

are set forth in the May 20, 1986 Federal Register Notice.

Under 5 U.S.C 605(b), I certify that this action will not have a significant economic impact on a substantial number of small entities (see 46 FR 8709).

This action does not require review by the Office of Management and Budget under the requirements of section 3 of Executive Order 12291.

List of Subjects in 40 CFR Part 52

Air pollution control,
Intergovernmental relations, Reporting
and recordkeeping requirements.

Dated: August 12, 1988.

Lee M. Thomas,
Administrator.

Part 52 of Chapter I, Title 40 of the Code of Federal Regulations is as follows:

PART 52—[AMENDED]

Subpart NN—Pennsylvania

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401-7642.

§ 52.2023 [Amended]

2. Section 52.2023 is amended by removing paragraph (h).

[FR Doc. 88-18731 Filed 8-17-88; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 261

[SW-FRL-3431-2]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Final Exclusion Rule

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) today is granting a final exclusion from the lists of hazardous wastes contained in 40 CFR 261.31 and 261.32 to Eli Lilly and Company, for certain wastes generated at its Clinton, Indiana facility. This action responds to a delisting petition submitted under 40 CFR 260.20, which allows any person to petition the Administrator to modify to revoke any provision of Parts 260 through 268, 124, 270, and 271 of Title 40 of the Code of Federal Regulations, and under 40 CFR 260.22, which specifically provides generators the opportunity to petition the Administrator to exclude a waste on a "generator-specific" basis from the hazardous waste lists.

EFFECTIVE DATE: August 18, 1988.

ADDRESSES: The public docket for this final rule is located at the U.S. Environmental Protection Agency, 401 M Street SW., (sub-basement), Washington, DC 20460, and is available for viewing from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding Federal holidays. Call (202) 475-9327 for appointments. The reference number for this docket is "F-88-ELEF-FFFF." The public may copy material from any regulatory docket at a cost of \$0.15 per page.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline, toll free at (800) 424-9346, or at (202) 382-3000. For technical information concerning this notice, contact Scott Maid, Office of Solid Waste (OS-343), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (202) 382-4783.

SUPPLEMENTARY INFORMATION:

I. Background

A. Authority

Under 40 CFR 260.20 and 260.22, facilities may petition the Agency to remove their wastes from hazardous waste control by excluding them from the lists of hazardous wastes contained at 40 CFR 261.31 and 261.32. Petitioners must provide sufficient information to EPA to allow the Agency to determine that (1) the waste to be excluded is not hazardous based upon the criteria for which it was listed, and (2) that no other hazardous constituents are present in the wastes at levels of regulatory concern.

B. History of this Rulemaking

Eli Lilly and Company petitioned the Agency to exclude from hazardous waste control certain wastes it has generated. After evaluating the petition, on November 27, 1985, EPA proposed to exclude specific wastes generated by thirteen facilities, including Eli Lilly and Company (see 50 FR 48911, November 27, 1985) from the lists of hazardous waste contained at 40 CFR 261.31 and 261.32. Final decisions were published for eleven of these facilities in earlier notices. One of the proposed exclusions will be addressed in a future notice. This notice addresses only the delisting petition for Eli Lilly and Company.

II. Disposition of Petition

Eli Lilly and Company, Clinton, Indiana

1. Proposed Exclusion

Eli Lilly and Company (ELC) petitioned the Agency to exclude from 40 CFR 261.31 its EPA Hazardous Waste Nos. F002, F003, and F005, consisting of

its incinerator scrubber effluent entering and contained in its on-site surface impoundment and its settled incinerator scrubber effluent solids contained in its surface impoundment and disposed in the solids retention area. ELC based its petition on the low concentrations of the listed constituents for these wastes. In the proposed rule, the Agency concluded that data submitted by ELC substantiate their claim that the listed constituents of concern are not present in the wastes above levels of regulatory concern. Furthermore, ELC submitted data on other non-listed hazardous constituents used in the manufacturing process which would be expected to be present in the petitioned wastes. An evaluation of these data indicated that no other hazardous constituents are present in these wastes at or above levels of regulatory concern. See 50 FR 48943, November 27, 1985, for a more detailed explanation of why EPA proposed to grant ELC's petition for these wastes.

2. Agency Response to Public Comments

One commenter stated that the Agency should deny this petition because the facility did not submit ground-water monitoring data. The commenter asserted that the Agency could not evaluate adequately the potential health and environmental hazard of the wastes without these data.

At the time that ELC submitted their petition, and at the time that the Agency proposed to exclude ELC's waste, EPA was not requesting petitioners to submit ground-water monitoring data as part of their petition. Additionally, once EPA began to request ground-water monitoring data (see below), EPA did not request ELC to submit ground-water monitoring data because of an enforcement consent agreement that ELC and the State of Indiana entered into on February 25, 1986. This consent agreement stated that if EPA granted an exclusion for certain hazardous wastes, ELC would not be required to comply with ground-water monitoring requirements. If the petition were denied, ELC would be required to install ground-water monitoring wells and submit closure and post-closure plans for the units handling the petitioned wastes. Under the agreement, no wells were to be installed until EPA made a decision on the delisting petition. Thus, the Agency has not required ELC to submit ground-water monitoring data.

