jurisdiction in Bernalillo County on lands under the jurisdiction of the Albuquerque/Bernalillo County Air Quality Control Board.

[FR Doc. 05–12657 Filed 6–24–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[RCRA–2001–0021; FRL–7928–8]

RIN 2090–AA14

Project XL Site-Specific Rulemaking for the Ortho-McNeil Pharmaceutical, Inc. Facility in Spring House, PA Involving On-Site Treatment of Mixed Wastes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is today finalizing this rule to implement a pilot project under the Project XL program, providing site-specific regulatory flexibility under the Resource Conservation and Recovery Act (RCRA), as amended, for the Ortho-McNeil Pharmaceutical, Inc. facility in Spring House, Pennsylvania (OMP Spring House). The principal objective of this XL project is to obtain information helpful to determining whether regulatory oversight by the Nuclear Regulatory Commission (NRC), or NRC Agreement States, under authority of the Atomic Energy Act (AEA) is sufficient to ensure protection of human health and the environment regarding the management of certain small volumes of mixed wastes (*i.e.,* RCRA hazardous wastes that also contain radioactive materials) that are both generated and treated in an NRC-licensed pharmaceutical research and development laboratory. If, as a result of this XL project, the Agency determines that certain small volumes of low-level mixed wastes (LLMW) generated and managed under NRC oversight need not also be subject to RCRA hazardous waste regulations to ensure protection of human health and the environment, EPA may consider adopting the approach on a national basis.

DATES: *Effective Date:* This final rule is effective on June 27, 2005.

ADDRESSES: EPA has established a docket for this action under Docket ID No. RCRA–2001–0021. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the RCRA Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the RCRA Docket is (202) 566–0270.

FOR FURTHER INFORMATION CONTACT: Mr. Charles Howland, U.S. Environmental Protection Agency, Region III (3OR00), 1650 Arch Street, Philadelphia, PA, 19103–2029. Mr. Howland can be reached at (215) 814–2645 (or *howland.charles@epa.gov*).

SUPPLEMENTARY INFORMATION:

Outline of Today's Rule

The information presented in this preamble is organized as follows:

I. Authority

EPA is publishing this regulation under the authority of sections 2002, 3001, 3002, 3003, 3006, 3007, 3010, 3013, and 7004 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act, as amended (42 U.S.C. 6912, 6921, 6922, 6923, 6926, 6927, 6930, 6934, and 6974).

II. Overview of Project XL

The Final Project Agreement (FPA) sets forth the intentions of EPA, Pennsylvania Department of Environmental Protection (PADEP), and the OMP Spring House facility with regard to a project developed under Project XL, an EPA initiative that allows regulated entities to achieve better environmental results with additional regulatory flexibility. This final regulation, along with the FPA (contained in the docket for this rule under Docket ID No. RCRA–2001–0021), will facilitate implementation of the project. Project XL —''eXcellence and Leadership''— was announced on March 16, 1995, as a central part of the Agency's effort to reinvent environmental protection. See 60 FR 27282 (May 23, 1995). Project XL provides a limited number of private and public regulated entities an opportunity to develop their own pilot projects to request regulatory flexibility that will result in environmental protection that is superior to what would be achieved through compliance with current and reasonably-anticipated future regulations. For more information about the XL Program in general, and XL project criteria and project development processes in detail, readers should refer to *http://www.epa.gov/projectxl/.* Additional background information on the proposed OMP Spring House Project XL site-specific rulemaking published is available at *http://www.epa.gov/projectxl/ortho/index.htm* and published in the **Federal**

Register, specifically: July 24, 2001 (66 FR 38396), two descriptive documents published in the **Federal Register** (60 FR 27282, May 23, 1995 and 62 FR 19872, April 23, 1997), and the December 1, 1995 ''Principles for Development of Project XL Final Project Agreements'' document. For further discussion as to how the OMP Spring House XL project addresses the XL criteria, readers should refer to the Final Project Agreement available from the EPA RCRA docket (Docket ID No. RCRA–2001–0021; see **ADDRESSES** section of today's preamble).

III. Overview of the OMP Spring House XL Pilot Project

Today's final rule will facilitate implementation of the FPA that has been developed by EPA, PADEP, the OMP Spring House facility, and other stakeholders. Today's final rule will become effective under Pennsylvania State law in accordance with the Commonwealth's hazardous waste program, as described further in section IV of this preamble.

To implement this XL project, today's final rule provides a site-specific exemption from the regulatory definition of hazardous waste for the mixed wastes generated and treated in OMP's Spring House research and development laboratory. The terms of the overall XL project are contained in an FPA which is included in the docket for today's final rule. A draft version of the FPA was the subject of a Notice of Availability published in the **Federal Register** on September 1, 2000 in which EPA solicited comment. The FPA was signed on September 22, 2000 by representatives of EPA, the Pennsylvania Department of Environmental Protection (PADEP), and Ortho-McNeil Pharmaceutical. The exemption from the regulatory definition of hazardous waste of the mixed wastes generated at the OMP Spring House facility will remain in effect only for the five-year term of this XL project, and begins upon the effective date of this final rule.

