ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[FRL–7017–4]

RIN 2090–AA14

Project XL Site-Specific Rulemaking for the Ortho-McNeil Pharmaceutical, Inc. Facility in Spring House, Pennsylvania

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing this rule to implement a pilot project under the Project XL program that would provide site-specific regulatory flexibility under the Resource Conservation and Recovery Act (RCRA), as amended, for the Ortho-McNeil Pharmaceutical, Inc. (OMP) facility in Spring House, Pennsylvania. The principal objective of this XL project is to determine 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 are also radioactive) that are both generated and treated in an NRC-licensed pharmaceutical research and development laboratory. Specifically, this XL project will allow for the treatment (through high-temperature catalytic oxidation) of small volumes of low-level mixed wastes (LLMW) to destroy the organic portion of the waste, generating a residual (in which the hazardous organic constituents are no longer detected) that can be managed as a low-level radioactive waste (i.e., no longer designated as a RCRA mixed waste and thus, no longer subject to RCRA regulatory requirements). If, as a result of this XL project, the Agency determines that certain small volumes of mixed wastes generated and managed in a research and development facility 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.

To implement this XL project, this proposed rule, when finalized, will provide a site-specific exclusion from the regulatory definition of hazardous waste for the mixed wastes generated and treated in OMP's research and development laboratory. The terms of the overall XL project are contained in a Final Project Agreement (FPA) which is included in the docket for this proposal. A draft version of the FPA was the subject of a Notice of Availability published in the **Federal Register** on September 1, 2000 (65 FR 53297) in which EPA solicited comment. The FPA was signed on September 22, 2000 by representatives of EPA, the Pennsylvania Department of Environmental Protection, and Ortho-McNeil Pharmaceutical. This proposed rule, when finalized, will allow for the implementation of the FPA.

DATES: *Public Comments:* Comments on the proposed rule and/or FPA must be received on or before August 23, 2001. All comments should be submitted in writing to the address listed below.

Public Hearing: Commenters may request a public hearing by August 7, 2001, during the public comment period. Commenters requesting a public hearing should specify the basis for their request. If EPA determines that there is sufficient reason to hold a public hearing, it will do so by August 14, 2001, during the last week of the public comment period. Requests for a public hearing should be submitted to the address below. If a public hearing is scheduled, the date, time, and location will be available through a **Federal Register** notice or by contacting Mr. Charles Howland at the U.S. EPA Region III office, at the address below.

ADDRESSES: *Comments:* Written comments should be mailed to the RCRA Information Center Docket Clerk (5305W), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460. Please send an original and two copies of all comments, and refer to Docket Number F–2001–OMPP–FFFFF.

Request for a Hearing: Requests for a hearing should be mailed to the RCRA Information Center Docket Clerk (5305G), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, D.C. 20460. Please send an original and two copies of all comments, and refer to Docket Number F–2001–OMPP–FFFFF. A copy should also be sent to Mr. Charles Howland at U.S. EPA Region III. Mr. Howland may be contacted at the following address: U.S. Environmental Protection Agency, Region III (3OR00), 1650 Arch Street, Philadelphia, PA, 19103–2029, (215) 814–2645.

Viewing Project Materials: A docket containing the proposed rule, Final Project Agreement, supporting materials, and public comments is available for public inspection and copying at the RCRA Information Center (RIC), located at Crystal Gateway, 1235 Jefferson Davis Highway, First Floor, Arlington, Virginia. The RIC is open from 9:00am to 4:00pm Monday through Friday, excluding Federal holidays. The public is encouraged to phone in advance to review docket materials. Appointments can be scheduled by phoning the Docket Office at (703) 603–9230. Refer to RCRA docket number F–2001-OMPP-FFFFF. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost 15 cents per page. Project materials are also available for review for today's action on the World Wide Web at *http://www.epa.gov/projectxl/*.

A duplicate copy of the docket is available for inspection and copying at U.S. EPA Library, Region III, 1650 Arch Street, Philadelphia, PA 19107 during normal business hours. Persons wishing to view the duplicate docket at the Philadelphia location are encouraged to contact Mr. Charles Howland in advance, by telephoning (215) 814–2645.

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*). Further information on today's action may also be obtained on the World Wide Web at *http://www.epa.gov/projectxl/*.

SUPPLEMENTARY INFORMATION: All other hazardous wastes generated and/or managed at the OMP facility remain subject to current RCRA Subtitle C regulations. Similarly, mixed wastes generated in other pharmaceutical research and development facilities remain subject to current RCRA regulations. 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 may determine whether mixed wastes generated and treated in similar circumstances should also be excluded from the regulatory definition of hazardous wastes (and thus, RCRA regulatory control) by providing such regulatory flexibility 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 the implementation of the regulatory flexibility on a national basis.