The Agency's vertical and horizontal spread (VHS) model was used to predict the concentration of constituents from ELC's wastes in the ground-water at a hypothetical downgradient compliance point. See 50 FR 48896 (November 27,

1985). The VHS model considers the mobility of constituents from a specified volume of the petitioned waste. That evaluation indicated that no hazardous constituents would be present at the downgradient compliance point above levels of regulatory concern. EPA believes that the evaluation of data showing low total constituent concentrations of the constituents of concern, in this particular case, provide sufficient confidence of non-hazardousness even without ground-water monitoring data to allow a final determination to be made.

However, the Agency agrees with the commenter that ground-water monitoring data are additional, useful information to aid the evaluation of delisting petitions. Facilities petitioning for exclusion of a waste managed on-site are expected to be in compliance with the ground-water monitoring requirements of 40 CFR Part 264 or 265 and EPA generally requests them to submit, as part of their petition, four consecutive rounds of ground-water monitoring data from a monitoring system determined to be adequate under Subpart F of those regulations. These data are requested in order to assess the impact of past disposal of the petitioned waste on underlying ground water.

In this case, however, EPA has concluded that it is appropriate to grant the petition without reviewing ground-water monitoring data. ELC has informed EPA that it has not installed a ground-water monitoring system because the state of Indiana signed a consent agreement waiving ground-water monitoring requirements at the facility. In these circumstances, it is appropriate to rely on the VHS modeling evaluation to conclude that ELC's wastes will not threaten human health or the environment. This result is consistent with a small number of recent decisions to grant delisting petitions without ground-water monitoring data. In each of these cases, the facility had either qualified for a monitoring waiver under EPA's Subpart F regulations or obtained a waiver from a State agency or EPA Regional Office in a signed consent agreement. We believe it is inequitable to request monitoring data as part of the delisting evaluation where a regulatory agency has granted a waiver as part of a settlement of an enforcement claim. And it is unnecessary to obtain it where a facility has demonstrated, pursuant to 40 CFR 264.90 or 265.90, that monitoring is unnecessary because it is extremely unlikely that hazardous constituents will ever migrate to ground water. In all other circumstances, however, EPA

intends to continue to request ground-water monitoring data.

The commenter also stated that EPA should not make the proposed exclusion final until an appropriate methodology for evaluating the potential for ground-water contamination from surface impoundments is available.

The Agency believes that the commenter is generally correct in stating that the landfill model is not a perfect tool for evaluating the effects of impounded waste on the underlying aquifer. The Agency, however, does believe that the VHS model is the best model currently available in this case to evaluate the waste's potential effect on the underlying aquifer.

The Agency is currently developing a fate and transport model to evaluate the potential behavior of wastes managed in surface impoundments. However, this model is not ready for use in delisting evaluations, as it has not been fully documented and reviewed. When the Agency believes that the model is sufficiently developed for the purposes of delisting decision-making, it intends to announce the model's availability, describe its parameters and assumptions, and request comments on the model. Subsequent use of the model in the evaluation of specific delisting petitions would be proposed in the Federal Register in each instance, and comments on the appropriateness of such use would be requested and fully considered before promulgation of a final decision.

To delay petition evaluations until such time as other analytical tools (such as the surface impoundment model discussed above) are developed would result in curtailing the processing of many of the delisting petitions already submitted and does not seem equitable to those petitioners whose data were already evaluated and for whom, in some cases, proposed decisions were made, using the VHS landfill model.

In spite of this, EPA considered the key variations between landfill and surface impoundment scenarios. The primary difference between the VHS model and a surface impoundment model is expected to be the consideration in the impoundment model of hydraulic head, sorption and retardation, and clogging. Hydraulic head tends to force leachate into the aquifer, displacing ground water, resulting in potentially higher concentrations at the receptor well (*i.e.*, compliance point). Sorption and retardation of dissolved contaminants with the aquifer solids encountered through migration in the ground water tend to reduce the concentration of the

contaminant in the aquifer. Clogging occurs in surface impoundments when either fine material filters out in the impoundment bottom materials, or when fine material settles on the bottom of the impoundment. A potential result of clogging is the lowering of the hydraulic conductivity of the impoundment bottom material to that which approaches the hydraulic conductivity of clay, thus reducing the leakage of impoundment liquid into the aquifer.

To some extent, however, the mechanisms of sorption and retardation and clogging counteract hydraulic head as measured by the impact on ground water at a receptor well. Without completing ongoing model development efforts, it is difficult to predict what impact these competing mechanisms will have on the calculation of a predicted compliance-point concentration.

EPA believes that the VHS model is currently adequate to assess reasonable worst-case disposal of wastes at surface impoundments, because the VHS model is conservative in all of its assumptions. Specifically, the VHS landfill model does not account for the likely reduction in the total concentrations of hazardous constituents occurring through volatilization and degradation, thereby providing an additional margin of safety, regardless of whether the waste is disposed of in a landfill or surface impoundment scenario. For these reasons, the Agency believes that the application of the VHS model, in this case, adequately protects human health.