A. To Which Facilities Does the Final Rule Apply?

This final rule will apply only to the OMP Spring House facility. Thus, mixed wastes generated in other pharmaceutical research and development facilities remain subject to current Resource Conservation and Recovery Act (RCRA) Subtitle C regulations. (The Agency notes that the term ''RCRA Subtitle C regulations'' includes the exemptions and exclusions specific to mixed wastes that have been promulgated as part of the regulatory program.) Further, the regulatory modification will only affect the mixed waste that is the focus of this XL project; hazardous wastes resulting from any other operations at the OMP Spring House facility are not affected by today's final rule.

B. What Problems Will the OMP Spring House XL Project Attempt To Address?

The OMP Spring House facility does not believe the RCRA Subtitle C regulatory controls, as applied to the low-level mixed wastes (LLMW) it generates and treats, provide any additional environmental protection than is otherwise provided by the Atomic Energy Act (AEA) oversight, and indeed believes that RCRA Subtitle C regulatory controls serve as a major disincentive to environmentally protective on-site treatment of the small volume of mixed wastes generated at the facility.

While limited commercial off-site treatment for such wastes is available, the on-site, bench-scale, high-temperature catalytic oxidation unit OMP Spring House will use to treat the mixed wastes has been demonstrated to be more efficient in preventing the emission of radioactivity to the atmosphere and at least as efficient, if not more, at destroying the organic components than available commercial treatment. (The on-site treatment of OMP Spring House's mixed wastes has been tested under a ''treatability study'' exemption provided in 40 CFR 261.4(f), and granted by PADEP.) According to OMP Spring House, it has not sought a RCRA hazardous waste treatment permit for the catalytic oxidation unit because the costs of permitting cannot be justified from a business standpoint for the small volume of LLMW generated. Nor does OMP Spring House intend to become a commercial mixed waste treatment facility, receiving mixed wastes from off-site facilities which might enable it to recover the costs of a RCRA permit. Finally, OMP Spring House has asserted (as have many of those who commented on EPA's July, 2001 proposed rule) that the costs of existing off-site commercial treatment for the small volume of mixed wastes typically generated in the pharmaceutical research industry are very high and therefore hinder the research and development of new pharmaceuticals.

1. Current Regulatory Status of Mixed Wastes

Mixed waste comprises radioactive hazardous waste, subject to two statutory authorities: (1) The RCRA as implemented by EPA (or States authorized by EPA) with jurisdiction over the hazardous waste component; and (2) the AEA as implemented by either the Department of Energy (DOE), or the Nuclear Regulatory Commission (NRC) (or its Agreement States) with jurisdiction over the radioactive component of the waste. Therefore, absent today's regulatory modification, the management of the mixed wastes that are the subject of this XL pilot project would continue to be subject to both RCRA permitting and NRC licensing requirements and regulatory oversight from the point the waste is generated through to its final disposal.

Members of the regulated community have raised concerns that this dual regulatory oversight of LLMW is unduly burdensome, duplicative and costly, without providing any additional protection of human health and the environment beyond that achieved under one regulatory regime. In response to these concerns, on April 30, 2001, EPA Administrator Christine Todd Whitman signed a final mixed waste rule modifying the existing regulatory framework to provide flexibility related to the storage, treatment (of certain types), transportation and disposal for LLMW (see 66 FR 27217, May 16, 2001). This rule became effective on November 13, 2001 (''Mixed Waste Rule'').

In developing the Mixed Waste Rule, EPA assessed NRC regulations for storage, treatment, transportation and disposal of low-level wastes (LLW) and compared them with EPA's regulations for hazardous waste storage, treatment, transportation and disposal applicable to LLMW. The Agency found that given NRC's regulatory controls, protection of human health and the environment from chemical risks would not be compromised by deferral to NRC's LLW management requirements under the circumstances set forth in the Mixed Waste Rule. Accordingly, through the Mixed Waste Rule, the Agency adopted a conditional exemption from certain RCRA hazardous waste management requirements for NRC-licensed generators of LLMW, in specified circumstances.

