comply with this requirement would be for the receiving reverse distributor to require the healthcare facility or pharmaceutical reverse distributor that initiates the shipment of potentially creditable hazardous waste pharmaceuticals to utilize some form of “delivery confirmation” mechanism that is provided by the shipper that confirms that a shipment to a reverse distributor has reached its destination and is under the custody and control of the recipient (e.g., delivery confirmation tracking with return receipt). This “delivery confirmation” notice can be paper-based or electronic. As part of the delivery confirmation system, a signature (paper or electronic) or other confirmation from a representative of the receiving pharmaceutical reverse distributor would be required. The signature by the pharmaceutical reverse distributor would provide assurance that the shipment was received by the reverse distributor. Without the signature or other confirmation of a representative of the pharmaceutical reverse distributor, it is possible for the shipper to state that delivery to the location has occurred, but it would not necessarily indicate that the recipient was there to receive the shipment. This proposed requirement is in direct response to concerns expressed by commenters over the lack of tracking of pharmaceuticals in the 2008 Pharmaceutical Universal Waste proposal.

Alternatively, EPA has learned that some stakeholders use bar-coding on the pharmaceuticals or on the boxes to track shipments. The barcodes contain detailed information, including the exact quantities and types of pharmaceuticals included in the shipment. Typically, when a reverse distributor receives a barcoded shipment, it will scan in the shipment and the sender will receive electronic notification that the shipment has arrived. This type of bar-code tracking would meet the delivery confirmation requirement of this proposed rule, but other mechanisms of “delivery confirmation” are offered by common carriers, such as the U.S. Postal Service, FedEx or United Parcel Service (UPS), would also be acceptable.

Under this proposal, healthcare facilities and reverse distributors may use common carriers, such as the U.S. Postal Service, United Parcel Service, or FedEx 139 for shipments of potentially creditable hazardous waste pharmaceuticals to and between pharmaceutical reverse distributors. EPA believes that common carriers are able to provide safe shipment since these potentially creditable hazardous waste pharmaceuticals present low transportation risk. We note that healthcare facilities and pharmaceutical reverse distributors must meet the applicable Pipeline and Hazardous Materials Safety Administration (PHMSA) Hazardous Materials Regulation (HMR; 49 CFR parts 171–180) shipping requirements, including preparing proper shipping papers when shipping potentially creditable hazardous waste pharmaceuticals. A RCRA hazardous waste that does not meet DOT hazard classes 1–8 in the HMR, are only Class 9 hazardous materials when defined as a RCRA hazardous waste that requires a manifest. As a result, the DOT shipping requirements will apply when potentially creditable hazardous waste pharmaceuticals are shipped to pharmaceutical reverse distributors only when the hazardous wastes are DOT class 1–8 hazardous materials.

EPA notes that a pharmaceutical reverse distributor is not required to sort the potentially creditable hazardous waste pharmaceuticals from the potentially creditable non-hazardous waste pharmaceuticals when they are destined for another reverse distributor. However, if the potentially creditable pharmaceuticals are not sorted, the pharmaceutical reverse distributor must follow the tracking procedures in this proposal for the entire shipment. On the other hand, if a pharmaceutical reverse distributor chooses to sort the potentially creditable hazardous waste pharmaceuticals from the creditable non-hazardous waste pharmaceuticals prior to shipping to another reverse distributor, only the potentially creditable hazardous waste pharmaceutical portion would have to be shipped according to these proposed standards. EPA asks for comment on whether the proposed tracking system and controls are sufficient to protect human health and the environment.

a. What Happens if a Healthcare Facility or Pharmaceutical Reverse Distributor Initiates a Shipment and Does Not Get Confirmation of Delivery?

If a healthcare facility or pharmaceutical reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation from the intended recipient within seven calendar days, EPA is proposing that the healthcare facility or pharmaceutical reverse distributor...
distributor that initiated the shipment must contact the shipper and the intended recipient promptly to (1) report that the confirmation was not received and (2) to determine the status and whereabouts of the potentially creditable hazardous waste pharmaceuticals that were shipped. The Agency requests comment on whether any additional requirements, such as reporting to the implementing agency, are necessary in such cases.

b. Importing/Exporting Potentially Creditable Hazardous Waste Pharmaceuticals

If a healthcare facility or pharmaceutical reverse distributor imports potentially creditable hazardous waste pharmaceuticals, then it must comply with the proposed requirements for the shipment of potentially creditable hazardous waste pharmaceuticals. The proposed requirements would be in lieu of those for manifested hazardous waste imports found at 40 CFR part 262, subpart F. EPA requests comment on whether potentially creditable hazardous waste pharmaceuticals are imported into the U.S. and, if so, how they are currently declared to customs when imported.

If a healthcare facility or pharmaceutical reverse distributor exports potentially creditable hazardous waste pharmaceuticals then it must generally comply with 40 CFR part 262, subpart E, except that it is not required to manifest the potentially creditable hazardous waste pharmaceuticals.140 c. Recordkeeping for Shipments of Potentially Creditable Hazardous Waste Pharmaceuticals

EPA is proposing to require healthcare facilities and reverse distributors to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Specifically, we are proposing that healthcare facilities and reverse distributors that initiate a shipment to another pharmaceutical reverse distributor keep (1) records of advance notification regarding shipments of potentially creditable hazardous waste pharmaceuticals, (2) shipping papers, and (3) confirmation of receipt of shipment for three years after the shipment was initiated. These records are necessary to ensure that potentially creditable hazardous waste pharmaceuticals are reaching their intended destination and not diverted.

In most cases, retaining records for 3 years should be sufficient for inspection purposes; however, we are proposing that the periods of retention are automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator. The Agency seeks comment on whether additional recordkeeping is necessary to document the cases when the pharmaceutical reverse distributor does not receive a shipment of potentially creditable pharmaceuticals within 7 calendar days and the steps must be taken to locate the shipment.

G. What are the proposed standards for pharmaceutical reverse distributors?

1. Background on Pharmaceutical Reverse Distributor Operations

Pharmaceutical reverse distributors act as intermediaries between healthcare facilities and pharmaceutical manufacturers. They receive shipments of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for those pharmaceuticals. From stakeholder input and EPA site visits, EPA’s understanding is that when a pharmaceutical reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its computer system. Based on manufacturers’ return goods policies, the pharmaceutical reverse distributors determine which potentially creditable hazardous waste pharmaceuticals can be credited, as well as which must be sent on to another reverse distributor for completion of the crediting process.

In many cases, there is more than one reverse distributor involved in establishing and verifying manufacturer’s credit for a particular potentially creditable hazardous waste pharmaceutical. For instance, reverse distributors may have contracts with specific pharmaceutical manufacturers such that only a specific pharmaceutical reverse distributor may facilitate credit for a particular manufacturer’s pharmaceuticals. If the receiving reverse distributor has a contract with the healthcare facility, but not with the pharmaceutical manufacturer, then the receiving pharmaceutical reverse distributor sends the returned pharmaceutical on to the reverse distributor that has a contract with the pharmaceutical manufacturer in order to facilitate the credit process.

Because manufacturers’ return goods policies change over time, sometimes a pharmaceutical reverse distributor receives a potentially creditable hazardous waste pharmaceutical that is not eligible for credit immediately, and the pharmaceutical reverse distributor retains the potentially creditable hazardous waste pharmaceutical on-site until it is credit eligible. EPA requests comment on how often this happens and how long the potentially creditable hazardous waste pharmaceuticals are kept on-site at reverse distributors to await changes in manufacturers’ return goods policies.

In some cases, even after the pharmaceutical reverse distributor has awarded credit, a pharmaceutical manufacturer may request that the hazardous waste pharmaceuticals be transported back to the manufacturer to inventory and verify the amount of pharmaceuticals and credit. In developing this proposed rule, EPA considered all of the previous scenarios as part of the crediting process.

On the other hand, if the potentially creditable hazardous waste pharmaceuticals are not sent onward to another pharmaceutical reverse distributor, the pharmaceutical reverse distributor awards the manufacturer’s credit to the healthcare facility and then manages the hazardous waste pharmaceuticals on-site until they are sent off-site for treatment and disposal. As discussed previously in this proposal, after a potentially creditable hazardous waste pharmaceutical has been evaluated and either credited or deemed non-creditable and no additional pharmaceutical reverse distributors will be involved in the crediting process, EPA proposes to use the term “evaluated hazardous waste pharmaceutical.” This is to distinguish between the potentially creditable hazardous waste pharmaceuticals awaiting determination within the reverse distribution system versus credited and non-creditable hazardous waste pharmaceuticals that have been through the reverse distribution process and are destined to be managed by a permitted or interim status TSDF. Both are considered hazardous waste pharmaceuticals, but they are managed differently under the proposed regulations.

EPA is not aware of any pharmaceutical reverse distributors that facilitate manufacturer’s credit that also has interim status or a permit to treat or dispose of hazardous waste on-site. Therefore, EPA anticipates that pharmaceutical reverse distributors eventually send all evaluated hazardous waste pharmaceuticals off-site for

140 The Controlled Substances Import and Export Act prohibits controlled substances from being imported or exported unless permitted by DEA, even when the controlled substances are wastes. See 21 U.S.C. 952 and 953.
treatment and disposal. EPA requests comment on whether the processes described previously are representative of the pharmaceutical reverse distribution process.

2. EPA’s Rationale for Proposing New RCRA Management Standards for Pharmaceutical Reverse Distributors

This proposed rule is establishing standards for the management of both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that pharmaceutical reverse distributors receive and manage. The Agency notes that the management standards discussed in this section apply only to reverse distributors of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals and do not apply to reverse distribution or reverse logistics systems that may exist for other consumer products.

The current federal RCRA hazardous waste regulations at 40 CFR part 262 provide that only RCRA-permitted and interim status TSDFs may receive hazardous waste from off-site for treatment, storage, or disposal. However, the Agency does not believe it is necessary for pharmaceutical reverse distributors to obtain permits or have interim status to store hazardous waste pharmaceuticals in order to protect human health and the environment. Thus, EPA proposes a new category under RCRA called a “pharmaceutical reverse distributor,” which we proposed to define as any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer’s credit. The definition specifies that any person, including forward distributors and pharmaceutical manufacturers, which processes pharmaceuticals for the facilitation or verification of manufacturer’s credit is considered a pharmaceutical reverse distributor. EPA is proposing that pharmaceutical reverse distributors are not required to have interim status or a RCRA permit to accumulate hazardous waste pharmaceuticals and they may only accept potentially creditable hazardous waste pharmaceuticals from off-site provided they comply with the proposed standards in this rule. Pharmaceutical reverse distributors may not treat or dispose of hazardous waste on-site unless authorized to do so as a RCRA-permitted or interim status TSDF.

As discussed previously, EPA’s existing interpretation allows pharmaceutical reverse distributors to be generators of hazardous waste pharmaceuticals after a decision is made about whether the pharmaceuticals will be repurposed. As a generator, a pharmaceutical reverse distributor currently must comply with the LQG, SQG, or CESQG generator requirements, depending on the total volume of hazardous waste generated in a calendar month. Some smaller pharmaceutical reverse distributors might stay under the hazardous waste quantity limits for CESQGs, which would mean that under the federal RCRA requirements, these CESQG pharmaceutical reverse distributors would not have to notify EPA as a generator and their hazardous waste pharmaceuticals could be disposed of with municipal and non-municipal solid waste (see § 261.5).

However, the Agency has concerns with CESQG pharmaceutical reverse distributors not notifying EPA that they are managing hazardous waste. EPA is even more concerned about pharmaceutical reverse distributors that currently qualify as CESQGs placing the hazardous waste pharmaceuticals into the municipal and non-municipal solid waste stream and sending them to non-hazardous waste landfills. Some limited studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems. Landfill leachate is generally transported to a wastewater treatment plant to be treated before discharge; however, some pharmaceutical compounds pass through treatment and are discharged, becoming a potential contributor of the pharmaceutical compounds detected in our nation’s waters.

EPA is proposing to revise its position regarding potentially creditable hazardous waste pharmaceuticals, such that they will be first considered discarded at the healthcare facilities, not at the reverse distributors. This revision is based on new information demonstrating to EPA that pharmaceuticals returned to a reverse distributor are rarely, if ever, recycled or reused, and therefore the decision to send a potentially creditable hazardous waste pharmaceutical to a pharmaceutical reverse distributor is a decision to discard the pharmaceutical (as discussed previously in Section V.D.1). Other comments on the December 2008 Pharmaceutical Universal Waste proposal indicated that notification to EPA by pharmaceutical reverse distributors and tracking of shipments of potentially creditable hazardous waste pharmaceuticals are critical and must be included in any regulatory scheme to ensure the safe management of potentially creditable hazardous waste pharmaceuticals.

As previously discussed, only between 2–6 percent of the potentially creditable hazardous wastes that are received by pharmaceutical reverse distributors are listed or characteristic hazardous wastes. Therefore, the vast majority of the potentially creditable pharmaceutical waste that a pharmaceutical reverse distributor receives is not considered a characteristic or listed hazardous waste pharmaceutical under the existing definition of hazardous waste. This stands in contrast to a typical TSDF, which primarily manages hazardous waste. As a result, a pharmaceutical reverse distributor generally manages a smaller volume of hazardous waste than a typical permitted TSDF.

In addition, because the pharmaceuticals in the reverse distribution system are receiving credit, they are moved through the system efficiently. In fact, one national pharmacy retail chain informed EPA that the value of the credit they receive from manufacturers for returned pharmaceuticals is approximately $1 billion a year. Healthcare facilities and reverse distributors have a vested interest in having potentially creditable hazardous waste pharmaceuticals processed and credited quickly and managed appropriately so money is not lost in the process.

Furthermore, potentially creditable hazardous waste pharmaceuticals generally present a low risk of release to the environment as they typically are still in the manufacturer’s packaging. Since there is a low human health and environmental risk of release associated with the low volumes of potentially creditable hazardous waste pharmaceuticals shipped to reverse distributors for crediting purposes, and because EPA is not aware of any incidents of mismanagement resulting

144 See EPA’s request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA–HQ–RCRA–2007–0932.

in environmental harm or releases of hazardous waste pharmaceuticals by reverse distributors, EPA believes that it is not necessary to require reverse distributors to obtain RCRA hazardous waste storage permits with respect to typical reverse distribution operations, such as receiving, sorting, consolidating, and reshipping potentially credible hazardous waste pharmaceuticals.

Thus, EPA is proposing to take a “middle-of-the-road” approach to regulating pharmaceutical reverse distributors by regarding them as a new type of RCRA hazardous waste entity—a pharmaceutical reverse distributor. This proposed approach addresses comments that EPA received on the December 2008 Pharmaceutical Universal Waste proposal and reflects EPA’s proposed revised interpretation that the point of generation for potentially credible hazardous waste pharmaceuticals is at the healthcare facility, not the reverse distributor. EPA proposes to establish management standards for pharmaceutical reverse distributors in 40 CFR part 266, subpart P. These entities would not be subject to 40 CFR parts 262, 264, or 265. Generally, EPA is proposing that pharmaceutical reverse distributors comply with standards that are similar to the current federal LQG standards, in combination with certain requirements that permitted or interim status hazardous waste TSDFs must meet. We are establishing one set of requirements for all pharmaceutical reverse distributors, regardless of the amount of potentially credible hazardous waste pharmaceuticals they receive. EPA believes this uniform set of standards will make it easier for pharmaceutical reverse distributors to comply with the new proposal, since the burden of having to count hazardous waste pharmaceuticals on a monthly basis, especially the 1 kg of acute hazardous waste pharmaceuticals, will be removed.

EPA proposes that a pharmaceutical reverse distributor will not be required to have a hazardous waste permit or interim status for on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals provided it follows the proposed pharmaceutical reverse distributor standards. However, for activities such as treatment or disposal of hazardous waste pharmaceuticals or other hazardous waste, a pharmaceutical reverse distributor must either obtain a RCRA permit or have interim status. This proposal requires pharmaceutical reverse distributors to comply with standards that are similar to LQG standards for on-site accumulation of hazardous waste that are found in §262.34(a) and (b). We are proposing these requirements because, as discussed previously, the value of the potentially credible pharmaceuticals creates an incentive for proper management and the risk of release is low. Furthermore, many pharmaceutical reverse distributors are already LQGs and therefore this proposed rule should not represent a large shift in current practices or increased burden. However, once credit is provided, the value of the pharmaceuticals is eliminated and therefore the evaluated hazardous waste pharmaceuticals have a greater potential for mismanagement. As a result, we are proposing that pharmaceutical reverse distributors have additional standards for the management of evaluated hazardous waste pharmaceuticals. Note that while the LQG accumulation standards are found in §§262.34(a) and (b), these generator regulations reference many interim status TSDF standards in part 265. However, in the regulatory text and preamble for this rule, we reference the standards in part 265 directly for the applicable accumulation standards for pharmaceutical reverse distributors (rather than §262.34(a) which would then simply refer the reader to part 265). However, the Agency requests comment as to whether we should include the regulatory standard directly in 40 CFR part 266, subpart P, instead of providing a cross-reference to the standard in 40 CFR part 265 in an effort to make the rules easier to follow and comply with.

3. Detailed Discussion of Proposed Pharmaceutical Reverse Distributor Standards

The proposed standards for pharmaceutical reverse distributors are organized into three sections. The first section applies to the pharmaceutical reverse distributor for the management of all potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. The second section includes additional standards that would apply to the management of the potentially creditable hazardous waste pharmaceuticals that will be sent to another pharmaceutical reverse distributor for further evaluation or verification of credit and therefore continue to be regulated as potentially creditable hazardous waste pharmaceuticals. The third section includes additional standards that apply to the management of the evaluated hazardous waste pharmaceuticals that will not be sent to another pharmaceutical reverse distributor, but instead will be sent to a permitted or interim status TSDF.

a. Standards for Pharmaceutical Reverse Distributors

This portion of the preamble discusses the proposed standards that apply to pharmaceutical reverse distributors for the management of all hazardous waste pharmaceuticals on-site. Unlike the following two sections, the standards discussed in this section apply to all pharmaceutical reverse distributors, regardless of the subsequent destination of the hazardous waste pharmaceuticals. We note that a pharmaceutical reverse distributor must follow the proposed standards for the management of hazardous waste pharmaceuticals even if it generates other, non-pharmaceutical hazardous waste that is managed under 40 CFR part 262.

i. Notification. The first proposed requirement is that a pharmaceutical reverse distributor must notify EPA of its hazardous waste pharmaceutical activities via the Site ID form (EPA form 8700–12). Under the current RCRA Subtitle C program, both LQGs and TSDFs must submit a Site ID form to EPA. Thus, EPA believes it is appropriate, and in line with comments received on the 2008 Pharmaceutical Universal Waste proposal, to require pharmaceutical reverse distributors to notify EPA. A pharmaceutical reverse distributor that does not have an EPA ID number will be required to submit the Site ID form to obtain one. If this proposal is finalized, the Agency plans on revising the Site ID form to include a box to allow notifications by pharmaceutical reverse distributors. For those pharmaceutical reverse distributors that already have an EPA ID number, they will need to re-notify EPA as a pharmaceutical reverse distributor. Some pharmaceutical reverse distributors may also be generators of other types of hazardous waste (e.g., from cleaning and maintenance operations). Therefore, it is possible that a pharmaceutical reverse distributor may notify on the same notification form as both a generator of hazardous waste and as a pharmaceutical reverse distributor.

ii. Inventory. EPA is proposing a new provision that is specific to pharmaceutical reverse distributors: the requirement is to keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on-site. The inventory must include the identity (e.g., name or national drug code (NDC)) and quantity of each hazardous waste pharmaceutical and evaluated hazardous waste pharmaceuticals. EPA
also recommends as a best management practice that pharmaceutical reverse distributors also keep an inventory of their non-hazardous waste pharmaceuticals as well. An inventory is a key requirement to protect public health by helping to prevent the diversion of hazardous waste pharmaceuticals. An inventory will allow the pharmaceutical reverse distributor to know which pharmaceuticals they have on-site at any time. The Agency believes that in many cases, pharmaceutical reverse distributors already maintain inventories and this proposed requirement is not expected to be burdensome for the pharmaceutical reverse distributors to implement. In fact, according to responses from pharmaceutical reverse distributors to a request for information, four out of eight of them indicated that they already keep inventories as best management practices or because it is required by the Board of Pharmacy in their state. However, EPA requests comment on whether this practice is already commonly followed.

iii. Security of the pharmaceutical reverse distributor. EPA is proposing that pharmaceutical reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. Specifically, due to increased thefts of narcotics from pharmacies reported in recent years in major media outlets, this is a concern. EPA is concerned that pharmaceutical reverse distributors could also face such thefts since they accumulate unused pharmaceuticals or those that have exceeded their expiration date. Further, commenters on the 2008 Pharmaceutical Universal Waste proposal suggested that pharmaceutical universal waste handlers should meet the TSDF facility security requirement. EPA agrees with the commenters that the requirements that appear in the interim status TSDF security regulations would be appropriate to adopt and apply to pharmaceutical reverse distributors to prevent the illicit use of these pharmaceuticals and safeguard human health and thus, has included this requirement for pharmaceutical reverse distributors. The security of the facility requirement of § 265.14(a) requires a facility to “prevent the unknowing entry, and minimize the possibility for the unauthorized entry, of persons or livestock onto the active portion of his facility.” EPA is proposing a similar requirement for pharmaceutical reverse distributors: they must prevent unknowing entry, and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (e.g., a receiving area and accumulation area).

Based on site visits, EPA recognizes that many pharmaceutical reverse distributors may already meet the proposed security standard through the use of key cards that allow only authorized personnel into specific areas of the pharmaceutical reverse distributor, camera surveillance systems, and cages for storing pharmaceuticals. Some pharmaceutical reverse distributors may use fences and signs. EPA is including several examples of acceptable security measures in the regulatory text, but pharmaceutical reverse distributors are not limited to the examples provided. Further, if a pharmaceutical reverse distributor already meets the performance-based security standard by complying with other regulations, such as DEA’s regulations, then the pharmaceutical reverse distributor would not need to install additional security.

iv. Maximum 90 days for on-site accumulation and petition for an extension of accumulation time.

EPA is proposing that, like LQGs, pharmaceutical reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for up to 90 calendar days without having interim status or a permit. However, because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, the Agency has decided not to propose specific container management standards. The 90-day time limit begins when the potentially creditable hazardous waste pharmaceuticals initially arrive at the pharmaceutical reverse distributor. The 90-day time limit follows the potentially creditable pharmaceutical, even after it becomes an evaluated hazardous waste pharmaceutical. That is, there is a single 90-day accumulation limit for the hazardous waste pharmaceutical at each pharmaceutical reverse distributor. However, some hazardous waste pharmaceuticals travel through more than one pharmaceutical reverse distributor to receive manufacturer’s credit. In such cases, each pharmaceutical reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a new 90-day accumulation limit. EPA requests comment on the 90-day timeframe and whether this timeframe is sufficient, or whether an alternative timeframe should be allowed.

As discussed previously, EPA is proposing that a pharmaceutical reverse distributor must inventory potentially creditable hazardous waste pharmaceuticals upon arrival. Many pharmaceutical reverse distributors utilize barcoding and scanners to log potentially creditable pharmaceuticals into a database upon arrival or soon after a shipment arrives. Current inventory systems may be adapted to provide verification of the time limits. For example, if a pharmaceutical reverse distributor includes the date of arrival in the inventory, then the pharmaceutical reverse distributor will be able to use the inventory to verify that potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are not accumulated on-site for more than 90 calendar days. EPA is not proposing a specific method that pharmaceutical reverse distributors must use to document that accumulation does not exceed 90 calendar days. We anticipate that most pharmaceutical reverse distributors would use the inventory system to verify the 90-calendar day timeframe rather than using an additional requirement of labeling containers with dates for verification, but we request comment on this issue. We also request comment on whether EPA needs to specify a method of documenting that 90 calendar days is not exceeded.

Pharmaceutical reverse distributors have informed EPA that there are times when pharmaceutical returns may need to be consolidated for longer periods because they are subject to litigation and the pharmaceutical reverse distributor is not allowed to move them.

Pharmaceutical reverse distributors may also need to handle large recalls of hazardous waste pharmaceuticals and might not be able to process all of the returned items within 90 calendar days. Therefore, EPA is proposing to allow a pharmaceutical reverse distributor to request from EPA an extension of the 90-day accumulation time limit for situations when the hazardous waste pharmaceuticals are involved in litigation, a recall, or in unforeseen circumstances beyond the control of the pharmaceutical reverse distributor. A pharmaceutical reverse distributor

145 See all the responses EPA received from pharmaceutical reverse distributors in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).

seeking an extension must submit a written request to the EPA Regional Administrator (in writing or electronically), explaining the reason for the extension, the approximate volume or weight of the hazardous waste pharmaceuticals that will be stored for more than 90-days and the amount of additional time requested. Under the existing RCRA subtitle C regulations, the extension of time typically allowed is limited to an extra 30 days for LQGs. However, due to the complex nature of pharmaceutical litigation and recalls, EPA is proposing to allow the EPA Regional Administrator to grant a time extension at their discretion on a case-by-case basis. EPA requests comment on whether it is necessary to place a limit on the length of time for which an extension may be granted.

v. Contingency plan and emergency procedures. The Agency is proposing to require that pharmaceutical reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan and emergency procedures at 40 CFR part 265, subpart D. EPA believes that a pharmaceutical reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Since many pharmaceutical reverse distributors are already LQGs, they should already have contingency plans to address the hazards on-site. It may be possible that the pharmaceutical reverse distributors will have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but we believe that such modifications should not impose much burden.

vi. Closure. Due to the generally low risk of release of the hazardous waste pharmaceuticals that pharmaceutical reverse distributors will accumulate on-site, as well as the nature of the hazardous waste pharmaceuticals, EPA is proposing to require a performance-based closure standard that is based on the federal LQG closure standard found at § 265.111. Specifically, when a pharmaceutical reverse distributor closes its operations related to hazardous waste pharmaceuticals, it must control or minimize post-closure releases of hazardous waste constituents into the environment. This will entail removing the containers of hazardous waste pharmaceuticals (both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals) from the facility before closure.

vii. Reporting. In some instances, a pharmaceutical reverse distributor may receive a shipment from a healthcare facility that includes items that are not potentially creditable pharmaceuticals. These shipments can include wastes that are clearly not eligible to receive credit, such as patient care waste (e.g., IV tubing), contaminated personal protective equipment (PPE), medical waste, or other inappropriate wastes. Pharmaceutical reverse distributors are not the appropriate waste management facility for medical or infectious wastes and these wastes must be managed and transported from the healthcare facility directly to an appropriate waste disposal facility. In some cases, these non-creditable wastes may be hazardous waste. These non-creditable hazardous wastes are prohibited from being transported from a healthcare facility to a pharmaceutical reverse distributor; rather they should be manifested to a designated facility, such as a permitted or interim status TSDF. Nevertheless, a healthcare facility might incorrectly ship non-creditable hazardous wastes to a pharmaceutical reverse distributor.

EPA is proposing that if a pharmaceutical reverse distributor receives a shipment from a healthcare facility that includes hazardous waste that it is not authorized to receive, such as non-creditable hazardous waste or hazardous waste that is not a pharmaceutical waste, the pharmaceutical reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 15 days of receiving the hazardous waste. We have adapted the existing requirement for situations when permitted and interim status TSDFs receive unmanifested hazardous waste (§ 264.76 and § 265.36, respectively) to make it appropriate for pharmaceutical reverse distributors that receive unauthorized hazardous waste. However, we are also proposing two additional requirements for pharmaceutical reverse distributors that receive inappropriate hazardous waste. First, the pharmaceutical reverse distributor must send a copy of the unauthorized hazardous waste report to the healthcare facility that sent the unauthorized hazardous waste. This requirement is intended to alert the healthcare facility of its mistake in order to prevent further shipments of non-creditable hazardous waste or non-pharmaceutical hazardous waste. Second, the pharmaceutical reverse distributor must manage the unauthorized hazardous waste that it receives in accordance with all applicable regulations. The Agency expects that the pharmaceutical reverse distributor will likely pass these additional costs (e.g., medical waste incineration) on to the healthcare facility for the management of the hazardous waste and this will act as an incentive for the healthcare facility to take measures to prevent further shipments of unauthorized hazardous waste. We request comment on whether EPA’s understanding regarding this type of situation is representative.

In order to prevent exposing employees to unnecessary risk, EPA recommends as a best management practice that pharmaceutical reverse distributors avoid sorting through shipments that contain non-creditable waste since the shipment may include hazardous waste, including infectious or radioactive healthcare waste. As a result, it is possible that a pharmaceutical reverse distributor receiving a shipment that includes non-creditable waste may be unsure whether the shipment includes hazardous waste. In such cases, EPA recommends that the pharmaceutical reverse distributor assume the shipment includes hazardous waste and submit an unauthorized waste report. Further, we recommend that pharmaceutical reverse distributors work with their clients to reduce the occurrence of inappropriate shipments.

viii. Recordkeeping. EPA is proposing three recordkeeping requirements to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, a pharmaceutical reverse distributor must keep a copy of the notice (EPA form 8700–12) to EPA to indicate that it is a pharmaceutical reverse distributor operating under 40 CFR part 266, subpart P. A pharmaceutical reverse distributor must keep the record of notification for as long as it is subject to these requirements. Second, a pharmaceutical reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This includes a copy of the advance notification from the healthcare facility or other pharmaceutical reverse distributor, a copy of delivery confirmation, shipping papers and any unauthorized waste reports. We propose that these shipping records must be kept for three years from the date the pharmaceutical reverse distributor receives the shipment. We request comment on whether additional recordkeeping is necessary to document cases when shipments of potentially creditable hazardous waste pharmaceuticals do not reach their intended destination within 7 calendar days.
days. Third, a pharmaceutical reverse distributor must keep a copy of its current inventory at all times as long as the pharmaceutical reverse distributor remains in operation. The inventory is a living document that will constantly be updated and must be available for inspection. Finally, we propose that periods of record retention indicated previously for a pharmaceutical reverse distributor will be automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

Note that additional recordkeeping requirements may also pertain to pharmaceutical reverse distributors. For example, a pharmaceutical reverse distributor that manifests its non-pharmaceutical hazardous waste is subject to the manifest recordkeeping requirements of § 262.40. Further, as discussed in subsequent sections, there are additional recordkeeping requirements that apply to pharmaceutical reverse distributors for the management of potentially creditable hazardous waste pharmaceuticals destined for another pharmaceutical reverse distributor and others that apply to pharmaceutical reverse distributors for the management of evaluated hazardous waste pharmaceuticals.

ix. Evaluating potentially creditable hazardous waste pharmaceuticals within 21 days. Based on stakeholder input and site visits, EPA has learned that when a pharmaceutical reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its system. The pharmaceutical reverse distributor then determines which potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor and which ones will be credited and then sent off-site for treatment and disposal. EPA is proposing that this evaluation process must be completed within 21 days of arriving at the pharmaceutical reverse distributor. Likewise, if the pharmaceutical reverse distributor is a manufacturer, EPA is proposing that the manufacturer must finish verifying the appropriate credit within 21 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals.