3. Final Agency Decision

For the reasons stated in the proposal, the Agency believes that both the incinerator scrubber effluent entering and contained in the on-site surface impoundment, and the settled incinerator scrubber effluent solids contained in the on-site surface impoundment and disposed in the retention area, are not hazardous and, as such, should be excluded from hazardous waste control.

In further confirmation of the Agency decision, EPA re-evaluated the organic constituents detected in ELC's incinerator scrubber effluent using the VHS model. This re-evaluation was performed because the Agency had applied the Organic Leachate Model (OLM) to the liquid phase; therefore, the Agency decided to recalculate new compliance-point concentrations for those constituents detected. See 50 FR 48943, November 27, 1985 and 51 FR 27061, July 29, 1986. (The OLM is used to predict the leachable portion of an organic constituent from a solid waste.

The Agency does not use the OLM to predict the leachable portion of an organic constituent from a liquid waste because EPA believes that the entire portion of a liquid waste is available for leaching. Therefore, it is unnecessary to use the OLM.) Table 1 presents the maximum total constituent concentrations of each of the detected constituents. Table 2 presents the results of the VHS model analysis. These results confirm the Agency's prior data demonstrating that the scrubber effluent is not hazardous.

TABLE 1.—MAXIMUM TOTAL CONSTITUENT CONCENTRATIONS
[Scrubber Effluent]

Constituents	Scrubber effluent (ppm)
Benzene	¹ ND
Carbon tetrachloride	0.0007
Chloroform	0.0009
1,2-Dichloroethane	0.0003
Methylene chloride	0.122
Methyl ethyl ketone	0.215
Toluene	0.0175
1,1,1-Trichloroethane	0.0002
1,1,2-Trichloroethane	0.018
Trichlorofluoromethane	0.0001
Acetone	² 0.051
Bromodichloromethane	0.0011

ND: Not detected. Denotes concentrations below the following detection limit: benzene—0.0001.

¹ The Agency determined, using the Dixon extreme value test, that the maximum reported value of 0.009 ppm for benzene was a statistical outlier. This value, therefore, was not used in our analysis.

² The Agency determined, using the Dixon extreme value test, that the maximum reported value of 8.931 ppm for acetone was a statistical outlier. This value, therefore, was not used in our analysis.

As indicated in Table 2, the waste exhibited levels of the above organic constituents at the compliance point below levels used in delisting decision making. The Agency did not evaluate the mobility of benzene since it was not detected in the waste using the appropriate SW-846 test method.

TABLE 2.—VHS MODEL: COMPLIANCE-POINT CONCENTRATIONS

Constituents	Compliance-point concentrations (ppm)	Levels of regulatory concern (ppm) ¹
Carbon tetrachloride	0.00011	0.005
Chloroform	0.00014	0.0005
1,2-Dichloroethane	0.000047	0.005
Methylene chloride	0.019	0.056
Methyl ethyl ketone	0.034	1.8
Toluene	0.0028	10.5
1,1,1-Trichloroethane	0.003	0.2
1,1,2-Trichloroethane	0.0028	0.0061
Trichlorofluoromethane	0.000015	10.5
Acetone	0.008	4.0
Bromodichloromethane	0.00017	0.02

¹ See "Docket Report on Health-Based Regulatory Levels and Solubilities Used in the Evaluation of Delisting Petitions," June 8, 1988, located in the RCRA public docket.

The Agency, as stated in 51 FR 27061 (July 29, 1986), did not use the OLM/VHS model to evaluate the retention area solids because, using the appropriate SW-846 test method, none of the polynuclear aromatic hydrocarbons (PNAHs) or other constituents (detected in the scrubber effluent) were detected. Therefore, the Agency did not evaluate the non-detected constituents in the OLM/VHS model.

In support of its petition, ELC submitted analytical data characterizing the incinerator scrubber effluent and the settled incinerator scrubber effluent solids disposed of in the retention area. ELC, however did not provide analytical data characterizing the settled incinerator scrubber solids contained in its on-site surface impoundment. As a result, ELC was requested to characterize the settled incinerator scrubber effluent solids to demonstrate that the solids were of similar composition to the retention areas solids.

On September 18, 1987, ELC submitted results obtained from a modified classical stirred tank model simulating the partitioning of constituents between water and solids. ELC's model was a "worst-case" model in that it used as inputs the maximum total constituent concentrations of the constituents detected in the scrubber effluent, while assuming conservation of mass, no volatilization, no biodegradation, and a total organic carbon (TOC) content of five percent (the maximum observed TOC level of ELC's waste was 3.8 percent (see 50 FR 48943, November 27, 1985)). Table 3 presents the predicted constituent concentrations or organic constituents in ELC's settled incinerator scrubber effluent solids contained in the surface impoundment. (The Agency limited its evaluation of the settled incinerator scrubber effluent to those constituents actually detected in the scrubber effluent entering the surface impoundment.)