Basically, the Mixed Waste Rule allows generators of LLMW to claim a conditional exemption from the RCRA regulatory definition of hazardous waste for mixed wastes stored, treated, transported or disposed of under the NRC regulatory regime, acknowledging the protectiveness of NRC regulations for LLW (of which LLMW is a part). (For the complete text of the Mixed Waste Rule, see 66 FR 27217, May, 16, 2001.) More specifically, the conditional exemption allows, among other things,

a generator to treat LLMW generated under a single NRC or NRC Agreement State license, in tanks or containers, without having to obtain a RCRA treatment permit, provided the form of treatment is allowed under its NRC or NRC Agreement State license. The conditional exemption for storage and treatment is only available to generators of LLMW that are licensed by the NRC or NRC Agreement States. In addition, the Mixed Waste Rule provides that LLMW that meets the applicable Land Disposal Restrictions (LDR) standards (either as generated or through treatment) may be transported and disposed of as LLW at an NRC or NRC Agreement State licensed low-level radioactive waste disposal facility (LLRWDF), which need not also possess a RCRA treatment, storage, or disposal permit.

2. Site-Specific Considerations at the OMP Spring House Facility

OMP Spring House conducts research and development of pharmaceuticals/drugs at its Spring House, Pennsylvania facility. As part of this work, OMP Spring House develops and utilizes radiolabeled compounds to study the bioabsorption and metabolism of the drugs, in compliance with Food and Drug Administration (FDA) requirements. The radiolabeled compounds typically consist of an isotopically-labeled organic compound and a solvent (the specific solvent varies with the research being conducted). The solvent is mixed with a radioisotope (typically carbon-14 (^{14}C) or tritium (^{3}H)), yielding both the desired radiolabeled compound, and a waste mixture that consists of radioactive materials (over which NRC has jurisdiction) and a hazardous organic component (over which EPA has jurisdiction). This radioactive/hazardous organic waste mixture is the LLMW that is the focus of this XL pilot project. The estimated volume of mixed waste produced per batch by OMP Spring House ranges from less than 50 milliliters to several liters, with an annual total volume of less than 50 liters.

OMP Spring House has developed an innovative bench-scale treatment process (using high-temperature catalytic oxidization), which oxidizes the mixed waste, thereby destroying its hazardous waste components (yielding water and CO_2) and capturing the radioactivity in the aqueous residuals or as radioactive CO_2. In this process the liquid LLMW is completely reacted with oxygen or air at high temperature in the presence of an oxidation catalyst. [For a general physical description of the bench-scale high-temperature catalytic oxidizing unit and how it operates, the reader is referred to the July 24, 2001 proposed rule (see 66 FR at 38399). For a more complete technical description of the unit, operations parameters and analytical methodology, the reader is referred to the document titled ''A Prototype High-Temperature Catalytic Oxidation Process For Mixed Waste In A Pharmaceutical Research Laboratory,'' available in the docket for today's final rule under Docket ID No. RCRA–2001–0021.]

OMP Spring House's treatment of carbon-14 labeled compounds generates radioactive CO_2 (which is subsequently converted to potassium carbonate) and the treatment of tritium labeled compounds generates radioactive (i.e., tritiated) water (^{3}H). These residual low-level wastes could then be sent off-site for stabilization, recycling, or disposal under NRC or NRC Agreement State regulation. [The Agency notes that because the treatment process yields one of two residuals from a variety of LLMW, they are more amenable to recycling (*e.g.,* recovery of tritium). However, recycling the small volumes of residuals being generated at the OMP Spring House facility is not currently economically viable. OMP Spring House has been working to support efforts to facilitate the recovery of radioactivity from residuals like those it generates in its high-temperature catalytic oxidization process.] For tritium containing compounds, the volume of the treatment residual is generally the same volume as the wastestream being treated. For carbon-14 containing compounds, the volume of the treatment residuals is generally slightly higher than the volume of the original wastestream being treated. The yearly estimated volume of the treatment residuals generated by the high-temperature catalytic oxidation of LLMW at OMP Spring House is 50 liters per year, which is about the same as the volume of the original LLMW.

OMP Spring House has been operating this innovative catalytic oxidation process for the treatment of the mixed wastes it generates since 1996 under a ''treatability study exemption'' approved by the PADEP, which is authorized to carry out portions of the RCRA hazardous waste program in Pennsylvania. This treatability study has been conducted to evaluate the performance of the catalytic oxidation process on the organic component of these mixed wastes and the capture of the radioactive components.

