Treatability Studies Exemption
Part VII

Environmental Protection Agency

40 CFR Part 261
Identification and Listing of Hazardous Waste, Treatability Studies Sample Exclusion; Rule
Hazardous Waste Management System: Identification and Listing of Hazardous Waste; Treatability Studies Sample Exclusion

SUMMARY: On July 19, 1988 (52 FR 27290), EPA issued a rule that conditionally exempted from Subtitle C hazardous waste regulation waste samples collected for purposes of conducting small-scale treatability studies. 40 CFR 261.4(e)-(f). This rule was promulgated in recognition of the inhibiting effect of the stringent source conservation and Recovery Act (RCRA) Subtitle C requirements on the development of new treatment capacity, and the minimal public health and environmental risks involved in conducting small-scale treatability studies. The rule identified specific quantities of various types of wastes which could be transported, stored and used in treatability studies without the need for RCRA Subtitle C regulation.

On July 7, 1993 (58 FR 38387), EPA proposed amendments to the existing rule which would increase the quantity limits for major classes of contaminated media which could be employed in treatability studies. The rule identified specific quantities of various types of wastes which could be transported, stored and used in treatability studies without the need for RCRA Subtitle C regulation.

EPA is issuing a final rule which increases the quantity and time limits for contaminated media to be used in treatability studies. The rule would increase the exempt amounts from 1000 kg up to 10,000 kg of media contaminated with acute hazardous waste and from 250 kg to 2500 kg of media contaminated with acute hazardous waste, when used in treatability studies.

The existing case-by-case variance provision (40 CFR 261.4(e)(3)) is increased from 500 kg to 5000 kg for media contaminated with non-acute hazardous waste and from 250 kg to 2500 kg for media contaminated with acute hazardous waste. The existing variance provision focuses on allowing limited additional quantities after the initial increment of material is processed. EPA is adding criteria to the variance provision to allow the additional quantity to be requested in advance.

EPA is also increasing the time limits for treatability studies involving bio remediation. Treatability studies involving bio remediation have an initial period of two years to complete testing, and under the case-by-case variance provisions discussed below, may request up to an additional two years. The remainder of the preamble discusses the major comments received on the proposed rule and EPA's response to them. All other comments are discussed in a separate document that is available in the RCRA docket.

II. Discussion

A. Summary of the Existing Treatability Sample Exclusion Rule

The existing Treatability Sample Exclusion rule imposes limits on the quantity of material which may be shipped, stored or treated under the exemption. In order to qualify for the conditional exclusion; laboratory and test facilities must comply with the following quantity and time limitations as well as notification, reporting and record-keeping requirements:

Shipment—The mass of each sample shipment may not exceed 1000 kg of "as received" hazardous waste, 1 kg of acute hazardous waste, or 250 kg soils, water, or debris contaminated with acute hazardous waste. 40 CFR 261.4(e)(2)(ii). "As received" refers to the waste...
shipped by the generator or sample collector as it arrives at the laboratory or testing facility. 40 CFR 261.4(f)(3).

Storage—The laboratory or testing facility may store up to 1000 kg of non-acute hazardous waste. This limitation can include 500 kg of soils, water, or debris contaminated with acute hazardous waste or 1 kg of acute hazardous waste. 40 CFR 261.4(f)(4).

Treatment—The laboratory or testing facility, on a per waste stream per treatment process basis, may conduct treatability tests on up to 1000 kg of non-acute hazardous waste, 250 kg of soils, water, or debris contaminated with acute hazardous waste, or 1 kg of acute hazardous waste. 40 CFR 261.4(f)(4). The rule imposes a treatment initiation rate limit of 250 kg per day, or as received waste for entire laboratory or testing facility.

Time Limits—The existing exclusion requires that the laboratory or testing facility return the sample to the generator or sample collector, or send it to a designated facility within 90 days of completion of the treatability study, or no more than one year from the time the generator or sample collector shipped the sample to the laboratory or testing facility, whichever date first occurs. 40 CFR 261.4(f)(3). EPA did not seek comment on the propriety of these exemption levels or criteria, but merely sought comment on amendments that would expand the scope of the existing rule.

3. Time Limits for Sample Retention

The preamble to the proposed rule contained an extensive discussion of the reasons the Agency felt that amendments to the existing rule were desirable. 58 FR 36387 (July 7, 1993). Interested readers are referred to that document for further information.

C. Response to Major Comments

1. Quantity Limits

All commenters supported an amendment to increase the quantity limits in the exemption for soil and debris samples by at least the quantities proposed. Almost 50% of the comments suggested adopting higher exemption limits on either an across-the-board or a case-by-case basis.

Commenters noted the significant challenge posed in designing and testing ancillary system components—e.g., material handling equipment, getting the waste material into the treatment unit in an appropriate physical state and condition), and emission control equipment. Smaller-scale tests conducted at the laboratory or bench scale often do not involve ancillary system components, or may not utilize sufficient throughput to adequately test these components.

Suggestions to further increase the quantity limits ranged as high as 25,000 kg. Other comments suggested that quantity limits higher than those proposed be set on a case-by-case basis. These comments identified site size, the nature of the waste and/or the remediation technology, the concentration of hazardous constituents in the waste matrix, and the intent of the study as possible factors to be considered in these case-by-case determinations.

EPA is aware that the larger the scale of the technology development or remedy selection treatability study, the more likely the results will represent the performance of full-scale remedial equipment. Furthermore, EPA's proposal identified the need to address materials handling problems as a major basis for the proposed revision.

The data adduced by EPA in the proposed rule support the conclusion that many of the technologies can be tested within the limits proposed. Nevertheless, EPA's own data also confirm that there are situations where additional quantities may be necessary in order to conduct treatability studies at an appropriate scale.

The existing rule has a provision for case-by-case approval of additional quantities. 40 CFR 261.4(f)(3). As discussed further below, EPA is modifying the variance provision to allow advance approval, on a case-by-case basis, of conducting studies on additional quantities of contaminated media. Due to the potential for delay in processing case-by-case applications, laboratory and testing facilities should carefully consider the tradeoffs in seeking advance approval of additional quantities.

2. Scope of the Exemption

All comments supported the basic proposal to increase the quantity limits for soil and debris. In response to EPA's solicitation of comment on increasing the scope of the revision beyond soil and debris, a substantial majority of the comments recommended extending the quantity increases to various other forms of hazardous waste. Comments differed on the exact scope beyond soil and debris—e.g., all hazardous waste, remediation waste, wastewater and/or groundwater.

Reasons suggested for increasing the scope beyond soil and debris included the difficulty of determining the boundary between sludge and media in, for example, unlined lagoons; the low concentration of contaminants in groundwater; the need for longer-duration continuous flow tests; and the need to develop integrated, optimized remediation approaches in the case of remediation waste in general. A number of commenters also suggested extending the increases to all forms of hazardous waste, which would include newly-generated industrial hazardous wastes.

In response to these comments, and in light of EPA's own experience regarding the variety of contaminated media encountered in cleanup efforts, EPA is at this time modifying the scope of the exemption to cover contaminated media, including groundwater, surface water, soils, sediment, and debris that contain listed hazardous waste or that themselves exhibit a characteristic. However, the proposal did not focus on samples of newly-generated waste or waste sludges, and the Agency is not taking final action on those materials at this time. EPA is considering additional rulemaking to allow larger scale treatability studies on other forms of hazardous waste.

3. Time Limits for Sample Retention

As discussed above, EPA proposed to allow up to two years for treatability studies involving bioremediation. EPA solicited comment on whether these time frames were sufficient, and whether testing involving other technologies also required longer time frames. No negative comments were received on this proposal. Comments included suggestions that the allowable time period be even longer and/or that additional technologies (e.g., phytoremediation and solidification/stabilization) be eligible for longer duration studies.

With regard to the time limits, EPA believes that two years should be adequate for most treatability testing involving bioremediation.

Nevertheless, as discussed below, EPA is modifying the case-by-case variance provisions to allow up to an additional

1 As noted by several commenters, sludges will have often become commingled with underlying media, and present difficulty for those attempting to refine media samples for shipment. EPA agrees that it may be difficult to distinguish sludges from underlying media. Where uncontainerized sludges have come into contact with nonreclaiming media, EPA does not expect sample collectors to undertake extraordinary efforts to assure that samples consist only of contaminated media.

2 As a point of clarification, for purposes of this rule, EPA considers phytoremediation to be a form of bioremediation.
two years for completion of such studies.

EPA expects that this provision will be used judiciously. Laboratory and testing facilities cannot exceed the limits in the rule on the amount of material which may be stored and treated. (e.g., 10,000 kg of media contaminated with non-acute hazardous waste plus 5000 kg if a full variance quantity request is granted). On going studies reduce the quantity of materials which may be stored for use in new studies.

With regard to stabilization/solidification, EPA's experience in the Superfund Innovative Technology Evaluation (S.I.T.E) program indicates that a one-year time frame is generally adequate. Modifications discussed below which allow retaining small samples of treated materials should address some of the concerns underlying suggestions for allowing longer duration studies for this technology (e.g., to ensure the long-term efficacy of the stabilization). Several comments addressed the desirability of retaining samples of treated material for future analysis. EPA understands that such a provision may be useful for technologies such as solidification/stabilization where the attributes of treated material such as compressive strength and leachability of contaminants may change over time, or solvent extraction where there may be issues of the long-term histotoxicity of residual solvent in treated soil.

In response to these comments, EPA is promulgating a provision allowing up to 500 kg of treated material from a particular wastestream from treatability studies to be stored by the laboratory or testing facility for up to 5 years. Material archived for future analysis must be included in the storage quantity limit for the facility—e.g., a facility which archives two 500 kg samples from separate waste streams may only store up to 9,000 kg (plus 5000 kg if a variance is granted) of additional material, and must be identified as such in facility records and reports.