EPA has chosen to propose 21 calendar days to ensure that the pharmaceutical reverse distributor has a long enough of time to make the evaluation, yet a short enough time to ensure that potentially creditable hazardous waste pharmaceuticals do not linger awaiting evaluation. The Agency requests comment on this timeframe and whether it should be shortened or lengthened. We also want to emphasize that the 21 calendar days for evaluating the potentially creditable hazardous pharmaceuticals counts as part of the total 90 calendar days that the hazardous waste pharmaceuticals are allowed to accumulate on-site.

Once an evaluation is made on the incoming potentially creditable hazardous waste pharmaceuticals, if they are destined for another pharmaceutical reverse distributor, they are still considered potentially creditable hazardous waste pharmaceuticals. There are additional regulations in this proposal at § 266.510(b) that pertain to these potentially creditable hazardous waste pharmaceuticals (discussed in Section V.G.3.b.). If, however, they are destined for an interim status or permitted TSDF, they are considered “evaluated hazardous waste pharmaceuticals.” There are additional regulations in this proposal at § 266.510(c) that pertain to these evaluated hazardous waste pharmaceuticals (discussed in Section V.G.3.c.).

b. Additional Standards for Pharmaceutical Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Pharmaceutical Reverse Distributor

This section discusses the additional standards that apply to a pharmaceutical reverse distributor for the management of potentially creditable hazardous waste pharmaceuticals that require further evaluation or verification of manufacturer’s credit at another pharmaceutical reverse distributor. These hazardous waste pharmaceuticals continue to be considered potentially creditable hazardous waste pharmaceuticals. Until manufacturer’s credit is finalized, the potentially creditable hazardous waste pharmaceuticals retain their value and there is greater incentive to manage them carefully in order to receive full manufacturer’s credit. Therefore, EPA is proposing few regulatory standards for the management of the potentially creditable hazardous waste pharmaceuticals that are destined for another pharmaceutical reverse distributor.

i. Where potentially creditable hazardous waste pharmaceuticals can be sent. The proposed regulations for pharmaceutical reverse distributors are structured so that there is a limit to the number of transfers of potentially creditable hazardous waste pharmaceuticals that may occur before they are ultimately transported to a TSDF for treatment and disposal. Stakeholders expressed concern that the 2008 Pharmaceutical Universal Waste proposal would have allowed hazardous waste pharmaceuticals to be shipped repeatedly and indefinitely from one universal waste handler to another. From discussions with pharmaceutical reverse distributors and reviewing information submitted via EPA’s request for information, the Agency believes a reasonable limit is three transfers of potentially creditable hazardous waste pharmaceuticals before the pharmaceutical hazardous waste is ultimately transported to a TSDF. The three possible types of transfers are: 147

(1) a healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor, which may or may not be a manufacturer;

(2) the first pharmaceutical reverse distributor may send the potentially creditable hazardous waste to another pharmaceutical reverse distributor, which may or may not be a manufacturer;

(3) the second pharmaceutical reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a pharmaceutical reverse distributor that is a manufacturer.

EPA anticipates that healthcare facilities that are CESQGs will send their potentially creditable hazardous waste pharmaceuticals directly to pharmaceutical reverse distributors, and that the accumulation mechanism that we are proposing will be used to send only non-creditable hazardous waste pharmaceuticals to off-site healthcare facilities (see Section V.C.15.). However, EPA requests comment on whether CESQG healthcare facilities would benefit from being able to consolidate potentially creditable hazardous waste pharmaceuticals off-site, as well. Depending on comments, EPA will consider allowing a fourth transfer (for this limited situation) when potentially creditable hazardous waste pharmaceuticals are sent from a CESQG healthcare facility to an on-site healthcare facility for accumulation, as would also be allowed by proposed § 266.504(a).

147 A healthcare facility or pharmaceutical reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA permitted or interim status TSDF.
This chain of transfers ensures that the potentially creditable hazardous waste pharmaceuticals will be accumulated for no more than 270 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and disposal (assuming no accumulation time extensions are granted). EPA requests comment as to whether the three-transfer and 90-day limits are appropriate and whether more or fewer transfers are necessary for verification of manufacturer’s credit. Put another way, if a pharmaceutical reverse distributor receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility, the pharmaceutical reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor (which may or may not be a manufacturer) or must manage them as evaluated hazardous waste pharmaceuticals under proposed § 266.510(c). However, a pharmaceutical reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another pharmaceutical reverse distributor is more limited in where it can send the potentially creditable hazardous waste pharmaceuticals. It can send potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor that is the manufacturer or else must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c). Regardless of the destination, each pharmaceutical reverse distributor must make an evaluation of the hazardous waste pharmaceuticals within 21 calendar days and may only accumulate the hazardous waste pharmaceuticals on-site for a maximum of 90 calendar days, unless an extension is granted by the Regional Administrator before it ships them off-site to another pharmaceutical reverse distributor or a RCRA-permitted or interim status TSDF. In addition, all shipments of evaluated hazardous waste pharmaceuticals are subject to proposed § 266.508 and shipments of all potentially creditable hazardous waste pharmaceuticals are subject to proposed § 266.509.

ii. Recordkeeping for pharmaceutical reverse distributors shipping of potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor. Pharmaceutical reverse distributors must keep records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another pharmaceutical reverse distributor (whether it is a manufacturer or not). This includes a copy of the advance notification provided to the other pharmaceutical reverse distributor, a copy of delivery confirmation, as well as shipping papers or bill of lading. We propose that these shipping records must be kept for 3 years from the date it initiates the shipment.

c. Additional Standards for Pharmaceutical Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals

This section discusses the additional standards that apply to a pharmaceutical reverse distributor for the management of evaluated hazardous waste pharmaceuticals (i.e., a hazardous waste pharmaceutical that was a potentially creditable hazardous waste pharmaceutical, but it has been evaluated by a pharmaceutical reverse distributor to establish whether it is eligible for the manufacturer’s credit and will not be sent to another pharmaceutical reverse distributor for further evaluation or verification). Evaluated hazardous waste pharmaceuticals have been through the entire crediting process. In order to minimize the potential for their mismanagement, EPA believes it is necessary to have additional standards for the evaluated hazardous waste pharmaceuticals.

1. Accumulation area. As discussed previously, EPA is proposing that a pharmaceutical reverse distributor must complete its evaluation of a potentially creditable hazardous waste pharmaceuticals within 21 calendar days of arriving at the pharmaceutical reverse distributor. Once the evaluation has been completed and the pharmaceutical reverse distributor knows that it is destined for treatment and disposal at a RCRA-permitted or interim status TSDF, rather than another pharmaceutical reverse distributor, the pharmaceutical is considered an evaluated hazardous waste pharmaceutical. Under the proposal, a pharmaceutical reverse distributor must establish an on-site accumulation area where it will accumulate these evaluated hazardous waste pharmaceuticals. An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the potentially creditable hazardous waste pharmaceuticals.

2. Weekly inspections. EPA is proposing to require that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at least weekly to ensure containers are not leaking and that diversion of the hazardous waste pharmaceuticals is not occurring. Under the recordkeeping requirements for pharmaceutical reverse distributors, we are proposing that a pharmaceutical reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

iii. Personnel training. EPA is proposing to require that pharmaceutical reverse distributors meet the same federal classroom or on-the-job personnel training requirements that LQGs must meet (§ 265.16). However, we specify in this proposal that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals in the on-site accumulation area. EPA believes that these personnel are the individuals handling and managing the hazardous waste pharmaceuticals and must have appropriate hazardous waste training. The Agency requests comment on whether the training standards are appropriate for the specific reverse distributor personnel.

iv. Labeling and management of containers in on-site accumulation area. EPA is proposing container labeling similar to what was proposed under the 2008 pharmaceutical universal waste proposed rule. While containers of hazardous waste pharmaceuticals are in the accumulation area, they must be marked with the words, “Hazardous Waste Pharmaceuticals.” We are proposing this term in order to distinguish them from the non-hazardous waste pharmaceuticals and from the hazardous waste pharmaceuticals that are still considered potentially creditable. We are not proposing to require an accumulation start date on the label for the containers, because the reverse distributor’s inventory will likely be used to verify the accumulation start date. However, a pharmaceutical reverse distributor may choose an alternate method, such as marking the date on each container as it arrives, to ensure that the hazardous waste pharmaceuticals are not accumulated at the pharmaceutical reverse distributor for more than 90 days, provided an extension is not granted. As explained previously, EPA prefers to allow a performance-based standard that allows flexibility to verify the 90-day accumulation time rather than requiring date on container labels, but we request comment regarding this requirement and whether
it is necessary to specify a method for how a pharmaceutical reverse distributor must verify that the 90-day maximum accumulation time is not exceeded.

In terms of container management standards, the Agency is proposing requirements that are similar to the container management standards for LQGs—that is, the standards in 40 CFR part 265, but the Agency is also proposing to include some additional management requirements specific to hazardous waste pharmaceuticals. Specifically, under 40 CFR 262.34(a)(1)(i), LQGs must comply with the container management standards in 40 CFR part 265, subpart I, which includes a requirement that containers of hazardous waste must be kept closed, except when adding or removing waste. In this document, EPA is proposing to require that only containers with hazardous waste pharmaceuticals that are liquids or gels be kept closed during accumulation due to the low potential for release for those hazardous waste pharmaceuticals that are in a solid form. However, because most potentially creditable hazardous waste pharmaceuticals are in their original packaging, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (e.g., for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard. EPA requests comment on whether additional forms of hazardous waste pharmaceuticals (other than liquids and gels) need to be specified in the regulations and subject to the closed container requirement.

EPA is also proposing that containers of hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the hazardous waste pharmaceuticals placed in the container. In addition, we are proposing to require that a pharmaceutical reverse distributor that manages ignitable or reactive evaluated hazardous waste pharmaceuticals or that mixes or comingles incompatible evaluated hazardous waste pharmaceuticals must manage the container to prevent dangerous situations, such as fire, explosion, or release of toxic fumes.

Similar to healthcare facilities that accumulate non-creditable hazardous waste pharmaceuticals, pharmaceutical reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals.

There are also several existing LQG accumulation unit management standards in §§ 262.34(a) that EPA believes are not necessary to include for the management of evaluated hazardous waste pharmaceuticals. For instance, this proposal only sets standards for the accumulation of hazardous waste pharmaceuticals in containers. EPA does not think it is necessary to include accumulation units such as tanks, containment buildings, or drip pads because pharmaceutical reverse distributors do not currently use these types of accumulation units. However, if EPA is mistaken in this understanding and commenters indicate they would like to be able to use tanks, containment buildings, or drip pads, EPA would consider including in this proposal the LQG standards for accumulation in these units. The Agency solicits comment on this matter.

In addition, the Agency is not proposing to require pharmaceutical reverse distributors to meet the air emission standards found in 40 CFR part 265, subpart CC as required in § 262.34(a)(1)(i) because we anticipate that they will not be applicable. Specifically, § 265.1080(c) exempts tanks, surface impoundments, and containers from the organic air emission standards if the hazardous waste entering the accumulation unit has an average volatile organic concentration of less than 500 parts per million by weight, while § 265.1080(b)(2) exempts containers with a capacity of less than 0.1 m³ (26 gallons) from the standards. EPA understands that the only evaluated hazardous waste pharmaceuticals that have the potential for air emissions are liquids and gels, but they generally do not contain volatile organics. Thus, they do not release organic air emissions, which is what the 40 CFR part 265, subpart CC, air emission standards for tanks, surface impoundments, and containers were promulgated to control. Moreover, because hazardous waste pharmaceuticals are often in their original packaging, and we are proposing to require that liquid and gel hazardous waste pharmaceuticals must be in intact, sealed packaging or otherwise in closed containers, EPA believes that the container air emission standards are unnecessary. In addition, the Agency anticipates that the packaging material for hazardous waste pharmaceuticals will often have a capacity less than 0.1 m³ (26 gallons) further limiting the applicability of the container air emission standards.

Similarly, EPA does not anticipate that the 40 CFR part 265, subpart AA—air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are applicable to the activities of a pharmaceutical reverse distributor and its management of hazardous waste pharmaceuticals. Therefore, like 40 CFR part 265, subpart CC discussed previously, EPA is not proposing to require that 40 CFR part 265, subparts AA and BB apply to pharmaceutical reverse distributors. EPA requests comments on whether its current understanding is correct and whether the 40 CFR part 265, subparts AA, BB, and CC RCRA air emission standards should be applied to pharmaceutical reverse distributors.

v. Hazardous waste numbers (codes).

EPA is proposing to require that the containers of evaluated hazardous waste pharmaceuticals be labeled with the appropriate RCRA hazardous waste numbers. The hazardous waste numbers may be placed on the container label at any time during on-site accumulation, but they must be added prior to when the evaluated hazardous waste pharmaceuticals are transported off-site.

There are also several existing LQG accumulation unit management standards that are not necessary. In addition, the Agency is not proposing to require pharmaceutical reverse distributors to meet the air emission standards found in 40 CFR part 265, subpart CC because we anticipate that they will not be applicable.
§ 266.508(a). This includes the applicable DOT packaging, marking and labeling requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a designated facility.

vii. Rejected shipments. The Agency is proposing to require in § 266.510(c)(7) that pharmaceutical reverse distributors meet the same procedures as LQGs must meet for rejected shipments in § 262.42(c). If a designated permitted or interim status TSDF identified on the hazardous waste manifest cannot accept a shipment of evaluated hazardous waste pharmaceuticals from a pharmaceutical reverse distributor and the TSDF returns the shipment to the pharmaceutical reverse distributor, the pharmaceutical reverse distributor must sign the applicable item on the manifest. In addition, the pharmaceutical reverse distributor may consolidate the rejected hazardous waste pharmaceuticals on-site for up to 90 days provided they are managed in the on-site accumulation area and in accordance with this proposal’s pharmaceutical reverse distributor standards for evaluated hazardous waste pharmaceuticals. The reporting requirements associated with rejected shipments are discussed separately under the reporting section.

viii. Land disposal restrictions. EPA is proposing in § 266.510(c)(8) that pharmaceutical reverse distributors are subject to the same land disposal restrictions (LDRs) that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition, EPA is proposing to amend the testing, tracking, and recordkeeping requirements for generators, treaters and disposal facilities at § 268.7 to add the words, “pharmaceutical reverse distributors” to the title of that section to make the applicability of the treatment standards clear.

ix. Reporting by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals. (1) Biennial report. EPA is proposing that pharmaceutical reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. However, the BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a pharmaceutical reverse distributor sends to another pharmaceutical reverse distributor. Specifically, we are proposing in § 266.510(c)(9)(i) that a pharmaceutical reverse distributor comply with the LQG BR requirements in § 262.41, except for § 262.41(a)(7), which includes the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. The reason we are not requiring the pharmaceutical reverse distributor to provide such information is that they do not have control of the volume or toxicity of the hazardous waste pharmaceuticals it receives from the healthcare facility, and thus have no ability to reduce the volume or toxicity of the hazardous waste pharmaceuticals. Thus, EPA is not requiring the pharmaceutical reverse distributor to report this information in its BR.

(2) Exception reporting. For the reasons that EPA requires exception reporting generally—that is, to maintain the cradle to grave tracking system, EPA is proposing in § 266.510(c)(9)(ii)(A) that pharmaceutical reverse distributors provide an exception report when a TSDF does not return the hazardous waste manifest to the pharmaceutical reverse distributor for shipments of hazardous waste pharmaceuticals to a designated facility. Likewise, we are proposing in § 266.510(c)(9)(ii)(B) that pharmaceutical reverse distributors meet LQG exception reporting when a shipment from a pharmaceutical reverse distributor is rejected by the designated facility and forwarded onto an alternate facility.

x. Recordkeeping by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals. Many of the recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals have been discussed in the sections previously, but for clarity, it is useful to restate them in this recordkeeping section, so that pharmaceutical reverse distributors can refer to one section to determine their recordkeeping requirements related to evaluated hazardous waste pharmaceuticals. In particular, we are proposing five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors. First, EPA is proposing that a pharmaceutical reverse distributor keeps a log (written or electronic) of its weekly inspections of the on-site accumulation area. The other four recordkeeping requirements that we are proposing in § 266.510(c)(10) for pharmaceutical reverse distributors are the same as the LQG recordkeeping requirements that appear in §§ 262.40–42 and § 265.16: these include hazardous waste manifest records, records of biennial reports, exception reporting and training documentation.

EPA believes that these recordkeeping requirements are appropriate for pharmaceutical reverse distributors, many of whom are currently LQGs, but requests comment on this requirement.

EPA asks commenters to review the standards EPA is proposing for pharmaceutical reverse distributors and provide specific comment on whether the standards are appropriate and sufficient to protect human health and the environment.

d. When a Pharmaceutical Reverse Distributor Must Have a RCRA Hazardous Waste Permit

EPA is proposing to not require that a pharmaceutical reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the pharmaceutical reverse distributor follows all the conditions of the permitting exemption in § 266.510. In other words, a pharmaceutical reverse distributor would be subject to regulation as a TSDF and require a RCRA permit (or interim status) if it does not meet the conditions of § 266.510. In addition, a pharmaceutical reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on-site or if it accepts manifested hazardous waste from off-site. A pharmaceutical reverse distributor is required to reject shipments of manifested hazardous waste that it may inadvertently receive from off-site because a pharmaceutical reverse distributor is not a designated facility and therefore is not eligible to receive hazardous waste via a manifest. EPA believes that this approach to regulation of pharmaceutical reverse distributors that accumulate hazardous waste pharmaceuticals strikes an appropriate balance because it recognizes that pharmaceutical reverse distributors are different from typical hazardous waste TSDFs for permitting purposes, while it still imposes certain conditions for exemption from permitting requirements that provide the necessary environmental protection.

VI. Implementation and Enforcement

A. Healthcare Facilities

1. Determining Whether a Healthcare Facility is Subject to Part 266, Subpart P

EPA is proposing that healthcare facilities that are currently considered LQGs or SQGs are subject to the new 40 CFR part 266, subpart P requirements for the management of hazardous waste pharmaceuticals. Thus, a healthcare facility that generates (or accumulates)
more than 100 kg hazardous waste per calendar month, or more than 1 kg of acute hazardous waste per calendar month, or more than 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§261.31, or 261.33(e), must manage its hazardous waste pharmaceuticals in compliance with the 40 CFR part 266, subpart P requirements. In addition, healthcare facilities that are CESQGs are subject to the prohibition on sewer hazardous waste pharmaceuticals in §266.5052.

To determine whether a healthcare facility is a subject to 40 CFR part 266, subpart P, or a CESQG regulated under §261.5, a healthcare facility must count all the hazardous waste—pharmaceutical and non-pharmaceutical—it generates in a calendar month. In counting the amount of hazardous waste generated per calendar month, we note that EPA is proposing to change which pharmaceuticals will be considered hazardous wastes (i.e., potentially creditable hazardous waste pharmaceuticals). Specifically, EPA is proposing that potentially creditable hazardous waste pharmaceuticals transported to a pharmaceutical reverse distributor will be considered solid waste from the point of generation at the healthcare facility and therefore must be counted when determining whether the healthcare facility is a CESQG regulated under §261.5, or whether it is regulated under 40 CFR part 266, subpart P. This differs from current practice where, although a healthcare facility must count the non-creditable hazardous waste pharmaceuticals it generates each calendar month toward its hazardous waste generator category, it does not count the potentially creditable hazardous waste pharmaceuticals it sends to a pharmaceutical reverse distributor. Therefore, although a healthcare facility currently may be considered a CESQG, when it begins counting its potentially creditable hazardous waste pharmaceuticals, it may no longer be a CESQG. In that case, the healthcare facility would be subject to the 40 CFR part 266, subpart P requirements.


EPA is proposing that all healthcare facilities, with the exception of CESQGs, will be subject to the same regulations for the management of their hazardous waste pharmaceuticals, regardless of the quantity of hazardous waste pharmaceuticals generated. A healthcare facility that generates both pharmaceutical and non-pharmaceutical hazardous waste must manage the non-pharmaceutical hazardous waste pursuant to part 262, but need not count its hazardous waste pharmaceuticals toward the facility’s monthly hazardous waste generator category. In addition, if a healthcare facility does not want to keep track of the amount of hazardous waste it generates to ensure it does not exceed the CESQG quantity limits, it could choose to operate under this proposed rule. If it chooses to operate under this proposed rule, however, a healthcare facility must comply with all the requirements of this subpart for the management of its hazardous waste pharmaceuticals.

B. Pharmaceutical Reverse Distributors

1. Pharmaceuticals Sent to Pharmaceutical Reverse Distributors Are Solid Wastes

One difference between this proposal and the 2008 Pharmaceutical Universal Waste proposal is how RCRA would apply to pharmaceuticals returned to pharmaceutical reverse distributors to obtain manufacturer’s credit. EPA is proposing to change its existing position on this issue. If this rule is finalized, this change would mean that the decision by a healthcare facility to send a pharmaceutical to a pharmaceutical reverse distributor is the decision to discard the pharmaceutical. Therefore, under this proposed rule, once the healthcare facility makes the decision to send a pharmaceutical to a pharmaceutical reverse distributor for credit, it is a solid waste at the healthcare facility. It is likely that a portion of the potentially creditable solid waste pharmaceuticals at healthcare facilities that are destined for a pharmaceutical reverse distributor will also meet the definition of hazardous waste and as a result, these potentially creditable hazardous waste pharmaceuticals would need to be managed in accordance with the standards proposed in this document. However, until this rule is final and effective, EPA’s current position will remain in effect.

In addition, the Agency notes that the proposed change in EPA’s position concerning reverse distribution and the management standards discussed in this document pertain only to the reverse distribution of hazardous waste pharmaceuticals and does not apply to reverse distribution or reverse logistics of pharmaceuticals. This limitation is because EPA has studied and collected data for reverse distribution systems for hazardous waste pharmaceuticals, and not all consumer products.


Under this proposal, all pharmaceutical reverse distributors are subject to 40 CFR part 266, subpart P and will be subject to the same standards with respect to their pharmaceutical waste pharmaceuticals, regardless of the amount of hazardous waste pharmaceuticals they manage. Even pharmaceutical reverse distributors that are currently CESQGs will be regulated under 40 CFR part 266, subpart P for the management of their hazardous waste pharmaceuticals.

Therefore, as with healthcare facilities, a pharmaceutical reverse distributor subject to 40 CFR part 266, subpart P will no longer have to keep track of the amount of hazardous waste pharmaceuticals that it generates on a monthly basis.


Most, if not all, healthcare facilities and pharmaceutical reverse distributors generate hazardous wastes other than pharmaceuticals. These, non-pharmaceutical hazardous wastes will continue to be regulated under 40 CFR part 262 (and other applicable Subtitle C regulations). However, because a healthcare facility or pharmaceutical reverse distributor operating under 40 CFR part 266, subpart P no longer has to count its hazardous waste pharmaceuticals, including acute hazardous waste pharmaceuticals such as warfarin, it could result in a change in the facility’s overall generator category and thus change how its non-pharmaceutical hazardous waste must be managed. For example, the generator category for a healthcare facility or pharmaceutical reverse distributor may be reduced from an LQG to an SQG or even a CESQG, when it stops counting its hazardous waste pharmaceuticals, especially acute hazardous waste pharmaceuticals, toward its generator category.

If finalized, the standards established by this rulemaking apply only to the management of hazardous waste pharmaceuticals and do not apply to reverse distribution or reverse logistics of pharmaceuticals. This limitation is because EPA has studied and collected data for reverse distribution systems for hazardous waste pharmaceuticals, and not all consumer products.148

148EPA is examining the reverse logistics of non-pharmaceutical hazardous wastes as part of its analysis of comments received on the Retail Notice of Data Availability that was published on February 14, 2014 (79 FR 8926).
pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors. Healthcare facilities and pharmaceutical reverse distributors likely generate or manage other types of wastes. For example, hospitals may generate non-pharmaceutical hazardous wastes, such as solvents in their diagnostic laboratories; those hazardous wastes must still be managed in accordance with the RCRA Subtitle C requirements (such as the RCRA satellite accumulation regulations (§ 262.34(c)), or if it is a teaching hospital, the Academic Laboratories Rule (if it has opted into part 262, subpart K). Retail pharmacies in retail stores and grocery stores may have non-pharmaceutical hazardous wastes on-site as well, which must be managed in accordance with the 40 CFR part 262 requirements and all other applicable RCRA Subtitle C regulations. For example, fluorescent bulbs may be managed under the universal waste program (40 CFR part 273). For pharmaceutical reverse distributors, this proposed rule only applies to the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Some pharmaceutical reverse distributors may generate other non-pharmaceutical hazardous wastes from activities, such as cleaning and maintenance; other RCRA requirements will apply to those non-pharmaceutical hazardous wastes.

D. State Enforcement Activities and Interpretations

States have taken a variety of approaches regarding pharmaceutical hazardous wastes. One major goal of this proposed rule is to provide clarity on this topic, and thereby promote national consistency, which, in turn, should promote better compliance among healthcare facilities, including pharmacies.

California has taken numerous enforcement actions against national retail chains with pharmacies for not complying with the RCRA hazardous waste regulations. In recent years, the state took enforcement actions and imposed fines on the following chains: Kmart (2009), Walmart (2010), Target (2011), CVS (2012), Costco (2012), Walgreens (2012) and Rite-Aid (2013). In at least two settlement agreements, California directed the defendants (CVS and Rite Aid) to “initiate work with appropriate stakeholders from business and government, including the U.S. Environmental Protection Agency, the U.S. Food and Drug Administration, and the DTSC [Department of Toxic Substances Control], and thereafter either directly or through trade associations or informal coalitions of interested parties, undertake to promote federal regulatory reform regarding the proper management of nondispensable pharmaceuticals, including over-the-counter medications, through “reverse distribution.” Through these settlement agreements, California is seeking clarity from EPA about its longstanding interpretation about the regulatory status of pharmaceuticals that are routed through pharmaceutical reverse distribution systems.

In 2012, Connecticut’s Department of Energy and Environmental Protection (DEEP) took enforcement actions at seven CVS stores for violations of the RCRA hazardous waste regulations. Consent orders from Connecticut DEEP direct CVS stores in the state to follow a set of best management practices. A number of the practices developed in these consent orders mirror some of the practices we are proposing in this rule, particularly with regard to pharmaceuticals destined for a pharmaceutical reverse distributor. Connecticut DEEP asserts RCRA jurisdiction over the pharmaceuticals destined for pharmaceutical reverse distributors by applying specific practices to their management. For example, CVS must maintain records of each shipment of non-dispensable pharmaceuticals to a pharmaceutical reverse distributor, including confirmation of receipt of the non-dispensable pharmaceuticals from the pharmaceutical reverse distributor receiving them. The best practices also include procedures for addressing situations when CVS does not receive delivery confirmation of shipment to a pharmaceutical reverse distributor. Further, the consent order sets out separate, more comprehensive practices for the non-dispensable pharmaceuticals that are not suitable for pharmaceutical reverse distribution.

Aside from best management practices developed by Connecticut as part of a consent order, at least two other states have developed guidance documents that apply conditions to the management of hazardous wastes pharmaceuticals in exchange for enforcement discretion. In particular, in 2008, the Washington State Department of Ecology issued guidance titled, “Interim Enforcement Policy: Pharmaceutical Waste in Healthcare.” Like Connecticut’s consent orders with CVS, this enforcement discretion policy has some elements in common with this proposed rule for hazardous waste pharmaceuticals. For instance, a healthcare facility must notify the Department of Ecology that it is operating under the policy and must train its staff involved in pharmaceutical waste management.

In 2011, Minnesota’s Pollution Control Agency (MPCA) issued a fact sheet titled Reverse Distribution of Pharmaceuticals: Guidance for Minnesota Healthcare Providers. In this guidance, Minnesota states, “Whether a pharmaceutical is eligible for return credit does not affect its product or waste status. In Minnesota, if a pharmaceutical is not used or roused for its intended purpose, it is a waste. The MPCA considers health care practitioners and pharmacies to be generators of these pharmaceutical wastes. Nevertheless, the MPCA believes that the established reverse distribution system provides an environmentally protective method for handling waste pharmaceuticals. Therefore, it will allow Minnesota health care practitioners and pharmacies to manage certain pharmaceuticals through reverse distribution, subject to additional requirements discussed in this fact sheet.” This is similar to the approach that EPA is proposing for potentially creditable hazardous waste pharmaceuticals. For example, like EPA’s proposed rule, MPCA does not require hazardous waste pharmaceuticals destined for a pharmaceutical reverse distributor to be counted toward determining a healthcare facility’s generator category, and MPCA does not require hazardous waste pharmaceuticals to be accompanied by a hazardous waste manifest when shipped to a pharmaceutical reverse distributor. By adopting a rule that is consistent with state approaches, EPA is bringing national consistency to the management of hazardous waste pharmaceuticals.
of hazardous waste pharmaceuticals, while avoiding disruption to practices already in place.

VII. Request for Comment on EPA’s Efforts To Identify Additional Pharmaceutical Hazardous Wastes

Some of the comments EPA received in response to the 2008 Universal Waste proposal recommended that EPA add additional pharmaceutical wastes to the P and U hazardous waste lists (see § 261.33). Some commenters suggested that EPA assess the hazards from all discarded pharmaceuticals (especially chemotherapy drugs) that have come into the market since the promulgation of the original P and U hazardous waste lists and that EPA update these lists to include discarded pharmaceuticals that are hazardous. In response to these comments, the Agency began gathering and reviewing information related to pharmaceuticals that may exhibit hazardous properties. EPA identified 204 drugs, which include 172 drugs that the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) identified as hazardous, and 32 drugs that NIOSH proposed for addition to its hazardous drug list.154 EPA also collected toxicity data and other information for these 204 drugs. These findings, along with additional information regarding the management of pharmaceutical wastes, are presented in the final report entitled Data Collection on the Toxicity, Use, and Disposal of Hazardous Drugs Report (September 2011) placed in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).