TABLE 3.—Predicated Total Constituent Concentrations Settle Incinerator Scrubber Effluent Solids
[Contained in the On-Site Surface Impoundment]

Constituents	Total constituent concentrations (mg/kg)
Carbon tetrachloride	1.13x10 ⁻³
Chloroform	3.44x10 ⁻³
1,2-Dichloroethane	1.05x10 ⁻³
Methylene chloride	2.96x10 ⁻¹
Methyl ethyl ketone	7.36x10 ⁻¹
Toluene	5.70x10 ⁻¹
1,1,1-Trichloroethane	1.15x10 ⁻³
1,1,2-Trichloroethane	1.02x10 ⁻¹
Trichlorofluoromethane	1.27x10 ⁻³
Acetone	8.99x10 ⁻³
Bromodichloromethane	5.81x10 ⁻³

ELC attempted to use a mass-balance approach to model the total constituent concentration of the EP toxic metals, nickel, and cyanide in the settled incinerator scrubber effluent solids contained in the surface impoundment. The model used an experimentally derived retention factor (*i.e.*, the ratio of the concentrations of metals entering and leaving the surface impoundment). The Agency rejected ELC's model, however, because the retention factor was extremely sensitive, and any miscalculation of the smallest amount would cause the model to predict sufficient concentrations necessary to fail the VHS model analysis. EPA, therefore, requested ELC to collect representative samples of the settled incinerator scrubber effluent solids contained in the surface impoundment, and analyze for both the total constituent and EP toxicity concentrations of the EP toxic metals, nickel, and cyanide.

To collect representative samples from surface impoundments like ELC's, petitioners are normally requested to divide the unit into four quadrants and randomly collect five full-depth core samples from each quadrant. The five full-depth core samples are then composited (mixed) by quadrant to produce a total of four composite samples. See "Test Methods for Evaluating Solid Wastes: Physical/Chemical Methods," U.S. EPA, Office of Solid Waste and Emergency Response, Publication SW-846 (third edition), November 1986, and "Petitions to Delist Hazardous Wastes—A Guidance Manual," U.S. EPA, Office of Solid Waste, (EPA/530-SW-85-003), April 1985.

On October 28, 1987, ELC collected a total of four composite samples of the settled incinerator scrubber effluent solids from its surface impoundment. The surface impoundment was divided into four sections and from each section, five full-depth core samples were randomly collected. The five full-depth core samples were composited by section.

ELC use SW-846 method numbers 3010, 3020, 6010, 7421, and 7470 to quantify the total constituent concentrations of the EP toxic metals and nickel, and SW-846 method number 1310 to quantify the EP leachable concentrations of the EP toxic metals and nickel in the settled incinerator scrubber solids contained in the surface impoundment. Additionally, ELC used EPA method number 335.2 to quantify the total constituent concentration of cyanide. See "Methods for Chemical Analysis of Water and Wastes," EPA/4-79-020. Table 4 presents the maximum total constituent and EP leachate concentrations of the EP toxic metals, nickel, and cyanide.

TABLE 4.—MAXIMUM TOTAL CONSTITUENT AND EP LEACHATE CONCENTRATIONS SETTLED INCINERATOR SCRUBBER EFFLUENT SOLIDS

[Contained in the Surface Impoundment]

Constituents	Total constituent concentrations (mg/kg)	EP leachate concentrations (mg/l)
Arsenic.....	29.0	<0.098
Barium.....	1390.0	0.319
Cadmium.....	27.0	0.012
Chromium.....	350.0	<0.012
Lead.....	360.0	<0.045
Mercury.....	2.7	<0.015
Nickel.....	160.0	0.22
Selenium.....	5.0	<0.11
Silver.....	<20.0	<0.014
Cyanide.....	<0.5	<0.025

<: Denotes that the actual value is below the detection limit specified in the table.

¹ Leachable cyanide tests were not performed. However, leachable cyanide was determined by assuming a theoretical leaching of 100 percent and a twenty-fold dilution (100 grams of solids diluted with 2.0 liters of water) of the maximum total constituent concentration of cyanide.

The Agency evaluated the mobility of the inorganic constituents from ELC's waste using the VHS model. The results of the Agency's evaluation, using the waste volume of 160 cubic yards (the amount claimed by ELC to be in the surface impoundment) and the maximum EP leachate concentrations of the hazardous inorganic constituents of concern in the VHS model, are shown in Table 5. The Agency did not evaluate the mobility of arsenic, chromium, lead, mercury, selenium, silver, or cyanide from ELC's waste because they were not detected in the EP extract (see Table 4). If a constituent is not detected when using the appropriate SW-846 method, the Agency assumes that the constituent is not present.

TABLE 5.—VHS MODEL: PREDICTED COMPLIANCE-POINT CONCENTRATIONS SETTLED INCINERATOR SCRUBBER EFFLUENT SOLIDS

[Contained in the Surface Impoundment]

Constituents	Compliance-point concentrations (ppm)	Levels of regulatory concern (ppm) ¹
Barium.....	0.01	1.0
Cadmium.....	0.0004	0.01
Nickel.....	0.007	0.5

¹ See "Docket Report on Health-based Regulatory Levels and Solubilities Used in the Evaluation of Delisting Petitions," June 8, 1988, located in the RCRA public docket.