The exclusion from the regulatory definition of hazardous waste for the mixed wastes generated at this Ortho-McNeil Pharmaceutical facility will remain in effect only for the five-year term of this XL project. The five-year term begins upon the effective date of the final rulemaking promulgated to allow for the XL project to be implemented.

Today's proposed rulemaking will not in any way affect the provisions or applicability of any other existing or future regulations.

EPA is soliciting comments on this rulemaking. EPA will publish responses to comments in a subsequent final rule, or in a ''Response to Comments'' document that will be included in the docket for the final rule. The XL project will enter the implementation phase when the final rule (or other legal mechanism) is promulgated by EPA and the Pennsylvania Department of Environmental Protection (PADEP).

Outline of Today's Proposal

The information presented in this preamble is organized as follows:

I. Authority

EPA is publishing this proposed 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, PADEP, and the OMP Spring House, PA facility with regard to a project developed under Project XL, an EPA initiative that allows regulated entities to achieve better environmental results with limited regulatory flexibility. This proposed regulation, along with the FPA (contained in the docket for this proposal), will facilitate implementation of the project. Project XL—''eXcellence and Leadership''— was announced on March 16, 1995, as a central part of the National Performance Review and 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. These efforts are crucial to EPA's ability to test new strategies that reduce regulatory burden and promote economic growth while achieving better environmental and public health protection. EPA intends to evaluate the results of this and other Project XL projects to determine which specific elements of the projects, if any, should be more broadly applied to other regulated entities for the benefit of both the environment and the economy.

Under Project XL, participants in four categories—facilities, industry sectors, governmental agencies and communities—are offered the flexibility to develop common sense, cost-effective strategies that will replace or modify specific regulatory requirements, on the condition that they produce and demonstrate superior environmental performance.

The XL program is intended to encourage EPA to experiment with potentially promising regulatory approaches, both to assess whether they provide benefits at the specific facility affected, and whether they should be considered for wider application. Such pilot projects allow EPA to proceed more quickly than would be possible when undertaking changes on a nationwide basis. As part of this experimentation, EPA may try out approaches or legal interpretations that depart from, or are even inconsistent with, longstanding Agency practice, so long as those interpretations are within the broad range of discretion enjoyed by the Agency in interpreting the statutes that it implements. EPA may also modify rules, on a site-specific basis, that represent one of several possible policy approaches within a more general statutory directive, so long as the alternative being used is permissible under the statute.

Adoption of such alternative approaches or interpretations in the context of a given XL project does not, however, signal EPA's willingness to adopt that interpretation as a general matter, or even in the context of other XL projects. It would be inconsistent with the forward-looking nature of these pilot projects to adopt such innovative approaches prematurely on a widespread basis without first determining whether they are viable in practice and successful in the particular projects that embody them. Furthermore, as EPA indicated in announcing the XL program, EPA expects to adopt only a limited number of carefully selected projects. These pilot projects are not intended to be a means for piecemeal revision of entire programs. Depending on the results in these projects, EPA may or may not be willing to consider adopting the alternative interpretation again, either generally or for other specific facilities.

EPA believes that adopting alternative policy approaches and interpretations, on a limited, site-specific basis and in connection with a carefully selected pilot project, is consistent with the expectations of Congress about EPA's role in implementing the environmental

statutes (provided that the Agency acts within the discretion allowed by the statute). Congress' recognition that there is a need for experimentation and research, as well as ongoing re-evaluation of environmental programs, is reflected in a variety of statutory provisions, such as section 8001 of RCRA.

XL Criteria

To participate in Project XL, applicants must develop alternative environmental performance objectives pursuant to eight criteria: superior environmental performance; cost savings and paperwork reduction; stakeholder involvement and support; test of an innovative strategy; transferability; feasibility; identification of monitoring, reporting and evaluation methods; and avoidance of shifting risk burden. The XL projects must have the full support of the affected Federal, State, local and tribal agencies to be selected.

For more information about the XL criteria, readers should refer to the 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 XL project addresses the XL criteria, readers should refer to the Final Project Agreement available from the EPA RCRA docket or Region III library (see **ADDRESSES** section of today's preamble).

XL Program Phases

The Project XL program is compartmentalized into four basic developmental phases: the initial pre-proposal phase where the project sponsor comes up with an innovative concept that they would like EPA to consider as an XL pilot project; the second phase where the project sponsor works with EPA and interested stakeholders in developing an XL proposal; the third phase where EPA, local regulatory agencies, and other interested stakeholders review the XL proposal; and the fourth phase where the project sponsor works with EPA, local regulatory agencies, and interested stakeholders in developing a Final Project Agreement and legal mechanism. After promulgation of the final rule (or other legal mechanism) that provides the flexibility required for the XL pilot project, and after the Final Project Agreement has been signed by all designated parties, the XL pilot project proceeds onto implementation and evaluation.