4. Variances for Requesting Additional Quantities and Extended Time Limits

Several commenters suggested that the variance provisions in the existing rule (40 CFR 261.4(e)(3)) be increased by the same factor applied to the base quantity allowed. For example, under the existing rule laboratories or testing facilities could request approval for further testing on up to an additional 300 kg from a particular wastestream. Comments included raising the variance limit for contaminated media by the same amount as the basic proposal. The variance provisions allow additional quantities of materials to be used in treatability studies on a case-by-case basis if specified conditions are met—e.g., mechanical failure during the initial treatability study or need to verify the results of a previously conducted study. As with the comments relating to quantity limits in general, commenters suggested across-the-board and case-by-case approaches to variances.

EPA finds the suggestion to allow increased quantities of contaminated media to a set maximum on a case-by-case basis to be reasonable. EPA is modifying the variance quantity by the same factor by which it is increasing the basic quantity limit.

Thus, laboratory and testing facilities may request up to an additional 5000 kg of media contaminated with non-acute hazardous waste, or 2500 kg of media contaminated with acute hazardous waste. The Agency considers this to be a conforming change to the general concept of allowing larger quantity studies, and views it as a logical outgrowth of the proposed rule.

Furthermore, as discussed above, in response to comments that quantities beyond those proposed be allowed on a case-by-case basis, EPA is also adding a provision that will allow laboratory and testing facilities to apply for advance authorization for variances. Factors to be considered in reviewing advance requests for additional quantities include the nature of the technology, the type of process (e.g., batch versus continuous), size of the unit undergoing testing (particularly in relation to scale-up considerations), time/quantity of material required to reach steady-state operating conditions, and test design considerations such as mass balance calculations.

Finally, the case-by-case variance provision has been modified to allow laboratory and testing facilities conducting bioremediation treatability studies to request a variance of up to 2 additional years to complete their studies.

5. Treatability Studies at Federal Facilities

Several comments requested clarification of the status of federal facilities for purposes of eligibility for the treatability study sample exclusion. Federal facilities are often large in size, with numerous different contamination problems for which solutions must be developed and applied. EPA notes that the rule identifies "laboratory or test facilities" as the entities which may take advantage of the conditional exclusion. The Agency would not consider a large federal installation with numerous laboratories or testing sites to be a single "laboratory or test facility" for purposes of this rule. Distinguishing attributes include the requirement to obtain an EPA Identification number for each laboratory or test facility. 40 CFR 261.40(b)(2).

6. Promulgation/State Adoption

Comments on State Authorities are addressed below in the "State Authority" section.

III. State Authority

A number of comments indicated that the efficacy of this rule depends to a considerable extent on the availability of the exclusion at the State level. Since the original treatability sample exclusion rule was promulgated under RCRA and not the Hazardous and Solid Waste Act Amendments of 1984 (HSWA), this revision is also promulgated pursuant to RCRA. As with the existing rule, the revisions promulgated today are not immediately effective in authorized States, since this rulemaking does not impose requirements or prohibitions contained in HSWA. Thus this regulation will be applicable only in those States that do not have final authorization for the non-HSWA base RCRA program.

In a State authorized to implement the base RCRA program, the proposed regulation would not be applicable until the State revises its program to adopt equivalent regulations under State law. However, as with the original rule these proposed changes are less stringent or reduce the scope of the Federal program. Therefore, although EPA strongly encourages timely adoption, authorized States are not required to modify their programs to adopt regulations consistent with and equivalent to this rulemaking. The Agency plans to work with States to encourage timely adoption of this rule because of its benefits to the development of treatment capacity.

IV. Effective Date

This rule is effective immediately upon publication. HSWA amended section 3010 of RCRA to allow rules to become effective in less than 6 months when the regulated community does not need the 6-month period to come into compliance. This is the case here, because this rule reduces the existing requirements for laboratories and test facilities conducting treatability studies on contaminated media. An effective date 6 months after publication would impose unnecessary and regulatory burden upon those persons the rule is designed to benefit, and
might delay the achievement of the rule’s objective of improving CERCLA response activities and RCRA corrective actions by facilitating treatability studies. These reasons also provide a basis for making this rule effective immediately upon final promulgation under the Administrative Procedures Act, 5 U.S.C. 553(d).

V. Regulatory Analyses

A. Executive Order 12866

OMB has determined that this rule is not a significant rule within the meaning of Executive Order 12866.

B. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., whenever an Agency is required to publish general notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the impact of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions).

The purpose of the original rule was to eliminate time-consuming and costly permitting requirements. This revision extends the scope of activities which may be conducted without requirements to obtain permits, and will thus have additional positive effects on small entities.

This amendment will have no adverse economic impact on small entities. In fact, it should reduce the burden imposed on small entities that conduct treatability studies and comply with the provisions of this rulemaking. Accordingly, I hereby certify that this rule will not have a significant economic impact on a substantial number of small entities. This regulation therefore does not require a regulatory flexibility analysis.

C. Paperwork Reduction Act

This rule does not contain any new information collection requirements subject to OMB review under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

To the extent that this rule discusses information collection requirements imposed under existing regulations, these requirements have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., and have been assigned OMB control number 2050-0053.

List of Subjects in 40 CFR Part 261

Hazardous waste, Recycling.
kg of media contaminated with acute hazardous waste or 250 kg of other "as received" hazardous waste is subject to initiation of treatment in all treatability studies in any single day. "As received" waste refers to the waste as received in the shipment from the generator or sample collector.

(4) The quantity of "as received" hazardous waste stored at the facility for the purpose of evaluation in treatability studies does not exceed 10,000 kg, the total of which can include 10,000 kg of media contaminated with non-acute hazardous waste, 2500 kg of media contaminated with acute hazardous waste, 1000 kg of non-acute hazardous wastes other than contaminated media, and 1 kg of acute hazardous waste. This quantity limitation does not include treatment materials (including nonhazardous solid waste) added to "as received" hazardous waste.

(5) No more than 90 days have elapsed since the treatability study for the sample was completed, or no more than one year (two years for treatability studies involving bioremediation) have elapsed since the generator or sample collector shipped the sample to the laboratory or testing facility, whichever date first occurs. Up to 500 kg of treated material from a particular waste stream from treatability studies may be archived for future evaluation up to five years from the date of initial receipt. Quantities of materials archived are counted against the total storage limit for the facility.
Dear Mr. Paulick:

This responds to your letter of November 12, 1991 requesting clarification of the federal Resource Conservation and Recovery Act regulations concerning notification for treatability studies. You ask whether, under 40 CFR 261.4(f)(1), the owner/operator of a facility is required to submit a one-time notification to the Regional Administrator (or State Director if located in an authorized state) no less than 45 days before beginning to conduct treatability studies, or to submit a notification 45 days before conducting each individual treatability study.

To provide some context for the answer to your question, the general intent of this provision is to ensure that the U.S. EPA Regional Office (or state agency) is aware that a facility is conducting treatability studies. More specific information about the individual treatability studies is obtained through the other reporting requirements found in 261.4(f).

More specifically, 261.4(f)(1) requires only that the owner/operator of a facility submit a one-time notification indicating that treatability studies will be conducted at the facility under the provisions of 261.4(f). 261.4(f)(11) then requires that the owner/operator again notify the Regional Administrator (or State Director) when he or she is no longer planning to conduct treatability studies at the locality (see footnote 1).

In addition, there are several other reporting requirements for facilities conducting treatability studies found in 261.4(f). First, records must be maintained for three years demonstrating compliance with the treatment rate limits and the storage time and quantity limits (261.4(f)(7)). Second, copies of treatability study contracts and treatability sample shipping papers must be maintained for three years (261.4(f)(8)). Finally, annual reports must be submitted to the Regional Administrator (or State Director) by March 15 of each year including detailed information about treatability studies conducted the previous year, and estimates of the number of treatability studies to be conducted and the amount of waste to be used in these studies during the current year (261.4(f)(9)).

Please note, however, that state agencies generally implement the RCRA program within each state (although some parts of the program may be implemented by the U.S. EPA Regional Office), and that state regulations may be different (although no less stringent) than the federal regulations. Thus, you should contact
the appropriate state environmental agency or U.S. EPA Regional Office to determine how the regulations of that particular state will apply to any treatability studies you are planning.

Thank you for your interest in the safe and effective management of hazardous waste.

Sincerely,
David Brussard
Director, Characterization and Assessment Branch

1 If treatability studies were later to be resumed at the facility after notifying of the cessation of such studies under 261.4(f)(11), the facility would again be required to notify of the intent to conduct treatability studies 45 days before conducting any studies under 261.4(f)(1).

9432.1991(01)

United States Environmental Protection Agency
Washington, D.C. 20460
Office of Solid Waste and Emergency Response

September 27, 1991

Robert H. Scarberry
Chemical Waste Management
1155 Connecticut Avenue, N.W.
Suite 800
Washington, D.C. 20036

Dear Bob:

In your letter of July 9, 1991, you request clarification of the RCRA definition of "designated facility" with respect to the treatability study exclusion, which was published on July 19, 1988 (53 FR 27290). You also ask the Agency to reconsider whether this exclusion is a HSWA requirement.

On January 23, 1990, EPA clarified the definition of "designated facility" (see 55 FR 2342). This amendment to the definition in 260.10 clarifies that EPA's regulations allow waste shipments from a state where a waste is subject to the hazardous waste regulations as a result of a listing determination to a facility in a state where the waste is not yet regulated as hazardous. In this situation, the designated facility might not need to be permitted or under interim status, provided that the receiving facility is allowed by the receiving state to accept such waste.

In your letter, you describe a situation similar to the one addressed in the January, 1990 clarification notice, regarding "the transportation and management of treatability study samples. In your example, a treatability sample is transported from a state which regulates the treatability sample as a hazardous waste (because it does not have the exclusion), to a state that has adopted the exclusion, and therefore does not regulate the sample as a hazardous waste. You ask whether the hazardous waste manifest, which is required in the originating state, can specify a treatability study facility as the "designated facility" even though it does not have a permit or interim status. Furthermore the
facilities which perform the treatability studies in some cases do not have permits or interim status.