The settled incinerator scrubber effluent solids exhibited barium, cadmium, and nickel levels at the compliance point below the levels used in delisting decision making.

The Agency calculated the mobile portion of the total constituent

concentrations of the organics (detected in the scrubber effluent) in the settled incinerator scrubber effluent solids using the OLM. See 51 FR 41084, November 13, 1986. The leachable concentrations of the detected organic constituents were then evaluated using the VHS model. Table 6 presents the results of the OLM/VHS model analysis.

As indicated By Table 6, none of the organic constituents exhibited compliance-point concentrations at levels exceeding the health-based levels. The Agency was unable to evaluate the mobility of bromodichloromethane since a value for solubility was not available. As a matter of policy, where a compliance-point concentration cannot be calculated, EPA will not evaluate that particular constituent.

TABLE 6.—OLM/VHS MODEL: PREDICTED COMPLIANCE-POINT CONCENTRATIONS SETTLED INCINERATOR SCRUBBER EFFLUENT SOLIDS

[Contained in the Surface Impoundment]

Constituents	Compliance-point concentrations (ppm)	Levels of regulatory concern (ppm) ¹
Carbon tetrachloride.....	3.78×10^{-5}	5.0×10^{-3}
Chloroform.....	4.02×10^{-5}	5.0×10^{-4}
1,2-Dichloroethane.....	1.83×10^{-5}	5.0×10^{-3}
Methylene chloride.....	1.15×10^{-3}	5.64×10^{-3}
Methyl ethyl ketone.....	5.63×10^{-3}	1.8
Toluene.....	4.65×10^{-4}	10.5
1,1,1-Trichloroethane.....	1.02×10^{-3}	2.00×10^{-3}
1,1,2-Trichloroethane.....	3.20×10^{-4}	6.10×10^{-3}
Trichlorofluoromethane.....	1.00×10^{-3}	10.5
Acetone.....	2.21×10^{-3}	4.0
Bromodichloromethane.....	NC ²	2.00×10^{-3}

¹ See "Docket Report on Health-based Regulatory Levels and Solubilities Used in the Evaluation of Delisting Petitions," June 8, 1988, located in the RCRA public docket.

² Not calculated due to the lack of a value for solubility.

Additionally, although ELC did not test the settled incinerator scrubber effluent solids contained in the surface impoundment for the characteristics of ignitability, corrosivity, and reactivity, the Agency believes that the characteristics testing previously performed on the settled incinerator scrubber solids stored in the retention area can be used to demonstrate that the settled solids contained in the surface impoundment do not exhibit the characteristics of ignitability, corrosivity, and reactivity. The retention area solids are the same waste, except for solids content (*i.e.*, the settled sludge contained in the surface impoundment has a higher percent solids content). The characteristics testing performed on the settled solids disposed in the retention area, by inference, indicates that the settled solids contained in the surface impoundment do not exhibit the

characteristics of ignitability, corrosivity, and reactivity.

The Agency, therefore, is granting a final exclusion to Eli Lilly and company for both its incinerator scrubber effluent entering and contained in its on-site surface impoundment, and the incinerator scrubber effluent solids contained in its on-site surface impoundment and disposed of in the solids retention area. These wastes result from the incineration of waste solvents. These wastes are listed as EPA Hazardous Waste Nos. F002, F003, and F005, and are generated at ELC's Clinton, Indiana facility. The exclusion remains in effect unless the wastes vary from those originally described in the petition (*i.e.*, the wastes are altered as a result of changes in the manufacturing or treatment process). The facility would require a new exclusion if its manufacturing or treatment processes are altered, and accordingly would need to file a new petition. The facility must treat waste generated from changed processes as hazardous until a new exclusion is granted.

Although management of the wastes covered by this petition is relieved from Subtitle C jurisdiction, the generator of a delisted waste must either treat, store, or dispose of the waste in an on-site facility, or ensure that the waste is delivered to an off-site storage, treatment, or disposal facility, either of which is permitted, licensed, or registered by a State to manage municipal or industrial solid waste. Alternatively, the delisted waste may be delivered to a facility that beneficially uses or reuses, or legitimately recycles or reclaims the waste, or treats the waste prior to such beneficial use, reuse, recycling, or reclamation.

III. Effective Date

This rule is effective immediately. The Hazardous and Solid Waste Amendments of 1984 amended section 3010 of RCRA to allow rules to become effective in less than six months when the regulated community does not need the six-month period to come into compliance. That is the case here because this rule reduces, rather than increases, the existing requirements for persons generating hazardous wastes. In light of the unnecessary hardship and expense that would be imposed on this petitioner by an effective date six months after promulgation and the fact that a six-month deadline is not necessary to achieve the purpose of section 3010, EPA believes that this rule should be effective immediately upon promulgation. These reasons also provide a basis for making this rule effective immediately, under the

Administrative Procedures Act, pursuant to 5 U.S.C. 553(d).