Final Project Agreement

The Final Project Agreement (FPA) is a written voluntary agreement between the project sponsor and regulatory agencies. The FPA contains a detailed description of the proposed pilot project. It addresses the eight Project XL criteria, and the expectation of the Agency that the XL project will meet those criteria. The FPA identifies performance goals and indicators that the project is yielding the expected environmental benefits, and specifically addresses the manner in which the project is expected to produce superior environmental benefits. The FPA also discusses the administration of the FPA, including dispute resolution and termination. The FPA for this XL project is available for review in the docket for today's action, and also is available on the World Wide Web at *http://www.epa.gov/projectxl/.*

III. Overview of the OMP XL Pilot Project

EPA is today requesting comments on the proposed rule to implement key provisions of this Project XL initiative. Today's proposed rule would facilitate implementation of the FPA that has been developed by EPA, the Pennsylvania Department of Environmental Protection (PADEP), the Ortho-McNeil Pharmaceutical Spring House, PA facility, and other stakeholders. Today's proposed rule, when finalized, will automatically become effective under Pennsylvania State law in accordance with the Commonwealth's hazardous waste program, as described further in section IV.F. of this preamble.

A. To Which Facilities Will the Proposed Rule Apply?

This proposed rule, when finalized, would apply only to the OMP Spring House, PA facility. Further, the regulatory modification being proposed only affects the mixed waste that is the focus of this XL project; hazardous wastes resulting from any other operations at the facility are not affected by this proposed rule (or the final rule, when finalized).

B. What Problems Will the OMP XL Project Attempt to Address?

OMP does not believe the RCRA Subtitle C regulatory controls, as applied to the LLMW it generates and treats, provide any additional environmental protection than is otherwise provided by AEA oversight, but rather, RCRA Subtitle C regulatory controls serve as a major disincentive to the environmentally protective on-site treatment of the small volume of mixed wastes generated at the facility. While commercial treatment for such wastes is available, the on-site, bench-scale, high-temperature catalytic oxidation unit OMP 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 organics than available commercial treatment. (The on-site treatment of OMP's mixed wastes has been extensively tested under a ''treatability study'' exemption provided in 40 CFR 261.4(f) granted by PADEP.) According to OMP, it does not intend to pursue 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 waste generated. Nor does OMP intend to become a commercial mixed waste treatment facility and receive mixed wastes from off-site in order to recover the costs of a RCRA permit. Further, the costs of existing off-site commercial treatment for the small volume of mixed wastes generated are very high and therefore limit the research and development of new pharmaceuticals because the waste management costs associated with these activities represent such a large percentage of the research and development budget.

1. Current Regulatory Status of Mixed Wastes

Mixed waste is a radioactive hazardous waste, subject to two statutory authorities: (1) The Resource Conservation and Recovery Act (RCRA) as implemented by EPA (or States authorized by EPA) with jurisdiction over the hazardous waste component; and (2) the Atomic Energy Act (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. The management of the mixed wastes that are the subject of this XL pilot project are therefore 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 low-level mixed waste (LLMW) is excessively burdensome, duplicative and costly without providing any additional protection of human health and the environment than 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 current regulatory framework to provide flexibility related to the storage, treatment (certain kinds of treatment), transportation and disposal for LLMW (see 66 FR 27217, May 16, 2001). This rule will become effective on November 13, 2001.

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. Accordingly, the Agency adopted a conditional exemption from certain RCRA hazardous waste management requirements for NRC-licensed generators of LLMW.

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. (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, provided the form of treatment is allowed under its NRC or NRC Agreement State license. The conditional exemption is only available to generators of LLMW that are licensed by the NRC or NRC Agreement States. In addition, LLMW that meets the applicable LDR standards (either as generated or through treatment) may be transported and disposed of as a LLW at an NRC or NRC Agreement State licensed low level radioactive waste disposal facility (LLRWDF).

The treatment technology being employed by OMP is not exempted under the Mixed Waste Rule because it does not within a tank or container. The Agency determined that more specific controls (as are provided under RCRA) are more appropriate for certain forms of treatment, such as incineration, due to the complexity of the treatment 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.

2. Site-Specific Considerations at the OMP Facility

Ortho-McNeil Pharmaceutical (OMP) in Spring House, Pennsylvania conducts research and development of pharmaceuticals/drugs. OMP develops and utilizes radiolabeled compounds to conduct this research and development, specifically to study the bioabsorption and metabolism of the drugs, in compliance with Food and Drug Administration (FDA) requirements. The radiolabeled compounds 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 (for which NRC has jurisdiction) and a hazardous organic component (for which EPA has jurisdiction). This radioactive/hazardous organic waste mixture is the low-level mixed waste (LLMW) that is the focus of this XL pilot project. The estimated volume of mixed waste produced per batch ranges from less than 50 milliliters to several liters, with an annual total volume of less than 50 liters.