As an initial matter, you should be aware that the interpretation of the definition of "designated facility" in an authorized state is a matter of state law. An authorized state may interpret the provisions of this regulation in a more stringent manner. Therefore, any interpretation of the term expressed in this letter reflects only EPA's interpretation of the definition of "designated facility" and should be confirmed with the appropriate state agency in the authorized state.

The primary reason for the January 23, 1990 amendments was to state clearly that EPA interprets the manifest requirement and the designated facility definition as not prohibiting the shipment of hazardous wastes from states where the waste is hazardous to authorized states where the waste is not hazardous. The clarifying amendment to the definition of "designated facility" was to address one specific scenario to which this interpretation applies. By adding the clarifying language regarding newly listed wastes, EPA did not intend to preclude the interstate waste shipment of wastes in similar situations. EPA believes that the shipment of treatability samples is directly analogous to the shipment of newly regulated wastes. In both cases, protection of human health and the environment is somewhat assured by the threat of potential future liability for the generator and the receiving facility arising out of management of the wastes and by federal and state standards that apply to the receiving facility. EPA noted that Subtitle D standards would apply to facilities receiving newly listed wastes; facilities conducting treatability studies would have to comply with 261.4(f). Finally, it is plainly apparent that this interpretation is consistent with the purposes of the treatability exemption. If you choose to follow this interpretation, the generator should arrange for the designated facility owner or operator to sign and return the manifest to the generator, and for out of state transporters to sign and forward the manifest to the designated facility. Although the receiving state may not require the completion of the manifest loop, the originating state would likely require the return of the manifest.

You suggest that an alternative approach to address the interstate shipment problem would be to determine that the treatability study exclusion is a HSWA provision. In the course of the rulemaking, the Agency determined that the exclusion was not a "requirement or prohibition" pursuant to HSWA. We believe that any reexamination of this matter would result in the same conclusion. Furthermore, a HSWA designation would not be a panacea for the transportation of samples since even a HSWA exclusion would not supersede an existing, more stringent state requirement, and therefore would have no practical effect in states where the treatability exclusion has not yet been adopted.

If you have any further questions regarding this clarification of the term "designated facility," please call Wayne Roepe of my staff at (202) 260-2245.

Sincerely,
Sylvia K. Lowrance
Director
Office of Solid Waste
Part IV

Environmental Protection Agency

40 CFR Parts 260 and 261
Identification and Listing of Hazardous Waste Treatability Studies Sample Exemptions; Final Rule
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260 and 261

Identification and Listing of Hazardous Waste Treatability Studies Sample Exemption

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: On September 16, 1987, the Environmental Protection Agency (EPA) published a Notice of Data Availability, which requested comment on whether the sample exclusion provision should be expanded to include waste samples used in small-scale treatability studies. The sample exclusion provision exempts waste samples collected solely for the purpose of monitoring or testing to determine their characteristics or composition. The Notice also presented information and requested comment concerning the appropriate limitations that could be imposed if the sample exclusion was expanded.

As a result of comments received, EPA is today issuing a final rule that conditionally exempts waste samples used in small-scale treatability studies from Subtitle C regulations. Consequently, generators of the waste samples and owners or operators of laboratories or testing facilities conducting such treatability studies will be exempt from the Subtitle C hazardous waste regulations, including the permitting requirements, when certain conditions are met.

DATE: This regulation becomes effective on July 19, 1988.

ADDRESSES: The OSW Docket is located in the sub-basement at the following address and is open from 8 a.m. to 4 p.m. Monday through Friday, excluding Federal holidays: EPA RCRA Docket (sub-basement), 401 M Street, SW., Washington, DC 20460.

The public must make an appointment (to review docket materials) by calling (202) 475-8888, Ext. 221475. Refer to Docket Number SWH-FRL-3350-4. For technical information contact Mike Petruske, Office of Solid Waste (SW), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 475-8888.

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I. Background

On September 25, 1981 (see 45 FR 47429), EPA issued an interim final rule that conditionally exempted waste samples collected solely for the purpose of monitoring or testing to determine their characteristics or composition. These regulations include the generator and transporter requirements of Parts 262 and 266, and the storage, treatment, and permitting requirements of Parts 264, 265, and 266. In particular, the regulations exempt waste samples from the Subtitle C requirements when: (1) The sample is being transported to the laboratory for testing or is being transported back to the sample collector after the testing; (2) the sample is being stored by the sample collector or laboratory before testing or after testing prior to its return to the generator; (3) the sample is being analyzed to determine its characteristics or composition; or (4) the sample is being stored at the laboratory for a specific purpose such as a court case or enforcement action. However, samples subject to the exemption must still comply with U.S. Department of Transportation (DOT), U.S. Postal Service (USPS), or other applicable shipping requirements. The sample must be packaged so that it does not leak, spill, or vaporize from its packaging.

The Agency granted this exclusion because of the de minimis public health and environmental risks involved. In particular, the Agency found that certain incentives already existed that would assure protection of human health and the environment without requiring these samples to be subject to the full set of Resource Conservation and Recovery Act (RCRA) hazardous waste regulations. These incentives include (1) the costs associated with sample collection, shipping, analysis, and storage; (2) the generator's need to obtain results of analyses to determine if and how they must comply with the RCRA hazardous waste requirements; and (3) the considerable likelihood that a testing laboratory would return the sample to the generator as part of a contractual agreement (partly based on the generator's desire to protect proprietary information and partly based on the testing laboratory's desire to avoid the costs of disposal), reducing the concern that the sample would be indiscriminately disposed. The preamble stated that the exclusion did not cover large-size samples that are used in treatability or other testing at pilot scale or experimental facilities. However, the preamble did not specify whether the exclusion applied to small- or bench-scale treatability studies at laboratories or other testing facilities. Today's final rule directly addresses this issue.

The preamble of the 1981 interim final rule also stated that the Agency had considered and rejected a quantity limit for the samples subject to the exclusion. Its basis for this was that the available information indicated that the size of samples shipped for characterization or analytical purposes usually did not exceed 1 gallon. Therefore, the Agency saw no need to set a specific quantity limit. However, the preamble also stated that EPA would consider imposing a
limit on sample size if comments or experience indicated that such a limit was necessary (46 FR 47427).

While the comments received on the 1991 interim final rule generally supported the exclusion for samples shipped for waste characterization, a large percentage of commenters also recommended that the sample exclusion provision be expanded to include waste samples used in treatability studies, including large-scale samples used in pilot-scale units or at experimental facilities.

Furthermore, on June 2, 1987, the Hazardous Waste Treatment Council (HWTC) submitted a rulemaking petition requesting that the Agency promulgate regulations to provide limited exemptions from the permitting requirements of RCRA to facilities conducting treatability studies. The petition proposed a three-part solution: (1) Expand the sample exclusion provision to allow treatability tests to be conducted from regulation; (2) expand the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) permits exclusion at 40 CFR 300.68(a)(3) to include off-site treatability testing when performed at the direction of an EPA or State on-scene coordinator to implement a response consistent with CERCLA section 121; and (3) issue interim guidance to implement, at least in part, the suggested changes described in (1) and (2) above (i.e., interpret the existing sample exclusion in 40 CFR 261.4(d) to include treatability studies, and issue interim guidance to on-scene coordinators regarding off-site treatability studies). The petition proposed several limitations for small-scale treatability studies. The petition also recommended regulatory changes that would allow large-scale treatability studies to be conducted provided that the facility complies with the manifesting requirements and certain interim status standards. (See section II.C. Limitations, discussed below.)

The petition asserted that immediate regulatory relief was needed because the present RCRA Subtitle C permitting requirements unnecessarily interfere with the experimentation and research necessary to evaluate the various treatment options for CERCLA cleanup activities. HWTC further argued that these same problems will have a similar affect on RCRA corrective action.

Agency experience with the Superfund Innovative Technology Evaluation (SITE) program and CERCLA cleanup actions support the HWTC's assertion.

Based on these factors (i.e., comments on the sample exclusion interim final rule, the HWTC petition, and EPA's own experience), EPA published a Notice of Data Availability and Request for Comment on September 18, 1987 (50 FR 33273). The Notice reopened the comment period on the earlier interim final rule and specifically asked whether EPA should expand the sample exclusion provision in 40 CFR 261.4(d) to include waste samples used in small-scale treatability studies. The Notice also presented information and requested comment concerning the appropriate limitations that could be imposed if the sample exclusion provision were expanded.

Almost all commenters to the notice recommended that the Agency expand the sample exclusion provision to include waste samples used in small-scale treatability studies. The commenters generally agreed that the Agency could promulgate such an exclusion and allow meaningful studies to be conducted because of the de minimis risk to human health and the environment. However, almost a number of commenters argued that the limitations discussed in the Notice were overly stringent and suggested that higher limitations be allowed.

Based on the Agency's own experience and the comments received, EPA is today issuing a final rule that conditionally exempts waste samples used in small-scale treatability studies from regulation under Subtitle C of RCRA. The Agency will address the second part of HWTC's petition concerning larger scale studies at a later date. The remainder of the preamble discusses the major comments received on the Notice of Data Availability and EPA's response to them. All other comments, both from the Notice of Data Availability and to the original interim final rule, are discussed in a background document that is available in the docket to this rulemaking. (See EPA RCRA docket address in preceding section.)

II. Discussion of Major Issues

A. Introduction

A total of 40 comments were received in response to the Notice of Data Availability. The commenters in general agreed with HWTC that the Agency should expand the sample exclusion provision to apply to waste samples used in small-scale treatability studies. However, there was a wide range of opinion as to the scope of activities that should be allowed under the exemption and the appropriate limitations that the Agency should impose. Before discussing these, however, it is appropriate to discuss the need and rationale for today's rulemaking.