IV. Limited Effect of Federal Exclusion

The final exclusion being granted today is being issued under the Federal (RCRA) delisting program. States, however, are allowed to impose their own, non-RCRA, regulatory requirements that are more stringent than EPA's pursuant to section 3009 of RCRA. These more stringent requirements may include a provision which prohibits a Federally-issued exclusion from taking effect in the State. Since a petitioner's waste may be regulated under a dual system (*i.e.*, both Federal and State programs), petitioners are urged to contact their State regulatory authority to determine the current status of their wastes under State law.

V. Regulatory Impact

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This rule to grant an exclusion is not major since its effect is to reduce the overall costs and economic impact of EPA's hazardous waste management regulations. This reduction is achieved by excluding waste generated at a specific facility from EPA's lists of hazardous wastes, thereby enabling the facility to treat its waste as non-hazardous. There is no additional economic impact, therefore, due to today's rule.

VI. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601-612, whenever an agency is required to publish a general notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis which describes the impact of the rule on small entities (*i.e.*, small businesses, small organizations, and small governmental jurisdictions). The Administrator may certify, however, that the rule will not have a significant economic impact on a substantial number of small entities.

This amendment will not have an adverse economic impact on small entities since its effect will be to reduce the overall costs of EPA's hazardous waste regulations and is limited to one facility. Accordingly, I hereby certify that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation, therefore, does not require a regulatory flexibility analysis.

List of Subjects in 40 CFR Part 261

Hazardous materials, Waste treatment and disposal, Recycling.

Authority: Sec. 3001 RCRA, 42 U.S.C. 6921.

Date: August 10, 1988.

Jeffery D. Denit,

Deputy Director, Office of Solid Waste.

For the reasons set out in the preamble, 40 CFR Part 261 is amended as follows:

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
Eli Lilly and Company.	Clinton, Indiana	Incinerator scrubber liquids, entering and contained in their on-site surface impoundment, and solids settling from these liquids originating from the burning of spent solvents (EPA Hazardous Waste Nos. F002, F003, and F005) contained in their on-site surface impoundment and solids retention area on August 18, 1988 and any new incinerator scrubber liquids and settled solids generated in the surface impoundment and disposed of in the retention area after August 18, 1988.

[FR Doc. 88-18732 Filed 8-17-88; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 498

[BERC-371-F]

Medicaid Program; Appeals From Cancellation of Approval of Medicaid Long-Term Care Facilities

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This rule corrects an oversight by setting forth time limits for new issues that may be considered by an Administrative Law Judge (ALJ) during a hearing afforded a Medicaid skilled nursing facility (SNF) or intermediate care facility (ICF) because the Secretary proposes to cancel its approval under section 1910(c)(1) of the Social Security Act (the Act).

This amendment is necessary because current rules do not take account of the fact that hearings under section 1910(c) of the Act (unlike Medicare hearings) may take place *before* the cancellation is put into effect.

The purpose is to establish time limits appropriate to section 1910(c) situations.

DATE: This rule is effective September 19, 1988.

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

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

Authority: Secs. 1006, 2002(a), 3001, and 3002 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), 6921, and 6922).

2. In Appendix IX, add to table 1 the following wastestreams in alphabetical order:

FOR FURTHER INFORMATION CONTACT: Pete Burdette, (301) 866-6772.

SUPPLEMENTARY INFORMATION:

Background

Final regulations with comment period, published on June 12, 1987 at 52 FR 22444, had a dual purpose:

- To update and clarify the rules on appeals from determinations that affect the participation of providers, suppliers, and practitioners in the Medicare program; and

- To redesignate those rules (previously in Subpart O of Part 405 of the Medicare rules) as a new Part 498.

As part of the updating process, we made those Medicare regulations applicable to situations in which, under section 1910(c) of the Act, the Secretary proposes to cancel the approval of a Medicaid SNF or ICF. As explained in the preamble to the June 12 rules, this is appropriate because—

- The appeals procedures in Part 498 are based on sections 205(b) and 205(g) of the Act; and

- Section 1910(c) of the Act gives the Medicaid facility affected by a proposed cancellation under that section the right to hearing and to judicial review under sections 205(b) and 205(g) of the Act.

As a means of limiting the scope of the hearing to matters directly relevant to the determination that is being appealed, § 498.56 retains the time limits (previously set forth in § 405.1542) for new issues that may be considered by the ALJ. For terminations, it provides that the ALJ may not consider any issues that arise after "the effective date

of the termination of a provider agreement".

Comments

We received two comments on the June 12 publication. One was from a law firm, recommending substantive changes in the hearings procedures and in the availability of case decisions, indices, and pleadings. These comments will be considered in developing a Notice of Proposed Rulemaking (NPRM) that will amend Part 498 to make substantive changes that could not be made by the June 12 rules for which NPRM was waived.