The treatment technology being employed by OMP Spring House is not included under the 2001 Mixed Waste Rule because it is not conducted within a ''tank'' or ''container,'' as those terms are defined in RCRA. The Agency determined that more specific controls (as are presently provided under RCRA) are generally more appropriate for certain forms of treatment, such as thermal treatment (including incineration) which take place outside of a ''tank'' or ''container,'' due to the complexity and variety of such processes and the specificity of RCRA requirements. This XL pilot project affords the Agency an opportunity to test whether a defined subset of LLMW (e.g., small volumes of research and development laboratory-generated mixed wastes being treated within the NRC-licensed laboratory in which the wastes are generated) may safely be treated outside of a tank or container (e.g., use of a bench-scale high temperature catalytic oxidation process) without RCRA regulatory controls (i.e., a treatment permit pursuant to Subtitle C of RCRA), instead relying on AEA regulations implemented by the NRC. Thus, this pilot project is intended to assess the appropriateness of the dual oversight (i.e., concurrent RCRA and AEA regulatory controls) exerted over the small volumes of mixed wastes generated and treated at this pharmaceutical research and development facility, and to characterize those factors that could inform EPA's decision whether mixed wastes generated and treated in similar circumstances should also be exempted from the regulatory definition of hazardous wastes (and thus, RCRA regulatory control) on a national basis (in effect, deferring regulatory oversight of these specific types of mixed wastes to NRC or NRC Agreement States). The pilot project will also provide the Agency additional data regarding the performance of the on-site, bench-scale high-temperature catalytic oxidation unit used to treat the mixed wastes, which will also be considered as part of any future determination regarding possible changes to the types of units included in RCRA's May 2001 Mixed Waste Rule.

To date, OMP Spring House's treatability study has yielded extremely positive results, demonstrating that the full range of organics used to produce radiolabeled compounds are effectively eliminated (routinely achieving destruction and removal efficiencies (DRE) of 99.999% to 99.99999%) by the high-temperature catalytic oxidation process. The treatment process exceeds Land Disposal Restricitons (LDR) treatment standards for organics, and

releases only negligible amounts of radioactivity[1]1.

The catalytic oxidation unit is housed in a laboratory fume hood within OMP Spring House's radiosynthesis laboratory suite. All seven fume hoods in the lab suite are connected to a dedicated stack for air emissions. This air pollution control system employs high efficiency particulate arresting (HEPA) filtration to capture any fugitive dusts or particulate matter. No other pharmaceutical research operations, or other processes performed at the facility are tied into this system. Air emissions monitoring for radioactivity is performed whenever the process is operating. The monitoring is of the consolidated non-turbulent air stream within the ventilation system after the juncture of the seven hoods and prior to emissions into the atmosphere via the dedicated stack.

C. What Solution Is Being Tested by the OMP Spring House XL Project?

OMP Spring House originally proposed that EPA address its LLMW in one of three ways:

—Exempt the bench-scale treatment of mixed wastes from permitting requirements,

—Provide permit-by-rule exemptions for the bench-scale treatment of mixed wastes, or

—De-list post-oxidation wastes pursuant to 40 CFR 260.20 and 260.22 to allow the treatment of the LLMW.

Under each of these alternatives, OMP Spring House noted that the laboratory in which the wastes are generated and treated would continue to be subject to an NRC license, which it believed would be sufficient to protect human health and the environment during the generation and treatment of its LLMW, especially considering the very small volumes of wastes being generated and treated, the small size of the treatment unit, the proximity of the treatment unit to the point of generation (the wastes are both generated and treated within the same laboratory room), the sophisticated level of expertise of the technicians that work in the lab, and the protective controls (*e.g.*, emission limits) required by the NRC license.

EPA and the PADEP agreed that applicability of OMP Spring House's NRC license conditions was likely sufficient to ensure that OMP Spring House's high-temperature catalytic oxidation would be operated so as to be protective of human health and the environment absent RCRA regulatory controls, and EPA determined that the most appropriate mechanism to confirm this was by exempting OMP Spring House's LLMW from RCRA's definition of hazardous waste, as discussed below.

D. What Regulatory Changes Are Being Made To Implement This Project?

To allow for this XL project to be implemented, the Agency proposed on July 24, 2001 to provide a site-specific exemption in 40 CFR 261.4(b) (*i.e.*, ''Solid wastes which are not hazardous wastes'') for the mixed wastes generated and treated in OMP Spring House's pharmaceutical research and development (R&D) laboratory (see 66 FR 38396). The Agency is today finalizing this site-specific rule, albeit clarifying that it comprises an exemption to RCRA's definition of hazardous waste, not an exclusion to RCRA's definition of solid waste.[2] The effect of this exemption, assuming all the conditions are met, is to remove these wastes from RCRA Subtitle C regulation at the point of their generation. Further, because the residuals resulting from the catalytic oxidation treatment process will not be derived from hazardous wastes, no ''delisting'' is required for these residuals (since the original wastestream will no longer comprise a RCRA ''listed'' waste). The Agency believes that this regulatory mechanism is the most efficient way to provide OMP Spring House with the regulatory outcome it seeks and implement the XL pilot project.

The site-specific exemption being finalized today is conditioned on various reporting requirements intended to provide the Agency with the data necessary to determine whether this XL pilot project is a success and obtain the information to help it decide whether the regulatory change should be ''transferred'' to the national program (which, if it occurs, would happen through normal rulemaking procedures). The specific conditions are further discussed in section III.I.