1. Need and Rationale for Today's Rulemaking

In the Agency's experience, permitting requirements for offsite treatability studies have resulted in delays in evaluating remediation alternatives for both CERCLA site cleanups and the RCRA corrective action program. Additionally, the current and upcoming Land Disposal Restrictions Program is another factor arguing strongly for a need to develop alternative treatment technologies.

The overriding objective of Congress in the 1984 RCRA Amendments—to reduce land disposal of hazardous wastes—has already resulted both in heavy demands for existing treatment technologies and in increased urgency for developing new and better treatment methods as an alternative to the land disposal of hazardous waste. In addition, developing techniques to minimize the generation of hazardous waste, and to promote recycling and reuse of waste, are all important Agency goals and Congressional mandates. EPA is committed to facilitating research and development activities that will help meet these objectives.

The Agency believes the current regulatory framework that sets forth RCRA permitting requirements for Subtitle C facilities is unnecessarily stringent for regulating certain activities, e.g., small-scale treatability studies. As noted above, comments in 1981 suggested a need to extend the sample exclusion provision to treatability studies because of the low risk and the large benefits of conducting these studies if RCRA permits were not required.

The HWTC petition summarizes this position on behalf of many facilities that conduct treatability studies as part of their research activities. In addition, HWTC stressed that the development of new treatment capacity, needed to meet the demands placed on industry as the land disposal restrictions take effect, is not facilitated by the current regulations. The potential lack of treatment capacity, using either new or improved existing technologies, means that EPA may have to issue additional variances to the land disposal restrictions, posing an increased threat of ground water and surface water contamination.

Maintaining unnecessary regulatory barriers to conducting treatability studies is, therefore, contrary to the Agency's implementation of the mandated land disposal restrictions. Furthermore, these regulatory barriers send the wrong message to the regulated
community. The Agency intends to promote, not defeat, research and development in support of the national objectives to reduce land disposal of hazardous wastes and to increase reliance on waste minimization and treatment technologies that reduce risk to human health and the environment. However, the Agency remains pledged to carry out its primary statutory obligation to ensure that removing regulatory barriers does not result in unwarranted or increased risks to human health and the environment. The Agency has determined that this balance can be properly maintained in promulgating a RCRA exemption for small scale treatability studies.

2. Determination of De Minimis Risk

Since Congress passed RCRA in 1976, the Agency has developed and implemented a "cradle to grave" program to protect human health and the environment from the improper management of hazardous wastes. A principal purpose of the RCRA hazardous waste regulations is to ensure that hazardous wastes are safely transported to facilities properly designed and operated to manage these wastes in a manner that will minimize the threat to human health and the environment. Hazardous waste generators, transporters, and owners and operators of treatment, storage, and disposal facilities (TSDFs) each have specific responsibilities for properly managing those wastes defined as hazardous.

The Agency believes that it can exempt hazardous waste that is used in small-scale treatability studies from the RCRA hazardous waste regulations because a number of factors will combine to ensure that the risks to human health and the environment are de minimis. These factors include: (1) A limitation on the size of the sample that is exempted; (2) the high cost of collecting and shipping the sample; (3) a limitation on the quantity of waste that can be shipped at any one time; (4) the applicability of the Department of Transportation (DOT), U.S. Postal Service (USPS), or other regulations governing the transportation of hazardous materials; (5) a limitation on the amount of hazardous waste that can be stored at a laboratory or testing facility; (6) a limitation on the amount of hazardous waste that may be processed (i.e., testing in a treatability unit) in any one day; (7) the prohibitive costs involved in conducting legitimate treatability studies as an alternative to commercial treatment and disposal; (8) a limitation on the time that a waste sample used in a treatability study or any residues generated from such studies may remain at the laboratory or testing facility without being subject to the hazardous waste regulations; (9) the RCRA requirement that any unused sample and residues from a treatability study must still be managed as a hazardous waste; (10) certain reporting and recordkeeping requirements that will enable the Agency to conduct inspections and bring enforcement actions against persons who abuse this exemption. In addition, regulations and requirements administered by other Federal agencies such as the Occupational Safety and Health Administration (OSHA) also ensure proper management.

The Agency believes that all the above factors contribute to an argument for de minimis risk. Some factors, such as the sample size, shipment size, transportation standards, and storage limitations, directly relate to the de minimis risk in each phase of the treatability study process. Other factors such as the recordkeeping and reporting requirements and the one-time 1000 kg per waste stream limitation ensure that treatment and disposal of hazardous waste do not occur under the guise of conducting treatability studies.

More specifically, under the conditional exemption being promulgated today, the generator or sample collector may not ship more than one of the following in any single shipment: (1) 1000 kg of non-acidic hazardous waste; (2) 1 kg of acute hazardous waste (see 40 CFR 261.33(e)); or (3) 250 kg of acute hazardous waste that is contained in soil, water, or some other contaminated medium. Since the shipments remain subject to DOT, USPS, or other applicable shipping regulations, they must be packaged and labeled in the same manner as other shipments of hazardous materials. One difference is that these waste samples will not require a manifest. EPA believes that a manifest is not required in this situation, since the generator is spending large sums of money to obtain the results of a treatability study. Thus, it is highly unlikely that the sample would be indiscriminately disposed. Furthermore, the generator or sample collector is likely to have a contractual arrangement with the laboratory or testing facility conducting the treatability study either to have the facility return any unused sample and/or any residues that are generated from the treatability study for subsequent manifesting and shipment to a designated facility (see 40 CFR 260.10) or recycling facility or to have the laboratory or testing facility directly manifest and ship the wastes to an appropriate designated facility within specified time limits. Unless the context otherwise requires, the use of this term in today's preamble and rule does not imply that the facility is required to be permitted or to have interim status. The generator must also maintain copies of the shipping papers and the contract with the testing facility for a period ending 3 years from the completion date of the study.

The operator of a vehicle transporting waste samples is still required to comply with the applicable DOT requirements, including notification of the National Response Center in the event of a hazardous material spill of more than a reportable quantity and initiation of cleanup measures in accordance with 49 CFR 171.15.

Owners and operators of a laboratory or testing facility conducting such treatability studies must comply with the limitations regarding shipment, storage, treatment rate, and disposition of unused sample and residues after completion of the studies. The overall limitations on storage and treatment rates, discussed later in today's preamble, are sufficiently restrictive to compel a laboratory or testing facility to carefully coordinate the size and timing of treatability sample shipments. The owners and operators of these laboratories or testing facilities must also comply with applicable regulations promulgated by OSHA.

Further business and financial incentives compelling a laboratory or testing facility to properly handle these samples include the cost-intensive nature of conducting treatability studies, the need to provide the client with documented test results, the desire of the laboratory or testing facility to maintain its corporate reputation, and the desire to avoid any liability. After the treatability study is completed, the owners or operators of a laboratory or testing facility must either return the unused sample and residues to the generator or manifest and ship them to a RCRA designated facility (if the material is a RCRA hazardous waste) within the time limitations specified. A laboratory or testing facility not operating within these limitations must comply with the appropriate RCRA requirements.

Finally, the Agency is stipulating recordkeeping and reporting requirements that will document compliance with the limitations and will allow the Agency to take enforcement action against persons who attempt to abuse the exemption. The specific reporting and recordkeeping
requirements are discussed later in today's preamble.

D. Scope of the Exemption

1. Definition of Treatability Study

In the Notice of Date Availability, the Agency included a definition of "treatability study" similar to that proposed by HWTC. According to this definition, a treatability study is one in which a relatively small amount of hazardous waste is subjected to a known treatment process to determine whether the waste is amenable to a treatment process; what pretreatment (if any) is required; the optimal process conditions needed to achieve the desired treatment; the efficiency of the treatment process; and (5) the characterististics and volume of residuals from a particular treatment process. (See 52 FR 35280.)

The commenters generally agreed with the definition of treatability study. However, many commenters expressed concern that the use of the term "known treatment process" was overly restrictive and might hinder the development of innovative technologies. Thus, these commenters recommended that the word "known" be deleted from the definition in the final rule. HWTC's proposed regulatory language did not include a restriction to "known" technologies.

The Agency agrees with these commenters. As stated earlier, it is important to promote the development of treatment technologies that will reduce the hazardous waste disposal and increase the reliance on waste minimization and treatment technologies that reduce risk to human health and the environment. In doing so, EPA does not want to restrict industry to the technologies that are already established or "known". Rather, it wants to promote the development of innovative technologies. Therefore, the Agency has modified the definition of "treatability study" accordingly. At the same time, it is concerned that the treatability study sample exemption may be improperly used as a means to avoid regulation when regulation is warranted. To prevent this, EPA has included specific language in the definition of treatability study to guard against such abuse. This language makes it clear that the exemption is for the evaluation of a treatment process and not to be used for commercial treatment or disposal of hazardous waste. Furthermore, the Agency emphasizes that the definition of treatability studies covered under the exemption does not apply where the practice could result in a significant uncontrolled release of hazardous constituents to the environment. It would, therefore, include neither open burning nor any type of treatment involving placement of a hazardous waste on the land (e.g., in situ stabilization).

Several commenters also suggested that the Agency list, in the rule, the types of treatment studies to be included in the final definition. Although the Agency can see some merit in this suggestion, it has decided not to incorporate a specific list into the regulations. EPA believes that such a list could hinder the development of innovative technologies. For example, if it included a list in the rule, the Agency would be required to go through rulemaking before new or innovative treatment technologies would get the benefit of the treatability exemption. As previously discussed, the Agency believes that as long as the limitations imposed in today's rule are met, any treatability study will pose a de minimis risk. Examples of the types of treatability studies included in the exemption are physical/chemical/biological treatment, thermal treatment (incineration, pyrolysis, oxidation, combustion) solidification, sludge dewatering, volume reduction, toxicity reduction, and recycling feasibility.