Commenters specifically referred to EPA’s P and U hazardous waste lists under the RCRA subtitle C regulations. Generally, in its hazardous waste determinations, EPA has evaluated both “production wastes” (from specific or non-specific sources; see §§ 261.31 and 261.32) and “commercial chemical products” that, when discarded, become wastes (§ 261.33). This latter category (commercial chemical products that are discarded) is the most relevant of the listed hazardous wastes to the pharmaceutical wastes discussed elsewhere in this preamble, and to which commenters referred in the 2008 Universal Waste proposal. As discussed in Section IV.A of this preamble, commercial chemical products listed in § 261.33 are (when discarded) defined as either P-listed “acute” hazardous wastes, or U-listed (non-acute) hazardous wastes. The criteria for listing a solid waste as hazardous under RCRA Subtitle C are described in § 261.11. A waste may be identified as a P-listed waste if it is shown to be fatal to humans or animals at low doses (see § 261.11(a)(2)). Thus, lethality data for any chemical is the principal factor for making a determination that a discarded commercial chemical product is a P-listed hazardous waste.155

In contrast, a waste may be identified as a U-listed waste if it contains any of the toxic constituents listed in Appendix VIII of 40 CFR part 261, and if, after examining each of 10 factors in § 261.11(a)(3), it is determined that the waste is capable of posing a “substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.”156 Examples of these 10 factors include the toxicity and concentration of the hazardous constituent in the waste, the plausible types of improper management to which the waste could be subjected, the quantities of the waste generated at individual generation sites or on a regional or national basis, the nature and severity of the human health and environmental damage that has occurred as a result of the improper management of wastes, and actions taken by other governmental agencies or regulatory programs based on the health or environmental hazard posed by the waste or waste constituent. EPA may only revise either of these lists of commercial chemical products through notice-and-comment rulemaking.

In its September 2011 report, EPA found that 11 drugs on the NIOSH or OSHA lists of hazardous drugs meet the specific criteria for acute toxicity in § 261.11(a)(2) (identified as “Tier 1” drugs in the report). An additional 114 drugs on the NIOSH or OSHA lists did not meet the specific criteria in § 261.11(a)(2) for acute toxicity, but did have lethal doses for other animals or humans (“Tier 2” drugs). The remaining 79 drugs had limited human or animal toxicity data, and no lethality data, and were designated “Tier 3” in the report. Thus, the vast majority of the NIOSH/OSHA hazardous drugs evaluated in the EPA 2011 report do not meet the criteria for listing as acute hazardous waste under RCRA subtitle C.157 As discussed previously, to include a drug on the U-list, the Agency must demonstrate that a discarded drug would be “capable of posing a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.” Therefore, for the NIOSH/OSHA drugs that do not meet the listing criteria for inclusion on the P-list, the Agency would have to examine the 10 factors in § 261.11(a)(3) to determine whether a drug meets the criteria to be included on the U-list. In addition to toxicity data (which is lacking in particular for the drugs identified as Tier 3), the types of information that would be relevant include waste volumes, EPA’s disposal management scenarios, exposure potential, damage cases, and actions taken by other governmental agencies or regulatory programs. To obtain this information for this class of materials poses a challenge. While EPA has some information—the September 2011 report includes summaries of drug management practices and references to others—there remain significant gaps.

In addition, as discussed in Section IV.D of this preamble, the EPA’s OIG has recommended that EPA identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste, and establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste. While EPA has an existing process generally for defining whether or not a solid waste is a listed hazardous waste or in a facility where the APA is not as the definition of hazardous under the RCRA subtitle C regulations.

151 May 19, 1980 Federal Register (45 FR 33084) and November 25, 1980 Federal Register (45 FR 78525).
154 See NIOSH’s Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings (http://www.cdc.gov/niosh/docs/2004-165/) and OSHA Technical Manual Section VI: Chapter 2—Controlling Occupational Exposure to Hazardous Drugs (https://www.osha.gov/dts/ostu/ostu/otm_v6/otm_v6_2.html). Note that the “hazardous” classification used by NIOSH and OSHA is not the same as the definition of hazardous under the RCRA subtitle C regulations.
155 § 261.11(a)(2) states “The Administrator shall list a solid waste as a hazardous waste only upon determining that the solid waste . . . has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, it has been shown in studies to have an oral LD 50 toxicity (rat) of less than 50 milligrams per kilogram, an inhalation LC 50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD 50 toxicity (rabbit) of less than 200 milligrams per kilogram or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness. [Waste listed in accordance with these criteria will be designated Acute Hazardous Waste].”
156 The Agency cannot list hazardous wastes under section § 261.11(a)(3) based on inherent toxicity alone without considering exposure factors, particularly the likelihood of mismanagement. That is, EPA needs to examine each of the 10 factors and, to the extent it does not use one or more of them, must explain why they are irrelevant or unimportant. See Dithiocarbamate Task Force v. EPA (No. 95–1249).
157 EPA emphasizes that this finding reflects the manner in which EPA defines acute hazardous waste under the RCRA subtitle C program; the NIOSH/OSHA lists are based upon different criteria related to preventing occupational exposure to these drugs.
waste (i.e., EPA has regulatory criteria for defining listed hazardous waste described previously; EPA has established policies for evaluating risk and other factors in making listing determinations;\(^\text{154}\) and EPA must use the notice-and-comment rulemaking process when proposing listing determinations), the OIG observed that EPA’s hazardous waste program has not kept pace with the large number of pharmaceuticals that have been developed since 1980. EPA plans to regularly review the NIOSH/OSHA lists of hazardous drugs, as they represent a source of valuable information on pharmaceuticals that have already been identified as having the possibility of posing risks that might warrant regulation as hazardous waste.

EPA is also exploring ways to identify new sources of information, along with alternative approaches that can most efficiently address these concerns. EPA is using the opportunity in this preamble to seek stakeholders’ input on the best course of action concerning regulation of additional pharmaceuticals as hazardous wastes. It is also an opportunity for stakeholders to provide additional information that they may have about potentially hazardous pharmaceuticals. Thus, before deciding on a possible proposal to list additional pharmaceuticals as hazardous wastes, we request comment on the September 2011 final report, and solicit information regarding additional potentially hazardous pharmaceuticals. We request information on the sources and identity of additional potentially hazardous pharmaceuticals along with annual product generation data, annual waste generation data, use information, toxicity data, waste storage and handling information, and disposal information.

In addition, we request stakeholder input for alternative approaches to making hazardous waste listing determinations for pharmaceuticals that do not meet the acute hazardous criteria. Based on the existing listing determination process described previously for non-acute wastes, there is no single toxicity effect (e.g., LD\(_{50}\)) to readily determine whether or not the waste is hazardous under RCRA subtitle C. As such, we are seeking ideas on alternative approaches to more efficiently evaluate potentially hazardous non-acutely discarded pharmaceuticals. For example, should EPA develop and promulgate new criteria specific to discarded pharmaceuticals that would allow it to establish a single hazardous waste listing for all discarded pharmaceuticals that meet the new criteria? Such approaches could also include consideration of whether discarded pharmaceuticals are already managed under a regulatory scheme that prevents mismanagement that a hazardous waste designation would otherwise address (similar to the hazardous waste listing factor that takes into account “actions taken by other governmental agencies or regulatory programs”). We also are seeking information on any innovative processes or programs that states may have for identifying, reviewing, and making a hazardous waste determination for discarded pharmaceuticals.

The Agency emphasizes that no regulatory action is being proposed with respect to expanding the number of pharmaceuticals that are considered hazardous waste. We will use the comments we receive to help inform how to proceed with evaluating discarded pharmaceuticals as listed or characteristic hazardous wastes. Any action taken would be part of a separate, proposed rulemaking in the future.

VIII. Request for Comment on EPA’s Efforts To Amend the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075)

A. Background

In 1980, as part of its final and interim final regulations implementing Section 3001 of RCRA, EPA promulgated the list of commercial chemical products or manufacturing chemical intermediates (40 CFR 261.33) that are hazardous wastes if they are discarded or intended to be discarded, which included nicotine and salts (45 FR 33124; May 19, 1980). The phrase “commercial chemical product or manufacturing chemical intermediate” refers to a “chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed, and all formulations in which the chemical is the sole active ingredient” (see the Comment following 40 CFR 261.33(d)). A chemical substance is listed in 40 CFR 261.33(e) as an acutely hazardous waste if it meets any of the criteria in 40 CFR 261.11(a)(2), which states that the waste “has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, it has been shown in studies to have an oral LD 50 toxicity (rat) of less than 50 milligrams per kilogram, an inhalation LC 50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD 50 toxicity (rabbit) of less than 200 milligrams per kilogram or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness.”

B. Basis for Original Listing

EPA listed nicotine and salts (referred to commonly as just nicotine) as acutely hazardous waste (P075) in § 261.33(e) based on an estimated oral LD50 toxicity to humans of 1 mg/kg and a dermal LD50 toxicity to rabbits of 50 mg/kg.\(^\text{155}\) As discussed previously, for humans, the standard in the regulations for acute toxicity is “fatal to humans in low doses” (see § 261.11(a)(2)). EPA’s Background Document for Section 261.33 from 1981 provides a basis for what is meant by “fatal to humans in low doses” for chemicals that have been given through the oral route (“fatal to humans upon ingestion of ≤100 mg/kg”). The estimated oral LD50 to humans of 1 mg/kg falls within the criteria for “fatal to humans in low doses.” However, the background listing document and its references do not provide sufficient detail to determine the concentration of nicotine that was used to establish the estimated oral LD50 in humans.

C. Rationale for EPA’s Efforts To Amend the P075 Listing

On February 14, 2014, EPA published a Notice of Data Availability (NODA) and Request for Comment (79 FR 8926) entitled “Hazardous Waste Management and the Retail Sector: Providing and Seeking Information on Practices to Enhance Effectiveness to the RCRA Program.” EPA received 44 comments in response to this NODA, many of which included comments related to pharmaceuticals, in particular comments concerning expired or returned low-concentration nicotine-containing smoking cessation products and e-cigarettes. The most detailed comments concerning the unsold low-concentration nicotine products were jointly submitted by the Retail Industry Leaders Association (RILA), the Food Marketing Institute (FMI), the National Association of Chain Drug Stores (NACDS), the National Retail Federation, and their members (referred to as the retail associations, retailers, or

\(^{154}\) EPA’s policy statement on hazardous waste listing determinations is contained in the Federal Register preamble to the first proposed Dyes and Pigments Listing Determination (59 FR 66072, December 22, 1994).

In their comments, the retail associations, representing a broad range of retailers within the retail industry, asked EPA to undertake a rulemaking to remove low-concentration nicotine products from the acute hazardous waste P075 classification under RCRA. The retailers believe these products do not meet RCRA’s requirements for acute hazardous waste. Thus, according to the retailers, the acute hazardous classification is inappropriately making them subject to RCRA’s LQG requirements, which become applicable when someone generates more than 1 kg/month of acute hazardous waste. The retailers also expressed concern that they are subject to increased economic burdens and reporting requirements because they are subject to RCRA’s LQG requirements.

The commenters, to support their request to EPA, state that EPA’s listing for nicotine and salts warrants a reevaluation, because in more recent literature concerning nicotine toxicity, doubts have been expressed about the estimated oral LD50 toxicity to humans of 1 mg/kg, used as a key basis for the listing. According to information provided by commenters, the estimated oral LD50 toxicity to humans of 1 mg/kg was based on extrapolations from toxicological effects observed as result of “self-experiments” performed with nonfatal doses of nicotine. However, according to the commenters, there are doubts about the 1 mg/kg estimate because people have survived after ingesting much larger amounts of nicotine.

The commenters also state that in 1980, when EPA listed nicotine and salts as acute hazardous waste, the nicotine products on the market contained a high concentration of the chemical (e.g., pesticides which contained 40 percent nicotine sulfate), but that these products are no longer on the market. The commenters stressed that the current nicotine products on the market are low-concentration nicotine products that do not meet the regulatory criteria for acutely hazardous wastes. The low-concentration nicotine-containing products that are currently on the market were identified by commenters as nicotine replacement therapy products (e.g., gums, lozenges, patches, inhalers, and nasal sprays) and e-cigarettes. These products, according to the commenters, generally contain less than 3 percent nicotine.

While it may be reasonable for the commenters to conclude that toxicity is higher at higher concentrations of a chemical and lower at lower concentrations of a chemical, EPA currently lacks sufficient information to conclude that low-concentration nicotine-containing products are not acutely toxic as defined under 40 CFR 261.11(a)(2). In addition, except for warfarin and zinc phosphide, the listings for commercial chemical products under 40 CFR 261.33(e) are not concentration-based listings. The warfarin and zinc phosphide listings were changed to concentration-based listings because companies using products containing lower concentration formulations of warfarin and zinc phosphide petitioned EPA to amend the listings and provided LD50 data for animals for the lower concentration products to support their petition (see 49 FR 19922; May 10, 1984). The Agency does not think that linear extrapolations from toxicity levels determined using higher-concentration nicotine products can be used to characterize the acute toxicity of low-concentration nicotine-containing products. Furthermore, although nicotine pesticides are no longer available, high concentration nicotine products still exist. For example, manufacturers of nicotine-containing products, such as e-cigarettes, buy concentrated nicotine solutions and dilute them for consumer use.

In summary, nicotine and salts are P075 listed acute hazardous wastes if the waste arises from the discard of an unused commercial chemical product, manufacturing chemical intermediate, or off-specification material. Additionally, the P075 waste code applies only if the nicotine is present in pure or technical grade form, or is the sole active ingredient in the chemical formulation when discarded. As such, unused (unsold, expired, or returned) nicotine-containing products, including patches, gums, lozenges, inhalers, nasal sprays and e-cigarettes, are classified as P075 listed acute hazardous wastes when discarded. When discarded, these unsold products are causing many retailers to notify and operate as LQGs, which has resulted in increased economic burdens and reporting requirements for retailers. EPA

See comments by the retail associations in response to EPA’s Retail NODA in the docket for the Retail NODA (EPA–HQ–RCRA–2012–0426–0019).


163 See memo from Johnson to DeWitt, May 8, 2015, regarding e-cigarettes, RCRA Online # 17850.

is aware that this is an issue of great concern to the retail associations and their members and would like to address the issue, if possible, by amending the P075 listing to conditionally exempt certain low-concentration nicotine-containing products. The Agency is considering two possible approaches, described below, for amending the P075 listing.

D. Two Possible Approaches for Amending the P075 Listing

1. Exemption from P075 Listing for FDA-Approved Over-the-Counter Nicotine-Containing Smoking Cessation Products

The over-the-counter (OTC) nicotine-containing smoking cessation products, referred to also as nicotine replacement therapy (NRT) products (i.e., nicotine patches, gums, and lozenges) are approved by the Food and Drug Administration (FDA), which ensures that the risk to the public using these products have been evaluated. EPA is currently trying to obtain the risk evaluation data for these products from FDA, which may provide data on the exact concentration of nicotine in the NRT products and any animal and/or human toxicity data associated with use of these products. The Agency is also trying to gather any publicly available animal and/or human toxicity data for these products, in particular toxicity data that could be compared to EPA’s acute toxicity criteria under § 261.11(a)(2). If the Agency is successful in obtaining the toxicity data to support the conclusion that FDA-approved over-the-counter nicotine-containing smoking cessation products do not meet the criteria for listing as an acutely hazardous waste, then the Agency will propose to exempt these products from the P075 listing.

Since e-cigarettes have not been approved by the FDA as smoking cessation products, we do not anticipate being able to obtain animal or human toxicity data from the FDA on nicotine concentrations in e-cigarettes. To complicate matters, the concentration of nicotine in e-cigarettes is not limited by any regulation or approval process and is therefore unpredictable. As a result, this option would likely be limited to excluding FDA-approved over-the-counter nicotine-containing smoking cessation products from the P075 listing and would not include e-cigarettes.

2. Concentration-Based Exemption From P075 Listing for Low-Concentration Nicotine-Containing Products

The comments from the retail associations have stressed that the low
concentration nicotine products currently in the market (generally containing less than 3 percent nicotine) should not be classified as acutely hazardous wastes under RCRA. However, they did not submit any human toxicological data or animal LD50 data for these products to demonstrate that these products are not acutely toxic as defined under §261.11(a)(2). Without these data, it is difficult for the Agency to justify exempting these products from the P075 listing. Furthermore, in order for the Agency to consider a concentration-based exemption for low-concentration nicotine-containing products from the P075 listing, the Agency needs human toxicological data and animal LD50 data for nicotine-containing products at maximum concentrations of nicotine in these products (e.g., 3 percent nicotine). If the toxicological data for nicotine-containing products at maximum concentrations of nicotine in these products show that these products are not acutely toxic as defined under §261.11(a)(2), then the Agency could propose a concentration-based exemption for these products (including e-cigarettes) from the P075 listing. However, depending on the toxicity data, the Agency may also propose to list the P075 exempt nicotine-containing products as non-acute hazardous wastes (U-listed wastes) under 40 CFR 261.33(l). In that case, the concentration-based exemption for nicotine-containing products from the P075 listing would be similar to what the Agency proposed for warfarin and zinc phosphide listings (see 48 FR 7714; February 23, 1983).

E. Request for Comments

EPA invites comments on all possible approaches to amend the acute hazardous waste listing for nicotine and salts, including the two approaches discussed above in Section VIII.D. We also request toxicity information for low-concentration nicotine-containing products that could help determine whether or not these products meet the criteria for acute hazardous wastes under §261.11(a)(2). The Agency emphasizes that no regulatory language is currently being proposed with respect to amending the P075 listing to exempt the low-concentration nicotine-containing products. However, depending on the information received during the comment period, EPA could finalize one of the approaches discussed previously without a separate proposed rulemaking in the future.

In addition, we request comments on whether we should exempt other low-concentration nicotine-containing smoking cessation products, such as inhalers and nasal sprays, from the P075 listing under approach 1, described in the Section VIII.D, above. These products are also FDA-approved, but require a prescription for purchase. The nicotine-containing patches, gums, and lozenges are sold over-the-counter, so they do not require a prescription for purchase. We are interested in finding out what the differences are between nicotine-containing smoking cessation products requiring a prescription and those products that do not require a prescription (e.g., in concentrations of nicotine, amount of nicotine delivered over time, health effects).

Finally, we request comment on whether we should include e-cigarettes and nicotine-containing e-liquids for the e-cigarettes within the scope of the definition of pharmaceutical. As described in this proposal, pharmaceutical hazardous wastes do not count toward generator category. Therefore, since e-cigarettes and nicotine-containing e-cigarette refill liquids (sometimes referred to as e-liquids or e-juice) are P075, if they are considered pharmaceuticals, they would not impact the hazardous waste generator category of the retailers. The retailers, however, would have to manage e-cigarettes and nicotine-containing liquids as hazardous waste pharmaceuticals under part 266, subpart P. We will use the comments we receive to help us decide whether and how to proceed with amending the scope of the definition of pharmaceutical to include e-cigarettes and nicotine-containing e-liquids.

IX. State Authorization

A. Applicability of Rules in Authorized States

Under Section 3006 of RCRA, EPA may authorize a qualified State to administer its own hazardous waste program within the State in lieu of the Federal program. Following authorization, EPA retains enforcement authority under Sections 3008, 3013, and 7003 of RCRA, although authorized States have primary enforcement responsibility. The standards and requirements for State authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities in that State, since only the State was authorized to issue RCRA permits. When new, more stringent federal requirements were promulgated, the State was obligated to enact equivalent authorities within specified time frames. However, the new federal requirements did not take effect in an authorized State until the State adopted the federal requirement as State law.

In contrast, under RCRA Section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized States at the same time that they take effect in unauthorized States. The statute directs EPA to implement these requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While the State must still adopt HSWA related provisions as State law in order to retain final authorization, EPA implements the HSWA provisions in authorized States until the States do so. Authorized States are required to modify their program only when EPA enacts federal requirements that are more stringent or broader in scope than the existing federal requirements. RCRA Section 3009 allows the States to impose standards more stringent than those in the federal program (see also §271.1). Therefore, authorized States may, but are not required to, adopt federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous federal regulations.

B. Effect on State Authorization

This action proposes to add a new subpart P to 40 CFR part 266, and it is being proposed in part under the authority of HSWA and in part under non-HSWA authority. The bulk of 40 CFR part 266, subpart P is being proposed under non-HSWA authority. Thus, when finalized, the amendments promulgated under non-HSWA authority would be applicable on the effective date only in those states that do not have final authorization of their base RCRA programs. However, the prohibition of sewering pharmaceutical hazardous wastes (§266.504) is being proposed under HSWA authority in section 3016 of RCRA. Thus, when finalized, the amendments promulgated under the authority of HSWA would be applicable on the effective date of the final rule in all states. Moreover, authorized states are required to modify 163EPA notes that decisions regarding whether a state rule is more stringent or broader in scope than the federal program are made when the Agency authorizes state programs.
their programs only when EPA promulgates federal regulations that are more stringent or broader in scope than the authorized state regulations. This proposed rule is considered, on the whole, to be more stringent than the current federal standards. Therefore, authorized states will be required to modify their programs to adopt the amendments, when finalized. When a state adopts this new subpart, if elements of the state program are more stringent than this new subpart, the state has the option of retaining those more stringent elements. Likewise, when a state adopts this new subpart, the state has the option of adding elements that are more stringent or broader in scope than this new subpart.

C. Effect on State Authorization in States That Have Added Pharmaceuticals to the Universal Waste Program

The Universal Waste program allows states to add wastestreams to their own state program, even when the waste stream has not been added to the federal Universal Waste program, provided the state has adopted and been authorized for the petition process in §§ 260.20 and 260.23. Two states have added hazardous waste pharmaceuticals to their Universal Waste programs: Florida and Michigan. Because this proposed rule is considered more stringent than either the “traditional RCRA” standards or the Universal Waste program, both Florida and Michigan will be required to modify their programs to adopt an approach at least as stringent as the amendments, if this rule is finalized. Furthermore, because the Agency has determined that it is not appropriate to add hazardous waste pharmaceuticals to the Universal Waste program, both Florida and Michigan must remove hazardous waste pharmaceuticals from their Universal Waste program when they adopt this new subpart, although they may continue to regulate non-hazardous waste pharmaceuticals under the Universal Waste program, to the extent allowed under state law. In addition, states may not add hazardous waste pharmaceuticals to their Universal Waste program in the future.

X. Adding and Reserving Part 266, Subpart O

In addition to proposing new standards for the management of hazardous waste pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors, EPA is proposing to add and reserve 40 CFR part 266, subpart O. Specifically, on May 22, 2001, EPA finalized a Project XL rule in 40 CFR part 266, subpart O (66 FR 28066) for US Filter Recovery Services. However, on July 2, 2008, EPA published a rule that withdrew 40 CFR part 266, subpart O (73 FR 37858). Generally, in order to avoid the potential for confusion that might be caused by reusing a subpart, EPA reserves a subpart that has already been used and removed. In 2008, when we removed 40 CFR part 266, subpart O, we neglected to reserve it. Consequently, we are proposing to add and reserve 40 CFR part 266, subpart O.

XI. Summary of Regulatory Impact Analysis

In order to meet the Office of Management and Budget (OMB) Circular A–4 requirement that EPA analyze the costs and benefits of regulations, we conducted an economic analysis of the proposed rule. The economic analysis follows OMB guidelines and estimates the costs and benefits of the rule. The economic analysis is titled “Regulatory Impact Analysis for EPA’s Proposed Healthcare Facility-Specific Regulations for the Management of Hazardous Waste Pharmaceuticals” and is hereafter referred to as the Regulatory Impact Analysis (RIA). The RIA is summarized here while the full RIA can be found at regulations.gov under docket number EPA–HQ–RCRA–2007–0932.

This proposed rule may affect several different types of healthcare facilities, including hospitals, physicians’ offices, dentists’ offices, outpatient care centers, pharmacies, veterinary clinics, nursing care facilities, coroners’ offices, other health practitioners, other ambulatory care services, and pharmaceutical reverse distributors. Based on data from the 2007 Economic Census and a limited number of states, the RIA estimates that the rule will affect approximately 174,000 facilities. Table 12 lists the number of facilities (by NAICS code) expected to be affected by the proposed rule. The vast majority of these (83.6%) are CESQGs, followed by SQGs (13.4%), and LQGs (3.0%).
We estimate that there is a total of approximately 139,000 tons of RCRA hazardous waste generated by healthcare facilities annually. Approximately 36,200 tons (26%) of this total are hazardous waste pharmaceuticals.

A. Costs of the Proposed Rule

The estimated costs of the proposed rule are the incremental costs over and above the “baseline” (i.e., assumptions about the way in which healthcare facilities currently dispose of their hazardous waste pharmaceuticals). The base case set of baseline assumptions reflects “full compliance” with the current RCRA hazardous waste requirements for the management of hazardous waste pharmaceuticals. A sensitivity analysis of baseline assumptions was also conducted that reflects only “partial compliance” with current regulations. To see the results for the partial compliance baseline sensitivity analysis, please see the RIA.

The estimated cost of the proposed rule, including the proposed prohibition on sewer ing of hazardous waste pharmaceuticals is estimated at $37 million annually under the full compliance baseline. However, there are also significant cost savings under the proposed rule: $24.3 million annually under the full compliance baseline. Therefore the net cost of the rule is $13 million annually ($37 million cost minus $24.3 million cost savings = $13 million net costs). Please see the RIA for more detailed analysis and results regarding the cost of the rule and the regulatory options analyzed.

B. Benefits of the Proposed Rule

The proposed rule for the management of hazardous waste pharmaceuticals is expected to yield a range of environmental benefits as hospitals, medical clinics, and other healthcare facilities divert hazardous waste pharmaceuticals currently disposed in sewers, municipal solid waste landfills (MSWLFs), municipal waste combustors (MWCs), and medical waste autoclaves and incinerators, to hazardous waste incinerators. The rule reduces the amount of hazardous waste pharmaceuticals sewered into waterways, provides regulatory clarity for industry and provides healthcare facilities and pharmaceutical reverse distributors with cost savings.

The largest quantified benefit is from avoided sewer ing of hazardous waste pharmaceuticals. Disposal of hazardous waste pharmaceuticals through sewer ing is believed to be a widespread practice of disposal. Sewering is believed to be one of the most deleterious disposal methods because active pharmaceutical ingredients (APIs) entering surface waters, often untreated by municipal wastewater treatment plants, pose the potential for adverse human health and environmental effects since they may be absorbed by humans and other organisms. Under the proposed rule, the Agency anticipates preventing approximately 6,400 tons of hazardous waste pharmaceuticals annually into waterways via a sewer ing ban. While the Agency was not able to quantify the human health and environmental benefits of reducing or eliminating the sewer ing of hazardous waste pharmaceuticals, EPA did estimate the cost savings of eliminating the wastewater treatment costs associated with sewer ing such pharmaceuticals. The estimated cost savings of eliminated wastewater treatment related to the prevented sewer ing of hazardous waste pharmaceuticals is estimated to be $4.3 million annually.

The proposed rule will yield other benefits beyond the reduction in sewer ing of hazardous waste pharmaceuticals. For example, under the proposed rule, healthcare facilities will no longer be required to count hazardous waste pharmaceuticals toward their RCRA generator category. This, in turn, will lead to changes in a healthcare facility’s generator category.
enabling them to realize an additional cost savings. The extent to which such changes in generator category will occur under the proposed rule is uncertain, but these changes would be most likely for those healthcare facilities for which hazardous waste pharmaceuticals make up a large portion of their overall hazardous waste generation. Please see the RIA for a breakout of cost savings by regulatory requirement.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735; October 4, 1993), this action is a “significant regulatory action” because it is likely to raise novel legal or policy issues under section 3(f)(4). Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821; January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action (EPA–HQ–RCRA–2007–0932).

Findings for the RIA indicate that the rule, as proposed, is projected to result in an aggregate annual cost of approximately $37 million based on a discount rate of 7%. However, the proposed rule will also achieve an annual cost savings, which is estimated to be $24.3 million. Therefore, the net cost of the rule is estimated at $13 million annually. The costs, which represents annualized incremental costs relative to the full compliance baseline, is below the $100 million threshold established under part 3(f)(1) of the Order.

In addition to calling for an assessment of regulatory costs, Executive Order 12866 also requires Federal agencies to assess benefits and, “recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.” As discussed previously, the cost savings for the rule are estimated to be $24.3 million annually. These cost savings are considered benefits of the rule. Also, EPA estimates that the proposed rule will lead to the diversion of approximately 6,440 tons annually of hazardous waste pharmaceuticals from sewer disposal to alternate forms of disposal. This reduction in sewer will likely reduce the concentration of active pharmaceutical ingredients in the nation’s waterways, potentially benefiting both ecosystems and human populations. Please see the RIA for more details on the benefits of the proposed rule.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2486.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

EPA is proposing in this rule, under a new subpart P to 40 CFR part 266, new and revised reporting and recordkeeping requirements for healthcare facilities and pharmaceutical reverse distributors managing hazardous waste pharmaceuticals. The proposed requirements, which are also identified in the ICR supporting this action, will enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals. The healthcare facilities must keep records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals for three years from the date of analyses. In addition, the proposed requirements include provisions for improved tracking of hazardous waste pharmaceuticals that are routed through pharmaceutical reverse distributors.

EPA will use the collected information to ensure that hazardous waste pharmaceuticals are being managed in a protective manner. The tracking requirements ensure that these wastes arrive at their intended destinations rather than diverted for illicit purposes or managed at facilities not equipped to manage these wastes. These tracking requirements will also help facilities identify shipments that do not arrive at their destination as planned, allowing generators to take corrective action that will ensure that future shipments are transported to the appropriate location. In addition, during a facility inspection, information kept in facility records will help EPA and state environmental regulatory agencies determine whether or not regulatory requirements are being followed. Information marked on containers of hazardous waste pharmaceuticals will assist handlers and transporters in ensuring proper management during storage and shipping.

EPA has carefully considered the burden imposed upon the regulated community by the proposed regulations. EPA is confident that those activities required of respondents are necessary and, to the extent possible, has attempted to minimize the burden imposed. EPA believes strongly that if the minimum requirements specified under the proposed regulations are not met, neither the facilities nor EPA can ensure that hazardous waste pharmaceuticals are managed in a manner protective of human health and the environment.

EPA estimates that the total annual respondent burden for the new paperwork requirements in the proposed rule is approximately 54,857 hours, and the annual respondent cost for the new paperwork requirements in the rule is approximately $3,457,478. The estimated annual hourly burden ranges from 0.1 to 3.5 hours per response for the 28,637 respondents. However, in addition to estimating the annual respondent burden associated with new paperwork requirements in the proposed rule, the Agency also estimated the annual benefits (hours and cost savings) to respondents from the new paperwork requirements in comparison to complying with the existing RCRA hazardous waste information collection requirements for hazardous waste pharmaceuticals (e.g., preparation of biennial reports, recordkeeping, etc.). Taking both the new proposed and existing RCRA requirements into account, EPA expects the proposed rule would result in a net annual paperwork burden to the 28,637 respondents of approximately 28,660 hours or $2,301,873. The net cost to EPA of administering the rule is expected to be negligible, since the Agency is not required to review and approve any information submitted by respondents. Burden is defined at 5 CFR 1320.3(b).