E. Why Is EPA Supporting This Approach To Removing RCRA Regulatory Controls Over a Mixed Waste?

The Agency agrees with OMP Spring House that this XL project has merit and has the potential to result in significant environmental and efficiency benefits should the regulatory change be adopted on a national basis. While the Agency adopted the Mixed Waste Rule to generically address the regulation of some mixed wastes, Project XL offers the Agency the opportunity to test alternative approaches, in this case, an alternative approach tailored to a specific subset of the generic category of mixed wastes not covered by the Mixed Waste Rule. The Agency believes this is the type of ''test'' that Project XL is intended to facilitate. The information and data gathered throughout the course of this XL project will provide the Agency with the ability to make a more informed determination regarding the appropriate regulatory controls for ''mixed waste'' generally, as well as certain discrete subsets of ''mixed waste'' that may be amenable to an alternative regulatory approach.

F. How Have Various Stakeholders Been Involved in This Project?

During the developmental stages of this XL pilot project, OMP Spring House cultivated stakeholder involvement from the local community and local environmental groups in a variety of ways. These methods included communicating through the local news media, announcements at Township meetings, public meetings and direct contact with interested parties. For a more detailed description of the methods used to involve stakeholders and the meetings held with the local community to discuss the pilot project, the reader is referred to the July 24, 2001 proposed rulemaking (see 66 FR at 38401).

[1] During calendar year 2003, air emissions monitoring revealed an annual average concentration of 7.54E–11 uCi/mL for tritium and 2.09E–11 uCi/mL for carbon-14 for all operations (i.e., not just emissions from the high-temperature catalytic oxidation process). These annual average concentrations of radionuclides in effluent air are less than 0.08% of the limits specified by NRC in 10 CFR Part 20 for allowable concentrations in effluent air (i.e., $1 \times 10E{-}7$ mCi/mL for tritium and $3 \times 10E{-}7$ uCi/mL for carbon-14 (present as carbon dioxide-^{14}C)). Note that these units are expressed in microcuries (10 E–6 curies)/milliliter.

[2] In its July, 2001 proposal, EPA characterized the regulatory flexibility to be offered under this XL Project as comprising a

''site specific exclusion in 40 CFR 261.4(b) (i.e. 'Solid wastes which are not hazardous wastes') for the mixed wastes generated and treated in OMP Spring House's pharmaceutical research and development (R&D) laboratory. The effect of this exclusion, assuming all the conditions are met, will be to exclude these wastes from RCRA Subtitle C regulation at the point of generation, * * * Instead of being considered 'mixed wastes,' these wastes will simply be considered low-level wastes (LLWs) subject to NRC or NRC Agreement State regulation.''

66 FR at 38400–01.

EPA has determined that its use of the word ''exclusion'' (which generally applies to materials excluded from RCRA's definition of solid waste under 40 CFR 261.4(a) rather than materials exempted from RCRA's definition of hazardous waste under 40 CFR 261.4(b)), and the potential implication that this regulatory change would result in clarification. In this final rule, EPA makes plain that the effect of this regulatory change is to conditionally exempt OMP Spring House's LLMW from RCRA's definition of hazardous waste under 40 CFR 261.4(b) (and thus from its hazardous waste regulations). OMP Spring House's LLMW remains a solid waste under RCRA and thus, is subject to EPA's enforcement authority under Section 7001 of RCRA.

OMP Spring House understands that stakeholder involvement is an integral part of the XL process and will continue to hold public meetings with the local community to provide updates and information on this XL pilot project, as needed.

G. Response to Major Comments Received on the Proposed Rule

The Agency received 65 comments in response to the July 24, 2001 proposed rule. Detailed responses to all of these comments is presented in the document titled ''Response to Comments on the OMP Spring House XL Project NPRM'' contained in the docket for today's final rulemaking under Docket ID No. RCRA–2001–0021. The vast majority of these comments were very supportive and generally encouraged the Agency to move quickly to consider similar regulatory flexibility on a national scale. However, two commenters submitted adverse comments, and several commenters provided editorial suggestions and requests for clarification.

The two commenters which opposed the proposed rule were both commercial LLMW treatment facilities, capable of treating OMP Spring House's's LLMW. (EPA does note that several other treatment facilities offered comments that were supportive of the proposal.) These two commenters questioned the merits of reducing regulatory oversight for such wastes (with the potential for increased risks); the impact of such an exemption on the existing commercial mixed waste treatment industry (which has invested substantial resources to obtain the necessary permits and licenses), and, (if the regulatory flexibility is adopted on a national scale for research and development laboratories) the advisability of having many facilities generating radioactive residuals (even if they are small in volume and recyclable) rather than a small number of commercial facilities generating such residuals (albeit in larger quantities).