2. Inclusion of Liner Compatibility and Other Studies

In the Notice of Date Availability, the Agency solicited comment as to whether the exemption should include other waste testing studies, such as liner compatibility studies. Many commenters agreed that the exemption should be expanded to include other types of studies. The commenters argued that, in addition to liner compatibility studies, the exemption should also include studies of corrosion, toxicological and health effects, and other material compatibility studies (e.g., pumps and personal protective equipment). While such studies are not strictly treatability studies under the proposed definition, the commenters argues that waste testing is necessary to develop improved hazardous waste management technologies.

The Agency agrees with the commenters that such studies, although not strictly treatability studies, are necessary for the further development of hazardous waste management technologies. Furthermore, the Agency believes that such studies can be conducted using small quantities of hazardous waste under laboratory conditions. Also, these types of studies are subject to the same financial and business incentives for safe handling as are treatability studies. Therefore, with the imposition of the limitations in this final rule, these studies will involve only de minimis risk and need not be subject to RCRA permitting regulations. The Agency is, therefore, allowing the following types of studies to be conducted and exempted under the hazardous waste regulations: liner compatibility studies, corrosion studies, toxicological and health effects studies, and other material compatibility studies (e.g., relating to leachate collection systems, geotextile materials, other land disposal unit requirements, pumps and personal protective equipment).

3. Effects on Exporters of Hazardous Waste

EPA, in today's rule, is exempting samples sent for treatability studies from Subtitle C requirements. These include the requirement to notify EPA prior to export of hazardous waste (40 CFR 262.50 et seq.). At the time export requirements were promulgated, EPA specifically focused the sample exemption in 40 CFR 261.4(d).

The rule promulgated today expands the scope of this exemption as contemplated in 1986. For the same reasons discussed in the August 6, 1986, rule relating to § 261.4(d) samples (51 FR 26664 et seq.), exporters of treatability study samples who comply with the limitations of today's rule are also exempt from the export notification requirements of Subpart E of Part 262.

While the Agency is exempting these treatability study samples from the export notification requirements at this time, the Agency is revisiting the question as to whether it should exclude unmanifested waste from the export notification requirements and modify its position in the future.

C. Limitations

In the Notice of Date Availability, the Agency requested specific comment on what types of limitations should be placed on the exemption if it were to be expanded to include treatability studies. In addition, EPA specifically requested comment on the limitations suggested by the HWTC in its petition. The HWTC suggested quantity limits for shipping, storage, and treatment of hazardous waste samples for the purpose of conducting a treatability study. In particular, the Notice suggested the following limits: (1) No shipment may
exceed 250 kg; (2) no more than 1999 kg derived from the treatability study may provide for meaningful treatability studies. No commenters suggested limits were protective of human health and the environment. The following indicates the range of quantity limits proposed by commenters for shipment, treatment, and storage:

**Shipment:**
- mean quantity: 554 kg
- standard deviation: 794 kg
- range: 250 to 4000 kg
- most frequently cited suggestion: 250 kg

**Treatment:**
- mean: 446 kg
- standard deviation: 417 kg
- range: 250 to 2000 kg
- most frequently cited suggestion: 250 kg

**Storage:**
- mean: 2000 kg
- standard deviation: 2285 kg
- range: 250 to 10,000 kg
- most frequently cited suggestion: 1000 kg

Many commenters were supportive of the limitations suggested by HWTC in its petition. However, some commenters argued that the limitations suggested in the notice were not sufficient; although these commenters provided no data suggesting that their limits were protective of human health and the environment, they maintained that larger quantities of waste sample were necessary to conduct treatability studies. In particular, some commenters argued that the storage limitations were unnecessarily restrictive. Additionally, some commenters urged that a higher treatability study limit was necessary as some of the treatability tests required quantities of waste in excess of 1000 kg. Finally, some commenters recommended that the Agency include a mechanism for approval of case-by-case variances from the HWTC quantity limitations or the quantity limitations ultimately chosen.

Nevertheless, all commenters generally agreed that suitable limitations combined with economic forces would prevent the exemption from becoming a means to circumvent the RCRA Subtitle C regulations for treatment and disposal of hazardous waste. Additionally, many commenters noted that it would not be economically feasible for a person to perform an endless series of tests, since treatability study costs are much higher than commercial treatment or disposal costs on a per pound basis. In particular, Shirco (TSEF-905) stated that most treatability test had unit costs greatly in excess of costs associated with treatment and disposal options. Shirco cited an example where treatability study costs were about $1,000 per pound versus $0.80 to $1.20 per pound for disposal at a commercial facility. Numerous other commenters stated that the high costs associated with performing treatability studies would render invalid any concern the Agency had that the exemption could become a “loophole” in the RCRA Subtitle C regulations.

The Agency believes that the limitations established in this exemption will ensure that it does not become a “loophole” and will ensure de minimis risk so that no significant threat to human health and the environment will occur. The following sections discuss the limits selected by the Agency and present the rationale for the limitations adopted.

1. **Quantity Limits per Waste Stream per Treatment Process**

In response to the Notice of Data Availability, several commenters recommended that limits should be set for each generated waste stream to guard against the possibility that generators and facilities might conduct a plethora of treatability studies in lieu of hazardous waste treatment or disposal. While data was provided that would suggest this would not happen, the Agency has decided that some limitations should be imposed as an extra precaution. Thus, to avoid the potential for such an abuse, the Agency has selected the above limits recognizing that in some instances there may be a need to evaluate alternative treatment processes. Finally, the Agency has decided not to put any limits on the number of treatability studies that a laboratory or testing facility can perform per year. However, if this proves to be a problem, the Agency may consider additional regulations.

As noted above, some commenters suggested that higher quantity limits are necessary in order to evaluate certain treatability study processes or that additional amounts of waste may be necessary in instances where unforeseen circumstances have affected the results of all or part of a treatability study evaluation. They suggested that case-by-case allowances in excess of the amounts specified above should be made available if need can be demonstrated. The Agency agrees that some flexibility should be made
available to allow studies to be completed properly. However, the Agency wishes to ensure that adequate controls are placed on all such evaluations to protect human health and the environment. Accordingly, the Agency has included a provision that allows the Regional Administrator to grant requests for waste stream quantity limits in excess of those specified above, up to an additional 500 kg of non-acute hazardous waste, 1 kg of acute hazardous waste, and 250 kg of soils, water, or debris contaminated with acute hazardous waste. The Regional Administrator shall only allow additional quantities of hazardous waste when it can be demonstrated that one of the following circumstances or situations exist: (1) There has been an equipment or mechanical failure and that additional waste is needed to conduct a study; (2) that there is a need to verify the results of a previously evaluated treatment process; (3) that there is a need to study and analyze alternative techniques within a previously evaluated treatment process; or (4) that there is a need to do further evaluation of an ongoing treatability study to determine final specifications for treatment. These adjustments may be authorized only if the 1 kg (or 250 kg) or acute hazardous waste, or 1 kg for acute hazardous waste) quantity limit per waste stream per treatment process has been subjected to a treatability study evaluation and insufficient data are available to properly design a treatment process. When authorizing additional quantities, the Regional Administrator will only authorize adjustments for the minimum quantity necessary to complete the treatability study evaluation. The Agency believes that most treatability studies can be completed utilizing an extra 250 kg of sample or less, and only in unusual circumstances will quantities greater than 250 kg be required.

Generators and/or sample collectors seeking such an authorization for additional quantities must furnish sufficient information to the Regional Administrators to verify that they have met the conditions allowing for quantity adjustments. Generators and/or sample collectors will be required to submit, in writing, the specific reason why an additional quantity of sample for the treatability study evaluation is necessary (i.e., one of the four situations described above). He or she shall also provide: (1) Verification of the additional quantity necessary; (2) documentation accounting for all samples of hazardous waste from the waste stream which has not previously been sent to a treatability study evaluation; (3) a description of the technical modifications or change in specifications which will be evaluated and the expected results; and, (4) if further study is being required due to equipment or mechanical failure, the generator and/or sample collector must include information from the laboratory or testing facility indicating what handling procedures or equipment improvements have been made to protect against further breakdowns. The Regional Administrator may perform or require additional analyses and investigations as are necessary to determine the minimal amount of additional waste necessary to conduct the study and gather the additional data necessary to properly design and evaluate the performance of the treatment process.

2. Transportation Shipment Limits—Generator and Facility

The HWTC, in its petition, suggested that shipments of waste samples weighing less than 250 kg (approximately one standard 55-gallon drum) should be exempted when such samples are being shipped for the purpose of conducting treatability studies. The petition also recognized that larger size samples might be necessary for conducting treatability studies on contaminated soils or water; hence, the HWTC recommended that a provision for exempting larger size samples should be available. A number of commenters indicated that the 250-kg shipment limit was too restrictive and suggested that the limit be increased to 1000 kg. These commenters argued that the risk associated with shipping a larger amount (e.g., 1000 kg) is no greater than that associated with four shipments of 250 kg each when one considers the potential for transportation accidents. After careful consideration of all the issues, the Agency has decided to set a single shipment limitation of 1000 kg of non-acute hazardous waste; 1 kg of acute hazardous waste; or 250 kg of soils, water, or debris contaminated with acute hazardous waste. These shipment limitations (which, in effect, govern the exemption from the RCRA hazardous waste transporter regulations and manifesting requirements) will apply to the shipment of waste samples from the generator or sample collector to the laboratory or testing facility when such samples are being sent for the purpose of conducting a treatability study. The exemption will also apply when unused waste samples and residues generated by the treatability study are returned to the generator or sample collector following completion of the study.

The Agency is setting this limit to be consistent with the quantity limits set on generators for the amount of waste that can be subject to the treatability study sample exemption as discussed in the previous section. The Agency agrees with commenters that the risk associated with shipping the maximum limit of 1000 kg is no greater than that associated with four shipments of 250 kg each. However, it also believes these levels will pose de minimis risk.