The other comment pointed out that the time-limit established by § 498.56(b)(1) for new issues was not appropriate for appeals under section 1910(c) of the Act.

Discussion

There is an important difference between HCFA's termination of a Medicare provider agreement and a proposal by the Secretary to cancel the approval of a Medicaid SNF or ICF under section 1910(c) of the Act. The hearing for a Medicare facility is always provided after the termination goes into effect. However, for the Medicaid facility, except when its deficiencies pose immediate and serious threat to patient health and safety, the Medicaid provider agreement remains in effect—

- Until the period for requesting a hearing has expired; or
- If a hearing is requested and granted, until the Secretary reaches a final decision after the hearing.

In developing the June 12 rules, we overlooked the need for a separate cut-off date for "pre-cancellation" hearings. The current Medicare rule (§ 498.56(b)(1)), if applied to such hearings, would make it difficult to reach a final decision within a reasonable period of time. A Medicaid facility could raise a "new issue"—that it had corrected all deficiencies after the section 1910(c) survey—and request resurvey. By repeatedly reporting compliance and requesting resurvey, the facility could prolong the appeals process indefinitely. Since the provider agreement could not be terminated until the ALJ issued a decision, the facility would continue to receive Medicaid payment—for new admissions as well as for previously admitted residents—and continue to pose a potential threat to the health and safety of all residents. We do not believe that this furthers the goals and objectives of the Medicaid program.

Since the issue before the ALJ is whether the Secretary properly determined that the facility's participation in the program ought to be

terminated, and since participating facilities are required to be continuously in compliance with the conditions of participation for SNFs or the standards for payment to ICFs, the appropriate cut-off date for a pre-cancellation hearing is the completion date of the survey or resurvey that is the basis for the proposed cancellation of approval.

When the deficiencies of a Medicaid facility pose immediate and serious threat to patient health and safety, approval is cancelled without waiting for a hearing. In that situation, the appropriate cut-off date for new issues is the effective date of cancellation.

Response to Comment

This rule makes a single change responsive to the second comment received regarding the final regulations published on June 12, 1987 (52 FR 22444). In § 498.56, we have added a new paragraph (b)(5) to provide separate time limits for new issues that may be considered by the ALJ at a hearing under section 1910(c) of the Act. In the case of a pre-cancellation hearing, the cut-off date is the completion date of the survey or resurvey that was the basis for the Secretary to propose cancellation of the approval of the Medicaid SNF or ICF. In an immediate and serious threat situation, the cut-off date is the effective date of cancellation of approval.

Regulatory Impact Statement

Executive Order 12291 requires us to prepare and publish a regulatory impact analysis for any regulation that is likely to have an annual impact of \$100 million or more, cause a major increase in costs or prices, or meet other thresholds specified in section 1(b) of the order.

We have determined that a regulatory impact analysis is not required for these rules because this minor change will have very slight budgetary impact.

Section 1102(b) of the Act requires a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals, that is, hospitals that are located outside a metropolitan statistical area and have fewer than 50 beds.

In addition, we generally prepare an initial Regulatory Flexibility Analysis that is consistent with the Regulatory Flexibility Act (5 U.S.C. 601 through 602) unless the Secretary certifies that the regulation would not have a "significant economic impact on a substantial number of small entities". A small entity is defined as a small business, a nonprofit enterprise, or a governmental jurisdiction (such as a county, city, or township) with a population of less than 50,000. We also consider all providers and suppliers as small entities.

We have determined, and the Secretary certifies, that this rule will not have a significant economic impact on a substantial number of small entities or on the operation of a substantial number of small rural hospitals.

Paperwork Reduction Act

This rule contains no information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (Pub. L. 96-511).

List of Subjects in 42 CFR Part 498

Administrative practice and procedure, Appeals, Medicare practitioners, Providers and suppliers, Medicaid, Nursing homes.

42 CFR Part 498 is amended as set forth below:

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM

1. The authority citation continues to read as follows:

Authority: Secs. 205(a), 1102, 1869(c), 1871, and 1872 of the Social Security Act (42 U.S.C. 405(a), 1302, 1395ff(c), 1395hh, and 1395ii) unless otherwise noted.)

2. In § 498.56 paragraph (a)(1) and the introductory text of paragraph (b) are republished for the reader's convenience, and paragraph (b)(5) is added to read as follows:

§ 498.56 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(b) *Time limits.* The ALJ will not consider any issue that arose on or after the following dates:

(5) With respect to Medicaid SNFs or ICFs surveyed under section 1910(c) of the Act—

(i) The completion date of the survey or resurvey that is the basis for a proposed cancellation of approval; or

(ii) If approval was cancelled before the hearings, because of immediate and serious threat to patient health and safety, the effective date of cancellation.

(Catalog of Federal Domestic Assistance Programs No. 13.714, Medical Assistance Programs)

Dated: April 12, 1988.

William L. Roper,
Administrator, Health Care Financing
Administration.

Approved June 6, 1988.

Otis R. Bowen,

Secretary.