OMP has developed an innovative bench-scale treatment process (i.e., a high-temperature catalytic oxidization unit), which oxidizes the mixed waste, thereby destroying its hazardous components (yielding water and C_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.

In general, the treatment unit consists of an electrically heated, stainless steel tube packed with platinum catalyst, with the heat being provided using a tube furnace equipped with three separately controlled heating zones. The commercially available tube furnace has an interior volume measuring 57.4cm long, with a diameter of 7.6cm. The catalyst tube measures 117cm long with an inside diameter of 28.6 mm, and is packed in three sections. The first section (i.e., the entrance to the catalyst bed) is packed with 15g of untreated alumina pellets. The second section (approximately 152mm long) is packed with 100g of 0.5% platinum metal coated on 3.2mm pellets of gamma alumina. The final portion of the catalyst bed consists of 430g of untreated alumina pellets. Liquid samples of LLMW are pumped into the heated (start-up temperature is set at 750°C, with a maximum operational temperature of 850°C) catalyst tube through a 0.51mm stainless steel inlet tube using a positive displacement pump providing a steady and pulseless flow. Either air or oxygen is used as the oxidant gas depending on the type of LLMW being processed.

A safety monitoring system providing basic on/off control of the pump monitors both high and low gas pressure and temperature during operation. An unsafe condition, such as no oxygen flow, excess back pressure or high temperature, is quickly detected and causes the monitor to turn off electric power to the sample pump, placing the unit in a safe standby mode until reset by an operator.

The tritiated water, radioactive carbon dioxide and other by-products of the catalytic oxidation of the LLMW are effectively collected in a series of pressure-tight trapping vessels. For tritium-labeled materials, three dry-ice cooled cold traps are used in series. For this type of LLMW, the hot effluent stream passes into a 2-liter flask cooled with dry ice, in which the vapors condense into liquids. Uncollected vapors are passed through a water-cooled reflux condenser and then through two dry-ice cooled 1L round bottom flasks connected in series to complete condensation. For carbon 14-labeled materials, the exit gases are first cooled by passing through a water-cooled glass heat exchanger and then through a series of four 1-liter gas scrubbing bottles. The bottles are charged with a 45% solution of potassium hydroxide, which is dilute enough to solubolize the potassium carbonate that is produced when completely saturated with carbon dioxide. Additional traps may be added in series for either type of LLMW to increase capacity or achieve greater recovery of radioactive by-products, and the materials collected in the trapping vessels can be run through the treatment process again to achieve a higher destruction and removal efficiency if the first pass was not effective. Also, other by-products of the treatment process (e.g., hydrochloric acid or nitric acid, depending on the composition of the LLMW) can be effectively trapped and recovered. [Note that a more complete

technical description of the treatment unit, operational parameters and analytical methodology is presented in a document titled ''A Prototype High-Temperature Catalytic Oxidation Process For Mixed Waste In A Pharmaceutical Research Laboratory,'' available in the docket for this proposal.]

The treatment of carbon-14 labeled compounds generates radioactive CO_2 (which, as described above, is converted to potassium carbonate) and the treatment of tritium labeled compounds generates radioactive (i.e., tritiated) water. These residual low-level wastes could then be sent off-site for stabilization and disposal under NRC or NRC Agreement State regulation. [The Agency notes that because the residuals are more homogeneous, they are more amenable to recycling (e.g., recovery of tritium); however, recycling the small volumes of residuals currently being generated at the OMP Spring House facility is not currently economically viable.] 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 only 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's Spring House facility is 50 liters per year, which is about the same as the volume for the original LLMW (i.e., less than 50 liters per year).

OMP 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 Pennsylvania Department of Environmental Protection (PADEP). This treatability study is being 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. To date, the 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. Therefore, the treatment process exceeds LDR treatment standards for organics and only negligible amounts of radioactivity are released.[1]

The catalytic oxidation unit is housed in a laboratory fume hood within OMP'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 Proposed by the OMP XL Project?

OMP's position is that it would like to continue to use the bench-scale high-temperature catalytic oxidation unit to treat the mixed wastes it generates without having to acquire a RCRA permit (although the laboratory in which the wastes are generated and treated will continue to be subject to an NRC license), and that the residuals from the treatment process be ''delisted'' (pursuant to 40 CFR 260.22) such that the residuals are no longer RCRA hazardous wastes (and thus not subject to RCRA manifesting or disposal permit requirements). OMP believes that the NRC license that covers the laboratory during the development of the radiolabeled compounds and the generation of the mixed waste (as well as the treatment of the mixed waste) is sufficient to protect human health and the environment, 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. An additional requirement to obtain a RCRA permit will not afford any increase in protectiveness.