Respondent’s affected entities: Private entities.

Respondent’s obligation to respond: Mandatory per 40 CFR part 266, subpart P.

Estimated number of respondents: 28,637.

Frequency of response: Once.

Total estimated burden: 54,857 hours.

Total estimated cost: $3,457,478, includes $1,038,856 annualized capital or operation & maintenance costs.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA’s regulations in 40 CFR are listed in 40 CFR part 9. Submit your comments on the Agency’s need for this information, the accuracy of the
provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB’s Office of Information and Regulatory Affairs via email to oir.a_submissions@omb.eop.gov. Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than October 26, 2015. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Small Business Analysis

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are indicated in Table 13. The Agency has determined that costs of the regulation for a facility are less than 1 percent of annual revenue.

To assess the number of small entities in the regulated universe, EPA consulted NAICS-level data from the 2007 Economic Census and tallied the number of facilities, by NAICS code, owned by entities with revenues below SBA’s threshold for consideration as small. Entities in revenue categories above the SBA threshold are not considered small. See Table 12 for the SBA thresholds and revenues.

<table>
<thead>
<tr>
<th>FACILITY TYPE</th>
<th>SBA SIZE STANDARD (FIRM-LEVEL, ANNUAL REVENUE)</th>
<th>PERCENTAGE OF GENERATORS CONSIDERED “SMALL” UNDER SBA STANDARD</th>
<th>NUMBER OF GENERATORS THAT ARE SMALL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacies</td>
<td>$27.5 million</td>
<td>46%</td>
<td>5,390</td>
</tr>
<tr>
<td>Veterinary Clinics</td>
<td>$7.5 million</td>
<td>95%</td>
<td>7,416</td>
</tr>
<tr>
<td>Physicians’ Offices</td>
<td>$11.0 million</td>
<td>88%</td>
<td>53,577</td>
</tr>
<tr>
<td>Dentists’ Offices</td>
<td>$7.5 million</td>
<td>97%</td>
<td>33,932</td>
</tr>
<tr>
<td>Other Health Practitioners (e.g., chiropractors)</td>
<td>$7.5 million</td>
<td>93%</td>
<td>32,036</td>
</tr>
<tr>
<td>Outpatient Care Centers (excluding dialysis centers)</td>
<td>$15.0 million</td>
<td>68%</td>
<td>4,787</td>
</tr>
<tr>
<td>Outpatient Care Centers (kidney dialysis centers)</td>
<td>$38.5 million</td>
<td>14%</td>
<td>161</td>
</tr>
<tr>
<td>Other Ambulatory Health Care Services</td>
<td>$15.0 million</td>
<td>66%</td>
<td>1,707</td>
</tr>
<tr>
<td>Hospitals</td>
<td>$38.5 million</td>
<td>25%</td>
<td>1,634</td>
</tr>
<tr>
<td>Nursing Care Facilities (e.g., assisted living facilities, nursing homes, U.S. veterans domiciliary centers)</td>
<td>$15.0 million</td>
<td>44%</td>
<td>1,985</td>
</tr>
<tr>
<td>Continuing Care Retirement Communities</td>
<td>$27.5 million</td>
<td>62%</td>
<td>1,023</td>
</tr>
<tr>
<td>Medical Examiners and Coroners’ Offices</td>
<td>Size standards not established</td>
<td>100%</td>
<td>552</td>
</tr>
<tr>
<td>Reverse Distributors</td>
<td>Various NAICS</td>
<td>50%</td>
<td>28</td>
</tr>
</tbody>
</table>

**Total Number of Small Facilities**: 144,228

**Source:**
U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes, effective July 14, 2014.

The percentage of facilities that qualify as small under SBA’s thresholds were estimated for each industry affected by the proposed rule. These percentages were applied to the number of facilities in the regulatory universe, as presented in the RIA. After estimating the number of small entities by NAICS code, the average cost per small entity was estimated based on the model facility costs presented in the RIA. Next, the EPA determined whether the per
facility costs incurred by small entities represent more than 1% of annual revenues, which required estimating small entities’ average annual revenues. For each NAICS code, the average per facility revenue of entities considered small under the SBA standard was estimated based on data from the 2007 Economic Census.

The proposed rule is expected to impact a total of 144,228 small entities (1,634 hospitals, 142,566 other healthcare facilities (i.e., healthcare facilities that are not hospitals) and 28 pharmaceutical reverse distributors). The highest cost impact to small entities is estimated to be 0.013% of revenues at other healthcare facilities and 0.002% of revenues at hospitals. Because pharmaceutical reverse distributors are in various NAICS codes, the Agency was not able to obtain revenue data for pharmaceutical reverse distributors. However, the estimated cost impact to small entity pharmaceutical reverse distributors is estimated at $5,300 annually, which the Agency does not anticipate will cause significant hardship on pharmaceutical reverse distributors that are small entities. However, the Agency requests comment on the cost impacts on small entity pharmaceutical reverse distributors that process creditable hazardous waste pharmaceuticals.

In the RIA, small entity impacts are presented incremental to the full compliance baseline. The annual per facility costs incremental to both baselines are estimated to be much less than 1% of average annual revenues. Since the incremental impact to the smallest healthcare facilities in terms of revenue is less than 1% of average annual revenues, the proposed rule is not expected to cause a significant impact to a substantial number of small businesses. Please see the RIA for a detailed analysis of cost impacts on small entities.

Although this proposed rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act (UMRA)

This rule does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. As indicated previously, the annual net cost is estimated to be $13 million annually after cost savings ($37 million cost minus $24.3 million in cost savings). Thus, this proposed rule is not subject to the requirements of sections 202 or 205 of UMRA.

This proposed rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. While some hospitals and coroners’ offices are publicly owned, the requirements affecting those facilities are not unique in that they are the same as those affecting all facilities in the proposed rule. Also, using data on revenues of hospitals owned by state and local governments, EPA estimated that the costs of the rule borne by state and local governments represent less than 0.001% of their revenues. Therefore, the costs incurred by small governments are not expected to be significant.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action may have tribal implications. However, it will neither impose substantial direct compliance costs on tribal governments, nor preempt tribal law.

To assess the potential tribal implications of the proposed rule, EPA compiled data on the number of tribally run healthcare facilities in the U.S. and estimated the costs of the proposed rule for these facilities. Estimates of tribally run healthcare facilities were obtained from the U.S. Department of Health and Human Services’ Indian Health Service (IHS), as summarized in Table 14.164 Data were not readily available on the size or hazardous waste generation amounts for the tribally run healthcare facilities identified by the IHS. To estimate the potential costs of each regulatory option, per facility costs derived in the RIA were applied to the IHS facility counts. Based on these values, Table 14 summarizes the costs that tribally run healthcare facilities are expected to incur under the proposed rule. OMB has not issued guidance on what constitutes a substantial burden on tribal governments under this executive order. The relatively low costs estimated for tribally run healthcare facilities in Table 14, however, suggest that the proposed rule will not impose a substantial burden on tribal governments. EPA welcomes comments on the proposed rule’s impact on tribal governments.

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The EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its development. A summary of that consultation is provided in the docket for this proposed rule (see EPA–HQ–RCRA–2007–0932).

As required by section 7(a), the EPA’s Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this proposed rule (see EPA–HQ–RCRA–2007–0932).

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This proposed rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

To examine whether the proposed rule has a disproportionate impact on children, the RIA uses a geographic analysis of demographics near wastewater treatment plants and hazardous waste combustion facilities. Table 15 summarizes the results of this analysis. As indicated in the table, this analysis finds that children (i.e., individuals under the age of 18) account for a slightly larger share of the population (28.5%) in the one-mile radius around wastewater treatment plants than they account for nationally (25.3%). Among the catchment zones of wastewater treatment plants, however, children make up a much smaller portion of the population (9.8%). Within both the one- and three-mile buffers around hazardous waste combustion facilities, children’s share of the population slightly exceeds their share nationally.

These data suggest that the proposed rule will not result in a disproportionate adverse impact on children. Because the children’s share of the population near hazardous waste combustion facilities is near the national average, any increase in the combustion of hazardous waste combustion that occurs as a result of the proposed rule is unlikely to have a significant disproportionate impact on children’s health. The data in Table 15 also show that the number of children living in close proximity to wastewater treatment plants, in areas likely to benefit from the rule, far exceeds the number of children who live near hazardous waste combustion facilities. This suggests that the diversion of hazardous waste pharmaceuticals from wastewater treatment plants to combustion facilities will benefit a much greater number of children than it may put at greater risk of adverse health effects. See Table 15 for the demographics of children surrounding wastewater treatment plants and hazardous waste combustion facilities. Please see the RIA for a detailed methodology of the children’s health analysis.

### Table 14: Cost Impacts for Healthcare Facilities Owned and Operated by Native American Tribes Using a 7 Percent Discount Rate (Millions of Year 2011)

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>Number of Facilities</th>
<th>Proposed Rule (Millions of Year 2011)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Annual Costs Incremental to Full Compliance Baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitals</td>
<td>16</td>
<td>$0.019</td>
</tr>
<tr>
<td>Tribal Operated Facilities</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Health Centers</td>
<td>258</td>
<td>$0.088</td>
</tr>
<tr>
<td>Alaska Village Clinics</td>
<td>164</td>
<td></td>
</tr>
<tr>
<td>Health Stations</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>529</td>
<td>$0.107</td>
</tr>
</tbody>
</table>

**Notes:**


2. Estimate reflects annual cost impact for tribal operated facilities, health centers, Alaska village clinics, and health stations combined.
**H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use**

This action is not a “significant energy action” as defined in Executive Order 13211, (66 FR 28355 (May 22, 2001)), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

The proposed rule does not directly regulate energy production or consumption. Changes in the management of hazardous waste pharmaceuticals stipulated in the proposed rule are not expected to impact energy production or distribution. Similarly, the management requirements outlined in the proposed rule will have minimal impact on energy consumption (e.g., from transporting hazardous waste pharmaceuticals that otherwise would have been sewered). Because the changes in energy production and consumption under the proposed rule are likely to be minimal, the proposed rule is not expected to have a significant adverse effect on energy supply, distribution, or use. In addition, no measurable adverse impacts are expected on energy prices or foreign supplies.

**I. National Technology Transfer and Advancement Act (NTTAA)**

This proposed rulemaking does not involve technical standards.

**J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations**

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects.
on minority, low-income or indigenous populations. The results of this evaluation are summarized in the following paragraphs. The evaluation is contained in the Regulatory Impact Analysis (RIA), which can be found at regulations.gov under docket number EPA–HQ–RCRA–2007–0932.

To meet the requirements of Executive Order 12898, EPA analyzed potential environmental justice impacts associated with the diversion of hazardous waste pharmaceuticals from sewer disposal to hazardous waste combustion facilities. Populations living near and downstream from wastewater treatment plants may also benefit from the elimination of sewer disposal of hazardous waste pharmaceuticals. To the extent that minority and/or low-income populations near or downstream from wastewater treatment plants make up a disproportionately high portion of the overall population, the proposed rule may result in positive environmental justice impacts. See Table 16 for the results of the Environmental Justice analysis.

Overall, EPA expects that the proposed rule may positively affect U.S. environmental justice populations, although the size of the impact will vary by wastewater treatment plant. As suggested by Table 16, the reduction in sewer disposal expected under the proposed rule may benefit relatively large minority and low-income populations in close proximity to or downstream from wastewater treatment plants. The diversion of hazardous waste pharmaceuticals to combustion facilities, however, may increase the environmental burden borne by environmental justice populations near these combustion facilities. Although these effects offset each other to a certain degree, the number of minority and low-income individuals near wastewater treatment facilities greatly exceeds the number near hazardous waste combustion facilities. This suggests that, on the whole, the proposed rule may benefit environmental justice populations.
### TABLE 16: DEMOGRAPHICS FOR POPULATIONS NEAR WASTEWATER TREATMENT FACILITIES & COMMERCIAL HAZARDOUS WASTE COMBUSTION FACILITIES

<table>
<thead>
<tr>
<th>GEOGRAPHIC AREA</th>
<th>MINORITY POPULATION</th>
<th>LOW-INCOME POPULATION</th>
<th>% OF NATIONAL POPULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wastewater treatment plants, one-mile radius</td>
<td>6.2 million (22.6%)</td>
<td>3.8 million (14.0%)</td>
<td></td>
</tr>
<tr>
<td>Wastewater treatment plants, catchment areas</td>
<td>3.8 million (8.6%)</td>
<td>2.2 million (4.9%)</td>
<td></td>
</tr>
<tr>
<td>Hazardous waste combustion facilities, one-mile radius</td>
<td>3,578 (18.7%)</td>
<td>3,130 (16.3%)</td>
<td>24.7%</td>
</tr>
<tr>
<td>Hazardous waste combustion facilities, three-mile radius</td>
<td>67,329 (26.6%)</td>
<td>42,782 (16.9%)</td>
<td>11.4%</td>
</tr>
</tbody>
</table>

#### NO. OF FACILITIES EXCEEDING:

<table>
<thead>
<tr>
<th>GEOGRAPHIC AREA</th>
<th>NATIONAL AVG. MINORITY %</th>
<th>NATIONAL AVG. LOW-INCOME %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wastewater treatment plants, one-mile radius</td>
<td>3,233</td>
<td>7,886</td>
</tr>
<tr>
<td>Wastewater treatment plants, catchment areas</td>
<td>3,151</td>
<td>7,358</td>
</tr>
<tr>
<td>Hazardous waste combustion facilities, one-mile radius</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Hazardous waste combustion facilities, three-mile radius</td>
<td>7</td>
<td>4</td>
</tr>
</tbody>
</table>

#### NO. OF FACILITIES EXCEEDING:

<table>
<thead>
<tr>
<th>GEOGRAPHIC AREA</th>
<th>STATE AVG. MINORITY %</th>
<th>STATE AVG. LOW-INCOME %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wastewater treatment plants, one-mile radius</td>
<td>3,596</td>
<td>7,949</td>
</tr>
<tr>
<td>Wastewater treatment plants, catchment areas</td>
<td>3,562</td>
<td>7,391</td>
</tr>
<tr>
<td>Hazardous waste combustion facilities, one-mile radius</td>
<td>7</td>
<td>13</td>
</tr>
<tr>
<td>Hazardous waste combustion facilities, three-mile radius</td>
<td>8</td>
<td>16</td>
</tr>
</tbody>
</table>

#### Notes:
1. Values in parentheses represent the proportion of the population considered a racial or ethnic minority or below the Federal Poverty Level.


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**List of Subjects**

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

40 CFR Part 266

Environmental protection, Energy, Hazardous Waste, Recycling, Reporting and recordkeeping requirements.
40 CFR Part 268
Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 273
Environmental protection, Hazardous materials transportation, Hazardous waste.

Dated: August 31, 2015.
Gina McCarthy,
Administrator.

For the reasons stated in the preamble, Title 40, chapter I, of the Code of Federal Regulations is proposed to be amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

2. Amend §261.5 by adding paragraph (c)(8) to read as follows:

§261.5 Special requirements for hazardous waste generated by conditionally exempt small quantity generators. * * * * *

(c) * * * * *

(8) Is a hazardous waste pharmaceuticals managed under 40 CFR part 266, subpart P.

3. Amend §261.7 by adding paragraph (c) to read as follows:

§261.7 Residues of hazardous waste in empty containers. * * * * *

(c) Healthcare facilities and pharmaceutical reverse distributors operating under 40 CFR part 266, subpart P are subject to §266.507 for the management of hazardous waste pharmaceuticals in containers, in lieu of this section.

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

4. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, and 6938.

5. Amend §262.10 by adding paragraphs (m) and (n) to read as follows:

§262.10 Purpose, scope and applicability. * * * * *

(m) All pharmaceutical reverse distributors (as defined in §266.500) are subject to 40 CFR part 266, subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

(n) Each healthcare facility (as defined in §266.500) must determine whether it is subject to 40 CFR part 266, subpart P for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including pharmaceutical hazardous waste and non-pharmaceutical hazardous waste). Healthcare facilities that generate (or accumulate) more than 100 kg (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, waste, or other debris, resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §261.31 or §261.33(e), are subject to 40 CFR part 266, subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

6. The authority citation for part 266 continues to read as follows:


Subpart O—[Reserved]

7. Add reserved subpart O:

Subpart P—Hazardous Waste Pharmaceuticals

Sec.
266.500 Definitions for this subpart.
266.501 Applicability.
266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.
266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.
266.504 Healthcare facilities that are conditionally exempt small quantity generators (CESQGs).
266.505 Prohibition of sewer hazardous waste pharmaceuticals.
266.506 Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances.
266.507 Management of hazardous waste pharmaceutical residues in containers.
266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a pharmaceutical reverse distributor.
266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a pharmaceutical reverse distributor to a pharmaceutical reverse distributor.

266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors.

Subpart P—Hazardous Waste Pharmaceuticals

§266.500 Definitions for this subpart.

The following definitions apply to this subpart:

Hazardous waste pharmaceutical means a hazardous waste pharmaceutical that was not potentially creditable hazardous waste pharmaceutical but has been evaluated by a pharmaceutical reverse distributor to establish whether it is eligible for manufacturer’s credit and will not be sent to another pharmaceutical reverse distributor for further evaluation or verification.

Hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in §261.2, and is listed in part 261, subpart D, or exhibits one or more characteristics identified in part 261, subpart C.

Healthcare facility means:

(1) Any person that:

(i) Provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

(ii) Sells or dispenses over-the-counter or prescription pharmaceuticals.

(2) This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians’ offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and hospitals.

Household waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in §261.2, but is exempt from being a hazardous waste under §261.4(b)(1).

Long-term care facility means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, assisted living, hospices, nursing homes, skilled nursing facilities, and the assisted living and skilled nursing care

266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors.
portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, and the independent living portions of continuing care retirement communities.

Non-creditable hazardous waste pharmaceutical means a hazardous waste pharmaceutical that is not expected to be eligible for manufacturer’s credit.

Non-hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in §261.2, and is not listed in 40 CFR part 261, subpart D, and does not exhibit a characteristic identified in 40 CFR part 261, subpart C.

Non-pharmaceutical hazardous waste means a solid waste, as defined in §261.2, that is listed in 40 CFR part 261, subpart D, or exhibits one or more characteristics identified in 40 CFR part 261, subpart C, but is not a pharmaceutical, as defined in this section.

Pharmaceutical means any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act, prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment, contaminated with pharmaceuticals, and clean-up material from spills of pharmaceuticals.

Pharmaceutical reverse distributor means any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer’s credit. Any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer’s credit is considered a pharmaceutical reverse distributor.

Potentially creditable hazardous waste pharmaceutical means:

(1) A hazardous waste pharmaceutical that has the potential to receive manufacturer’s credit and is:

(i) Unused or un-administered; and

(ii) Unexpired or less than one year past expiration date.

(2) The term does not include “evaluated hazardous waste pharmaceuticals,” residues of pharmaceuticals remaining in containers, contaminated personal protective equipment, and clean-up material from spills of pharmaceuticals.

§266.501 Applicability.

(a) A healthcare facility that is a conditionally exempt small quantity generator remains subject to §261.5 and is not subject to this subpart, except for §§266.504, 266.505, and 266.507(a) and (b).

(b) A healthcare facility that is a conditionally exempt small quantity generator has the option of complying with this subpart for the management of its hazardous waste pharmaceuticals, as an alternative to complying with the conditional exemption of §261.5.

(c) A healthcare facility or pharmaceutical reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in subsection (a), a healthcare facility is subject to:

(1) Sections 266.502 and 266.504 through 266.508 of this subpart with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals, and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a pharmaceutical reverse distributor.

(2) Sections 266.503 through 266.507 and 266.509 of this subpart with respect to the management of potentially creditable hazardous waste pharmaceuticals that are destined for a pharmaceutical reverse distributor.

(e) A pharmaceutical reverse distributor is subject to §§266.505 through 266.510 of this subpart with respect to the management of hazardous waste pharmaceuticals.

(f) This subpart does not apply to the management of hazardous waste pharmaceuticals that are generated or managed by entities other than healthcare facilities and pharmaceutical reverse distributors.

§266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

(a) Notification and withdrawal from this subpart for healthcare facilities managing non-creditable hazardous waste pharmaceuticals—(1) Notification. A healthcare facility must notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a healthcare facility operating under this subpart. A healthcare facility is not required to fill out Box 11 (Description of Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each site or EPA Identification Number.

(i) A healthcare facility that already has an EPA identification number must re-notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A healthcare facility that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification form (EPA form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(iii) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this subpart.

(2) Withdrawal. A healthcare facility that operated under this subpart but is no longer subject to this subpart, because it is a conditionally exempt small quantity generator under §261.5, and elects to withdraw from this subpart, must notify the appropriate EPA Regional Administrator using the Site Identification Form (EPA form 8700–12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 11 (Description of Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA Identification Number.

(i) A healthcare facility must submit the Site Identification Form notifying that it is withdrawing from this subpart before it begins operating under the conditional exemption of §261.5(b).

(ii) A healthcare facility must keep a copy of its withdrawal on file for three years from the date of signature on the notification of its withdrawal.

(b) Training of employees managing non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must ensure that all employees that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar
with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) Hazardous waste determination for non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility that generates a solid waste that is a pharmaceutical must determine whether the solid waste pharmaceutical is a hazardous waste pharmaceutical (i.e., it exhibits a characteristic identified in 40 CFR part 261, subpart C or is listed in 40 CFR part 261, subpart D) in order to determine whether the waste is subject to this subpart. A healthcare facility may choose to manage its solid waste pharmaceuticals as hazardous waste pharmaceuticals under this subpart even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261, subpart C and are not listed in 40 CFR part 261, subpart D.

(d) Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities. (1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) A healthcare facility that manages ignitable or reactive hazardous waste pharmaceuticals, or that mixes or commingles incompatible hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(i) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(iv) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(v) Through other like means threaten human health or the environment.

(3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) A healthcare facility may accumulate hazardous waste pharmaceuticals and non-hazardous pharmaceutical waste in the same container, except that hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of § 268.3(c) must be accumulated in separate containers.

(e) Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must label or clearly mark each container of hazardous waste pharmaceuticals with the phrase “Hazardous Waste Pharmaceuticals.”

(I) Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities. (1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals-on-site for one year or less without a permit or having interim status. A healthcare facility may accumulate for more than one year without a permit or having interim status, only if the requirements of paragraph (f)(3) of this section are met.

(2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals-on-site must demonstrate the length of time that the hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceutical being accumulated first became a waste;

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste; or

(iv) Any other method which clearly demonstrates the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating from the date it first became a waste.

(3) A healthcare facility may request from the EPA Regional Administrator an extension beyond the one year accumulation time limit for non-creditable hazardous waste pharmaceuticals involved in litigation, a recall, or unforeseen circumstances beyond the control of the healthcare facility.

(i) A request must be sent to the EPA Regional Administrator in writing (paper or electronic). The request for an extension must include an explanation of the reason an extension is requested, the approximate volume or weight of the hazardous waste pharmaceuticals that will be accumulated more than 90 days, and the amount of additional time requested.

(ii) The amount of time extension granted is at the discretion of the EPA Regional Administrator on a case-by-case basis.

(g) Land disposal restrictions for non-creditable hazardous waste pharmaceuticals. The hazardous waste pharmaceuticals generated by a healthcare facility are subject to the Land Disposal Restrictions of 40 CFR part 268. A healthcare facility that generates hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with § 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (codes).

(h) Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals. A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned hazardous waste pharmaceuticals-on-site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with paragraphs (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must:

(1) Sign either:

(i) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(2) Provide the transporter a copy of the manifest;

(3) Within 30 days of delivery of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Transport or offer for transport the returned shipment in accordance with the shipping standards of § 266.508(a).

(i) Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals—(1) Biennial report by healthcare facilities. Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to non-creditable hazardous waste pharmaceuticals managed under this subpart.

(2) Exception report by healthcare facilities for a missing copy of the manifest. (i) For shipments from a
A healthcare facility to a designated facility: If a healthcare facility does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(A) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located, and

(B) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(ii) For shipments rejected by the designated facility and shipped to an alternate facility: If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the handwritten signature of the owner or operator of the alternate facility within 60 days of the date the waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(A) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located, and

(B) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(3) Additional reports. The EPA Regional Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(i) Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals. A healthcare facility must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(2) A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

(3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) for at least three years from the date of the test, analysis, or other determination.

(4) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(k) Response to releases of non-creditable hazardous waste pharmaceuticals at healthcare facilities. (1) A healthcare facility must immediately contain all releases of non-creditable hazardous waste pharmaceuticals and other residues from non-creditable hazardous waste pharmaceuticals.

(2) A healthcare facility must determine whether any material resulting from the release is a non-creditable hazardous waste pharmaceutical, and if so, must manage the non-creditable hazardous waste pharmaceutical residues and spill cleanup materials in accordance with the requirements of this subpart.

(l) Long-term care facilities that manage non-creditable hazardous waste pharmaceuticals. A healthcare facility that is a long-term care facility and that has individuals that administer their own pharmaceuticals must collect any unused non-creditable hazardous waste pharmaceuticals from those self-administering individuals and manage them in accordance with this subpart.

(m) Accepting creditable and non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a CESQG. A healthcare facility may accept creditable and non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a conditionally exempt small quantity generator under § 266.509, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is operated under this subpart for the management of its hazardous waste pharmaceuticals,

(2) Is operating under this subpart for the management of its hazardous waste pharmaceuticals,

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off-site in compliance with this subpart, and

(4) Keeps records of the hazardous waste pharmaceutical shipments it receives from off-site for 3 years from the date that the shipment is received.

§ 266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

(a) Hazardous waste determination for creditable hazardous waste pharmaceuticals at the healthcare facility. A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable solid waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical (i.e., it listed in 40 CFR part 261, subpart D or exhibits a characteristic identified in 40 CFR part 261, subpart C). A healthcare facility may choose to manage its potentially creditable solid waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under § 266.509 even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261, subpart C and are not listed in 40 CFR part 261, subpart D.

(b) Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor.

(c) Biennial Report by healthcare facilities. Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

(d) Recordkeeping. (1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for 3 years from the date of shipment:
(i) A copy of the advance notification provided to the pharmaceutical reverse distributor;

(ii) The confirmation of delivery; and

(iii) The shipping papers or bill of lading.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

§ 266.504 Healthcare facilities that are conditionally exempt small quantity generators (CESQGs).

(a) Potentially creditable hazardous waste pharmaceuticals. A healthcare facility that is a conditionally exempt small quantity generator may send its potentially creditable hazardous waste pharmaceuticals to a pharmaceuticals reverse distributor.

(b) Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a CESQG. A healthcare facility that is a conditionally exempt small quantity generator may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided the receiving healthcare facility meets the conditions in § 266.502(m) of this subpart.

(c) Long-term care facilities that are CESQGs. A long-term care facility that is a conditionally exempt small quantity generator may dispose of its hazardous waste pharmaceuticals in a collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration and provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances, and combusted at one of the following:

(1) A permitted large municipal waste combustor (LMWC), subject to 40 CFR part 62, subpart FFF for existing LMWCs, or 40 CFR part 60, subparts Eb and Ee for new LMWCs, or

(2) A permitted small municipal waste combustor (SMWC), subject to 40 CFR part 62, subpart JJJ for existing SMWCs, or 40 CFR part 60, subparts Aaaa and BBBB for new SMWCs, or

(3) A unit that has a permit or interim status to burn hazardous waste and is covered by 40 CFR part 63, subpart EEE. A unit that is exempt from 40 CFR part 63, subpart EEE as specified in § 63.1200(b) of this chapter is not covered by subpart EEE.

§ 266.505 Prohibition of sewer hazardous waste pharmaceuticals.

All healthcare facilities and pharmaceutical reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. The exclusion in § 261.4(a)(1)(ii) for mixtures of domestic sewage and other wastes that pass through a sewer system to a publicly-owned treatment works does not apply to a hazardous waste pharmaceutical.

§ 266.506 Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances.

(a) The following are exempt from 40 CFR parts 260 through 273, provided the conditions of paragraph (b) of this section are met:

(1) A hazardous waste pharmaceutical that is also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

(2) An authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that collects controlled substances collected from an ultimate user (as defined by the Drug Enforcement Administration) and co-mingles them with hazardous waste pharmaceuticals that are exempt as a household waste under § 261.4(b)(1).

(b) Conditions for exemption. The hazardous waste pharmaceuticals must be collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances, and combusted at one of the following:

(1) A permitted large municipal waste combustor (LMWC), subject to 40 CFR part 62, subpart FFF for existing LMWCs, or 40 CFR part 60, subparts Eb and Ee for new LMWCs, or

(2) An authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that collects controlled substances collected from an ultimate user (as defined by the Drug Enforcement Administration) and co-mingles them with hazardous waste pharmaceuticals that are exempt as a household waste under § 261.4(b)(1).

(3) A unit that has a permit or interim status to burn hazardous waste and is covered by 40 CFR part 63, subpart EEE. A unit that is exempt from 40 CFR part 63, subpart EEE as specified in § 63.1200(b) of this chapter is not covered by subpart EEE.

§ 266.507 Management of hazardous waste pharmaceutical residues in containers.

(a) Dispensing and unit-dose containers. A dispensing bottle, vial, or ampule (not to exceed 1 liter or 1000 pills); or a unit-dose container, (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided:

(1) All pharmaceuticals have been removed from the dispensing bottle, vial or ampule; or the unit-dose container, (e.g., unit-dose packet, cup, wrapper, blister pack, or delivery device) using the practices commonly employed to remove materials from that type of container, and

(2) Any dispensing bottle or unit-dose container that is an original manufacturer’s product package is destroyed prior to disposal in such a manner as would prevent further use of the container.

(b) Dispensed syringes. The residues remaining in a syringe are not regulated as hazardous waste provided:

(1) The syringe has been used to administer the pharmaceutical to a patient, and

(2) The syringe is placed in a sharps container that is managed in accordance with all applicable federal, state, and local medical waste requirements.

(c) Other containers, including delivery devices. The residues remaining in all other types of unused or used containers that once held pharmaceuticals must be managed as hazardous waste pharmaceuticals, if the residues are listed in 40 CFR part 261, subpart D or exhibit a characteristic identified in 40 CFR part 261, subpart C. This includes, but is not limited to, the residues in intravenous (IV) bags and tubing, inhalers, aerosols, nebulizers, tubes of ointment, gels or creams.

§ 266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a pharmaceutical reverse distributor.