The Agency has considered the concerns expressed by these commenters; however, it believes this pilot project should go forward. The Agency believes that the NRC license provides sufficient protections, at least in this specific situation, such that a RCRA permit is not necessary. Thus, we disagree with the commenter who argues that the facility would be ''unlicensed/unpermitted.'' We also disagree with the commenter who suggested that this rulemaking would reduce the treatment standards for this waste. As has been demonstrated, the high-temperature catalytic oxidation unit utilized by OMP Spring House meets or exceeds the existing treatment standards that these wastes are subject to. Thus, we believe that the rule will not pose additional risks to workers or the public. Moreover, the Agency notes that since OMP Spring House's waste stream will remain a solid waste under RCRA, it retains the authority to require OMP Spring House to address any threat which it determines presents an imminent threat to the public health or the environment. See 42 U.S.C. 6973(a). Further, a core goal of EPA's XL initiative is to promote innovation, which includes considering whether new approaches are better able to protect the public health and the environment than existing regulatory requirements, even where the latter are long-established and required significant investment by facilities to comply. Therefore, while EPA understands the concerns expressed by these commercial mixed waste treatment facilities, the Agency does not believe that these concerns are sufficient to preclude the exploration of other approaches or, in this specific case, testing the proposition that an NRC license provides sufficient protections for the thermal treatment of small volumes of research and development LLMW in the same laboratory where the wastes are generated. (The Agency notes that these commenters did not suggest any specific RCRA regulatory requirement that they thought is necessary to protect human health and the environment at OMP Spring House's NRC-licensed facility.)

H. How Will This Project Result in Cost Savings and Paperwork Reduction?

OMP Spring House has stated that if it became required to obtain a RCRA permit to operate its catalytic oxidation unit, it would instead send its small volume of mixed wastes generated to a commercial treatment facility.[3] For mixed wastes, commercial treatment costs are typically based primarily upon the level of radioactivity (*i.e.*, number of curies) being treated, as well as the volume of the waste. The costs range from approximately $20,000–$35,000 per curie, with an average cost of $30,000/curie. This represents a $300,000/year cost for OMP Spring House, which generates up to 10 curies of mixed waste per year. OMP Spring House has stated that other cost savings, such as reduced transportation costs and administrative/paperwork savings resulting from no longer having its LLMW be defined as a RCRA hazardous waste, are relatively minor compared with the costs of commercial LLMW treatment.

EPA understands that pharmaceutical, medical, and academic research activities, such as the radiolabeling which generates OMP Spring House's mixed wastes, are often limited by the high costs of waste management. Because waste management costs are such a major factor in the budgets allocated to such R&D activities, the high cost of waste management can significantly reduce the money actually spent on R&D. With more cost-effective treatment (such as OMP Spring House's on-site bench-scale catalytic oxidation unit), more money could be spent on the actual research and development of pharmaceuticals.

I. What Are the Terms of the OMP Spring House XL Project and How Will They Be Enforced?

To implement this XL pilot project, EPA is today modifying 40 CFR 261.4(b) by providing a site-specific exemption from the regulatory definition of hazardous waste for OMP Spring House's LLMW generated and treated in their radiosynthesis laboratory, which is subject to a ''Type A Broad Scope'' NRC license for research and development. In accordance with 25 Pa. Code section 261a.1 of Pennsylvania's RCRA-authorized hazardous waste program, EPA's exemption of OMP Spring House's mixed waste from the regulatory definition of hazardous waste under RCRA is automatically incorporated in Pennsylvania's hazardous waste regulations because the State hazardous waste regulations incorporate 40 CFR 261.4(b) by reference, including any modification or additions made to that section by the Federal program.

Through the development of the Final Project Agreement (FPA), OMP Spring House had agreed to comply with several conditions for this exemption, which were included in the regulatory text that was proposed on July 24, 2001 and are being finalized today. These conditions focus on demonstrating the efficacy of the treatment technology, and to gather the data and other information that will allow the Agency to make a determination regarding the possible future adoption of this site-

[3] OMP Spring House believes that the current RCRA permitting requirements are intended to apply primarily to commercial hazardous waste treatment facilities, and that it would be difficult to justify investing the costs of obtaining and maintaining a RCRA Subtitle C permit unless it could recoup such costs through commercial activities (i.e., treating wastes generated by other generators for a fee). OMP Spring House has stated that it neither is nor intends to be in the commercial waste treatment business, and therefore it would not seek such a permit.

specific exemption as a nationwide generic exemption.

The site-specific exemption is limited to a total volume of 50 liters/year of mixed waste and only applies to mixed wastes that are generated and treated using OMP Spring House's high-temperature catalytic oxidation process within the OMP Spring House facility's radiosynthesis laboratory. In addition, the exemption is further conditioned such that OMP Spring House must report, on a semi-annual basis, the following:

(1) Analysis demonstrating the destruction and removal efficiencies for all organic components of the exempted wastes subject to treatment.

(2) Analysis demonstrating the capture efficiencies for the radioactive component of the exempted wastes subject to treatment, and an estimate of the amount of radioactivity that was released during the reporting period.