In addition, as already discussed, the Agency believes other factors exist that will ensure safe delivery of the waste samples to and from the laboratory or testing facility. For example, the waste samples will still be subject to the applicable DOT or USPS regulations regarding shipment of hazardous materials. If the shipments do not fall under DOT or USPS jurisdiction, the generator or sample collector and the laboratory or testing facility must follow the requirements for labeling and packaging as set forth by EPA in this amendment. The requirements state that a sample must be packaged so that it does not leak, spill, or vaporize from its packaging. In addition, the following information must accompany the sample: (1) the sample collector's name, address, telephone number, and EPA identification number; (2) the laboratory or testing facility's name, mailing address, telephone number, and EPA identification number; (3) the quantity of the sample; (4) the date of shipment; and (5) a description of the sample. Finally, the Agency believes that most shipments will be considerably smaller than the limit. Since other forces, such as storage limitations and treatment rates at the laboratory or testing facility, will require careful control of the amount of waste shipped to the laboratory or testing facility. The costs to conduct the study and to collect, pack, and ship the sample will tend to limit the sample size to the smallest amount practicable.

3. Treatment Rate Limit

The HWTC, in its petition, suggested that the treatment rate limit should be 250 kg per day per laboratory or testing facility. Many of the commenters agreed; however, others argued that the limit should be larger and that it should be based on either the number of treatment units or the number of treatment processes that the laboratory or testing facility was capable of conducting. For example, if a facility was capable of conducting several soil fixation studies or biological treatment studies at one
time, then the limit should be 250 kg per process. Other commenters argued for even higher limits, indicating that it should be 250 kg per unit.

After reviewing the available information and considering the comments, the Agency has adopted a treatment rate limit of 250 kg per day of "as received" waste for the entire laboratory or testing facility. The term "as received" has been chosen by the Agency because some of the treatment processes involve the addition of non-waste material to reduce the environmental mobility of hazardous constituents. "As received" refers to the waste shipped by the generator or sample collector as it arrives at the laboratory or testing facility. Based on the information provided by the HWTC, information submitted by other commenters in response to the Notice of Data Availability, and EPA's own experience, the Agency believes that most treatability studies can be conducted at or below the treatment rate limit of 250 kg per day.

The Agency believes this level will allow many wastes to be treated and evaluated as part of a treatability study, while posing only a de minimis risk to human health and the environment. For example, if a laboratory or testing facility were to conduct a treatability study on a waste using bench-scale incineration and the study achieved a 99.9% destruction/removal efficiency, only a small amount of toxic material would be released into the environment. In most instances, the amount released is much lower than any level of concern. In addition, since in most cases these studies will be conducted on an intermittent basis, there is less concern with repeated exposure.

Laboratories or testing facilities that are conducting treatability studies and that meet the treatment rate limit are exempted from the requirements to obtain a Subtitle C treatment permit. The Agency wants to emphasize that the purpose of the exemption is for conducting treatability studies, not for the commercial management of hazardous waste. The Agency believes that facilities anticipating the need to conduct an excessively large number of studies, or those having numerous treatment units allowing them to conduct many studies concurrently, will probably need to obtain a Research, Development, and Demonstration permit (40 CFR 270.65). It should also be noted that the Agency recently promulgated a new set of permitting standards under Subpart X of Part 264 (42 FR 46946, December 10, 1987) for miscellaneous hazardous waste management units. The Agency is also considering developing regulations under Subpart Y that would establish permitting standards for experimental facilities conducting research and development on the storage, treatment, or disposal of hazardous waste.

4. Storage Limits

The HWTC, in its petition, recommended that a facility be allowed to store 1000 kg of hazardous waste on site without a storage permit, as long as such waste is for the purpose of conducting treatability studies. HWTC argued that this amount is essentially equal to the small quantity generator (SQG) limits and that the 1000 kg of waste included all waste (both received waste and treated residue). Many commenters argued that the 1000-kg storage limit would not allow them sufficient inventory to conduct certain treatability studies or argued that the storage limit should be based on the number of units present at the facility.

After evaluating this issue, the Agency has decided to adopt a storage limitation of 1000 kg per laboratory or testing facility. However, the Agency has also decided to specify the 1000-kg storage limitation for "as received" waste. The 1000-kg storage limitation per laboratory or testing facility can include 500 kg of soils, water, or debris contaminated with acute hazardous waste or 1 kg of acute hazardous waste.

The Agency is making it clear in this rule that the storage exemption only applies to laboratories or testing facilities conducting treatability studies. The quantity limitations allow sufficient inventory to conduct small-scale treatability studies while ensuring de minimis risk to human health and the environment. Higher storage limits would not give us this same assurance. Also the Agency notes, as discussed previously, financial and business incentives are present that help to ensure de minimis risk levels are maintained.

The Agency limits for soils, water, and other debris contaminated with acute hazardous waste were selected to allow small scale treatability studies to be conducted on media contaminated with dioxin wastes and certain pesticides such as aldrin and dieldrin. Although the 500-kg storage limit is higher than that currently established for SQGs, the Agency believes that the 500-kg limit will still be protective of human health and the environment and pose de minimis risk, since in most instances the sample will only be stored for a short period of time prior to being utilized in a study. Furthermore, this category is limited to materials in which the acute hazardous waste involves a contaminant in a medium such as water or soil. Therefore, EPA would expect the concentration of the acute hazardous waste to be very low. Furthermore, the contaminant may be bound to the medium itself. For other acute hazardous wastes (i.e., the actual listed waste), the Agency has adopted a 1-kg limit consistent with the SQG regulations.

5. Residues and Unused Samples-Time Limitations

Although the Notice of Data Availability did not propose any time limitations for completion of a treatability study, some commenters strongly recommended that appropriate time limits be placed on the storage of the "as received" waste samples and the residues generated from the treatability study. Suggestions on appropriate time limits varied widely. However, the commenters generally indicated that 1 year provides ample time to complete most treatability studies.

The Agency is in agreement with commenters that specific time limits for completing treatability studies are necessary. Time limitations are necessary to guard against potential abuses such as use of a laboratory or testing facility for long-term storage to avoid treatment and disposal. Any untreated sample and any residue generated during the treatability study must be returned to the generator within 90 days of study completion or within 1 year from the date of shipment by the generator to the laboratory or testing facility, whichever is earlier. Otherwise, these materials must be managed, by the laboratory or testing facility conducting the treatability study, as a RCRA hazardous waste (unless the waste is no longer hazardous). These time limits provide the laboratory or testing facility conducting the treatability study enough time to do the evaluation, but at the same time do not allow persons to store these wastes indefinitely. The 1-year time limit proved to be noncontroversial when adopted in other areas. For example, the 1-year time limit is consistent with the speculative accumulation provision and the closed-loop tank provision. Under these provisions, persons or facilities holding materials have 1 year to accumulate them before they are potentially subject to regulation.

Laboratories or testing facilities that do not return the unused sample or the residues to the generator or sample collector within the specified time limits are subject to appropriate regulation. Facilities must determine if they meet
the SQC requirements of § 261.5 or the accumulation requirements of § 262.34, and they may need to obtain a storage permit and comply with its conditions. Once samples and residues are returned to the generator, they are no longer exempt under today’s rule. Ultimately, the unused sample and residues that are still hazardous must be manifested and disposed of in a RCRA-designated facility by the laboratory or testing facility, the waste generator, or sample collector.

6. Mobile Treatment Units

Although the issue of mobile treatment units (MTUs) was not addressed in the Notice of Data Availability and Request for Comment, concern was expressed over how this exemption applies to MTUs. EPA has determined that MTUs conducting treatability studies may qualify for this exemption. However, each MTU or group of MTUs operating at the same location is subject to the treatment rate, storage, and time limitations and the notification, recordkeeping, and reporting requirements that are applicable to stationary laboratories or testing facilities conducting treatability studies. That is, a group of MTUs operating at one location will be treated as one MTU facility for purposes of § 261.4 (e) and (f). Furthermore, these requirements apply to each location where an MTU will conduct treatability studies.

D. Reporting and Recordkeeping Requirements

Although the Notice of Data Availability did not specifically recommend that reporting and recordkeeping provisions be adopted, some commenters suggested that some form of reporting and recordkeeping should be required in the treatability study exemption. They argued that, without some form of reporting or recordkeeping requirements, EPA would not have a means of determining who is violating the exemption or the amount of waste subjected to treatability studies.

The Agency strongly agrees with the commenters and believes that reporting and recordkeeping requirements are necessary to facilitate inspector review and, if necessary, to assist in enforcement action. In fact, 40 CFR 211.2(f) already requires that persons who claim that their waste is conditionally exempt from regulation must provide appropriate documentation that they meet the conditions of the exemption. Therefore, the Agency is stipulating specific reporting and recordkeeping requirements that will document compliance with the quantity and time limitations set forth in this rulemaking. The reporting and recordkeeping requirements stipulated below are the minimum requirements necessary to ensure compliance with the limitations in the treatability sample exemption.

1. The generator of the sample (who may also be the shipper or sample collector) and the laboratory or testing facility conducting the treatability study must keep the following records for 3 years after the completion of the study:
   a. A copy of the contract (between the generator and the laboratory or testing facility) to conduct the treatability study;
   b. Copies of all shipping documents. (If the waste was shipped to an MTU, copies of the shipping papers must be kept with the unit for inspection.)

2. Generators and sample collectors must also maintain records indicating the following: (1) The amount of waste (per waste stream and treatment process) shipped under the exemption; (2) to whom the shipment was sent (name, address, and EPA identification number of the laboratory or testing facility conducting the study); (3) the date shipment was made; and (4) whether all the sample or any residue generated from the treatability study was returned. In addition, beginning in 1999, generators must report this information in their biennial reports.