(a) A healthcare facility or pharmaceutical reverse distributor that ships either non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, respectively, off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility), must comply with:

(1) The following pre-transport requirements, before transporting or offering for transport off-site:

(i) Packaging. Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 177, and 180.

(ii) Labeling. Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172, subpart E.

(iii) Marking. (A) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172, subpart D.

(B) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety

Vol. 80, No. 186 / Friday, September 25, 2015 / Proposed Rules 58087
authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Pharmaceutical Reverse Distributor's Name and Address _

Healthcare Facility's or Pharmaceutical Reverse Distributor's EPA Identification Number _

Manifest Tracking Number _

(iv) Placarding. Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR part 172, subpart F.

(v) Shipping papers. Prepare shipping papers in accordance with 49 CFR part 172, subpart C.

(2) The manifest requirements of 40 CFR part 262, subpart B, except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list hazardous waste codes in box 13 of EPA Form 8700–22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the words “hazardous waste pharmaceuticals” in Box 14 (the special handling instructions and additional information) of EPA Form 8700–22.

(b) Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. A healthcare facility or pharmaceutical reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262, subpart E.

(c) Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262, subpart F. A healthcare facility or pharmaceutical reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, unless they have a permit or interim status that allows them to accept hazardous waste from off-site.

§ 266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a pharmaceutical reverse distributor to a pharmaceutical reverse distributor.

(a) A healthcare facility or a pharmaceutical reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a pharmaceutical reverse distributor must:

(1) Provide advance notice (paper or electronic) to the pharmaceutical reverse distributor of the intent to ship potentially creditable hazardous waste pharmaceuticals to the receiving pharmaceutical reverse distributor before each shipment of potentially creditable hazardous waste pharmaceuticals is sent, and

(2) Comply with the pre-transport requirements of § 266.508(a)(1)(i) through (v).

(b) Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving pharmaceutical reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or pharmaceutical reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived.

(c) If a healthcare facility or pharmaceutical reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor that initiated the shipment must contact the shipper and the intended recipient (i.e., the pharmaceutical reverse distributor) promptly to report that the confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) Exporting potentially creditable hazardous waste pharmaceuticals. (1) A healthcare facility or pharmaceutical reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the following requirements in addition to paragraphs (a) through (c) of this section:

(i) Comply with the requirements applicable to a primary exporter at 40 CFR 262.53, 262.56(a)(1) through (4), (a)(6), and (b) and 262.57;

(ii) Export such potentially creditable hazardous waste pharmaceuticals only upon consent of the receiving country and in conformance with the EPA Acknowledgement of Consent as defined in 40 CFR part 262, subpart E; and

(iii) Provide a copy of the EPA Acknowledgement of Consent for the shipment to the transporter transporting the shipment for export.

(2) A transporter of potentially creditable hazardous waste pharmaceuticals to a foreign destination other than those countries specified 40 CFR 262.58(a)(1) (in which case the transporter is subject to the requirements of 40 CFR part 262, subpart H) may not accept a shipment if the transporter knows the shipment does not conform to the EPA Acknowledgment of Consent. In addition the transporter must ensure that:

(i) A copy of the EPA Acknowledgment of Consent accompanies the shipment; and

(ii) The shipment is delivered to the facility designated by the person initiating the shipment.

(e) Importing potentially creditable hazardous waste pharmaceuticals. Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to paragraphs (a) through (c) of this section in lieu of 40 CFR part 262, subpart F.

§ 266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors.

A pharmaceutical reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off-site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on-site without a permit or without having interim status, provided that it complies with the following conditions:

(a) Standards for pharmaceutical reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(1) Notification. A pharmaceutical reverse distributor must notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a pharmaceutical reverse distributor operating under this subpart.

(i) A pharmaceutical reverse distributor that already has an EPA identification number must re-notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a pharmaceutical reverse distributor operating under this subpart.

(ii) A pharmaceutical reverse distributor that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a pharmaceutical reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.
(2) **Inventory by the pharmaceutical reverse distributor.** A pharmaceutical reverse distributor must maintain an inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on-site.

(i) A pharmaceutical reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the pharmaceutical reverse distributor. The inventory must include the identity (e.g., name or national drug code (NDC)) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(ii) The inventory must include separate security measures to prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(iii) Examples of methods that may be used to prevent unknowing entry and minimize unauthorized entry include, but are not limited to:

(A) 24-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) Means to control entry, such as keycard access.

(iv) If the pharmaceutical reverse distributor already meets the security requirements of this paragraph because of other regulatory requirements, such as Drug Enforcement Administration regulations, the facility is not required to provide separate security measures pursuant to this section.

(3) **Security at the pharmaceutical reverse distributor facility.** A pharmaceutical reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize unknowing entry include, but are not limited to:

(A) 24-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) Means to control entry, such as keycard access.

(ii) The amount of time granted for an extension is at the discretion of the EPA Regional Administrator on a case-by-case basis.

(6) **Contingency plan and emergency procedures at a pharmaceutical reverse distributor.** A pharmaceutical reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of 40 CFR part 265, subpart D.

(7) **Closure of a pharmaceutical reverse distributor.** When closing an area where a pharmaceutical reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the pharmaceutical reverse distributor must control, minimize, or eliminate to the extent necessary to protect human health and the environment, post-closure escape of hazardous waste, leachate, contaminated run-off, or hazardous waste decomposition products to the ground or surface waters or to the atmosphere.

(8) **Reporting by a pharmaceutical reverse distributor—(i) Unauthorized waste report.** A pharmaceutical reverse distributor must submit an unauthorized hazardous waste report if the pharmaceutical reverse distributor receives hazardous waste from off-site that it is not authorized to receive (e.g., non-creditable hazardous waste pharmaceuticals, non-pharmaceutical hazardous waste). The pharmaceutical reverse distributor must prepare and submit an unauthorized waste report to the EPA Administrator within 15 days after receiving the unauthorized hazardous waste and the pharmaceutical reverse distributor must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized hazardous waste. The pharmaceutical reverse distributor must manage the unauthorized hazardous waste in accordance with all applicable regulations for generators of non-pharmaceutical hazardous waste. The unauthorized waste report must be signed by the owner or operator of the pharmaceutical reverse distributor, or his authorized representative, and contain the following information:

(A) The EPA identification number, name and address of the pharmaceutical reverse distributor;

(B) The date the pharmaceutical reverse distributor received the hazardous waste;

(C) The EPA identification number, name and address of the healthcare facility that shipped the hazardous waste, if available;

(D) A description and the quantity of each unauthorized hazardous waste distributed by the pharmaceutical reverse distributor received;

(E) The method of treatment, storage, or disposal for each unauthorized hazardous waste; and

(F) A brief explanation of why the waste was unauthorized, if known.

(ii) **Additional reports.** The EPA Regional Administrator may require pharmaceutical reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(9) **Recordkeeping by pharmaceutical reverse distributors.** A pharmaceutical reverse distributor must keep the following records (paper or electronic):

(i) A copy of its notification on file for as long as the facility is subject to this subpart;

(ii) A copy of the advance notification, delivery confirmation, the shipping papers or bill of lading for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date it receives the shipment;

(iii) A copy of its inventory for as long as the facility is subject to this subpart; and

(iv) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.
(10) A pharmaceutical reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 21 calendar days of arriving at the pharmaceutical reverse distributor to establish whether it is destined for another pharmaceutical reverse distributor for further evaluation or verification of manufacturer’s credit or for a permitted or interim status treatment, storage or disposal facility. This 21 calendar days is part of the 90 calendar days allowed for on-site accumulation.

(i) A potentially creditable hazardous waste pharmaceutical that is destined for another pharmaceutical reverse distributor is still considered a “potentially creditable hazardous waste pharmaceutical” and must be managed in accordance with paragraph (b) of this section.

(ii) A potentially creditable hazardous waste pharmaceuticals that is destined for a permitted or interim status treatment, storage or disposal facility is considered an “evaluated hazardous waste pharmaceutical” and must be managed in accordance with paragraph (c) of this section.

(11) A pharmaceutical reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer’s credit within 21 calendar days of arriving at the facility and must manage the evaluated hazardous waste pharmaceuticals in accordance with paragraph (c) of this section. This 21 calendar days is part of the 90 calendar days allowed for on-site accumulation.

(b) Additional standards for pharmaceutical reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another pharmaceutical reverse distributor. A pharmaceutical reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in paragraph (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another pharmaceutical reverse distributor for further evaluation or verification of manufacturer’s credit:

(1) A pharmaceutical reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor with 90 days from when the potentially creditable hazardous waste pharmaceuticals arrived or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A pharmaceutical reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another pharmaceutical reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor that is a pharmaceutical manufacturer within 90 days from when the potentially creditable hazardous waste pharmaceuticals arrived or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(3) A pharmaceutical reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another pharmaceutical reverse distributor in accordance with §266.509.

(4) Recordkeeping. A pharmaceutical reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another pharmaceutical reverse distributor, for at least three years from the date of shipment:

(i) A copy of the advance notification provided to the pharmaceutical reverse distributor;

(ii) The confirmation of delivery; and

(iii) The shipping papers or bill of lading.

(c) Additional standards for pharmaceutical reverse distributors managing evaluated hazardous waste pharmaceuticals. A pharmaceutical reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in paragraph (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

(1) Accumulation area at the pharmaceutical reverse distributor. A pharmaceutical reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) Weekly inspections of on-site accumulation area. A pharmaceutical reverse distributor must inspect its on-site accumulation area at least weekly, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) Personnel training at a pharmaceutical reverse distributor. Personnel at a pharmaceutical reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of §265.16.

(4) Labeling and management of containers at on-site accumulation area. A pharmaceutical reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(i) Label the containers with the words, “hazardous waste pharmaceuticals”;

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(v) A pharmaceutical reverse distributor that manages ignitable or reactive evaluated hazardous waste pharmaceuticals, or that mixes or commingles incompatible evaluated hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(E) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of §268.3(c) (e.g., arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the pharmaceutical reverse distributor.

(5) Hazardous waste numbers. Containers of evaluated hazardous waste pharmaceuticals must be marked with the applicable hazardous waste number(s) (i.e., hazardous waste code(s)) prior to transport off-site.

(6) Shipment. A pharmaceutical reverse distributor must ship evaluated hazardous waste pharmaceuticals that...
are destined for a permitted or interim status treatment, storage or disposal facility, in accordance with §266.508(a).

(7) Procedures for a pharmaceutical reverse distributor for managing rejected shipments. A pharmaceutical reverse distributor who sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility must have the understanding that the designated facility can accept or return the waste, and later receives the original manifest. Upon receipt of the returned shipment, the pharmaceutical reverse distributor must:

(i) Sign either: (A) Item 18 of the original manifest if the original manifest was used for the returned shipment; or (B) Item 20 of the new manifest if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 days of delivery of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the pharmaceutical reverse distributor; and

(iv) Transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals on-site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with §264.72 or §265.72 of this chapter, may accumulate the returned hazardous waste pharmaceuticals on-site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with paragraph (a) of this section. Upon receipt of the returned shipment, the pharmaceutical reverse distributor must:

(A) Submit to the transporter a copy of the manifest with the handwritten signature of the owner or operator of the designated facility which received the shipment back as a rejected load in accordance with the shipping standards of §266.508(b).

(B) For shipments rejected by the designated facility and shipped to an alternate facility:

1. A pharmaceutical reverse distributor that does not receive a copy of the manifest with the handwritten signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the pharmaceutical reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

2. A pharmaceutical reverse distributor must submit an exception report to the EPA Regional Administrator for the Region in which the pharmaceutical reverse distributor is located if it has not received a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

(i) A legible copy of the manifest for which the pharmaceutical reverse distributor does not have confirmation of delivery; and

(ii) A cover letter signed by the pharmaceutical reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(8) Land disposal restrictions. Evaluated hazardous waste pharmaceuticals are subject to the Land Disposal Restrictions of 40 CFR part 268. A pharmaceutical reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must comply with the land disposal restrictions in accordance with §268.7(a) requirements.

(9) Reporting by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals. (i) Biennial report by a pharmaceutical reverse distributor. A pharmaceutical reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of a biennial report to the EPA Regional Administrator by March 1 of each even numbered year in accordance with §262.41, except §262.41(a)(7).

(ii) Exception reporting by a pharmaceutical reverse distributor for a missing copy of the manifest. (A) For shipments from a pharmaceutical reverse distributor to a designated facility:

1. If a pharmaceutical reverse distributor does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the pharmaceutical reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

2. A pharmaceutical reverse distributor must submit an exception report to the EPA Regional Administrator for the Region in which the pharmaceutical reverse distributor is located if it has not received a copy of the manifest with the handwritten signature of the owner or operator of the alternate facility within 45 days of the date the hazardous waste was accepted by the initial transporter. The 45-day timeframe begins the date the hazardous waste is accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility. The Exception Report must include:

(i) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(ii) A cover letter signed by the pharmaceutical reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(10) Recordkeeping by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals. (i) A pharmaceutical reverse distributor must keep a copy of each manifest signed in accordance with §262.23(a) for three years or until it receives a signed copy from the designated facility which received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date of the inspection.

(ii) A pharmaceutical reverse distributor must keep a copy of each biennial report for at least three years from the due date of the report.

(iii) A pharmaceutical reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(iv) A pharmaceutical reverse distributor must keep records to document personnel training, in accordance with §265.16.

(d) When a pharmaceutical reverse distributor must have a permit. A pharmaceutical reverse distributor is an operator of a hazardous waste treatment, storage or disposal facility and is subject to the requirements of 40 CFR parts 264, 265, and 267 and the permit requirements of 40 CFR part 270, if the pharmaceutical reverse distributor:

(1) Does not meet the conditions of this section;

(2) Accepts manifested hazardous waste from off-site; or

(3) Treats or disposes of hazardous waste on-site.
PART 268—LAND DISPOSAL RESTRICTIONS

9. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

10. Amend Section 268.7 by revising the section heading and the paragraph (a) subject heading to read as follows:

§ 268.7 Testing, tracking, and recordkeeping requirements for generators, pharmaceutical reverse distributors, treaters, and disposal facilities.

(a) Requirements for generators and pharmaceutical reverse distributors:

11. Amend § 268.50 by adding paragraphs (a)(4) and (5) to read as follows:

§ 268.50 Prohibitions on storage of restricted wastes.

(a) * * *

4. A healthcare facility accumulates such wastes in containers on-site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the healthcare facility complies with § 266.502 of this chapter.

5. A pharmaceutical reverse distributor accumulates such wastes in containers on-site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the pharmaceutical reverse distributor complies with § 266.510 of this chapter.

PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT

12. The authority citation for part 273 continues to read as follows:

Authority: 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

13. Amend § 273.80 by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 273.80 General.

(a) Except as provided in paragraph (d), any person seeking to add a hazardous waste or category of hazardous waste to this part may petition for a regulatory amendment under this subpart and 40 CFR 260.20 and 260.23.

(d) Pharmaceutical hazardous waste is regulated by 40 CFR part 266, subpart P and may not be added as a category of hazardous waste for management under this part.

[FR Doc. 2015–23167 Filed 9–24–15; 8:45 am]
BILLING CODE 6560–50–P
CASA Regulatory Subgroup
Water Committee

The November 12, 2015 meeting is a Conference Call
Dial-in Number: (712) 432-1212
Meeting ID: 408-153-751#

Committee Conference Call
10:30 AM – 12:30 PM

This Call will be held concurrently with the CASA RWG Land Committee Conference Call

Next Meeting – December 10, 2015
Annual Luncheon and Holiday Gift Exchange
Boy Scout Council
San Leandro, CA
<table>
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<th>Topic</th>
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<td>FOG and Co-Digestion at POTWs</td>
<td>Jackie Zipkin</td>
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<td><strong>3.</strong></td>
<td>BMPs for Centralized Waste Treatment (CWT) Facilities</td>
<td>Adam Link</td>
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<td>Mitch Mysliwiec</td>
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<td>CASA RWG Strategic Planning</td>
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**Updates**

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<td><strong>10.</strong></td>
<td>Positive Train Control (PTC) Rule</td>
<td>Adam Link</td>
<td>5</td>
<td>Federal Leg PTC Update [Attached]</td>
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<td><strong>11.</strong></td>
<td>LA County Pharma Workgroup and Draft Ordinance</td>
<td>Adam Link</td>
<td>5</td>
<td><a href="http://publichealth.lacounty.gov/pharma.htm">http://publichealth.lacounty.gov/pharma.htm</a> [Stakeholder Mtg. November 13]</td>
</tr>
<tr>
<td><strong>13.</strong></td>
<td>Presentation on Upcoming Rulemakings from USEPA</td>
<td>Adam Link / Chris Stacklin</td>
<td>5</td>
<td>USEPA Slides from WEFTEC</td>
</tr>
</tbody>
</table>

**Items that are out there:**

- SWRCB Bacteria Objectives - [http://www.waterboards.ca.gov/bacterialobjectives/](http://www.waterboards.ca.gov/bacterialobjectives/)
- SWRCB Groundwater Anti-Deg - [http://www.swrcb.ca.gov/plans_policies/antidegradation.shtml](http://www.swrcb.ca.gov/plans_policies/antidegradation.shtml)
- Final Water Quality Fee Schedule Filed - [http://www.waterboards.ca.gov/resources/fees/water_quality/docs/fy1516_fee_schedule.pdf](http://www.waterboards.ca.gov/resources/fees/water_quality/docs/fy1516_fee_schedule.pdf)
Findings and Recommendations of the Expert Review Panel of the State of California Environmental Laboratory Accreditation Program

Draft for Stakeholder Feedback

Southern California Coastal Water Research Project

SCCWRP Technical Report XXX
Findings and Recommendations of the Expert Review Panel of the State of California Environmental Laboratory Accreditation Program

Lara Phelps (Expert Review Panel Chair)
U.S. Environmental Protection Agency

Jordan Adelson
U.S. Navy

Stephen Arms
State of Florida Department of Health

Mitzi Miller
Dade Moeller & Associates

David Speis
Eurofins QC, Inc.

Draft for Stakeholder Feedback
Technical Report XXX
# Table of Contents

Foreword ....................................................................................................................................... ii
Acknowledgements ....................................................................................................................... ii
Executive Summary ..................................................................................................................... iii

Chapter 1: Introduction ................................................................................................................. 1
  1.1 Background ......................................................................................................................... 1
  1.2 Expert Review Panel ........................................................................................................... 3
  1.3 The Panel Charge ............................................................................................................... 4
  1.4 The Report .......................................................................................................................... 5

Chapter 2: Programmatic Problems Identified During the Review ................................................ 6
  2.1 Poor Credibility with the Stakeholder Community ............................................................... 6
  2.2 Lack of Effective Accreditation Process .............................................................................. 7
  2.3 Absence of Routine Management Processes ..................................................................... 8
  2.4 Inadequate Resources ........................................................................................................ 9

Chapter 3: Solutions ................................................................................................................... 10
  3.1 Establish a Management System ...................................................................................... 10
  3.2 Adopt Laboratory Accreditation Standards ........................................................................ 12
  3.3 Ensure Relevant Analytical Methods ................................................................................. 14
  3.4 Expand Resources ............................................................................................................ 15
  3.5 Enhance Communication .................................................................................................. 19

Chapter 4: Timeline for Action .................................................................................................... 22
  4.1 Establish a management system for ELAP based on ISO/IEC 17011 .............................. 22
  4.2 Adopt accreditation standards for laboratories .................................................................. 22
  4.3 Implement a structured system for communicating with stakeholders, including communications training for staff........................................................................................................... 23
  4.4 Accept accreditation from other recognized accreditation bodies ................................... 24
  4.5 Establish procedures for enforcement actions ................................................................. 24
  4.6 Ensure accreditation is based on current and relevant analytical methods ...................... 24
  4.7 Further reduce assessor backlog by (a) using commercial software for managing PT data, and (b) investigating mechanisms for remote laboratory assessments ........................................ 24
  4.8 Revise ELAP fee structure ............................................................................................... 25

Appendix A: Panel’s Response to Charge Questions ................................................................... 26

Appendix B: Biographies of Panel Members .............................................................................. 34
  Jordan Adelson ....................................................................................................................... 34
  Stephen Arms .......................................................................................................................... 34
  Mitzi Miller ............................................................................................................................... 34
  Lara Phelps ............................................................................................................................... 35
  David Speis ............................................................................................................................. 35

Appendix C: Stakeholder Advisory Committee (SAC) Membership ............................................ 36

Appendix D: Meeting Agendas ................................................................................................... 37
FOREWORD

This report was produced under California State Water Resources Control Board contract to the Southern California Coastal Water Research Project (Agreement Number 15-037-400) under the direction of Dr. Stephen Weisberg. The views and perspectives expressed in this report by the members of the Expert Review Panel are their own, and do not necessarily reflect the views of their employer or any other entity with which they are affiliated.

ACKNOWLEDGEMENTS

The Expert Review Panel wishes to thank Christine Sotelo, Program Chief of the California Environmental Laboratory Accreditation Program, and Karen Larsen, Deputy Director of the California State Water Resources Control Board, for their openness and willingness to provide unfettered access to, and unfiltered information about, the program and its staff. The authors also wish to thank the members of Stakeholder Advisory Committee, especially Chair Andy Eaton, for advice, counsel and support, and the numerous speakers whose invaluable perspectives informed the Panel’s deliberations. Finally, the authors wish to thank Dr. Steve Weisberg, Dr. Nate Dodder and Scott Martindale of the Southern California Coastal Water Research Project for their guidance and support.
EXECUTIVE SUMMARY

An Expert Review Panel was convened in 2015 to conduct an external examination of the State of California’s Environmental Laboratory Accreditation Program (ELAP). The Panel identified a number of fundamental weaknesses in ELAP that hinder the program’s ability to achieve its mission of ensuring the State has access to quality data for use in its environmental decision-making. More importantly, the Panel observed that these deficiencies have cost the program credibility among key constituencies – notably, the state agencies that rely on data generated by ELAP-accredited laboratories.

During three in-person meetings to assess ELAP and gather perspectives from stakeholders, the Panel identified five main programmatic deficiencies: (1) ELAP lacks a clear management system with established procedures to which staff are trained and held accountable; (2) ELAP does not have a relevant accreditation standard on which to base its laboratory inspections; (3) the list of analytical methods for which ELAP accredits laboratories is outdated; (4) ELAP has insufficient resources to accomplish its mission; and (5) ELAP’s poor communication has caused a rift with its clients.

There is, however, hope. The recently installed ELAP management team recognizes the challenges and appears receptive to change. Some stakeholders also have embraced a fresh start, although all parties must let go of the past to be successful in the future. To that end, the Panel believes ELAP is well-positioned to reestablish itself as a respected accreditation program, and recommends moving forward with a series of immediate reforms. These reforms should be weighed and evaluated through the lens of a clear Mission Statement, which the Panel recommends as: “Implementation of a sustainable accreditation program to effectively evaluate the competency of organizations generating environmental and public health data of known and documented quality to meet stakeholder needs.” The Panel’s recommended reforms fall into five main themes:

- **Establish a management system:** ELAP should rapidly establish standards of operation for itself. At present, there are no procedures that define internal processes and job requirements for staff. ELAP should design a management system with performance criteria to which all staff and management can be held accountable.

- **Adopt laboratory accreditation standards:** The use of an appropriate accreditation standard by which laboratories are assessed is critical to ELAP’s credibility, to the usability of the data generated, and to the general success of the program. The laboratory standards ELAP is using are insufficient and out of date. The State should adopt an existing, external set of accreditation standards as an immediate remedy and, in the future, refine it to enhance alignment with State-specific needs. The accreditation standards chosen must include quality system and method-based requirements.

- **Ensure relevant analytical methods:** ELAP should update the list of analytical methods to which laboratories are accredited and assessed. The list of methods the program is using are incorporated into the California Code of Regulations, which have not been updated since 1994 and are seriously out of date. State regulations should be altered to remove references to specific methods, which will provide ELAP the flexibility to adopt
current, relevant methods that laboratories and regulatory authorities need to adequately protect California’s health and environment.

**Expand resources:** ELAP should take several steps to expand the resources at its disposal: (1) Additional investment in staff development to increase productivity, including a management plan that defines employee expectations and establishes employee performance metrics; (2) a revised fee structure that eases ELAP’s financial constraints and allows the program to fully recover its costs; and (3) incorporation of third-party, private-sector assessors and acceptance of qualifying laboratory accreditation programs into ELAP’s accreditation process, both to clear ELAP’s immediate backlog and to provide long-term support as necessary. Maintaining staffing at the current level will only work if management sets requirements and holds staff accountable.

- **Enhance communication:** ELAP should develop a communications plan, have ELAP staff undergo communication training, and codify expectations into a management system that ensures staff are held accountable for proper responsiveness and communication etiquette. ELAP should also reinvigorate the Environmental Laboratory Technical Advisory Committee (ELTAC), which serves as a vital conduit by which the laboratory community can help improve ELAP’s programmatic foundation.

Although ELAP is not presently achieving its mission, ELAP’s new management team understands its charge to comprehensively overhaul the program. The State should support ELAP’s efforts to implement these initial recommendations and hold ELAP accountable for their execution. The Panel will revisit ELAP’s progress in late 2016 and prepare a second Panel report that codifies any mid-course corrections and additional recommendations. If ELAP is successful in implementing the recommended reforms, the Panel believes ELAP can regain credibility, achieve financial sustainability, operate an accreditation process that the State and stakeholders can support, and reliably ensure that environmental and public health data being used in State decision-making are of known and documented quality.
CHAPTER 1: INTRODUCTION

1.1 Background

Effective stewardship of the environment and protection of public health require generation of data to inform managers of the effectiveness of regulatory actions. Such data may include the concentration of chemical contaminants in drinking water, identification of harmful bacteria at beaches, or toxicity of sediments. The field and laboratory methods employed to obtain these measurements are often complex, and the procedures and analytical instrumentation evolve as technology improves. Through the use of accreditation to oversee laboratories that provide these analytical services to the State, the State is able to ensure that laboratories generate data of a known minimum quality, that data obtained from different laboratories are comparable, and that laboratories compete on an even playing field.

1.1.1 ELAP History

In January 1988, the California Environmental Laboratory Improvement Act (i.e., Assembly Bill 3739, Chapter 894, Statutes of 1988) established the State’s Environmental Laboratory Accreditation Program (ELAP) to provide evaluation and accreditation of environmental testing laboratories. ELAP ensures the analytical data used for regulatory oversight of the State's drinking water, wastewater, shellfish, food, and hazardous waste programs meet State requirements. All environmental testing laboratories are required to receive accreditation prior to providing analytical data used for State regulatory purposes.

ELAP was one of the eleven original state accreditation programs to become a recognized accreditation body by the National Environmental Laboratory Accreditation Program (NELAP), which was formed in 1999. The goal of NELAP is to foster cooperation among accreditation activities of different states and other governmental agencies, and to unify state and federal agency standards. Each accreditation body agreed to implement standards written by the National Environmental Laboratory Accreditation Conference (NELAC), and accept the accreditation of laboratories accredited by other NELAP accreditation bodies. In 2006, The NELAC Institute (TNI) was established for the long-term management of NELAP and development of standards.

ELAP withdrew from TNI NELAP in 2014 following the identification of programmatic deficiencies in a TNI programmatic evaluation. The evaluation affirmed the concerns expressed by local California laboratories regarding ELAP’s effectiveness as an accreditation body. Shortly after ELAP’s withdrawal from TNI, ELAP transitioned from the California Department of Public Health to the California State Water Resources Control Board Division of Drinking Water (herein referred to as the State Board). With new ELAP management in place under the State Board, ELAP asked for an external, independent programmatic review to help the program frame its future directions. This review was intended to cover internal management procedures, staffing, finances, the laboratory assessment process, and communication strategies, with an overarching goal of improving ELAP’s effectiveness.

1.1.2 ELAP Operation

ELAP presently has a staff of 25 full-time employees and an annual budget of $3.3 million. According to the Environmental Laboratory Improvement Act, ELAP is to be fully fee-
supported; however, accreditation fees only bring in annual revenue of $1.9 million, with the deficit covered by State general funds. The ELAP fee structure is based on the number of fields of testing (FOTs) in which the laboratory applies for accreditation. Laboratories are accredited by ELAP per FOT, which defines a set of analytes in a particular environmental matrix and the method of measurement (e.g., Toxic Chemical Elements in Wastewater, Microbiology of Drinking Water).

ELAP accredits nearly 600 in-state and 100 out-of-state laboratories. Approximately 55% of the laboratories are privately owned; the remainder are government-operated, including federal, state, and municipal laboratories (Table 1). According to a non-scientific survey conducted by ELAP, 40% of the laboratories reviewed by ELAP have 5 analysts or less, 75% have 20 analysts or less, and 5% have 85 analysts or more.

**Table 1. Number and type of laboratories accredited by ELAP, as of August 31, 2015.**

<table>
<thead>
<tr>
<th>Government</th>
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<tr>
<td></td>
<td>127 Public Wastewater System</td>
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<tr>
<td></td>
<td>65 City</td>
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<td>58 Public Water System</td>
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<td>10 Federal</td>
</tr>
<tr>
<td></td>
<td>6 State</td>
</tr>
<tr>
<td></td>
<td>4 Academic Institute</td>
</tr>
<tr>
<td></td>
<td>2 Recycling Facility</td>
</tr>
<tr>
<td></td>
<td>1 Tribal</td>
</tr>
<tr>
<td></td>
<td>331 Total</td>
</tr>
<tr>
<td>Private</td>
<td>317 Commercial</td>
</tr>
<tr>
<td></td>
<td>45 Industrial</td>
</tr>
<tr>
<td></td>
<td>362 Total</td>
</tr>
<tr>
<td>In-State</td>
<td>602</td>
</tr>
<tr>
<td>Out-of-State</td>
<td>91</td>
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</tbody>
</table>

ELAP provides accreditation for FOTs based on the needs of its clients (i.e., the State agencies that are required to use laboratories that are accredited). FOTs are reviewed for accreditation through two mechanisms: proficiency testing (PT) and laboratory assessments against specific method requirements. PT programs evaluate whether a laboratory can analyze a sample of unknown composition and produce results within specified acceptance criteria. Laboratory assessments are carried out by ELAP assessors using checklists that cover multiple aspects of the sample preparation, instrument operation, and quality assurance (QA)/quality control (QC) required by the method specified in the FOT.

The Environmental Laboratory Technical Advisory Committee (ELTAC) was created by ELAP to provide assistance and advice regarding technical, scientific, and administrative matters, which is required under Section 100863 of the Health and Safety Code. The members of ELTAC
are representative of different technical fields within the laboratory community and regulatory agencies.