Moreover, OMP has stated that if it is required to obtain a RCRA permit to operate the catalytic oxidation unit, it will cease to operate the unit and instead will opt to send the small volumes of mixed wastes off-site to a commercial mixed waste facility. And although the commercial facility has a RCRA permit, OMP's position is that the catalytic oxidation unit is more efficient at destroying the organics and preventing the release of radioactivity, thus providing a superior environmental performance relative to existing commercial treatment available for mixed wastes.

Therefore, OMP's opinion is that the most practical outcome of this project is for OMP to continue to be able to treat the small volumes of mixed wastes within the same laboratory that created the wastes, under the regulatory oversight provided by the NRC license (rather than RCRA), and that the residual wastestream (after treatment in the catalytic oxidation unit) be removed from RCRA jurisdiction because the organics (i.e., the constituents that initially ''trigger'' RCRA regulation of the mixed wastes) are no longer found in the treatment residuals.

As an additional point, should the regulatory flexibility (and the resulting significant cost savings), provided for this XL project be promulgated on a permanent basis, OMP expects to be able to invest significantly more in research and development of pharmaceuticals to the benefit of society as a whole. One side effect of such a boon to pharmaceutical research and development, however, is the generation of greater volumes of LLMW. OMP estimates that if the regulatory flexibility being provided through this XL project were to be promulgated permanently, the volume of curies of LLMW being generated through the research and development activities could increase from the current 10 curies/year to approximately 50 curies/year. OMP notes that even if greater volumes of LLMW are generated, the environment will continue to benefit through the use of the high-temperature catalytic oxidation to treat the mixed wastes because of its superior performance in destroying organics and capturing radioactivity, relative to available commercial treatment capacity for mixed wastes.

D. What Regulatory Changes Will Be Necessary To Implement This Project?

To allow for this XL project to be implemented, the Agency is proposing in today's notice to provide a site-specific exclusion in 40 CFR 261.4(b) (*i.e.*, ''Solid wastes which are not

[1] During calendar year 1999, air emissions monitoring revealed an annual average concentration of 3.55E-12 uCi/mL for tritium and 3.03E-11 uCi/mL for carbon-14. This volume of air emissions is less than 0.05% of the limits specified by NRC in 10 CFR Part 20 for allowable concentrations in effluent air (i.e., 2.00E-8 uCi/mL for tritium and 6.00E-8 uCi/mL for carbon-14). Note that these units are expressed in microcuries (10–6 curies)/milliliter.

hazardous wastes'') for the mixed wastes generated and treated in OMP'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, an approach that varies slightly from the approach taken in the Mixed Waste Rule. Instead of being considered ''mixed wastes,'' these wastes will simply be considered low-level wastes (LLWs) subject to NRC or NRC Agreement State regulation. 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 was not a RCRA ''listed'' waste). And while this is not the specific regulatory flexibility that OMP requested, the Agency believes this regulatory mechanism is the most efficient way to provide OMP with the regulatory outcome it seeks.

The site-specific exclusion being proposed 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 whether the regulatory flexibility 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.H.

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

The Agency agrees with OMP that this XL project has merit and has the potential to result in significant environmental benefits should the regulatory flexibility be adopted on a national basis. While the Agency has recently adopted the Mixed Waste Rule to generically address the regulation of mixed wastes, Project XL offers the Agency the opportunity to test alternative approaches, and in this case, an alternative approach tailored to a specific subset of the generic category of ''mixed wastes.'' EPA's Mixed Waste Rule, which conditionally exempts LLMW from the RCRA regulatory definition of hazardous waste for certain waste management activities that are subject to an NRC or NRC Agreement State license, however, will not provide the regulatory flexibility that OMP seeks (the rule does not exempt OMP's high temperature catalytic oxidation process). While the Agency continues to maintain that, as a general rule, mixed waste treatment processes that cannot be undertaken in a tank or container warrant RCRA oversight, the Agency also believes it is appropriate to test whether a particular mixed waste treatment process (that occurs outside of a tank or container) for a discrete subset of mixed wastes may be adequately regulated under the NRC regulatory regime.