3. In addition, laboratories or testing facilities conducting or intending to conduct treatability studies must accomplish the following:
   a. Send a letter to the EPA Regional Administrator informing the Agency that the laboratory or testing facility intends to conduct small-scale treatability studies. This letter must be received no less than 45 days before the facility begins conducting treatability studies. The letter should indicate the address and EPA identification number of the laboratory or testing facility conducting the study and the number of studies anticipated. Owners and operators of facilities that do not have an EPA identification number must obtain one before conducting any treatability studies under this exemption. This reporting requirement and the requirement to obtain an EPA identification number apply to owners and operators of MTUs at every treatability study location (except at CERCLA sites where, under CERCLA section 121(a)(1) and 40 CFR 300.68(a)(3), RCRA permits are not required).
   b. Maintain appropriate records and documentation for a period of 3 years following completion of each treatability study that show compliance with the appropriate quantity and time limitations addressed in the final rule. The records must indicate that the laboratory or testing facility is meeting the requirements for shipment limits, treatment rate limits, and storage limits. Specific minimum information, by treatability study, that must be maintained include the following:
      - The name, address, and EPA identification number of the generator or sample collector of the waste samples;
      - The date the shipment was received;
      - The quantity of waste accepted;
      - The quantity of “as received” waste stored in each day;
      - The date the treatability study was initiated and the amount of “as received” waste introduced to treatment each day;
      - The date the treatability study was concluded; and
      - The date the unused sample and residue were returned to the generator or, if sent to a designated facility, the name of the facility and its EPA identification number. As noted above, the laboratory or testing facility must keep copies of all shipping documents associated with transport of the waste to and from the facility.

b. By March 15 of each year, submit a report to the authorized State or Regional Administrator that includes an estimate of the number of studies and the amount of waste expected to be used in treatability studies during the current year and the following information for the previous calendar year:
   - The name, address, and EPA identification number of the generator or sample collector of each waste sample;
   - The date the shipment was received;
   - The quantity of waste accepted;
   - The total quantity of “as received” waste in storage each day;
   - The date the treatability study was initiated and the amount of “as received” waste introduced to treatment each day;
   - The date the treatability study was concluded; and
   - The date any unused sample and residues generated from the treatability study were returned to the generator or sample collector or, if sent to a designated facility, the name of the facility and the EPA identification number.

d. Notify the Regional Administrator or authorized State by letter when and if the laboratory or testing facility is no longer planning to conduct any
treatability studies at the site. (For example, when an MTU completes a treatability study at a site, the owners or operators must submit the required notice that they will no longer be conducting treatability studies at that site.)

E. EPA Identification Numbers—Applicability of OSHA Training Requirements

Some commenters suggested that any laboratory or testing facility conducting treatability studies should be required to have an EPA identification number. These commenters argued that such a restriction would ensure that the facility is in compliance with the requirements to have a facility contingency plan, has established emergency procedures, and is in compliance with OSHA's hazardous waste workers' training and medical monitoring requirements. (See 29 CFR 1910.120, 51 FR 45654, December 19, 1986.)

The Agency partially agrees and is requiring any laboratory or testing facility conducting treatability studies to notify the Agency and obtain an EPA identification number if the facility does not already have one. However, as already explained, the Agency believes laboratories or testing facilities conducting treatability studies within the limits specified present a de minimis risk. For example, the OSHA hazardous waste operators and emergency response requirements (29 CFR 1910.120) are applicable except for SQGs and facilities complying with the accumulation time requirements of 40 CFR 282.34. Other OSHA requirements, such as the OSHA laboratory standards and general duty clause (29 USC 654(a)(1)), may apply depending on the type of laboratory or testing facility and the nature of its activities. Thus, EPA believes requirements such as contingency plans and emergency procedures are not necessary for the protection of human health and the environment.

F. Incentives for Safe Transport

In the Notice of Data Availability, the Agency specifically requested comment on whether the incentives for safe transport and storage of waste characterization samples would also apply to treatability samples. Most commenters agreed that suitable incentives exist to ensure proper handling and shipping of treatability study samples.

The Agency generally agrees. In particular, a principal purpose of the generator and transporter requirements is to assure that shipments of hazardous wastes are safely delivered to an appropriate destination (i.e., a permitted or interim status hazardous waste management facility). This is accomplished through the requirements for manifesting, recordkeeping, packaging, and labeling of hazardous waste. The principal purpose of the manifest system is to ensure 'cradle to grave' accountability for shipments of hazardous waste from the generator to a TSDF.

In the case of treatability study samples, EPA wants to ensure that the samples are delivered to the facility conducting the treatability study, and that both the unused sample and all residues generated in the treatability study are sent back to the generator or sample collector or, alternatively, shipped to a designated facility if the waste remains hazardous.

The Agency believes that sufficient incentives and requirements are in place to provide for the safe shipment of samples to and from laboratories and testing facilities conducting treatability studies. In particular, they include:

1. Maintenance of corporate reputation and public confidence;
2. The high cost of these studies coupled with the generator's or sample collector's need for properly documented results;
3. The need for the generator or sample collector to verify results of a treatability study; and
4. Requirements in today's rule for either returning the unused samples and residues to the generator or sample collector, or for manifesting and shipping these materials to a TSDF for ultimate disposal.

The Agency believes that the above incentives and requirements will guard against any facility not complying with the limitations or conducting bogus treatability studies. Furthermore, DOT or other regulations and guidelines control the transportation of such samples even in the absence of EPA regulation. The requirements to comply with DOT shipping regulations regarding packaging and labeling will be substantially the same as present requirements for shipping hazardous waste. Additionally, the USPS has stringent guidelines governing the shipment of hazardous materials, including samples. (See the "Domestic Mail Manual," Part 124 and Publication 52, "Acceptance of Hazardous or Perishable Articles.") For the above reasons, the Agency believes that the transport of small quantities of hazardous waste poses de minimis risk during shipment to a laboratory or testing facility or when being returned to the generator or sample collector.

III. Today's Amendment

The Agency believes that the full complement of the hazardous waste regulations found in 40 CFR, Parts 261 through 270, when applied to waste samples used in small-scale treatability studies, are more comprehensive than necessary to adequately protect human health and the environment. In addition, the Agency believes that it needs to promote research and the development of innovative technologies to manage hazardous wastes. Therefore, EPA is amending the regulations to conditionally exempt sample waste samples processed in small-scale treatability studies from the hazardous waste regulations under certain conditions.

In particular, EPA is today adding new paragraphs (e) and (f) to 40 CFR 261.4 which accomplish the following: First, persons who generate samples are exempted from the generator and transporter requirements when samples are shipped by the generator, or any other person who collects the sample (the "sample collector"), to a laboratory or testing facility for the purpose of conducting a treatability analysis, or when shipped from the facility back to the sample collector, provided that certain packaging and labeling requirements are met. Second, any laboratory or testing facility that conducts treatability studies may store these waste samples and residues generated from the treatability study within the quantity and time limits specified and not be subject to the requirements of 40 CFR, Parts 261, 265, and 270. Third, the actual testing of the samples does not require a permit, provided the laboratory or testing facility complies with the limitations specified in today's rule.

Laboratories and testing facilities that conduct treatability studies must also keep records and documents regarding each treatability study as enumerated in the D.B. above. Additionally, today's rule requires facilities conducting treatability studies to submit an annual report to the authorized State or Administrator of the EPA Region in which the laboratory or testing facility is located. The required annual report must be a distinct document prepared by the owner and/or operator of the laboratory or testing facility indicating the previous calendar year's activities regarding treatability studies. The report must be submitted by March 15 of the year and must identify the laboratory or testing facility by name, EPA identification number, and the location (site address) at which the treatability
studies were conducted. Paragraph II.D.3.c. above lists specific information required in the report. The obligation to submit annual reports continues until the laboratory or testing facility discontinues treatability studies, returns all unused "as received" samples and any residues generated in the treatability studies back to the generator or sample collector, and notifies the Regional Administrator or State Director that the laboratory or testing facility no longer plans to conduct any treatability studies at the site.

Paragraph (e), Treatability Study Samples. Provides an exemption for generators of samples of hazardous waste to be evaluated in treatability studies, while they are being prepared for transport or being transported, provided that these samples and their residues are returned to the generator within specified time limits. The exemption limits the sample collector or generator from shipping more than 1000 kg per acute hazardous waste stream per treatment process (or 250 kg of soils, water, or debris contaminated with acute hazardous waste, or 1 kg of acute hazardous waste). Shipments must comply with the applicable DOT, USPS, or other applicable regulations for shipping hazardous materials.

The generator or sample collector must also maintain records indicating the amount of waste shipped under the exemption, the name and address of the laboratory or testing facility, the facility EPA identification number, type of study, and the expected duration of the study. Beginning in 1989, the generator or sample collector must also include the above information in its biennial report.

Paragraph (f), Samples Undergoing Treatability Studies at Laboratories or Testing Facilities, describes the limitations that apply to a facility conducting treatability studies under this exemption. The facility may subject no more than 250 kg of "as received" waste to treatability studies in any one day. The facility may store a maximum of 1000 kg of "as received" waste, of which 500 kg can be soils, water, or debris contaminated with acute hazardous waste or 1 kg of acute hazardous waste. The facility must also return any unused sample and residues to the generator within 90 days after completion of the study or within 1 year after initial shipment (whichever is earlier), or otherwise manage the sample and residue as a RCRA hazardous waste, if the residue is still hazardous.

The facility must meet certain specified reporting requirements. The facility must provide notification (by letter) to the Regional Administrator or authorized State indicating that the facility intends to conduct treatability studies under the exemption. It must obtain an EPA identification number if it does not have one. The facility must also maintain records documenting compliance with the specified time and quantity limits for treatment and storage and must keep records of all shipping documents for 3 years from the completion of the treatability study.