1.1.3 General Program Operation

Other states also accredit environmental testing laboratories. Some operate as independent accreditation bodies and develop their own standards by which to assess laboratory performance. At present, 14 accreditation bodies in 13 states belong to the national program organized by TNI, and two additional states require accreditation from another source, with NELAP being one option. As previously noted, TNI has been managing NELAP since 2006 and maintaining a common set of consensus standards for state accreditation bodies to follow. The latest TNI standard (2009) contains two relevant sections for accreditation bodies and the laboratories they accredit: Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis, and Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories. The other volumes in the 2009 TNI standard cover requirements for PT providers and the accreditors of PT providers.

TNI Volume 1 describes management and technical requirements for environmental laboratories, including implementation of a quality system. A quality system is a structured and documented management system describing how the laboratory ensures the quality of its processes and products. TNI Volume 2 describes requirements for the internal activities of accreditation bodies, such as ELAP, including management, document control, human resources, and how the accreditation process is tracked. Prior to its separation from TNI in 2014, ELAP operated a two-tiered accreditation system, wherein laboratories could be accredited and assessed under either the full TNI standard or the State’s own standard.

Although some elements of the TNI standard are similar to ELAP’s own standard, such as the technical requirements for the analytical methods, laboratory quality systems are not required by ELAP. ELAP also does not explicitly follow TNI Volume 2.

The TNI standards are based on International Organization for Standardization (ISO) 17025 for testing laboratories and ISO 17011 for accreditation bodies (i.e., ELAP-type organizations), with added specificity for environmental laboratories and their accreditation bodies. For more details about ELAP and the standards under which its accreditation processes operate, go to http://www.waterboards.ca.gov/drinking_water/certlic/labs/index.shtml.

1.2 Expert Review Panel

In 2014, ELAP’s newly installed management team asked for an external, independent programmatic review to improve ELAP’s effectiveness. The State Board turned to the Southern California Coastal Water Research Project Authority (SCCWRP) to establish an Expert Review Panel (Panel) to develop recommendations for improving ELAP.

An 11-member Stakeholder Advisory Committee (SAC) was formed to vet the Panel nomination process. SAC members (listed in Appendix C) represented municipal and private environmental laboratories operating in California, as well as State agency users of data from ELAP-accredited laboratories. Candidates for the Panel were nominated based on nationally recognized expertise and a requirement they not be part of an organization regulated by or having official interactions
with ELAP. To ensure the Panel was well-rounded, candidates were grouped according to their categories of expertise, such as laboratory operation, operation of accreditation bodies, and on-site assessment. The SAC then ranked the nominated panelists within each category and was given the opportunity to eliminate any of the candidates from consideration. This vetting process ensured the Panel members were both highly qualified and free from bias regarding the issues on which they would deliberate.

The five-member Panel, established in March 2015, consists of:
- Dr. Jordan Adelson, U.S. Navy
- Stephen Arms, State of Florida
- Mitzi Miller, Dade Moeller & Associates
- Lara Phelps (*Panel Chair*), U.S. Environmental Protection Agency
- David Speis, Eurofins QC, Inc.

Brief biographies of the Panel members are provided in Appendix B.

To orient the Panel to ELAP and allow public participation in the Panel’s review process, three public meetings (March, August, and October) and one public webinar (June) were held in 2015. Meeting agendas (provided in Appendix D) were developed by the Panel and SCCWRP, with SAC assistance on topic development and identification of speakers to provide the Panel with the most complete range of information and perspectives. For presentations on topics intended to inform the direction of Panel recommendations (as opposed to informational or background presentations), the Panel deliberately invited speakers with different perspectives. For example, the Panel heard from speakers representing both large commercial laboratories and smaller government laboratories, and heard both the pros and cons of utilizing third-party, on-site assessors. Members of the Panel, SAC, and public were given time to ask questions of the speakers, and an email listserv was created to inform interested parties about upcoming meetings and other updates. The meeting agendas, background materials provided to the Panel, presentation slides, and written public comments were posted to a public website ([http://www.sccwrp.org/ELAP](http://www.sccwrp.org/ELAP)).

### 1.3 The Panel Charge

Panel charge questions were developed by ELAP with the assistance of the SAC. The Panel was tasked with answering the following eight questions:

1. What should the State’s role be in the accreditation process? Are the philosophies, objectives and scope of ELAP clearly defined? Are they appropriate? Does ELAP have the capacity to support the program?
2. How can California’s accreditation standards be improved?
3. What should California’s approach be to recognizing accreditation by other states, national entities or private accreditation services? Should California rejoin NELAP?
4. How can ELAP’s laboratory inspection program be made more robust? What are the appropriate qualifications for auditor/inspector team members in each of the specialty areas that ELAP certifies laboratories?
5. How can California improve its PT program for quantifying laboratory quality?
6. How can California improve its process for responding to concerns expressed by (a) laboratories that have concerns about the certification process, or (b) clients who have concerns about the quality of a laboratory that has been accredited by ELAP?
7. How should ELAP plan for future programmatic, testing and management needs?
8. Which program improvements are most urgent and can be accomplished within existing resources and authorities? Which are the highest-priority, longer-term program improvements?

1.4 The Report
This report provides the Panel’s observations about the present condition of the program, recommended solutions, and an implementation timetable for the recommendations. Appendix A provides direct answers to the Panel’s charge questions, which also are covered extensively throughout this document.

This report is the first of two reports that the Panel will ultimately produce. The Panel will reconvene in approximately one year to assess ELAP’s responsiveness to the recommendations in this report and to provide additional recommendations, as well as make any suggested course corrections based upon the successes and challenges experienced by the program during the year.
CHAPTER 2: PROGRAMMATIC PROBLEMS IDENTIFIED DURING THE REVIEW

The Panel identified a number of problems during its review that hinder ELAP’s ability to achieve its mission to ensure the quality of data used by the State of California in its environmental decision-making. The problems fall into four main categories: (1) Poor credibility with the stakeholder community; (2) lack of effective accreditation practices; (3) absence of routine management processes; and (4) inadequate resources. These problems are described in the following sections of this chapter.

2.1 Poor Credibility with the Stakeholder Community

During the course of its deliberations, the Panel had an opportunity to interview numerous stakeholder groups to assess their perceptions of the program. During these discussions, it was apparent that overall perception of the program is low and that ELAP is no longer trusted by the stakeholder community to operate an effective process for verifying laboratory competency. The program also lacks transparency, with the decision process for determining an unacceptable laboratory ill-defined, and evidence that ELAP has failed to remove noncompliant laboratories from the accredited community. These sentiments were shared across a range of stakeholders, including clients of the program and the ELAP-accredited laboratory community, as elaborated below.

2.1.1 Program Clients

ELAP provides services to a range of State agencies, which rely upon the data produced by laboratories that ELAP accredits. The Panel found that ELAP had not communicated with these clients for many years. ELAP was not even aware of the identity of all the clients it serves, which has led to a poor understanding of the data needs and competency requirements that each program requires.

In meeting with these clients, it was also apparent that ELAP staff does not possess the technical expertise to meet some of the client needs. ELAP does not have an accreditation process for laboratories conducting ambient air analysis in California because there is not air monitoring expertise on staff. There are other programs, such as shellfish, where ELAP has expertise, but where the program would better reside in the Department of Public Health, where monitoring can be performed according to U.S. Food and Drug Administration specifications.

2.1.2 Laboratories

Laboratories accredited by ELAP provided extensive input regarding the program’s lack of competency. They feel that laboratory assessments lack consistency from assessor to assessor and, in many cases, do not reflect knowledge of the accreditation requirements or technical aspects of the methods being assessed. Laboratories reported that assessors have expertise in only a limited number of FOTs, meaning that assessments are conducted sequentially and inefficiently. They complained that assessors frequently documented deficiencies in areas they had not even evaluated.

Laboratories expressed a reticence to file complaints to ELAP management for fear of retaliation by ELAP staff. Without a clear, documented process for complaints, laboratories do not envision
management holding staff accountable or having a mechanism to properly respond to complaints.

Laboratories that provided input to ELAP stated that ELAP customer service is poor, including a lack of professionalism when interacting with clients during laboratory assessments and in telephone communications. The feedback provided by the laboratories during in-person meetings with the Panel is consistent with the findings from a survey of laboratories conducted by the American Council of Independent Laboratories, which was provided to the Panel as additional background information.

2.1.3 Other States

ELAP is no longer part of NELAP, nor is ELAP’s accreditation recognized by other states. ELAP was one of eleven original states to be recognized by NELAP, which was created to foster cooperation among accreditation activities of different states and other governmental agencies, and to unify the state and federal agency standards. ELAP withdrew from NELAP in 2014, after being cited for a number of programmatic deficiencies during a routine evaluation in 2012.

NELAP’s evaluation of ELAP’s accreditation process, which was conducted by other NELAP member states, showed ELAP’s execution of NELAP’s requirements were unsatisfactory, resulting in numerous activities that required corrective action. The Panel met with the lead NELAP evaluator as part of its deliberations and found all the NELAP-identified deficiencies to be accurate and relevant to program integrity. The Panel further observed that ELAP failed to subsequently address those deficiencies.

2.2 Lack of Effective Accreditation Process

ELAP has lost the ability to effectively evaluate the quality and competency of laboratories, which jeopardizes the validity of data produced by accredited laboratories and creates the perception of a lower level of confidence in data used to make decisions regarding human health and the environment. This results from (1) poorly defined assessment standards, (2) assessing for outdated methods, and (3) inadequate staff qualifications.

2.2.1 Poorly Defined Assessment Standards

ELAP does not have a systematic approach for determining the competency of a laboratory that is seeking or maintaining accreditation. The assessment and accreditation processes are not properly defined and disseminated to the assessors, resulting in problems with assessor competency and inconsistency among the parameters by which laboratories are assessed.

Moreover, ELAP does not address quality management in its assessing practices. The lack of a systematic process for quality assurance absolves the laboratory’s management of responsibility for ensuring data quality, while placing the entire burden on the bench analysts. Part of this problem is due to the fact that ELAP lacks current assessment standards. For example, ELAP’s enabling statute for NELAP accreditation specifies the November 1998 version of the NELAC standards, which were never adopted by NELAC itself nor used by NELAP accreditation bodies. The current NELAP standard employed by NELAP-recognized states is the 2009 version, which contains numerous updates and specification changes from previous editions.
ELAP lacks a systematic process for reviewing PT samples results, which laboratories are required to submit annually. These data are not regularly reviewed for compliance by ELAP staff as part of the assessment process. Reviews of corrective actions for failed PTs performed by the laboratory are also not evaluated by ELAP staff during on-site assessments. Laboratory suspension of accreditation for continued PT failures is sporadic to nonexistent. Staff performs PT evaluations manually, which is an inefficient process compared to the utilization of computer software solutions.

2.2.2 Assessing to Outdated Methods
ELAP’s assessment processes are woefully out of date, referencing analytical methods and quality specifications that have since been replaced. States typically adopt laboratory methods that are promulgated by the U.S. Environmental Protection Agency, which advances consistency among states. However, in California’s case, those methods were incorporated into regulation (Title 22 Division 4 Chapter 9 Article 6 – Section 64811 of the California Code of Regulations). As a result, these methods have not been updated since the article’s inception in 1994. Although the State ostensibly permits the use of alternate test methods, the State does not specify a defined procedure for approving new methods, nor an approach for laboratories to receive accreditation with them.

The State law does not make clear whether ELAP is legally permitted to accredit a laboratory for analytes that do not appear in either an approved method or in California regulations. There are no defined procedures to obtain accreditation for parameters not listed under an ELAP FOT. This is needed by laboratories that have a regulatory or client requirement to report data for non-standard contaminants. This further complicates accreditation assessments, and often forces laboratories to obtain this recognition from another accreditation body at a significant additional expense.

2.2.3 Inadequate Staff Qualifications
The Panel had the opportunity to interview multiple ELAP staff members. The Panel found several exceptional staff members, but also encountered several staff members who lack the necessary training to perform laboratory assessments and other aspects of the job, including customer service. Unfortunately, the inadequacies of those staff are known to their peers, which lessens morale among the highly committed employees. The result is a subjective, inconsistent accreditation process that varies significantly among assessors and between assessments. There is also an absence of trained, skilled staff in some technical areas for which laboratories are required to hold accreditation to produce regulatory data in California. In some cases, ELAP cannot even accredit commonly used technologies or FOTs, affecting the sustainability of the program and placing an additional accreditation burden on affected laboratories.

2.3 Absence of Routine Management Processes
ELAP management prior to the program’s transfer to the State Board was ineffective. Panel interviews with current management and staff indicated that past management did not define employee expectations or adequately assess their performance. Previous management also did not use metrics to assess the performance of the program as a whole. Consequently, ELAP
management did not have a process for verifying whether laboratory assessments were being performed correctly, was indifferent to known operational problems, and was unresponsive to client complaints.

These shortcomings fostered a work environment plagued by a lack of understanding of staff responsibilities and program direction. Some employees were operating with their own agenda and without accountability to superiors.

2.4 Inadequate Resources

Staff resources are inadequate to meet minimum accreditation requirements or timeliness. Many drinking water laboratories have not been assessed on site in five years or more, exceeding the U.S. Environmental Protection Agency requirement of at least once every three years. Assessors have an excessive backlog of unprocessed laboratory assessments, exacerbating the on-site assessment backlog. The result is an inability to verify competency of the laboratories producing data for acceptable drinking water quality and other key areas.

2.4.1 Staffing Resources

ELAP accredits the largest number of laboratories of any state program in the nation, but it does not have the capacity to fulfill its mission, as evidenced by the backlog of assessments. While the size of ELAP’s staff may appear adequate, many ELAP staff members lack the qualifications and expertise necessary to perform on-site laboratory assessments. ELAP has 25 employees, a staffing level that should be sufficient for a state the size of California. However, only seven of these employees are presently conducting assessments, about half the number needed to fulfill the program’s workload. This deficiency is more than a staffing allocation issue, and reflects the lack of a well-defined management system with performance criteria to which staff and management are held accountable.

2.4.2 Financial Resources

ELAP is required to run a self-sustaining program. Despite collecting fees that are among the highest in the nation, ELAP is operating at a loss and relying on general fund subsidies to continue operations. Last year, operation of the program cost $3.3 million, and fees generated only $1.9 million. The laboratory community also expressed concerns that the ELAP fee structure is inequitable, demonstrating a financial bias toward specific groups. This issue is likely to become more antagonistic as essential systems are added to the program, necessitating further fee increases due to higher operating costs.
CHAPTER 3: SOLUTIONS

Although ELAP continues to face a number of challenges (see Chapter 2), the Panel believes ELAP can be reestablished as a respected, financially solvent entity by implementing the reforms recommended in this chapter. These recommendations, which are divided into five main categories, build upon program improvements made by ELAP staff over the past few months, including enhancing ELAP’s transparency, communication, and sense of mission and purpose.

Since ELAP’s reconstitution under the State Board, ELAP management has demonstrated a renewed commitment to correcting the shortcomings of the past and developing a vision focused on its future. For ELAP and the stakeholder community to achieve their mutual goals, all parties should focus on ELAP’s vision for the future, rather than dwelling on its past. Simultaneously, each party should hold all others accountable for their respective responsibilities under the revitalized accreditation program.

3.1 Establish a Management System

ELAP should immediately work to establish a management system built around performance criteria under which both the management and staff can be trained and held accountable. To avoid the time and resource investments of developing a complex new standard, the Panel recommends ELAP adopt an already established standard (see Section 3.2) covering multiple aspects of accreditation body operations.

3.1.1 Issue

Lack of a robust, comprehensive internal management system for conducting operational functions is at the root of several chronic problems identified by the Panel and stakeholders. This shortcoming has resulted in a workplace environment characterized by widespread lack of understanding of staff responsibilities and program direction. ELAP management needs processes in place to verify whether laboratory assessments are being performed effectively, to respond to operational problems, and to address client complaints. ELAP also needs to more clearly define employee expectations, metrics for assessing these expectations, and metrics for assessing program performance as a whole.

3.1.2 Recommendation

To establish its management system, ELAP should adopt one of two widely respected standards:

- **Option 1:** *Conformity Assessment: General Requirements for Accreditation Bodies* 
  Accreditng Conformity Assessment Bodies, 2004-09-01, by the International Organization for Standardization (ISO)/International Electro-technical Commission (IEC) 17011. This ISO/IEC standard is generally applicable to a variety of situations. In this case, the term “conformity assessment bodies” refers to laboratories.

- **Option 2:** Volume 2 of *General Requirements for Accreditation Bodies (ABs) Accrediting Environmental Laboratories*, EL-V2-2009, published by The NELAC Institute (TNI). This standard is based on the ISO/IEC 17011:2004 with added detail for state agency environmental laboratory accreditation programs, particularly for enforcement actions under legal requirements.
Regardless of which standard is adopted, the Panel recommends ELAP’s management structure contain at minimum two elements: (1) operational processes to carry out ELAP’s functions and (2) internal reviews to assess performance. Additional details about development of a management standard are provided in Appendix E.

3.1.2.1 Operational Processes
ELAP management should clearly define the procedures that staff are expected to carry out, convey this to the staff, and use these definitions to assign appropriate training. The procedures should be defined for each operational function. For example, they could encompass: (1) applications for accreditation, including gathering required information, the application review process, and maintenance of records; (2) assignment of the laboratory assessment team, preparation, and schedule; and (3) laboratory assessment reports that describe the evidence for a decision. More specific operation process items that should be included in the management system are outlined below.

Document control: ELAP should develop guidelines and, if necessary, obtain tools for document control, an area that should encompass version control, quality system documentation, and forms for distribution. To ensure the proper document is being used for a given task and to safeguard confidential documents, there should be a control element that includes steps such as requiring an approval date, a change control number, and/or a version number. Additionally, ELAP should expand the number of documents outlining key procedures, such as assessment, corrective action review, and generating assessment reports.

Record-keeping: ELAP should establish a procedure for maintenance of records. Records being produced include application submissions, PT results from laboratories, accreditation certificates, records of actions taken, and staff training records. By developing processes to document and maintain records, and by training staff to use these processes, laboratory services will be improved. For example, the loss of application documents and the time needed to deliver assessment reports to the laboratories will be minimized. These processes also should serve as an objective method that ELAP management can use to assess staff and manage staff performance.

Quality system: Because a basic template for a quality system is recommended for every laboratory, ELAP should develop a management quality system that contains the same basic components that California laboratories use in their quality systems, ensuring ELAP assessors work within a system similar to that of the laboratories they accredit. When assessors are trained to this system, they will develop a better understanding of quality processes.

Proficiency testing: Although proficiency testing is only one component of an accreditation program, it is critical for the accreditation body to review PTs at regular intervals. ELAP requires one PT per year, but does not effectively use the results in its evaluation process. ELAP should focus on making better use of the PT results. Under ISO 17011, PTs are required, but the AB can set the frequency. Under the TNI standard, two PTs are required each year from a TNI-accredited provider, one in each half of the year. Because ELAP should focus on more effectively using its existing PT results, the Panel does not recommend requiring a second PT annually at this time.
Enforcement: The Panel heard testimony that ELAP either lacks the ability or the will to conduct enforcement activities when warranted. ELAP should work closely with the State Board’s Office of Enforcement to develop a unit of ELAP staff that focuses on developing enforcement procedures, reviewing laboratory data for irregularities, and issuing enforcement actions when there are violations of ELAP regulations. Although there will be cases in which decisive enforcement action is prudent, ELAP should view its primary goal as achieving compliance, with legal action against a laboratory’s accreditation used as a last resort. While enforcement is a necessary function of accreditation bodies (enforcement is recognized in ISO 17011, Section 7.13), enforcement in and of itself should not be the main goal. ELAP should focus on defining a clear pathway for progressive compliance, a documented process that ELAP presently lacks. ELAP also should establish procedures for addressing nonconformities identified in laboratories and for documenting corrective actions with root causes.

Complaints: ELAP should have a documented process for addressing complaints from laboratories about ELAP, as well as complaints about the laboratories. It also should include procedures for corrective actions, and systems to evaluate the effectiveness of those actions.

3.1.2.2 Internal Reviews
Internal audits: ELAP should establish periodic internal audits that verify the program adheres to the adopted standard (e.g., ISO/IEC 17011). These audits should be performed by ELAP staff who are qualified to do so and who are not assigned to the audited activity. ELAP should have a quality assurance manager who oversees the quality systems of the program, including the internal audits. During the audit process, the performance of all individual staff should be assessed according to their assigned responsibilities. In particular, assessor performance should be periodically evaluated through direct monitoring of the assessor’s laboratory assessment work. Management should inform staff of the outcomes of the internal assessments and engage the staff in identifying opportunities for improvement.

Full programmatic review: Separate from the internal audit, ELAP should establish a process for a periodic programmatic review. Whereas the internal audit should assess conformance to the adopted standard only, the programmatic review should be more comprehensive and forward-looking. ELAP management should assess information from a variety of internal and external sources, including stakeholder feedback, complaints received by the program, a review of potential new areas of accreditation, and status and trends of performance metrics for ELAP functions. These results should be used to determine if budget, resource allocation, internal policies, and program objectives are optimal and, if not, how they can be improved. In particular, the review should demonstrate that ELAP has an adequate number of competent personnel with skill sets necessary to carry out each programmatic function. Typically, these reviews should occur once per year and result in an annual plan for the coming year. Upon completion, the review would serve as the basis for an improvement plan to be executed by management.

3.2 Adopt Laboratory Accreditation Standards
ELAP should adopt an existing standard for conducting laboratory accreditations as an immediate remedy, and look to modify an accreditation standard in the future to more effectively meet State-specific needs.
3.2.1 Issue
Accreditation bodies need accreditation standards that are clearly written, auditable, enforceable and, perhaps most importantly, relevant to the intended use of the data. As stated in Section 2.2.1, the assessment and accreditation process are not properly defined and disseminated to the assessors, resulting in problems with assessor competency and inconsistency among the parameters by which laboratories are assessed.

3.2.2 Recommendation
ELAP should implement a clear standard to which it accredits laboratories, and it should implement this standard as soon as possible because it is a foundation of many of the other Panel recommendations. The Panel envisions three possible routes the State could take to achieve this: (1) Create ELAP’s own State-specific standard, (2) modify and adopt an existing standard, or (3) adopt an existing standard.

Option 1: ELAP-created standard
The major benefit of creating a State-specific standard is that it would ensure that the resulting laboratory requirements meet program and client needs. This effort will allow the State to include only those requirements it considers important for laboratory performance. Major drawbacks are the difficulty, cost, and time associated with writing an original document. Additionally, this option would require the State to develop training protocols for ELAP assessors, and provide resources to communicate the new requirements to the laboratories. These drawbacks make selecting this option time- and cost-prohibitive.

Option 2: Modification of an existing standard
The major benefit of modifying an existing standard is that it would save time and resources compared to the development of a State-specific standard. The major drawback is that the savings of time and resources might be relatively small in comparison to Option 1. The Panel heard testimony at its August 2015 meeting about an effort by the State of Wisconsin to modify an existing standard. The Panel learned that reaching consensus on the modifications to the standard and the adoption process took an extensive amount of time and, in the end, resulted in an imperfect standard. This, in effect, isolated Wisconsin’s laboratory program, which is not recognized by other states, adding costs and placing restrictions on Wisconsin laboratories conducting business across state lines. Because California’s laboratory community is much larger than Wisconsin’s, the Panel believes that the timeframe for development and adoption of a modified standard would be more protracted than Wisconsin’s timeframe. From the information presented, it became clear to the Panel that this option is not practical for ELAP in the immediate future.

Option 3: Adopt an existing standard
The major benefit of adopting an existing standard is that the time and resources needed to implement it will be greatly reduced. The major drawback is the lack of ability to customize it to meet State-specific needs. Thus, it would be critical to select the correct standard. The State would need to ensure that the standard it selects meets its clients’ requirements and contains proper resources for both assessors and laboratories to ensure a smooth, consistent implementation.
Analysis: The Panel devoted considerable time to examining the type of standard ELAP should utilize, and recommends that the State adopt an existing standard as an immediate remedy. The Panel is aware of a number of state, national, and international laboratory standards that could meet the State’s needs, but recommends the standard developed by TNI as the most viable one for the State in the short term. The TNI standard is a standard the State has used to some degree previously, albeit not for all laboratories. Adopting a standard that has been implemented as broadly as the TNI standard would allow the State to take advantage of a wealth of available resources and support. Regardless of what existing standard is adopted in the short term, the State should look over the long-term to modify the existing standard to maximize the standard’s applicability to the State’s needs.

While the Panel heard dissenting opinions on the issue of quality management requirements, the Panel feels strongly that the State should implement a single standard that incorporates quality management requirements, as the TNI standard does. Because all data produced for regulatory environmental purposes and environmental decision-making are produced for the same broad purpose, a single standard that provides for equal levels of quality regardless of laboratory size is optimal. The Panel received comments indicating that adoption of a standard that incorporates a quality system approach would be overly burdensome for at least some small laboratories; this, however, was refuted by feedback presented during the Panel’s June 2015 webinar.

Regardless of the option chosen, the transition will take time, and ELAP should provide effective outreach, compliance assistance, and education to all stakeholders. ELAP also should integrate into its communication strategy a suite of tools that meets the diverse needs of the laboratories (e.g., small, medium, large) and decision-makers that ELAP serves. Just as some standards come with programs that offer resources to help with this process, ELAP should ensure it communicates the availability of its tools to all stakeholders and takes advantage of additional opportunities to simplify the transition for everyone, including via workshops, videos/films, webinars, training, and speaking engagements at conferences or symposiums.

3.3 Ensure Relevant Analytical Methods
ELAP should update the list of analytical methods it uses to conduct assessments to ensure the most relevant methods are used, and State regulations should be altered to remove references to specific methods, which will give ELAP more flexibility in updating its methods.

3.3.1 Issue
The list of analytical methods for which ELAP accredits is outdated. The analytical methods were incorporated into Title 22 Division 2 Chapter 9 Article 6 – Section 64811 of the California Code of Regulations, which have not been updated since 1994. State law appears to permit the use of alternate test methods, but the State lacks a defined procedure for approving new methods. Moreover, there is no defined procedure to obtain accreditation for parameters not listed under an ELAP FOT. As such, ELAP is not accrediting laboratories for the methods that ELAP, its clients, and regulatory authorities need and in some cases require (e.g., 40 CFR Part 136 for Waste Water Analysis) to adequately protect California’s health and environment.

3.3.2 Recommendation
**Ideal solution**: The simplest solution is to eliminate references to specific analytical methods in the regulations, allowing ELAP the flexibility necessary to accredit laboratories according to the methods that ELAP, its clients, and regulatory authorities need to adequately protect California’s health and environment. Other states (e.g., Florida) have successfully used this tactic to great advantage. If California’s Article 6 is not repealed, then it should be rewritten. The Panel believes that the intent of the ELAP’s enabling legislation may have been to provide for increased flexibility with analytical methods. The enabling legislation in the Health and Safety Government Code suggests that “performance based measurement system methods” are allowable and needed, which seems to indicate that the legislative intent was for ELAP to have the ability to accredit laboratories comprehensively – and perhaps even to accredit to methods yet to be contemplated. However, this interpretation has not been subjected to review by State legal counsel.

**Short-term solution**: Recognizing that the process of changing State regulations is arduous and time-consuming, the Panel looked for possible short-term alternatives within the context of the current rules. The Panel’s position is that the language of Subsections (f), (g), and (h) of Title 22 Division 2 Chapter 9 Article 6 – Section 64811 enables ELAP to use alternate methods as ELAP deems appropriate. Each of these three subsections opens with, “Laboratories may substitute alternate test methods for those allowed,” and then specifies how to obtain approval from ELAP to use these alternate methods. Because it is of mutual benefit to both ELAP and the laboratories to use newer analytical methods, ELAP should compile and publish a comprehensive list of all approved methods, and allow laboratories to seek accreditation via every method. ELAP should actively involve its regulatory program clients in the development of this list, and then widely advertise it and the new process to the laboratory community. To emphasize ELAP’s commitment to accreditation via this list, ELAP should establish a streamlined process by which laboratories can apply for and receive accreditation in an expedited fashion.

Simultaneously, ELAP should seek out advice and assistance from ELTAC as it begins training its own staff in the evaluation of these methods. ELAP’s assessors will need to be competent in a wide array of technologies. At a minimum, each assessor will need to have a fundamental understanding of the scientific disciplines and techniques under his/her purview, such that the assessor can competently assess a laboratory according to various methods and laboratories’ Standard Operating Procedures (SOPs). No single assessor needs to be an expert in all possible methods, but all assessors should have the requisite education and skills to adequately evaluate whether a laboratory is following the proper protocols. To ensure standardization and consistency, ELAP should develop standardized, thoroughly peer-reviewed checklists.

**Fall-back solution**: If it is not possible for ELAP to expand and/or modify the rigid, prescriptive language that characterizes its test methods, then ELAP should act with great speed in updating its permissible methods with the most current versions.

### 3.4 Expand Resources

ELAP should expand the resources at its disposal through: (1) additional investment in staff development to increase productivity, (2) a revised fee structure that allows ELAP to fully recover its costs, and (3) incorporation of commercial third-party assessors and the acceptance of qualifying laboratory accreditations from other states into ELAP’s accreditation process.
3.4.1 Issue
ELAP’s staff members are unqualified to meet the demands of their accreditation program. While the size of ELAP’s staff may appear adequate, many ELAP staff members lack the qualifications and expertise necessary to perform on-site laboratory assessments. These staffing limitations stem from a lack of training and insufficient management accountability for personnel performance. Even as ELAP brings new staff on board, these staff members cannot make up for the lack of qualifications and expertise of existing staff. These staffing challenges have led to inconsistent assessments, which pose a significant ongoing issue for laboratories, as well as a backlog that prevents the program from meeting the needs of its stakeholders.

ELAP’s financial constraints also remain an ongoing challenge for the program. ELAP’s inadequate fee structure was exacerbated by the program’s withdrawal from NELAP, as ELAP is no longer able to collect fees for NELAP accreditations. Simultaneously, ELAP has been filling previously vacant positions to meet programmatic needs, further compounding its funding imbalance.

3.4.2 Recommendation
3.4.2.1 Additional Investment in Staff Development
Given that ELAP has an established staff, with minimal opportunity for staff expansion, ELAP should work to enhance productivity of existing staff to resolve the persistent programmatic backlog. The Panel recommends the following three approaches to increasing productivity of ELAP’s existing staff: (1) Enhance training, particularly for assessors, (2) establish performance criteria to hold staff accountable, and (3) develop electronic support measures. Each of these approaches is described in more detail below.

3.4.2.1.1 Enhance training
Assessor training should be based on both quality system requirements and technical methods. Because the current regulations are not definitive with respect to quality systems, the Panel recommends using either ISO 17025 or TNI 2009 – the two most common quality system-based standards – to improve assessor training.