[FR Doc. 88-18703 Filed 8-17-88; 8:45 am]

BILLING CODE 4120-01-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

45 CFR Part 1160

Regulations Under Section 206(b) of the Museum Services Act

AGENCY: Institute of Museum Services, NFAH.

ACTION: Final regulations.

SUMMARY: The Institute of Museum Services issues final regulations under section 206(b) of the Museum Services Act relating to the award of contracts and cooperative agreements to professional museum organizations. The fiscal year 1988 appropriation statute for IMS provides the necessary appropriations act authority to implement this section. IMS is issuing regulations under this authority to assist applicants and recipients and to make the most effective use of available funds.

EFFECTIVE DATE: August 18, 1988.

FOR FURTHER INFORMATION CONTACT: Rebecca Danvers, Director of Programs, Institute of Museum Services, Room 609, 1100 Pennsylvania Avenue NW., Washington, DC 20506 (202-786-0539).

SUPPLEMENTARY INFORMATION:

1. General Background

The Museum Services Act ("the Act"), which is Title II of the Arts, Humanities, and Cultural Affairs Act of 1976, was enacted on October 3, 1976 and has been subsequently amended and extended.

The purpose of the Act is stated in section 202, 20 U.S.C. 961, as follows:

It is the purpose of [the Museum Services Act] to encourage and assist museums in their educational role, in conjunction with formal systems of elementary, secondary, and postsecondary education and with programs of nonformal education for all age groups; to assist museums in modernizing their methods and facilities so that they may be better able to conserve our cultural, historic, and scientific heritage; and to ease the financial burden borne by museums as a result of their increasing use by the public.

The Act establishes an Institute of Museum Services (IMS) consisting of a National Museum Service (Board) and a Director. IMS is an independent agency

placed under the statutory heading of the National Foundation on the Arts and the Humanities (National Foundation).

The Act lists a number of illustrative activities for which grants may be made, including assisting museums to meet their administrative costs for preserving and maintaining their collections, exhibiting them to the public, and providing educational programs to the public. During fiscal year 1988, IMS provides three types of grant assistance to museums: (1) General operating support; (2) conservation assistance; and (3) museum assessment assistance. This regulation covers a fourth type of support: contracts and cooperative agreements with professional museum associations to provide services.

2. Purpose and Scope of Regulations

Section 206(b) of the Museum Service Act, 20 U.S.C. 965(b), provides for financial assistance to professional museum organizations. Section 206(b) states:

The Director [of IMS], subject to the policy direction of the National Museum Services Board, is authorized to enter into contracts and cooperative agreements with professional museum organizations to provide financial assistance to such organizations in order to enable such organizations to undertake projects designed to strengthen museum services, except that any contracts of cooperative agreements entered into pursuant to this subsection shall be effective only to such extent or in such amounts as are provided in appropriations Acts.

Language in the fiscal year 1988 appropriation for IMS (Pub. L. No. 100-203) contains the necessary appropriations act authority to implement this section. IMS had no regulations or guidelines governing applications for such assistance or postaward conditions. Therefore, after receiving the policy direction of the Board, IMS issued, on February 5, 1988, proposed regulations for public comment.

The proposed regulations closely track section 206(b) with respect to those matters for which there is statutory language. They include provisions regarding eligibility, applications, activities for which assistance will be made available, and conditions for receipt of funds.

Section 1180.77 contains information collection requirements. As required by the Paperwork Reduction Act of 1980, the Institute of Museum Services will submit a copy of these requirements to the Office of Management and Budget (OMB) for its review. Organizations and

individuals desiring to submit comments on these requirements should direct them to the Office of Information and Regulatory Affairs, OMB, Room 30002, New Executive Office Building, Washington, DC 20503; Attn: Jim Houser.

3. Response to Comments

A. General

A number of comments were received in response to the February 5 notice of proposed rulemaking. The following paragraphs summarize these comments and the IMS response. All of the comments have been carefully studied by IMS and National Museum Services Board.

In general, commenters expressed approval of the regulations and of the manner in which IMS proposes to administer the program. Specific suggestions for improvement or clarification fall into two categories:

- Comments regarding provisions of the proposed regulations that repeat or reflect statutory requirements.
- Comments concerning provisions that were not required by statute, but which were developed by IMS to ensure effective program administration or clarify statutory requirements.

B. Regulations Governed by Statutory Provisions

IMS may not change regulatory provisions based upon the governing statute. Such comments are identified, summarized, and discussed below:

(1) *Eligibility status of public agencies and organizations.* A number of commenters expressed concern that the regulations did not permit public museum agencies or organizations to apply for assistance. The proposed regulations contained the following definition of the term "professional museum organization":

For the purpose of this subpart, the term "professional museum organization" means a private, nonprofit professional museum services-related organization, institution, or association which engages in activities designed to advance the well-being of museums eligible for assistance under this part and the museum profession * * *

This definition was taken from section 206(b)(4) of the Museum Services Act, 20 U.S.C. 965(b)(4), which provides:

For purposes of this subsection, the term "professional museum organization" means a private, nonprofit professional museum-related organization, institution, or association which engages in activities