In this specific XL pilot project, EPA is testing its belief that, in certain scenarios (*e.g.*, small volumes of pharmaceutical R&D-generated LLMW being treated by a bench-scale high temperature catalytic oxidation unit in an NRC-licensed laboratory), NRC regulatory oversight provides sufficient safeguards to ensure protection of human health and the environment without additional RCRA Subtitle C oversight. In other words, while the Agency maintains that its concerns regarding the general issue of certain forms of treatment of mixed wastes are warranted, EPA believes the case-specific considerations present here (*e.g.*, 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 sophisticated level of expertise of the technicians that work in the laboratory, and the protective controls required by the NRC license) warrant a test as an exception to the general rule.

Indeed, this is the type of ''test'' 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 generic ''mixed waste'' as well as possible discrete subsets of ''mixed waste'' that may be amenable to an alternative regulatory approach.

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

OMP and other industrial facilities in the local area enjoy a good working relationship with the local residential community. During the developmental stages of this XL pilot project, OMP 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.

The local community has been involved in this XL project through several means. OMP actively participates in two community environmental groups: the Lower Gwynedd Township Industrial Compact (''Compact'') and the Community Advisory Council (CAC). The Compact consists of members of the five major industrial facilities in Lower Gwynedd Township (LGT), including OMP, plus the LGT Supervisors, Township Manager, Fire Marshal and two township citizens. The Compact meets quarterly and provides a regular forum for open discussions about all relevant, useful information about the use of hazardous substances within LGT and other environmentally related issues. The Compact has provided a particularly useful venue for stakeholder outreach and participation.

As stated above, OMP is also a regular member of the CAC. The CAC has approximately 30 community residents who meet to discuss local business issues, including environmental issues, on a quarterly basis. During the development stages of this project, OMP provided continuous updates on this XL project to the Compact and CAC and plans to continue updating the community groups during the implementation of the XL pilot project.

Also, OMP hosted a public meeting at the OMP facility on this XL pilot project on February 28, 2000. OMP announced the acceptance of the project by EPA and invited the community to attend the public meeting at a LGT Supervisor meeting on February 16, 2000. A newspaper article announcing the public meeting was published in a local newspaper (The Reporter) on February 16, 2000. OMP also personally invited all the members of the LGT Compact and the CAC, as well as the Executive Director of the local Wissahickon Valley Watershed Association, to attend the public meeting. A post-public meeting article was published in the Ambler Gazette (another local newspaper) on March 1, 2000.

On July 18, 2000, OMP hosted a second stakeholder meeting at its Spring House facility. The meeting was attended by representatives from EPA, PADEP, OMP and Johnson & Johnson and focused specifically on concerns raised by the Sierra Club, which was also represented at the meeting. The Sierra Club representative was thoroughly briefed about the EPA Project XL Program, as well as about all aspects of this specific XL project, and attendees were given a tour of the radiosynthesis laboratory suite in which the mixed wastes are both generated and treated. After the meeting, the Sierra Club submitted extensive comments on the draft FPA (which was in development at the time). The FPA was modified to address these comments.

OMP will continue to hold public meetings with the local community to provide updates and information on this XL pilot project, as needed.

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

As stated earlier, if OMP is required to obtain a RCRA permit to operate the catalytic oxidation unit, it will decline to seek such a permit and instead will send the small volume of mixed wastes generated to a commercial treatment facility.[2] 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. For OMP, which generates up to 10 curies of mixed waste per year, this represents $300,000/year. Other cost savings, such as reduced transportation costs and administrative/paperwork savings resulting from no longer having this wastestream be defined as a RCRA hazardous waste (*i.e.*, mixed waste), are relatively minor compared with the costs of commercial LLMW treatment.

EPA understands that research activities, such as the radiolabeling which generates OMP'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 significantly reduces the money actually spent on R&D. With more cost-effective treatment (such as OMP's on-site bench-scale catalytic oxidation unit), more money could be spent on the actual research and development of pharmaceuticals. OMP estimates that if the synthesis research that currently generates the mixed wastes was not severely restricted by current waste disposal options and the costs associated with these options, the amount of curies of mixed wastes being generated at its facility could increase from the current 10 curies/year to approximately 50 curies/year (which could increase OMP's cost savings to $1.5 million annually).

[2] OMP's belief is that the current RCRA permitting requirements are intended to apply to commercial hazardous waste treatment facilities. Economically, it would be difficult to justify investing the costs of obtaining and maintaining a RCRA Subtitle C permit unless OMP sought to recoup such costs through commercial activities (*i.e.*, treating wastes generated by other generators and charging a fee for this service). OMP states that it is not in the commercial waste treatment business, nor does it ever intend to be, and therefore, it would not seek such a permit.

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

As stated earlier, to implement this XL pilot project, EPA proposes to amend 40 CFR 261.4(b) to provide a site-specific exclusion from the regulatory definition of hazardous waste for OMP's low-level mixed wastes 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 exclusion of OMP's mixed waste from the regulatory definition of hazardous waste under RCRA will be 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 has agreed to comply with several conditions for this exclusion, which will be included in the regulatory text of the exclusion being proposed today. These conditions are focused on proving 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-specific exclusion as a nationwide generic exclusion.