All ELAP assessors should be trained to assess quality systems. They should be trained to review the quality manual, to conduct staff interviews, and to recognize behaviors that are acceptable vs. those that are unacceptable. Standard assessor training also should teach the assessor how to deal with difficult laboratory employees and how to obtain information without coming across as judgmental and arrogant. The training should include preparing for the assessment, in-briefing, debriefing, and how to write up deficiencies.

The second part of assessor training – how to assess technical methods – should start with a classroom-based component: SOP review, data review, interviewing analysts, and how to write deficiencies. It should focus on showing staff how to compare laboratory SOPs to the published methods, and how to develop questions to ask the laboratory based on the provided technical SOPs and the data.
Following the classroom portion of technical assessor training, the trainee should shadow an experienced assessor who is performing the assessment, and then perform a part of the assessment with the experienced assessor observing. ELAP could ask some of the State laboratories to use their facilities and staff as practice locations for assessor training. The experienced assessor should mentor and train the trainee. Documentation of this experience should be kept to show that the person is trained. ELAP management should require this oversight training on a regular basis (Note: ISO 17011 recommends this training be conducted every three years). If performance is inadequate and feedback from the laboratories is negative, more frequent oversight training should be done.

3.4.2.1.2 Establish performance criteria
Training is a first step, but it should be coupled with performance criteria to ensure staff accountability. As indicated in Section 3.1.2.2, ELAP should conduct periodic reviews of its staff relative to these performance criteria and then take personnel actions for staff who are not achieving the required level of performance. For the management team, ELAP should seek out performance management training to better understand how to set goals, document performance issues, and outline improvement processes.

3.4.2.1.3 Add electronic support measures
Proficiency testing database: ELAP manages data for laboratory PT studies manually, which is inefficient and may be one of the reasons that PT sample data have not been incorporated into the routine accreditation process. ELAP should acquire a commercially available database to manage all of its PT data and train ELAP staff on its use.

Remote, augmented, or distance on-site assessments: To manage the geographical expanse of the program and more efficiently utilize resources, ELAP should embrace remote, augmented, or distance technologies to conduct on-site assessments. With the right combination of technology – laptop computers with cameras and Wi-Fi access plus the appropriate software – an assessment could either be partly or completely conducted from a remote location, which could increase efficiency and lower costs. For example, instead of relying on a single assessor who travels to the site and then fails to consider FOTs or methods beyond his or her areas of expertise, a team of assessors with all the expertise necessary could participate in an assessment with just one member of the team physically on site. Although this approach comes with inherent risks because remote assessors cannot see what is being hidden or not shown, this approach also engenders mutual trust, as each laboratory must attest to the assessor that all relevant information has been disclosed. The Panel does not endorse this strategy as a solution for every review and every laboratory, but it should be treated as a viable option.

3.4.2.2 Revise the ELAP Fee Structure
ELAP is required to operate a fully fee-supported program. Although ELAP fees are among the highest in the nation, ELAP is operating at a loss and relying on general fund subsidies to continue operations. The laboratory community conveyed to the Panel that the fee structure is inequitable, demonstrating a financial bias toward certain groups.

The Panel recommends that ELAP develop a new fee structure that improves fairness of the cost burden. ELAP has already taken an initial step toward acquiring legislative authority to increase
fees, but the fee structure remains undetermined. The Panel realizes that any change to the fee structure will be controversial because the laboratories that ELAP accredits vary widely in the number of accredited FOTs, in addition to being of varying sizes and financial resources. To mitigate these concerns, ELAP should seek stakeholder input on options for the new fee structure as part of the process of rewriting its regulations. While fees are likely to rise, the Panel believes the laboratories will realize increased value from their fees as the accreditation process improves. ELAP should consider a fee structure based on three functions: assessment, accreditation maintenance (e.g., PT evaluation, application processing, adding scope without assessment), and compliance assessments for significant issues or cause.

3.4.2.3 Incorporate Third-Party Assessors and Submission of Accreditation from Qualifying ABs

While there is a need for ELAP to provide its staff with training and resources to enhance staff productivity, the Panel acknowledges that improving staff proficiency is a gradual process. Thus, to immediately expand the resources at its disposal, ELAP should consider several approaches to link to external programs as a way of expanding its resources.

First, ELAP should consider temporarily accepting accreditation from laboratories that are accredited by other States with acceptable accreditation programs. ELAP’s backlog is unacceptable, and the program does not have enough qualified staff to resolve the backlog on its own. Accepting accreditation from other recognized accreditation bodies will allow staff members to prioritize their efforts on those labs most in need of examination. The program has already begun to implement this option.

Recognition of other State programs will not relieve ELAP of the responsibility of registering these laboratories, granting them an accreditation license for specified FOTs, or addressing irregularities identified by the program clients or in the evaluation of PT samples. However, it would ease the resource burden on ELAP staff and expand the staff’s access to accreditation resources.

Second, ELAP should consider authorizing laboratories to directly employ third-party assessors to assess its laboratories. This includes either qualified individual assessors or internationally recognized third-party ABs. Commercial ABs that operate under ISO 17011 are routinely evaluated to assure compliance with this standard. Third parties have been shown to be technically competent and operate with a high degree of bias-free professionalism. Permitting the use of third-party assessors also would provide an opportunity for the State to reduce assessment and accreditation expenses by allowing laboratories to contract with third-party ABs directly. The Panel understands that the use of third-party assessors may not be suitable for all laboratories, but allowing this option will provide viable alternatives for some laboratories. Under this approach, it is recommended that the State collect a licensing fee from laboratories that use a third-party assessor, offering a reasonable credit to laboratories choosing this option. This approach would mitigate the revenue losses to ELAP from allowing laboratories to retain third-party assessors, while simultaneously contributing to a reduction in ELAP program workload.
The use of qualified third-party assessors would be beneficial because it would supplement staff resources for resolving the assessment backlog, and present an alternative opportunity for laboratories unhappy with the professionalism and quality of ELAP assessors. Although use of third-party assessors is an expense for laboratories, some of them already employ assessors to obtain accreditation in other states that do not recognize California’s process as equivalent to their own; hence, the additional expense for these labs would be relatively small. Note that this recommendation can only be implemented if the third-party AB is proficient in the standard that will be used for the assessment, and if ELAP has adopted an accreditation standard as identified in Section 3.2. Because a number of third-party assessors are already operating under the TNI standard, this would be another advantage of ELAP adopting the TNI standard.

Third, the State should consider adopting as a permanent program feature the interim solutions of recognizing third-party AB laboratory accreditation and recognizing other qualifying ABs. Because ELAP would be gaining experience in the short term with using third-party ABs and with recognizing other states’ programs, the outcomes from these activities could inform whether making this feature a permanent program component is appropriate.

### 3.5 Enhance Communication

ELAP should develop a robust, comprehensive communications plan that requires staff to undergo communication training and codifies expectations into a management system. Also, ELAP should also reinvigorate ELTAC, which serves as a vital conduit by which the laboratory community can improve ELAP’s programmatic foundation.

#### 3.5.1 Issue

ELAP has not been effective in serving its clients because of poor staff communication and outreach to stakeholders. The communications-related complaints that ELAP has received include chronically failing to respond to phone inquiries, late responses on reports, and lack of responsiveness to suggestions from ELTAC. This communications breakdown has led to frustration and has cost the program credibility among its many constituents.

#### 3.5.2 Recommendation

To ensure ELAP is communicating effectively with its clients, ELAP should develop a communications plan. At minimum, this plan should be targeted at three groups: ELAP staff, the laboratories the ELAP accredits, and clients of the program.

#### 3.5.2.1 ELAP Staff Communication

Developing a communications plan should be initiated by codifying expectations for staff communication into a management system (see Section 3.1), ensuring every staff member is held accountable for proper communication procedures and etiquette. Once the communications plan is developed, all ELAP staff should undergo communication training. The communications training should stress policies regarding how to answer phone calls and emails in a polite manner, as well as ensuring consistently prompt responses to laboratories and clients.
3.5.2.2 Laboratory Communication

The communications plan should create a means for ELAP to inform and engage the laboratory community. The program is expected to undergo considerable change over the next several years, so it is important that laboratories be fully informed of programmatic changes before they occur. ELAP should provide effective outreach, compliance assistance, and education that meet diverse laboratory (e.g., small, medium, large) needs. ELAP should ensure it communicates the availability of its programmatic tools and takes advantage of other opportunities for engagement, such as workshops, videos/films, webinars, and speaking engagements at conferences or symposiums. Going forward, communication should be viewed by ELAP and other parties as a two-way street, and past communications breakdowns should not be allowed to stand in the way of productive dialogue going forward.

A significant part of enhancing communication should involve training laboratories on any new requirements established by ELAP. This training could be done in person or via webinar; it should be designed around helping laboratories understand and implement key processes, such as quality systems and application completion. ELAP should become a partner in helping laboratories achieve all new requirements created by the program.

Another significant part of enhancing communication with laboratories is to reinvigorate ELTAC. Doing so will provide a valuable feedback loop by which ELAP is able to weigh and receive feedback on future program alterations. The Panel is impressed by the level of involvement the greater laboratory community is willing to offer to help the program; the problem is that there is not yet an effective ELTAC through which this community can offer its support.

Reenergizing ELTAC will require creating a new ELTAC Charter that defines its membership, the kinds of tasks that will be assigned to ELTAC and, most importantly, the mechanism by which the ELAP management team adopts and/or responds to information provided by ELTAC. ELAP has already initiated this recommendation by working with the Stakeholder Advisory Committee to revise the ELTAC by-laws in a way that is likely to increase effectiveness of this advisory body. ELTAC’s membership should continue to be predominantly laboratories, with some representation by the State agencies using ELAP.

As ELAP is developing the ELTAC Charter, the program should consider the following technical tasks as a starting point for ELTAC. Each of these tasks is important in helping to foster cross-communication with ELTAC and providing training opportunities to newly hired ELAP assessors.

- Instruct ELTAC to review the technical checklists developed and used by ELAP, and merge ELAP and ELTAC checklists to one per method or technology.
- When conducting assessor training, instruct ELTAC labs to allow practice assessments at a few of the laboratories, with no regulatory penalty associated with findings uncovered by the practice assessments.
- Allow new assessors to visit some of the ELTAC laboratories to learn about technologies that these assessors have not previously assessed. This will allow the new assessors to gain firsthand instruction on how the process is supposed to work.
3.5.2.3 Communication with Program Clients
Communication with data users is key, as the data generated by accredited laboratories are used by these clients to make regulatory decisions. During the Panel’s meetings with representatives from several client organizations (see the August 2015 meeting agenda in Appendix D), the Panel noted that all of these clients seemed eager to engage with and assist ELAP. In particular, these clients expressed an interest in helping ELAP specify data needs, develop quality control, and implement performance-based methods. They also noted that implementing a process for accrediting performance-based methods would be helpful to them. ELAP should build off these initial positive interactions by establishing a regular forum for interacting with these groups.
CHAPTER 4: TIMELINE FOR ACTION

The recommendations made in the previous chapter have varying degrees of urgency, difficulty, and time required for completion to improve the performance and reputation of ELAP. This chapter presents a suggested timeline to assist ELAP in organizing and prioritizing its efforts to implement the Panel’s recommendations. The timeline for completion of each recommendation also is presented as a chart (Table 2). In particular, this chapter addresses Charge Question #8: “Which program improvements are most urgent and can be accomplished within existing resources and authorities?”

For each recommendation, the completion date listed refers to the amount of time following finalization of this report. Additionally, each timeline rationale indicates whether a recommendation cannot be initiated pending the completion of another. It should be noted that ELAP has already begun addressing some of these recommendations, based on verbal reports provided at the Panel’s March 2015 and August 2015 meetings. The Panel applauds ELAP for its initiative and early successes, and has noted in the sections below where progress has already been made.

The Panel’s second and final report, which will be produced after the Panel returns in 2016 to gauge ELAP’s progress, is expected to include additional recommendations intended to help elevate the program from adequate to exemplary. However, the Panel has not yet focused on developing these recommendations because the program first requires immediate attention to achieve adequacy. The Panel will place effort on these remaining recommendations when it has determined sufficient progress has been made on items critical to ELAP’s success.

4.1 Establish a management system for ELAP based on ISO/IEC 17011

**Timeline rationale:** ELAP should establish standards of operation for itself. ELAP’s own internal procedures should define and achieve a minimum level of performance prior to implementation of recommendations that involve client and laboratory interaction.

**Completion:** Within six months.

4.1.1 Establish an internal ELAP auditing process

**Timeline rationale:** Once fully implemented, ELAP’s management system should be regularly reviewed to ensure that the standard procedures are followed and that corrective action is implemented for deficiencies identified in the review.

**Completion:** Within two years.

4.2 Adopt accreditation standards for laboratories

**Timeline rationale:** Defined and technically appropriate assessment standards will help address many program inconsistencies, as well as form the foundation for assessor training and use of third-party assessors.

**Completion:** Within one year. The Panel would prefer to see this action completed sooner, but recognizes this is a challenging item that will require community involvement and potential State Board and/or legislative action.
4.2.1 Establish a training and evaluation program for ELAP’s assessors

**Timeline rationale:** This recommendation will address the concern that not all assessors are equally trained or adequately qualified. This recommendation should be implemented after the accreditation standard is adopted, so that assessors can be trained against the established standard.

**Completion:** Within one year.

4.2.2 Reduce the assessor backlog by developing a program that utilizes third-party assessors

**Timeline rationale:** This recommendation will optimize efficiency of the assessment process, but cannot be implemented until ELAP has adopted a laboratory accreditation standard and third-party assessors can utilize the established standard.

**Completion:** Within one year.

4.3 Implement a structured system for communicating with stakeholders, including communications training for staff

**Timeline rationale:** ELAP will be undertaking many changes over the next year and should be keeping the community informed of those changes. The program also should have a mechanism for determining the effectiveness of the actions being taken.

**Completion:** Within three months. ELAP has already initiated this recommendation by developing a system for communicating with stakeholders. ELAP is seeking community feedback on this system as of the publication of this report. Communications training for staff remains to be implemented.

4.3.1 Reinvigorate ELTAC

**Timeline rationale:** ELTAC is an essential part of the ELAP’s communication strategy, and can help the program decide on and implement the many changes that will take place over the next several years.

**Completion:** Within three months. ELAP has already initiated this recommendation by working with the Stakeholder Advisory Committee to revise the ELTAC by-laws in a manner that is likely to increase the effectiveness of this advisory body. The composition of ELTAC membership and the tasks that will be assigned to ELTAC have not been determined as of the publication of this report; however, these decisions are scheduled to be made by the end of 2015.

4.3.2 Working with ELTAC, revise method checklists so that all assessors are using the same version

**Timeline rationale:** Once ELTAC is reinvigorated (see Section 4.3.1), ELTAC should vet the checklists assembled by ELAP for correctness.

**Completion:** Within six months. ELAP has already revised the method checklists to create a single set. Vetting these checklists with ELTAC remains to be completed.

4.3.3 Training laboratories in the new ELAP standards

**Timeline rationale:** Once the new ELAP standards are in place (see Section 4.2), ELAP should provide training and document templates to the laboratories.

**Completion:** Within six months of completion of the new standards.
4.4 Accept accreditation from other recognized accreditation bodies

Timeline rationale: The Panel recognizes that the program backlog is unacceptable and that the program does not have enough staff to resolve the backlog on its own. Accepting accreditation from other recognized accreditation bodies will allow ELAP staff to focus efforts on reviewing laboratories most in need of examination.

Completion: The program has already acted on this suggestion and has been successful in reducing the State’s backlog. Completion of this recommendation is now dependent on the State documenting this process to ensure consistency and transparency associated with recognition by other programs.

4.4.1 Assess whether the short-term solution of recognizing laboratory accreditation from other programs to reduce backlog should be extended as a permanent program feature

Timeline Rationale: Once ELAP has experience with this short-term solution, it should assess the outcomes and determine if making external accreditation a permanent program component is appropriate and, if so, in what form.

Completion: Within three years.

4.5 Establish procedures for enforcement actions

Timeline rationale: Enforcement requires a clear understanding and documentation of a laboratory’s compliance status. Development of the procedures should take place following establishment of ELAP’s management system (especially for document control), staff training, and accreditation standards. Therefore, this recommendation should not be implemented until completion of the related timeline items of establishing a management system for ELAP (see Section 4.1) and adopting accreditation standards for laboratories (see Section 4.2).

Completion: Within one year.

4.6 Ensure accreditation is based on current and relevant analytical methods

Timeline rationale: ELAP is using out-of-date methods to assess laboratories, based on a constrained statutory interpretation. This interpretation should either be broadened or the statute should be repealed/modified. This recommendation can be initiated independent of the others outlined in this chapter.

Completion: Broaden interpretation within one year and repeal/modification within two years.

4.7 Further reduce assessor backlog by (a) using commercial software for managing PT data, and (b) investigating mechanisms for remote laboratory assessments

Timeline rationale: These recommendations have the potential to further optimize efficiency of the assessment process. These recommendations can be initiated independent of the others outlined in this chapter.

Completion: Within one year.
4.8 Revise ELAP fee structure

**Timeline rationale:** The program is not financially self-supporting as required by its enabling legislation. The State Board has provided supplemental resources temporarily as it looks to refine a troubled program, but an equitable new fee structure that allows the program to be self-sufficient should be developed. This recommendation can be initiated independent of the others outlined in this chapter.

**Completion:** Within one year, although this may be iterative because it will require considerable community involvement, as fee hikes are likely to be substantial.

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APPENDIX A: PANEL’S RESPONSE TO CHARGE QUESTIONS

1. What should the State's role be in the accreditation process?
ELAP is required to accredit laboratories within the State under the Safe Drinking Water Act to verify their competency for the analysis of drinking water. The certification requirement has been extended to laboratories producing data for use by other environmental programs within the State under the California Environmental Laboratory Improvement Act.

The certification process includes four sets of activities: (1) An application process where essential information regarding laboratory operations and management is provided to the State for review, (2) an on-site assessment to verify that the laboratories are conducting operations according to the methods and procedures detailed in their application and that their practices are compliant with ELAP regulations; this includes assuring that they follow the accepted analysis protocols for each field of testing for which they seek certification, (3) proficiency testing using performance evaluation samples to ensure that the laboratories are producing acceptable data, and (4) remedial and/or enforcement activities when laboratories fail to successfully navigate the assessments and/or performance evaluation samples, or when there are complaints from clients about suspect laboratory processes. The Panel believes that all of these activities are appropriate to the State and that California’s role in the accreditation of laboratory competency should continue.

Several commenters at the Panel meetings suggested that ELAP is an inefficient program and that some or all of these functions could be better achieved using a third-party system. The Panel believes that it is appropriate for the State to conduct all of these activities, although it agrees with the commenters that the program could be more efficient. As such, the Panel feels the State should look for opportunities to use third-parties to augment the State’s activities.

Are the philosophies, objectives and scope of ELAP clearly defined? Are they appropriate?
None of these are clearly defined at the present time, and the program currently operates with little regard to the needs of the internal programs being served, beyond drinking water. ELAP’s process should be clearly defined and include uniform specifications for technical competency and quality system management to assure that data being used to make decisions regarding human health and the environment can be used with confidence.

As such, the Panel offers the following recommended mission and vision statements for ELAP:

**Mission statement** – California will implement a sustainable accreditation program to effectively evaluate the competency of organizations generating environmental and public health data of known and documented quality to meet stakeholder needs.

**Vision statement** – Through the effective implementation and demonstration of a sustainable program, California should become a leader in accreditation of environmental and public health programs.
Does ELAP have the capacity to support the program?
ELAP has the largest number of laboratories seeking accreditation of any state program in the nation and does not have the capacity to fulfill its mission, as evidenced by the backlog of assessments. This affects ELAP’s ability to complete its mission and satisfy the objectives that should be its primary focus.

This deficiency is more than a staffing allocation issue. It reflects a need for staff accountability and the ability to maintain the discipline necessary to execute assigned responsibilities in a manner that is responsive to programmatic needs.

It also reflects a need for technical and management competency and the ability to interact with internal and external clients in a professional manner. Although these issues are challenging, they are correctable and should be of primary focus to restore the program’s credibility.

2. How can California’s accreditation standards be improved?
California’s accreditation standards do not reflect the rigor needed to verify the competency of laboratories producing data for environmental programs within the State. The current laboratory accreditation standards utilized are insufficient. As a result, laboratories do not know what to expect when on-site assessments are conducted. The use of an appropriate standard is critical to the credibility of ELAP, eventual usability of the data generated, and general success of the program.

ELAP’s current regulations focus on test method requirements with an emphasis on quality control. Although an argument can be made that quality control is a standard of performance, it is a one-dimensional view that does not reflect the need for a comprehensive approach to quality management. Without requiring laboratories to implement a quality management system, the laboratories will not have processes in place to train future staff or to require laboratory management to plan for implementation of quality control on an ongoing basis. A method-based accreditation system without quality system requirements does not ensure the laboratory has processes for training future staff or examining quality control for trends to prevent problems from occurring.

The State should incorporate a standard that reflects a focus on quality systems and technical requirements. These two elements complement each other in a manner that underscores technical requirements and methodological quality control. Quality control should be performed using a systematic process that ensures the quality is being managed in a manner that promotes process improvement.

There are three options for resolution:
- Option 1: Creation of ELAP’s own State-specific standard
- Option 2: Modification and adoption of an existing standard
- Option 3: Adoption of an existing standard
Chapter 3 explains the detailed logic of the Panel’s recommendation. In brief, the Panel recommends the State adopt a single existing standard as an immediate remedy. All data produced for regulatory environmental purposes or environmental decision-making are produced for the same broad purpose, underscoring the importance of holding accredited laboratories to a single standard. In this report, the Panel describes several state, national, and international laboratory standards that exist that could meet the State’s needs.

3. What should California’s approach be to recognizing accreditation by other states, national entities or private accreditation services?

The Panel envisions three possible approaches in which activities of other accreditation services can aid the California program. In addition, some laboratories conduct interstate business and need an accreditation system with mutual (state-to-state) recognition to other States. Mutual recognition demands that the requirements of the accreditation program are acceptable to these other states.

The first is for the State to accept accreditation from laboratories that are accredited by recognized accreditation programs meeting the requirements of the program specified in Question 2 above. This assures that laboratories accredited by these states will meet the requirements of ELAP. The program’s backlog is unacceptable, and the program does not have enough staff to resolve the backlog on its own. Accepting accreditation from other recognized accreditation bodies will allow staff to prioritize their efforts on those labs most in need of examination. The program has already begun to implement this recommendation.

Recognition of other State programs does not relieve California of the responsibility of registering these laboratories or of granting them an accreditation license for the specific FOTs, which is inherently a State function. However, it eases the resource burden on the ELAP staff and expands the staff’s access to accreditation resources, and it should be incorporated.

The second is for the State to consider authorizing laboratories to directly employ third-party assessors, including either qualified individual assessors or internationally recognized third-party accreditation bodies (ABs), to assess them. These commercial ABs operate under ISO 17011 for Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies to manage their accreditation processes. These ABs use the TNI 2009 standards based on ISO/IEC 17025 to assess and accredit environmental laboratories. Third-parties have been shown to be technically competent and operate with a high degree of bias-free professionalism. Third-party assessors also provide an opportunity for California to reduce assessment and accreditation expenses by allowing laboratories to contract with third-party ABs directly.

The use of qualifying third parties would resolve several issues. First, it would supplement the program’s staff resources and further contribute to resolving the backlog. Second, it would present an alternative opportunity for laboratories that are unhappy with the professionalism and quality of the State assessors. Use of third-party assessors would require added expense for these laboratories, but many of them already have assessments being conducted for accreditation in other states that do not recognize California’s certification process. This recommendation can only be implemented if the third-party AB knows the standard that will be used for the
assessment, which requires that the accreditation standard identified in response to Charge Question 2 has been established.

The third is for the State to consider whether to extend the short-term solution of recognizing laboratory accreditation from other programs (to extend the program’s resources and reduce backlog) as a permanent program feature. In the short term, ELAP will be gaining experience with the use of third-party ABs and recognition of other State programs, and can use the outcomes of these activities to determine if making it a permanent program component is appropriate.

Should California rejoin NELAP?

California should eventually consider a return to NELAP, although this should not be a goal for the next several years. There are much higher-priority issues that should be resolved before a NELAP return should be considered, including the need to develop a program that is internally robust and acceptable to program clients, as well as the laboratories it certifies. Next, the program should incorporate the requirements of NELAP to achieve recognition for that program.

The Panel does believe that an eventual return to NELAP is warranted and will provide programmatic benefits. First, NELAP membership assures that California will offer mutual recognition with every NELAP state and that every non-NELAP state recognizing NELAP accreditations will accept ELAP’s accreditations, providing a service to laboratories that operate in multiple states. Second, NELAP membership includes regular evaluations of the ELAP program by other NELAP states to ensure compliance with the conformity assessment requirements of the NELAP standard. A return to NELAP will provide benefits that will promote the credibility of ELAP.

If the panel recommendations are taken related to implementing ISO 17011 for the ELAP accreditation management and updating the regulations for laboratory accreditation to use an ISO/IEQ 17025-based program, then obtaining NELAP recognition as an AB will be easily achieved.

4. How can ELAP’s laboratory inspection program be made more robust?

ELAP’s laboratory accreditation program suffers from many challenges, including poor on-site assessments (inspections). ELAP’s absence of a management plan and program accountability is the root cause of the unfocused approach to laboratory assessments.

ELAP should rapidly establish a management system based on ISO 17011 with performance criteria to which staff are trained and held accountable. The internal management standard is required to establish procedures that are consistently followed for conducting an accreditation program. Several further recommendations described in this report, such as regular staff training and internal audits, will ensure these recommendations are properly carried out over the long term.

Improving ELAP’s assessment program begins with defining and documenting assessment procedures. Rather than inventing a process, ELAP should employ the existing procedures
routinely being used throughout the country, modifying these procedures as necessary to meet ELAP’s needs. Doing so requires adoption of both internal management standards (i.e., a quality management system) and accreditation standards, as identified in the response to Question 2. Both are in immediate need of improvement.

ELAP should conduct its technical assessments by focusing on the most current versions of the environmental methods used for regulatory programs in the United States. This requires that ELAP updates the methods incorporated into Title 22 Division 2 Chapter 9 Article 6 – Section 64811 of the California Code of Regulations, which have not been updated since the article’s inception in 1994. The methods the program is using for technical evaluations are seriously out of date. The simplest approach to avoid being bound to outdated methods is to eliminate specific methods from the regulation, which restricts use to only those methods specified in the rules. Doing so would allow ELAP the flexibility necessary to accredit laboratories according to the methods that ELAP, its clients, and the regulatory authorities need to adequately protect California’s health and environment.

The assessment process is ELAP’s opportunity to develop a relationship with external clients through face-to-face contact. Improving this relationship and restoring credibility to the program demand that ELAP employ a systematic assessment process that functions smoothly, regardless of the laboratory setting.

What are the appropriate qualifications for auditor/inspector team members in each of the specialty areas that ELAP certifies laboratories?

A robust assessment procedure should be accompanied by competent staff who have the training, technical background, and discipline to conduct each assessment. Assessor qualifications are specified in the standards recommended for ELAP adoption (ISO 17011 or TNI 2009 Volume 2), and are addressed as part of the recommended assessor training. Before conducting assessments, the staff should initially attend an assessor training course. Technical competency is also required to conduct an evaluation of all FOTs being assessed. The assessor staff should have demonstrated technical competency in any FOT being assessed. Additional staff training, which is readily available from numerous sources, should include quality systems, assessment of organic and inorganic methods, professional behavior, interviewing, and assessment reporting. Training records should be documented to verify staff training.

To ensure that ELAP has the appropriate skills to conduct assessments, ELAP management should assemble an assessor team that has the knowledge to address all areas of technology being offered for accreditation. This can be supplemented with outside consultants if staff expertise is unavailable. A laboratory assessment should never be conducted by assessors who do not have the technical foundation to address all FOTs requested. Finally, the management staff should hold the assessment team accountable for professionally executing each assessment according to procedure and for processing each report in a timely manner. The performance of the assessor staff should be evaluated regularly and refocused.
5. How can California improve its proficiency testing program for quantifying laboratory quality?

California ELAP does not have a managed, systematic procedure for evaluating PT data or for initiating required action against laboratories that routinely fail PT analysis. Failure to perform this function enables incompetent laboratories to continue to produce questionable data for California environmental programs.

There are two main activities the program should focus on to improve its PT program. The first is a timely examination of the data submitted by the laboratories. ELAP has recently developed a unit responsible for examining the performance evaluation samples, and the Panel applauds the program for doing so. ELAP consists of a large number of laboratories performing PT analysis, making PT data review an arduous task. Nonetheless, the program should also look to enhance and update its recordkeeping. This can be accomplished by making use of existing software and electronic tools that facilitate tracking and evaluation of PT data, enabling the program to take necessary action on a timely basis.

The second is to connect review of the performance evaluation samples to a remedial process. Action should be taken as required under existing statutes to ensure that deficient laboratories perform corrective action before they can continue to offer analysis for failed parameters. Furthermore, assessment teams should review a laboratory’s PT status before conducting the assessment, following up on any corrective actions to ensure it has been properly implemented.

Correcting the deficiencies in the PT program is a function of management accountability and discipline, which has been absent. The most straightforward approach is to develop an evaluation procedure using the suggestions above, assign staff to the evaluation unit, and make this staff accountable for timely completion of the evaluation tasks. Management should take responsibility for ensuring that occurs.

Currently, California requires one successful PT per FOT per year. In order to move forward to meet TNI standards, PT requirements would need to change. The TNI standards require two PTs per year for the Fields of Proficiency Testing (FOPTs) in the TNI FOPT tables. TNI also requires that PT providers be accredited to its standards.

6. How can California improve its process for responding to concerns expressed by: (a) laboratories that have concerns about the certification process, or (b) clients who have concerns about the quality of a laboratory that has been certified by ELAP?

California ELAP does not have a procedure for responding to concerns expressed by any stakeholder. A well-defined, documented complaint procedure is clearly needed. The Panel heard numerous comments from both laboratories that are accredited and from clients of the program that complaints were systematically ignored, and that management did not accept any responsibility for ensuring they were addressed, which was acknowledged by the new program management team. Concerns were expressed by laboratories that complaints regarding ELAP’s processes would result in repercussions against them.

The Panel recommends that ELAP implement a structured system for communicating with stakeholders and laboratories. A documented complaint process is an essential part of that
communication strategy. The process is also a component of the quality management system that the Panel is recommending, and management should take responsibility for timely responses and corrective action investigations without bias.