(3) Analyses of the constituent concentrations, including inorganic constituents, present and radioactivity of the exempted wastes prior to, and after, treatment.

(4) The volume of exempted wastes treated per batch, as well as a total for the duration of the reporting period.

(5) The final disposition of the radioactive residuals from the treatment of the exempted wastes.

In addition, OMP Spring House commits to work with other companies, organizations and research institutes to: (1) Further develop a standard, bench-scale off-the-shelf treatment unit, based on its high-temperature catalytic oxidation technology, to be made available to any company or institution that generates similar R&D quantities of mixed wastes, and (2) further develop the technology and market for the recycling and reuse of the radioactive component of the LLMW (*i.e.*, the LLW residuals resulting from the treatment of the LLMW).

As part of meeting this commitment, OMP Spring House will prepare (and submit to EPA for review and comment) a proposed plan summarizing how it will accomplish this goal. Because these two commitments involve the participation of other companies and entities outside OMP Spring House's control and thus are much less certain than the conditions discussed above, these commitments have not been made conditions of the exemption. However, in evaluating the success of this XL project, these ''non-enforceable'' commitments will be considered by EPA and the PADEP.

J. How Long Will This Project Last and When Will It Be Completed?

This project will be in effect for five years from the date that this final rulemaking becomes effective, unless it is terminated earlier or extended by all project signatories (if the FPA and rule are extended, this will be done through a rulemaking seeking the comments and input of stakeholders and the public). Any project signatory may terminate its participation in this project at any time in accordance with the procedures set forth in the FPA. The project will be completed at the conclusion of the five-year anniversary of today's final rulemaking or at a time earlier or later as agreed to by the parties involved.

IV. RCRA & Hazardous and Solid Waste Amendments of 1984

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified States to administer and enforce the RCRA program for hazardous waste within the State. (See 40 CFR Part 271 for the standards and requirements for authorization.) States with final authorization administer their own hazardous waste programs in lieu of the Federal program. Following authorization, a state continues to have enforcement responsibility under its State law to pursue violations of its hazardous waste program. EPA continues to have independent enforcement authority under sections 3007, 3008, 3013 and 7003 of RCRA.

After authorization, Federal rules issued under RCRA provisions that predate the Hazardous and Solid Waste Amendments of 1984 (HSWA), no longer apply in the authorized state. New Federal requirements imposed by non-HSWA rules do not take effect in an authorized State until the State adopts the requirements as State law.

In contrast, under section 3006(g) of RCRA, new requirements and prohibitions imposed by HSWA take effect in authorized States at the same time they take effect in nonauthorized States. EPA is directed to carry out HSWA requirements and prohibitions in authorized States until the State is granted authorization to do so.

B. Effect on Pennsylvania Authorization

Today's final rule is promulgated pursuant to non-HSWA authority. Pennsylvania initially received authority from EPA to implement its base hazardous waste program effective January 30, 1986 (see 51 FR 1791, January 15, 1986). Because EPA clarified that the hazardous waste component of mixed waste was subject to RCRA after Pennsylvania received its initial RCRA base authorization (see 51 FR 24504, July 3, 1986), mixed waste was not initially included within Pennsylvania's authorized base program. Pennsylvania subsequently applied to EPA, seeking approval that its hazardous waste program, as revised (including its adoption of regulations governing mixed waste), complied with RCRA. Under the terms of the Commonwealth's hazardous waste program, subsequent modifications and additions to EPA's RCRA regulations as published in the Code of Federal Regulations (with certain exceptions not relevant here) are automatically incorporated into the Commonwealth's hazardous waste program. See 29 Pa. Bull. 2367, 2370 (May 1, 1999), 65 FR at 57734 and 57736 (September 26, 2000).

On September 26, 2000, EPA published notice of Final Authorization of Pennsylvania's hazardous waste program, including specifically its regulation of mixed waste, effective November 27, 2000. See 65 FR 57734 and 57736 (September 26, 2000). EPA did not receive any adverse comments, and thus EPA's authorization of Pennsylvania's hazardous waste program (including mixed wastes) became effective on November 27, 2000.