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

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

(2) Analysis demonstrating the capture efficiencies for the radioactive component of the excluded 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 excluded wastes prior to and after being treated.

(4) The volume of excluded 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 excluded wastes.

In addition, OMP 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 all companies and institutions that generate 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 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's control and so are much less certain than the conditions discussed above, these commitments are not being made conditions of the exclusion. However, in evaluating the success of this XL project, these ''non-enforceable'' commitments will be considered by EPA and PADEP.

I. 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 the 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 the final rulemaking or at a time earlier or later as agreed to by the parties involved.

IV. Additional Information

A. How To Request a Public Hearing

A public hearing will be held, if requested, to provide opportunity for interested persons to make oral presentations regarding this regulation in accordance with 40 CFR Part 25. Persons wishing to make an oral presentation on the site-specific rule to implement the OMP XL project should contact Mr. Charles Howland of the Region III EPA office, at the address given in the **ADDRESSES** section of this document. Any member of the public may file a written statement before the hearing, or after the hearing, to be

received by EPA no later than August 23, 2001. Written statements should be sent to EPA at the addresses given in the **ADDRESSES** section of this document. If a public hearing is held, a verbatim transcript of the hearing, and written statements provided at the hearing will be available for inspection and copying during normal business hours at the EPA addresses for docket inspection given in the **ADDRESSES** section of this preamble.

B. How Does This Rule Comply With Executive Order 12866: Regulatory Planning and Review?

Because this rule affects only one facility, it is not a rule of general applicability and therefore not subject to OMB review and Executive Order 12866. In addition, OMB has agreed that review of site-specific rules under Project XL is not necessary.

C. Is a Regulatory Flexibility Analysis Required?

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This rule will not have a significant impact on a substantial number of small entities because it only affects the OMP facility in Spring House, PA and it is not a small entity. Therefore, EPA certifies that this action will not have a significant economic impact on a substantial number of small entities.

D. Is an Information Collection Request Required for This Project Under the Paperwork Reduction Act?

This action applies only to one facility, and therefore requires no information collection activities subject to the Paperwork Reduction Act, and therefore no information collection request (ICR) will be submitted to OMB for review in compliance with the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*

E. Does This Project Trigger the Requirements of the 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 to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA 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 of 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, enabling 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.

F. RCRA & Hazardous and Solid Waste Amendments of 1984

1. 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, Pennsylvania would continue 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 pre-date 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.

2. Effect on Pennsylvania Authorization

Today's proposed rule, if finalized, would be promulgated pursuant to non-HSWA authority, rather than HSWA. 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 issued regulations clarifying 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 (Sept. 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 at 57734 and 57736 (Sept. 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 November 27, 2000.

This XL project was undertaken and developed (by EPA, PADEP, and OMP) 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, incorporates RCRA's analogous provisions upon their promulgation, this rule, upon adoption by Pennsylvania, will have the effect of excluding OMP's mixed wastes from regulation by the Commonwealth as a hazardous waste under its hazardous waste program.

G. How Does This Rule Comply With Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks ?

The Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''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 potentially 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 it does not involve decisions based on environmental health or safety risks.

H. Does This Rule Comply With 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 and 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.''

The proposed 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 various levels of government, as specified in Executive Order 13132. The proposed rulemaking will only affect one facility, providing regulatory flexibility applicable to this specific site. Thus, Executive Order 13132 does not apply to this proposed rule.

I. How Does This Rule Comply With 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 proposed 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.

J. Does This Rule Comply With the National Technology Transfer and Advancement Act?

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 standard. This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards. EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

List of Subjects in 40 CFR Part 261

Environmental protection, Hazardous materials, Waste treatment and disposal.

Dated: July 18, 2001.

Christine Todd Whitman,

Administrator.

For the reasons set forth in the preamble, Part 261 of chapter I of title 40 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.

Subpart A—General

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

§ 261.4 Exclusions.

* * * * *

(b) * * *

(17) Mixed waste that would otherwise meet the definition of a hazardous waste pursuant to § 261.3 that is generated and treated using an on-site bench-scale high temperature catalytic oxidation unit at the Ortho-McNeil Pharmaceutical, Inc. (OMP) research and development facility in Spring House, Pennsylvania are excluded from the definition of hazardous waste provided that:

(i) The total volume of mixed waste that would otherwise meet the definition of a hazardous waste pursuant to 261.3 that is subject to this exclusion is no greater than 50 liters/year,

(ii) OMP submits a written report to the EPA Region III office once every six months beginning six months after [EFFECTIVE DATE OF THE FINAL RULE] 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 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 effect for 5 years from [the effective date of the final rule].