The complaint procedure should be periodically audited internally and externally to verify it is functioning. External oversight of this procedure is essential for restoring ELAP’s credibility. A benefit of employing a quality system that follows an established conformity assessment standard is that it includes regular external reviews of the complaint procedure. This results in an open process that can be readily reviewed by all stakeholders.

7. How should ELAP plan for future programmatic, testing and management needs?

ELAP’s responsiveness to future programmatic need is a vital component of its approach to client service. The primary driver of the program’s responsiveness is the ability to maintain the flexibility to make adjustments as dictated by the needs of internal and external clients, and by changes in regulations.

On a regular schedule, ELAP should establish a management review process to allow planning for improvement, follow-up actions, changes that could affect program management, analysis of complaints, trends of nonconformance, and corrective actions. The output of the management review will inform the allocation of budget and resources, the addition of new areas of accreditation, and actions to improve services to the laboratories. Typically, these reviews occur once per year and result in an annual plan for the coming year.

ELAP also should maintain open lines of communication with the internal programs being served. This will enable ELAP to clearly understand the future needs of the programs and make adjustments to the accreditation process to ensure that the program continues to serve that need. Making these adjustments will enable ELAP to continue to verify that laboratories are competent to produce data to changing program needs. An important component of this relationship is developing procedures that enable ELAP to offer accreditation for new methods, parameters, or compounds that have regulatory significance or that the State has indicated a desire to use that are not currently part of the State’s accreditation offering, which is directly related to the charge question. This includes developing the technical understanding to assess the new offering before on-site assessments are offered. Regardless of the type of change, the implementation of such changes in response to new or updated environmental regulations should be performed in a systematic and timely manner.

Procedures also should be in place to enable ELAP to respond to the accredited laboratory community’s request for new accreditation offerings. Because of the timeliness requirements that typically accompany these requests, these procedures should be sufficiently streamlined to enable the community to receive the requested accreditations quickly.

ELAP requires immediate attention to achieve adequacy, so the Panel has not yet focused on developing more forward-looking recommendations. The Panel will be returning after a year to gauge ELAP’s progress, and will provide additional recommendations for future program growth once the program had demonstrated sufficient progress in addressing the initial items appearing in this report that are critical to the program’s success.
8. Which program improvements are most urgent and can be accomplished within existing resources and authorities? Which are the highest-priority, longer-term program improvements?

The most urgent programmatic needs are described in Chapter 4 of this document.
APPENDIX B: BIOGRAPHIES OF PANEL MEMBERS

Jordan Adelson

Dr. Jordan Adelson has a Ph.D. in environmental analytical chemistry, and currently serves as the Director of the Navy’s Laboratory Quality and Accreditation Office (LQAO) and as the Chair of the DoD Environmental Data Quality Workgroup (EDQW). As Director of the LQAO, Dr. Adelson manages the accreditation programs for the Naval Shipyard Material Testing Laboratories and implements quality system requirements on all NAVSEA testing laboratories. As the Chair of the EDQW, Dr. Adelson oversees the DoD Environmental Laboratory Accreditation Program (DoD ELAP) and develops and recommends DoD policy with respect to environmental sampling and testing operations.

Stephen Arms

Stephen Arms is Administrator of the Florida Department of Health’s Environmental Laboratory Certification Program. He is responsible for oversight of the program’s quality system and day-to-day operations, and is the central point of contact for information, interpretations, and decision-making in all areas of certification for the State. He supervises staff assessors, and developed and manages contracts for provision of on-site assessment services. Mr. Arms works closely with the Florida Department of Environmental Protection to help ensure that programmatic needs are being met by having competent certified laboratories perform the testing upon which environmental decisions are made.

Mitzi Miller

Mitzi Miller is Vice President of Environmental Programs for Dade Moeller & Associates. Ms. Miller has served as a third party assessor to support State laboratory accreditation programs in Louisiana, Kansas, Florida, Minnesota, Texas and Illinois, averaging 25 audits a year. She is qualified in drinking water, non-potable and solid waste methods for chemistry, microbiology, whole effluent toxicity, and air. Ms. Miller is an expert in implementation of the data quality objectives process (DQO) and environmental data validation. She teaches classes in mass spectrometry and data interpretation, ISO 17025, internal auditing, corrective actions, TNI assessment, and data validation.
**Lara Phelps**

Lara Phelps (Panel Chair) is the Senior Advisor for Measurement, Modeling, Monitoring, and Laboratory Science Issues with the U.S. Environmental Protection Agency (EPA) in the Office of the Science Advisor (OSA). Over her years of government service, she has gained expertise in a wide range of areas including budgeting and program planning, quality systems, laboratory accreditation, monitoring and testing issues, proficiency testing, regulatory issues, modeling, statistical design and analysis, and innovative strategies and technologies. At present, she is not only an advisor for science issues, but is serving as the Director of the Forum on Environmental Measurements, Director for the Environmental Modeling Community of Practice, Designated Federal Official for the Environmental Laboratory Advisory Board, and Quality Assurance Manager for OSA. She has received numerous honors including the Association of Public Health Laboratories ‘On the Front Line’ award, four bronze medals, and service recognition in support of the Nation’s response to the Deepwater Horizon Oil Spill. Lara is also involved in several professional organizations.

**David Speis**

David Speis is the President of Eurofins QC, Inc. in Southampton, Pennsylvania. He has extensive senior staff and management experience in commercial environmental laboratories including technical operations, quality assurance, business development, and facility general management. Mr. Speis has served on the USEPA’s Environmental Laboratory Advisory Board as a member and Past Chair. He also serves as a Board member and Treasurer of The NELAC Institute (TNI) and had also served as past chair. He is a member of the Executive Committee of ACIL’s Environmental Sciences Section. He served on the board of the International Association of Environmental Testing Laboratories (IAETL), and during this time assisted in development of the initial framework for National Environmental Laboratory Accreditation.
APPENDIX C: STAKEHOLDER ADVISORY COMMITTEE (SAC) MEMBERSHIP

The members of the Stakeholder Advisory Committee are:

- Socorro Baldonado, Metropolitan Water District
- Cindy Ziernicki, Helix Water District
- Andy Eaton (Chair), Eurofins Eaton Analytical, Inc.
- Bruce Godfrey, Curtis & Tompkins Labs
- Calvin Liu, Contra Costa Water District
- Terry Powers, South Tahoe Public Utility District
- Pamela Schemmer, Test America, Inc.
- Josie Tellers, City of Davis
- Anthony Gonzalez, Sacramento County Public Health Laboratory
- Allison Mackenzie, Babcock Laboratories
- Pete Ode, California Department of Fish and Wildlife
APPENDIX D: MEETING AGENDAS

STATE OF CALIFORNIA ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (ELAP) EXPERT REVIEW PANEL

March 17-19, 2015
Meeting agenda

To be held at:
Southern California Coastal Water Research Project
3535 Harbor Blvd. Costa Mesa, CA 92626
Meeting will be webcast at conference.sccwrp.org

Day 1 – Tuesday, March 17 (open to public)

8:00   Coffee & pastries
8:30   Welcome and introductions  Steve Weisberg
       SCCWRP
8:40   Purpose of the review  Cindy Forbes
       SWRCB
8:50   Panel charge questions  Steve Weisberg
       SCCWRP
9:00   Origins and goals of ELAP  Karen Larsen
       SWRCB
9:30   Program overview  Christine Sotelo
       SWRCB
10:15  Break
10:30  Laboratory inspection program  Angela Anand
       SWRCB
11:00  Qualifications of the auditor/inspector team members  Christine Sotelo
       SWRCB
11:30  Proficiency testing program  Renee Spears
       SWRCB
12:00  Lunch (provided on site for $10)
1:00   Reasons for California’s dismissal from NELAP  Kristin Brown
       Utah Dept. of Health
1:30   Perspectives from a State not participating in NELAP  Steve Baker
       State of Arizona
2:00   Results from laboratory inter-calibration exercises  Rich Gossett
       conducted during regional monitoring in southern California  Physis Laboratories
2:30   Break

Stakeholder Perspectives
2:45   Commercial laboratory perspective  Andy Eaton
3:25 Municipal laboratory perspective
4:05 American Council of Independent Laboratories perspective
4:45 Public comments
5:15 Adjourn for the day
6:00 Dinner (Panel members & State personnel)

**Day 2 – Wednesday, March 18**

8:00 Panel deliberations (panel members only)

**Panel Interviews (closed session)**
10:00 Interviews with ELAP inspectors
11:00 Interviews with Environmental Laboratory Technical Advisory Committee (ELTAC)
12:00 Lunch (On site - Panel members & State personnel only)
1:00 Panel deliberations (panel members only)
5:00 Adjourn for the day
6:00 Dinner (panel members only)

**Day 3 – Thursday, March 19**

8:00 Panel deliberations (panel members only)

**Panel Report Out (open to public)**
10:30 The Panel’s Approach to the Tasks Panel Chair
11:00 Public comment and questions for the Panel Steve Weisberg
11:45 Summary and future meeting dates SCCWRP
12:00 Adjourn
Informational webinar for the Panel to hear pros/cons from laboratories that added quality systems to their laboratory operations

June 23, 2015
9:00 AM - 10:30 AM

9:00
Why has the Panel requested presentations on quality systems?
Mitzi Miller
Review Panel Member

9:10
Speaker 1: Nan Thomey
Environmental Chemistry Inc.
Houston, TX

9:30
Questions from the Panel

9:40
Speaker 2: Robin Cook
Regulatory Compliance Officer
City of Daytona Beach
Daytona Beach, FL

10:00
Questions from the Panel

10:10
Questions from the audience

10:30
Adjourn
STATE OF CALIFORNIA ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (ELAP) EXPERT REVIEW PANEL

August 10-13, 2015
Meeting agenda

To be held at:
CalEPA Headquarters
1001 I Street
Sacramento, CA 95812
Public portions of the meeting will be webcast via CalEPA Live Webcast by visiting this webpage:
http://www.calepa.ca.gov/broadcast/

Day 1 – Monday, August 10 (open to public)
Byron Sher Auditorium

9:30   Welcome and introductions                      Steve Weisberg
       SCCWRP
9:40   Opening remarks                                 Lara Phelps
       Review Panel Chair
10:00  Actions taken in response to initial Panel recommendations
       a) Develop a communications strategy
       b) Meet with your clients
       c) Re-energize ELTAC
       d) Review/update method checklists
       e) Temporarily accept accreditation/evaluations
           from a recognized program to lessen your backlog
11:15  Stakeholder Advisory Committee
       Comments on actions taken to date                 Andy Eaton
       Eurofins Eaton
       Analytical
11:30  Public comments on actions taken to date
12:00  Break

Input requested by the Panel on issues they are considering
1:00   What is the best way for California to develop auditing standards?

ISO 17025 and/or TNI standards                      Chris Gunning
Develop State-specific or hybrid standards
ELAP view for the best way to develop auditing standards
2:30 Break
2:45 Should California use third parties to assist with inspections and/or accreditation?

Challenges faced by California program, auditor qualifications/training, staffing needs
Christine Sotelo
SWRCB

Alternative models for using third parties
Chris Gunning
A2LA
Bruce Godfrey
Curtis & Tompkins
David Kimbrough
City of Pasadena

Arguments for a third party program
Andy Eaton
Eurofins Eaton
Analytical

Concerns with using third parties

4:00 Comments from the Stakeholder Advisory Committee

4:30 Public comments
5:30 Adjourn for the day
6:00 Dinner (Panel members & State personnel)

Day 2 – Tuesday, August 11
CalEPA Room 550

8:00 Panel deliberations (panel members only)
9:00 Interviews with clients of ELAP (panel members only)

Department of Toxic Substance Control
Carol Wortham, QA Manager
John Quinn, Supervisor-Environmental Chemistry Laboratory
Bruce LaBelle, Chief-Hazardous Materials Laboratory

California Air Resources Board
Michael Werst, Branch Chief
Michael Benjamin, Chief - Monitoring and Laboratory Division

California Department of Public Health
Dave Mazzera – Former Acting Chief of the Drinking Water Program

California Department of Fish and Wildlife
Gail Cho – Quality assurance manager
Pete Ode – Laboratory Director, Water Pollution Control Laboratory
Dave Crane – Laboratory Program Manager

US Food and Drug Administration - Shellfish Sanitation
Linda Chandler – Auditor/ELAP Trainer
State Water Resources Control Board/Regional Board Programs
Bruce Burton, Assistant Deputy Director, Division of Drinking Water

11:00  Panel deliberations (panel members only)
5:00  Adjourn for the day
6:00  Dinner (panel members only)

Day 3 – Wednesday, August 12
CalEPA Room 2510

8:00  Panel deliberations (panel members only)

Panel Report Out (open to public)
CalEPA Coastal Hearing Room (also available through webcast)

3:00  The Panel’s recommendations  Lara Phelps
      Panel Chair
3:30  Public comments and questions for the Panel
4:45  Summary and future meeting dates  Steve Weisberg
      SCCWRP
5:00  Adjourn for the day

Day 4 – Thursday, August 13
CalEPA Room 2510

8:00  Panel deliberations to consider public comments, develop assignments for preparing the
      Panel report, and begin report preparation (panel members only)
5:00  Adjourn
STATE OF CALIFORNIA ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (ELAP) EXPERT REVIEW PANEL

October 14-15, 2015
Meeting agenda

To be held at:
Southern California Coastal Water Research Project
3535 Harbor Blvd. Costa Mesa, CA 92626
Meeting will be webcast at conference.sccwrp.org

Day 1 – Wednesday, October 14 (open to public)

8:30 Welcome and introductions
Steve Weisberg
SCCWRP

8:45 ELAP actions taken to date
Christine Sotelo
SWRCB

9:15 Stakeholder Advisory Committee comments on actions taken
Andy Eaton
Eurofins Eaton Analytical

9:45 Public comments on actions taken to date

10:30 Summary of the Panel’s draft report
Lara Phelps
Review Panel Chair

11:00 Stakeholder Advisory Committee comments on Panel report
Andy Eaton
Eurofins Eaton Analytical

11:30 Public comments and questions for the Panel

12:00 Lunch (provided on site for $10)

1:00 Continued public comments and questions for the Panel

2:30 Panel deliberations to discuss public comments (panel members only)

5:00 Adjourn for the day

6:00 Dinner (panel members and State personnel only)
Day 2 – Thursday, October 15 (closed to public)

9:00   Panel deliberations and writing to finalize report (panel members only)

5:00   Adjourn for the day

6:00   Dinner (panel members only)
Subject: FW: [CASA Biosolids] FW: FOG <pH5 co-digestion at POTW
Date: Monday, November 2, 2015 at 2:10:56 PM Pacific Standard Time
From: Adam Link

From: Biosolids <biosolids-bounces@lists.casaweb.org> on behalf of "biosolids@lists.casaweb.org"
<biosolids@lists.casaweb.org>
Reply-To: Greg Kester <gkester@casaweb.org>
Date: Friday, October 23, 2015 at 6:10 AM
To: "biosolids@lists.casaweb.org" <biosolids@lists.casaweb.org>
Subject: [CASA Biosolids] FW: FOG <pH5 co-digestion at POTW

Hello everyone – I wanted to share with you a message from the State Water Boards which provides resolution to an issue we recently raised with them. On the eve of CalRecycle passing their regulations to provide an exemption to wastewater plants receiving hauled in organic waste for co-digestion, we became aware that pretreatment regulations in 40 CFR part 403.5(b)(2) might preclude a POTW from accepting such waste if the pH was less than 5.0. Fats, Oils, and Grease as shown in the attached summary may have a pH less than 5 so resolution was necessary. The pretreatment regulation does provide an exception if the receiving facilities are designed to accept such waste. At question was what would be required to demonstrate that the receipt of the waste would have no negative impact. We engaged in discussions with USEPA and the State Water Boards. We are very pleased to share the message below which confirms they believe the receipt of such waste is not an issue and will have no deleterious effect. Acknowledgement that such waste may be accepted should be included in Standard Operating Procedures (SOPs) which are developed and the template developed for SOPs at http://www.casaweb.org/documents/casa_fog-fw_receiving_station_sop_template_100614.pdf includes language to this effect. The State Boards reiterate the caveat that each POTW is ultimately responsible to ensure that there is no impact to either equipment or on effluent limits. Please let me know if you have any questions or comments. Thanks very much - Greg

Greg Kester
California Association of Sanitation Agencies
Director of Renewable Resource Programs
1225 8th Street, Suite 595
Sacramento, CA 95814
PH: 916 446-0388
Mobile: 916 844-5262
gkester@casaweb.org
Ensuring Clean Water for California
Purpose
These Best Management Practices (BMPs) have been endorsed by several major POTW’s in California that currently accept CWT waste discharges. These major California POTWs have developed and adopted these BMPs to serve as guidance, and to help assure uniform compliance among POTWs in California with their mandates under the U.S. EPA pretreatment program requirements.

These requirements are designed to protect POTW wastewater treatment processes and conveyance systems; to assure compliance with the regulations governing discharge of treated effluent, water reuse, biosolids disposal/reuse, and air emissions; and to protect worker and public safety and the environment.

Acknowledgement
The following agencies participated in the development and review of this BMP.
- City of Oxnard
- County Sanitation District of Los Angeles
- City of San Jose (SJ/SC Water Pollution Control Plant)
- City of Los Angeles
- Orange County Sanitation District

Background
Centralized Waste Treatment (CWT) facilities are defined in Rule 40 CFR 437 as those that accept hazardous or non-hazardous industrial metal-bearing wastes, oily wastes and organic-bearing wastes received from off-site for pretreatment processing before discharge to a water of the U.S., or to a Publicly Owned Wastewater Treatment (POTW) facility. Specifically, CWT Subcategory D dischargers are those that receive for treatment a combination of two or more any of the following three major categorical waste streams: metal-bearing wastes, oily wastes, and organic-bearing wastes.

CWTs are required to be permitted and to comply with all federal and local rules and regulations set by Rule 40 CFR 437. They are also required to meet those rules and regulations set by the local agency that owns and operates the POTW facility and administers the POTWs pretreatment program, if the CWT discharges to a POTW.

The EPA’s guidance document labeled “Small Entity Compliance Guide, Centralized Waste Treatment (CWT) Effluent Limitations and Guidelines and Pretreatment Standards (40 CFR 437) (EPA 821-B-01-003; June 2001; Version 3.0) ”sets guidance for businesses that are subject to the Rule in complying with the national regulations.
and limitations set forth in the Rule." A Subcategory D discharger must establish that its facility provides "equivalent treatment" in terms of comparable pollutant removals to the applicable treatment technologies used as the basis for the federal limitations and pretreatment standards (40 CFR 437.2).

Best Management Practices
The following summarizes the recommended Best Management Practices (BMPs) for CWT facilities discharging to California POTWs. These recommended BMPs are organized based on the following topical headings:

1. Waste Receiving Requirements
2. Treatment Requirements
3. Effluent Discharge and Sampling/Testing Requirements
4. Recommended Certification and Documentation Requirements.

1. Waste receiving requirements
   a. The waste hauler bringing waste to a CWT shall submit a Waste Manifest to the CWT upon arrival at the CWT processing facility. The Waste Manifest shall include the following minimum information:
      i. Information as defined in Chapter 5 of Small Entity Compliance Guide, Centralized Waste Treatment (CWT) Effluent Limitations and Guidelines and Pretreatment Standards (40 CFR 437) (EPA 821-B-01-003; June 2001; Version 3.0). This shall include a date and time stamp.
   b. The following mandatory tests shall be performed for confirmation of the Waste Manifest in accordance with 40 CFR 403 General Pretreatment Regulations and the analytical methods and sampling techniques stipulated in 40 CFR 136:
      i. Heavy Metals
      ii. Cyanides
      iii. Total Phenol
      iv. Sulfides
      v. Volatile Organic Compounds
      vi. Oil and Grease
      vii. Total Toxic Organics (TTOs)
      viii. BOD and TSS
   c. Combining waste from multiple location into one tank truck (i.e. "Milk Runs") is prohibited.
   d. Additional random sampling of waste haulers by the CWT may be requested by the POTW to confirm the waste characteristics are as described in the Waste Manifest.

2. Treatment requirements
b. Emergency shutoff and re-routing procedures must be in place.
c. Treatment reliability and redundancy requirements must meet. As a minimum, those that are established by the most recent version of the ‘Ten-State Standards (Board of State and Provincial Public Health and Environmental Managers, Health Research, Inc., Health Education Services Division).
d. Holding tanks for the purpose of dilution will not be allowed.
e. A logbook shall be maintained of the operating parameters of the treatment process.

3. Effluent discharge and sampling/testing requirements.
   a. Batch discharge will be required. Continuous discharge is not permitted.
   b. The batch tanks will be continuously mixed.
   c. A representative sample will be taken and analyzed by a POTW approved, State certified laboratory, before a decision is made to discharge to the POTW sewer system. Testing shall, as a minimum, be for the following:
      i. Local Limits as established by the POTW.
      ii. Applicable 40 CFR 437 Categorical Limits, adjusted by the combined waste stream formula if non-regulated waste streams are discharged at the compliance point.
      iii. Toxicity as determined by Specific Oxygen Uptake Rate (SOUR), Method 1683, EPA-821-R-01-014.
      iv. Any other limits imposed by the POTW.
   d. The batch discharge will only be allowed if the above test results meet the applicable discharge limits.
   e. Adequate emergency shut-off/rerouting procedures must be established. Incoming wastes must be halted or diverted to storage if an emergency shutdown of the treatment system is required.
   f. If the federal or local discharge limitations are not met for a parameter other than pH, then the tank contents shall to be returned to the beginning of the treatment process train for reprocessing. If the federal or local pH limits are not met based on pH only, then the CWT Facility can add an acid or base to bring the pH into the allowable range before discharge. The POTW may have restrictions on the acid or base chemical that can be used for pH adjustment.
   g. Installation of flow metering of the discharge to the POTW is required and must be maintained and calibrated routinely by a qualified professional.

Recommended General Certification and Documentation Requirements
Documents must be developed and submitted to the POTW, and be available for the POTW to review at the CWT site all times.

Note that all documents, forms, and other submittals must be certified and stamped by a registered professional engineer in California with expertise in industrial treatment. This list includes, but is not limited to the following.
1. Initial Certification Statement.
   a. Submit initial Certification Statement to the POTW in accordance with 40 CFR 437.41.
   b. The initial Certification Statement must be reviewed and approved by the POTW before a Permit to Discharge is granted to the CWT by the POTW.

2. Plans/Procedures
   a. Monitoring, Sampling and Testing Plan (MSTP). The MSTP shall specify: location, frequency, and methodology for all monitoring/sampling of waste received, treatment processes and performance, and treated effluent discharged to the POTW.
   b. Monitoring Plan Reporting: Monthly and annual reports shall be submitted summarizing all mandatory and self-monitoring data results.
   c. Slug Discharge Control Plan
   d. Spill Containment plan
   e. Flow Metering Plan
   f. Rainwater and Stormwater Management Plan (Note: stormwater cannot be commingled with received and/or treated CWT wastes).
   g. Solvent Management Plan
   h. Waste Minimization Plan

B. Treatment Process/Facility Information.
   a. O&M Manual
      i. Routine O&M Procedures
      ii. Emergency Response, Bypass, and Storage O&M Procedures
      iii. O&M Logbook
   b. Unit process sizing and design criteria. Information shall be sufficient for independently assessing the rated treatment capacity of all unit operations, including physical dimensions, and process design criteria (e.g. hydraulic detention times, overflow rates, pollutant removals, etc.).
   c. Engineering Design Drawings (100% Design Drawings/As-built).
   d. Process and Instrumentation diagram. This shall show the following information:
      i. Process flows for all major unit operations (routine and emergency conditions). This shall include identification of all flow and recycle streams for each treatment process
      ii. Process monitoring parameters (location and metrics). As a minimum these shall include:
         1. Flow rates
         2. pH
         3. Temperature
         4. Others as recommended by the POTW.
   e. Wastewater Treatment Operator Requirements.
   f. Water Usage. Copies of historical water bills and/or local well records showing water usage for a five-year (5) period.
g. **Operating Records.** All plant operating and performance records relating to wastewater discharge and waste manifests for up to five (5) years, including all monitoring, testing, and analytical results (See Testing and Monitoring Information, below).

**C. Received Waste Documentation**
   a. Comprehensive list of all generators accepted by the CWT.
   b. Waste Hauler Reports.
   c. Logbook of all prequalification for each of the CWTs clients, this includes;
      i. Generator information
      ii. Initial Sample information
      iii. Requalification tests
   d. Customer Laboratory Treatability Information.

**D. Testing and Monitoring Information**
   a. All sampling, testing and laboratory analyses must be performed by an independent testing laboratory that is licensed and certified in California.
   b. All laboratory analytical results, including QA/QC information, shall be submitted monthly, and records maintained for a five-year period.
   c. Effluent pH recordings from the previous 180 days
   d. Flow Meter Calibration and Maintenance Reports (Note: must be signed and stamped by a registered professional engineer in California).
      i. Flow meter locations
      ii. Flow meter descriptions
      iii. Flow meter system details
      iv. Calibration methods/results
      v. Corrective measures
   e. Discharge log (with signature(s) from responsible party at time of release from CWT facility to the POTW system.)
      i. Time, date, and volume of when the contents from the tank are discharged to the sewer
      ii. Signature from responsible operator
      iii. Other observations
   f. Chain of custody forms for monitoring samples with signatures.
   g. All other sampling reports.

**E. Compliance Paperwork**
   a. On-site Compliance Paperwork, as required by 40 CFR Part 437.47(a)(4)
   c. Facility shall continue to submit application information on a five-year cycle, with all applicable documentation and any information pertaining to changes planned for the future years. The information provided must include changes in the nature or volume of the discharge, or anticipated customers.
Notice of Stakeholder Meeting
CENTRAL VALLEY PYRETHROID PESTICIDES TOTAL MAXIMUM DAILY LOAD and BASIN PLAN AMENDMENT

Open to the Public
30 Nov 2015, 9:30 a.m. - 12:00 p.m.
Central Valley Water Board – Training Room
(916) 227-1132

NOTICE IS HEREBY GIVEN that staff of the Central Valley Regional Water Quality Control Board (Central Valley Water Board) will hold a stakeholder meeting to discuss and provide an update on the development of the Central Valley Pyrethroid Pesticides Total Maximum Daily Load and Basin Plan Amendment (Pyrethroids TMDL and BPA). Additional information about this project is available on the Central Valley Water Board’s website at: http://www.waterboards.ca.gov/centralvalley/water_issues/tmdl/central_valley_projects/central_valley_pesticides/pyrethroid_tmdl_bpa/index.shtml

The purpose of this meeting will be to discuss the external scientific peer review comments, project alternatives and next steps. Briefing materials for the meeting will be sent out at least two weeks before the meeting.

Date, Time and Location

<table>
<thead>
<tr>
<th>Location</th>
<th>Central Valley Regional Water Quality Control Board</th>
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<tbody>
<tr>
<td>Training Room</td>
<td>Training Room</td>
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<tr>
<td>11020 Sun Center Drive, Ste. 200</td>
<td>11020 Sun Center Drive, Ste. 200</td>
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<td>Rancho Cordova, CA 95670</td>
<td>Rancho Cordova, CA 95670</td>
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<td>Call-in number (916) 227-1132</td>
<td>Call-in number (916) 227-1132</td>
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<tr>
<td>Date</td>
<td>Monday, November 30, 2015</td>
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<td>Time</td>
<td>9:30 a.m.-12:00 p.m.</td>
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Participants are encouraged to attend in person in order to have full access to materials and fully participate in discussions, but a call-in number is available for those who cannot attend in person. The facilities are accessible to persons with disabilities. Individuals requiring special accommodations are requested to contact Danny McClure at (916) 464-4751 at least 5 working days prior to the meeting. TTY users may contact the California Relay Service at 1-800-735-2929 or voice line at 1-800-735-2922. Questions regarding this meeting should be directed to Danny McClure at (916) 464-4751 or Daniel.McClure@waterboards.ca.gov or Melissa Dekar at (916) 464-4603 or Melissa.Dekar@waterboards.ca.gov. Please bring the above information to the attention of anyone you know who would be interested in this matter.
SACRAMENTO (CN) - Pesticide manufacturers sued the California Water Board, claiming it violated the state's Clean Water Act by adopting a water quality plan based on data from an unofficial study.

The Pyrethroid Working Group claims the Central Coast Region of the State Water Resources Control Board used pesticide measurements from a UC Davis study to classify streams and rivers in the Santa Maria watershed as polluted.

The watershed is in northwestern Santa Barbara County and southwestern San Luis Obispo County, with its eastern edge in Ventura County.

The pesticide makers say the water board adopted UC Davis' numeric values to measure pesticide levels without having them thoroughly tested or approved by the state.

Pyrethroids are a class of active ingredients in insecticides, including bifenthrin, cyfluthrin and cypermethrin. They are used to kill flying insects such as flies, ants and silverfish, and are carcinogenic and highly toxic to fish and birds.

The pesticide makers claim: "The Central Coast Water Board did not evaluate the data and information relied upon to support additional impairment determinations for certain pyrethroid pesticides according to the decision rules provided in the listing policy and mandated by a weight-of-evidence approach."

The water board amended its water quality plan for the Central Coastal Basin in 2014, to include a total maximum daily load (TMDL) for pollutants.

The insecticide makers claim that before the board adopted the TMDL amendment, various waters in the basin were not listed as polluted by pyrethroids, and that the adopted water quality objectives are "narrative statements rather than set numeric values or limits."

The Pyrethroid Working Group is an alliance of pesticide manufacturers that informs farmers and customers of new state and federal regulations.

In 2012, the California Department of Pesticide issued surface water regulations to users of the insecticides to curb chemical runoff and protect surface water.

The Water Board declined to comment on the lawsuit, but told Courthouse News the Santa Maria water quality plan was "developed following extensive public comment and scientific peer review," and that "the plan was approved by the Central Coast Regional Water Quality Control Board, the State Water Resources Control Board, the California Office of Administrative Law and the U.S. EPA."

The pesticide group seeks writ of mandate invalidating the water board's determinations that the Santa Maria River and other tributaries are impaired for pyrethroid pesticides, and preventing the regulator from using the same process in evaluating the Salinas River Watershed.

The pesticide makers are represented by Theresa Dunham, with Somach Simmons & Dunn, who could not be reached for comment Tuesday.
Within the past hour, the U.S. Senate approved the House-passed surface transportation short term extension, H.R. 3819. There was no debate on the measure. This action means that the extension of the Positive Train Control compliance deadline is extended until 2018 upon enactment by the president signing H.R. 3819 into law. For CASA agencies, the decision by Senator Boxer not to oppose including the PTC extension in the short term surface transportation bill means that the uncertainty over delivery of treatment technologies, including chlorine gas and/or bleach, is no longer a concern over the next two years.

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