This XL project was undertaken and developed (by EPA, PADEP, and OMP Spring House) with the assumption that Pennsylvania would receive authorization for mixed wastes, necessitating the regulatory flexibility on the part of PADEP to implement the XL project. Since Pennsylvania has had RCRA authorization for mixed wastes since November 27, 2000, and because Pennsylvania's definition of hazardous waste under the Pennsylvania Solid Waste Management Act (PaSWMA), including its exclusions and exemptions, incorporates RCRA's analogous provisions upon their promulgation, this rule will have the effect of exempting OMP Spring House's mixed wastes from regulation by the Commonwealth as a hazardous waste under its hazardous waste program, which in turn allows Pennsylvania to implement this XL project.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735), the Agency must determine whether this regulatory action is ''significant'' and therefore subject to formal review by the Office of Management and Budget (OMB) and to

the requirements of the Executive Order, which include assessing the costs and benefits anticipated as a result of this regulatory action. The Order defines ''significant regulatory'' action as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Because this rule affects only one facility, it is not a rule of general applicability and therefore is not subject to OMB review and Executive Order 12866.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, since it applies to only one facility. It is exempt from OMB review under the Paperwork Reduction Act because it is a site-specific rule, directed to fewer than ten persons. 44 U.S.C. 3502(3), (10); 5 CFR 1320.3(c), 1320.4 and 1320.5.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

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 EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an Agency is required to publish a notice for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small governmental jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. This rule will not have a significant impact on a substantial number of small entities because it only affects the OMP Spring House facility, and it is not a small entity.

Based on the foregoing discussion, I hereby certify that this rule will not have a significant adverse economic impact on a substantial number of small entities. Consequently, the Agency has determined that preparation of a formal Regulatory Flexibility Analysis is unnecessary.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''federal mandates'' that may result in expenditures by state, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year.

Before promulgating a rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enable officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

As noted above, this rule is applicable only to one facility in Pennsylvania. EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. EPA has also determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.''

This rule does not have federalism implications. It will not have a substantial direct effect on States, on the relationship between the National Government and the States, or on the distribution of powers and responsibilities among the various levels of government, as specified in Executive Order 13132. Today's rule will only affect one facility, providing regulatory flexibility applicable to this specific site. Thus, Executive Order 13132 does not apply to this rule.

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

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.''

This final rule, does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. EPA is currently unaware of any Indian tribes located in the vicinity of the facility. Thus, Executive Order 13175 does not apply to this rule.

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

Executive Order 13045, ''Protection of Children From Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that EPA determines (1) is ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potential effective and reasonably feasible alternatives considered by the Agency.

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

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (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. It will not result in increased energy prices, increased cost of energy distribution, or an increased dependence on foreign supplies of energy.

I. National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA,'' Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. Today's rule does not establish technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

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

Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (February 11, 1994) is designed to address the environmental and human health conditions of minority and low-income populations. EPA is committed to addressing environmental justice concerns and has assumed a leadership role in environmental justice initiatives to enhance environmental quality for all citizens of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, income, or net worth bears disproportionately high and adverse human health and environmental impacts as a result of EPA's policies, programs, and activities.

Today's rule applies to one facility in Pennsylvania. Overall, no disproportional impacts to minority or low income communities are expected.

Today's rule applies to one facility in Pennsylvania. Overall, no disproportional impacts to minority or low income communities are expected.

K. Executive Order 12988: Civil Justice Reform

In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988, entitled Civil Justice Reform (61 FR 4729, February 7, 1996).

L. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules (1) rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability.

List of Subjects in 40 CFR Part 261

Environmental protection, Hazardous materials, Waste treatment and disposal.

Dated: June 20, 2005.

Stephen L. Johnson,

Administrator.

■ For the reasons set forth in the preamble, title 40, chapter I of the Code of Federal Regulations is 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.

Subpart A—General

■ 2. Section 261.4 is amended by adding paragraph (b)(17) to read as follows:

§ 261.4 Exclusions.

* * * * *

(b) * * *

(17) Solid waste that would otherwise meet the definition of low-level mixed wastes (LLMW) pursuant to § 266.210 of this chapter that is generated at the Ortho-McNeil Pharmaceutical, Inc. (OMP Spring House) research and development facility in Spring House, Pennsylvania and treated on-site using a bench-scale high temperature catalytic oxidation unit is not a hazardous waste provided that:

(i) The total volume of LLMW generated and treated is no greater than 50 liters/year, (ii) OMP Spring House submits a written report to the EPA Region III office once every six months beginning six months after June 27, 2005, that must contain the following:

(A) Analysis demonstrating the destruction and removal efficiency of the treatment technology for all organic components of the wastestream,

(B) Analysis demonstrating the capture efficiencies of the treatment technology for all radioactive components of the wastestream and an estimate of the amount of radioactivity released during the reporting period,

(C) Analysis (including concentrations of constituents, including inorganic constituents, present and radioactivity) of the wastestream prior to and after treatment,

(D) Volume of the wastestream being treated per batch, as well as a total for the duration of the reporting period, and

(E) Final disposition of the radioactive residuals from the treatment of the wastestream.

(iii) OMP Spring House makes no significant changes to the design or operation of the high temperature catalytic oxidation unit or the wastestream.

(iv) This exclusion will remain in affect for 5 years from June 27, 2005.

* * * * *

[FR Doc. 05–12658 Filed 6–24–05; 8:45 am]

BILLING CODE 6560–50–P