* * * * *

[FR Doc. 01–18408 Filed 7–23–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 268

[FRL–7017–2]

Land Disposal Restrictions: Notice of Intent to Grant Two Site-Specific Treatment Variances—U.S. Ecology Idaho, Incorporated in Grandview, Idaho and CWM Chemical Services, LLC in Model City, New York

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is proposing to grant two site-specific treatment variances from the Land Disposal Restrictions (LDR) standards for wastes generated at U.S. Ecology Idaho, Incorporated (USEII) in Grandview, Idaho, and CWM Chemical Services, LLC (CWM) in Model City, New York. Both these waste streams are derived from the treatment of multiple listed and characteristic hazardous wastes, including K088 (spent potliners from primary aluminum reduction). USEII and CWM are both requesting treatment variances for K088 derived from hazardous waste because they contend that the chemical properties of their wastes differ significantly from the waste used to establish the LDR treatment standard for arsenic in K088 nonwastewaters. Because we believe that the Petitioners are correct, we are proposing to grant an alternate treatment standard of 5.0 mg/L Toxicity Characteristic Leaching Procedure (TCLP) for the arsenic in the K088 derived emission control dust from the USEII facility and for the arsenic in the K088 derived baghouse dust, incinerator ash, and filtercake from the CWM facility.

If promulgated, USEII and CWM may dispose of their respective waste in on-site RCRA Subtitle C landfills provided the waste complies with the specified alternate treatment standard for arsenic in K088 nonwastewaters and meets all other applicable LDR treatment standards.

DATES: Comments will be accepted until August 14, 2001. Comments postmarked after the close of the comment period will be stamped ''late'' and may or may not be considered by the Agency.

ADDRESSES: Commenters should submit an original and two copies of their comments referencing Docket Number F–2001–TVLN–FFFFF to: (1) if using regular U.S. Postal Service mail: RCRA Docket Information Center, Office of Solid Waste (5305G), U.S. Environmental Protection Agency Headquarters (EPA–HQ), 1200 Pennsylvania Avenue, NW, Washington DC 20460–0002, or (2) if using special delivery, such as overnight express service: RCRA Docket Information Center (RIC), Crystal Gateway One, 1235 Jefferson Davis Highway, First Floor, Arlington, VA 22202.

You may view public comments and supporting materials in the RCRA Information Center (RIC), located at Crystal Gateway I, First Floor, 1235 Jefferson Davis Highway, Arlington, VA. The RIC is open from 9 am to 4 pm Monday through Friday, excluding federal holidays. To review docket materials, we recommend that you make an appointment by calling 703–603–9230. You may copy up to 100 pages from any regulatory document at no charge. Additional copies cost $0.15 per page. (The index is available electronically. See the ''Supplementary Information'' section for information on accessing them).

FOR FURTHER INFORMATION CONTACT: For general information, call the RCRA Hotline at 1–800–424–9346 or TDD 1–800–553–7672 (hearing impaired). The RCRA Hotline is open Monday–Friday, 9 am to 6 pm, Eastern Standard Time. For more detailed information on specific aspects of this proposal, contact Elaine Eby at 703–308–8449, eby.elaine@epa.gov, or write her at the Office of Solid Waste, 5302W, U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, DC 20460–0002.

SUPPLEMENTARY INFORMATION:

Electronic Comment Submission

You may submit comments electronically by sending electronic mail through the Internet to: rcra-docket@epa.gov. You should identify comments in electronic format with the docket number F–2001–TVLN–FFFFF. You must submit all electronic comments as an ASCII (text) file, avoiding the use of special characters or any type of encryption. If possible, EPA's Office of Solid Waste (OSW) would also like to receive an additional copy of the comments on disk in WordPerfect 6.1 file format.

You should not submit electronically any confidential business information (CBI). You must submit an original and two copies of CBI under separate cover to: RCRA CBI Document Control Officer, Office of Solid Waste (5305W), U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460–0002.

Availability of Rule on Internet

Please follow these instructions to access the rule: From the World Wide Web (WWW), type *http://www.epa.gov/epaoswer/hazwaste/ldr/cwm.htm.*

The official record for this action will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into paper form and place them in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the RIC listed in the **ADDRESSES** section at the beginning of this document.

EPA's responses to comments, whether the comments are written or electronic, will be in a notice in the **Federal Register** or in a response to comments document placed in the official record for this notice. EPA will not immediately reply to commenters electronically other than to seek clarification of electronic comments that may be garbled in transmission or during conversion to paper form, as discussed above.

How Can I Influence EPA's Thinking on This Rule?

We invite you to provide different views on options we propose, new