The owner or operator of a facility conducting treatability studies must also submit a report to the Regional Administrator or authorized State indicating the type and number of treatability studies conducted during the previous calendar year, for whom each study was conducted, the quantity of hazardous waste utilized in each treatability study, when each study was conducted, and the final disposition of residue and any unused sample. The report must include an estimate of the number of treatability studies to be conducted and the quantity of hazardous waste expected to be used in treatability studies during the coming year. The facility must also notify the Regional Administrator or authorized State by letter when and if the facility is no longer planning to conduct any treatability studies at the site.

IV. State Authority

A. Applicability of Rules in Authorized States

Under section 3008 of RCRA, EPA may authorize qualified States to administer and enforce the RCRA program within the State. (See 40 CFR, Part 271 for the standards and requirements for authorization.) Following authorization, EPA retains enforcement authority under sections 3008, 7003, and 3013 of RCRA, although authorized States have primary enforcement responsibility.

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

In contrast, under section 3009(g) of RCRA, 42 U.S.C. 6923(g), new requirements and prohibitions imposed by the HSWA take effect in authorized States at the same time that they take effect in nonauthorized States. EPA is directed to implement those requirements and prohibitions in an authorized State, including the issuance of permits, until the State is granted authorization to do so. While States must still adopt HSWA-related provisions as State law to retain final authorization, HSWA applies in authorized States in the interim.

B. Effect of State Authorizations

Today's announcement promulgates regulations that are not effective under HSWA in authorized States, since this rulemaking does not impose requirements or prohibitions contained in HSWA. Thus, the regulations will be applicable only in those States that do not have final authorization. In an authorized State, the regulations will not be applicable until the State revises its program to adopt equivalent regulations under State law.

40 CFR 271.21(e)(2) requires that States having final authorization must modify their programs to include equivalent regulations within a year of promulgation of these regulations if only regulatory changes are necessary, or within 2 years of promulgation if statutory changes are necessary. These deadlines can be extended in exceptional cases (40 CFR 271.21(e)(3)). Once EPA approves the modification, the State requirements become Subtitle C RCRA requirements.

States with authorized RCRA programs may already have regulations similar to those in today's rule. These State regulations are authorized by Federal authorization and are effective in nonauthorized States. EPA is not authorized to promulgate Federal regulations that are more stringent or broader than those in authorized States. This is a result of section 3009 of RCRA, which allows States to impose more stringent or broader regulations than the Federal program. The regulations promulgated today at
§ 261.4 (e) and (f) are considered to be less stringent than or reduce the scope of the existing Federal regulations because today's rule exempts certain activities now within the purview of RCRA. Therefore, authorized States are not required to modify their programs to adopt regulations consistent with and equivalent to this rulemaking.

Even though States are not required to adopt today's rulemaking, EPA strongly encourages States to do so as quickly as possible. As already explained in this preamble, today's rule is needed to facilitate evaluating remediation alternatives for CERCLA clean-ups and the RCRA Corrective Action Program, and to speed research and development for treatment alternatives to land disposal and waste minimization, recycling, and reuse. States are, therefore, urged to consider the adoption of today's rule; EPA will expedite review of authorized State program revision applications.

States are also encouraged to use existing authorities to provide for comparable treatability exemptions prior to adopting and receiving authorization for today's rule. Some States may have authority comparable to RCRA Section 7003, which allows EPA to order response action in the case of imminent and substantial endangerment to health or the environment "notwithstanding any other provision of this Act." An authorized State may use comparable section 7003-type authority to authorize treatability studies and may waive the generator, transporter, notification, and permit requirements consistent with today's rulemaking.

In addition to, or in lieu of, a section 7003-type authority, a State may have general waiver, permit waiver, or emergency permit authority. Consistent with this rule, states are encouraged to use any such authority to grant treatability exemptions in a manner consistent with today's rule.

V. Effective Date

Section 3010(b) of CRRA provides that EPA's hazardous waste regulations and revisions to those regulations take effect 6 months after promulgation. The purpose of this requirement is to allow facilities that handle hazardous wastes sufficient lead time to prepare for and to comply with major new regulatory requirements. Given the potential of this rule to increase the timeliness of CERCLA remedial clean-up activities, RCRA corrective actions, and compliance with the land disposal restrictions, the Agency believes that an effective date of 6 months after promulgation would unnecessarily disrupt implementation of the regulations and would not be in the public interest. Since this amendment reduces, rather than increases, the existing requirements for facilities that handle waste samples, there is no basis for allowing a lengthy time period to prepare for compliance. The same reasons provide good cause to make this rule effective immediately upon publication notwithstanding section 4(d) of the Administrative Procedure Act, 5 U.S.C. 555(d). Therefore, this amendment takes effect immediately upon publication in the Federal Register.

The application of this final rule is prospective only. Any treatability studies covered by this final rule that were conducted before the effective date of this regulation are subject to the Subtitle C hazardous waste regulations, including permitting requirements.

VI. Regulatory Analyses

A. Executive Order No. 12291

Under Executive Order No. 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This final regulation is not major because it will not result in an effect on the economy of $100 million or more, and it will not increase costs or prices to industry. Rather, this regulation will reduce the overall costs and economic impact of EPA's hazardous waste management regulations by eliminating permitting requirements for laboratories and testing facilities intending to conduct treatability studies. The Agency estimates that perhaps 400 facilities and laboratories nationwide will be affected by promulgation of this rule. Facilities and laboratories will be spared the time (as much as 2 years) and the costs (estimated to be between $200,000 and $250,000) otherwise necessary to obtain a RCRA permit. In addition, there will be no adverse effect on the ability of U.S.-based enterprises to compete with the non-U.S.-based enterprises in domestic or export markets. Because this amendment is not a major regulation, no Regulatory Impact Analysis has been conducted.

This amendment was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order No. 12291.

B. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., whenever an Agency is required to publish general notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that 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. As noted previously in this preamble, the universe of facilities affected is estimated to total about 400; of these, perhaps 200 are small business entities.

By eliminating time-consuming and costly permitting requirements, the Agency anticipates that promulgation of this rule will have a positive effect on small entities.

This amendment will have no adverse economic impact on small entities. In fact, it should reduce the burden imposed on small entities that conduct treatability studies and comply with the provisions of this rulemaking. Accordingly, I hereby certify that this final 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.

C. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., and have been assigned the OMB control number 2050-0068 [Treatability Studies Notification and Recordkeeping].

Public reporting burden for this collection of information is estimated to vary from 80 to 250 hours per response, with an average of 155 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

VII. Supporting Documentation

A background document in which EPA responds to any comments not addressed in this preamble, entitled "Summary and EPA Responses to Public Comments on the September 18, 1987 Notice of Data Availability and Request for Comment, and the September 25.
PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

1. The Authority Citation for Part 260 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6933.

4. Section 261.4 is amended by adding two new paragraphs (e) and (f) to read as follows:

§ 261.4 Exclusions.

(e) Treatability Study Samples. (1) Except as provided in paragraph (e)(2) of this section, persons who generate or collect samples for the purpose of conducting treatability studies as defined in section 250.10, are not subject to any requirement of Parts 261 through 263 of this chapter or to the notification requirements of Section 3070 of RCRA, nor are such samples included in the quantity determinations of §261.5 and §262.34(d) when:

(i) The sample is being collected and prepared for transportation by the generator or sample collector; or

(ii) The sample is being accumulated or stored by the generator or sample collector prior to transportation to a laboratory or testing facility; or

(iii) The sample is being transported to the laboratory or testing facility for the purpose of conducting a treatability study.

(2) The exemption in paragraph (e)(1) of this section is applicable to samples of hazardous waste being collected and shipped for the purpose of conducting treatability studies provided that:

(i) The generator or sample collector uses (in "treatability studies") no more than 1000 kg of any non-acute hazardous waste, 1 kg of acute hazardous waste, or 250 kg of soils, water, or debris contaminated with acute hazardous waste for each process being evaluated, for each generated waste stream; and

(ii) The mass of each sample shipment does not exceed 500 kg of non-acute hazardous waste, 1 kg of acute hazardous waste, or 250 kg of soils, water, or debris contaminated with acute hazardous waste.

(f) The sample must be packaged so that it will not leak, spill, or vaporize from its packaging during shipment and the requirements of paragraph A or B of this subparagraph are met:

(A) The transportation of each sample shipment complies with U.S. Department of Transportation (DOT), U.S. Postal Service (USPS), or any other applicable shipping requirements; or

(B) If the DOT, USPS, or other shipping requirements do not apply to the shipment of the sample, the following information must accompany the sample:

(1) The name, mailing address, and telephone number of the generator of the sample.

(2) The name, address, and telephone number of the facility that will perform the treatability study.

(3) The quantity of the sample:

(4) The date of shipment and

(5) A description of the sample, including its EPA Hazardous Waste Number.

(iv) The sample is shipped to a laboratory or testing facility which is exempt under §261.4(i) or has an appropriate RCRA permit or interim status.

(v) The generator or sample collector maintains the following records for a period ending 3 years after completion of the treatability study:

(A) Copies of the shipping documents;

(B) A copy of the contract with the facility conducting the treatability study;

(C) Documentation showing:

(1) The amount of waste shipped under this exemption;

(2) The name, address, and EPA identification number of the laboratory or testing facility that received the waste;

(3) The date the shipment was made; and

(4) Whether or not unused samples and residues were returned to the generator.

(vi) The generator reports the information required under paragraph (e)(v)(C) of this section in its biennial report.

3. The Authority Citation for Part 261 is revised to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6933.
(i) The reason why the generator or sample collector requires additional quantity of sample for the treatability study evaluation and the additional quantity needed:

(ii) Documentation accounting for all samples of hazardous waste from the waste stream which have been sent for or undergone treatability studies including the data each previous sample from the waste stream was shipped, the quantity of each previous shipment, the laboratory or testing facility to which it was shipped, what treatability study processes were conducted on each sample shipped, and the available results of each treatability study;

(iii) A description of the technical modifications or change in equipment or processes which will be evaluated and the expected results;

(iv) If such further study is being required due to equipment or mechanical failure, the applicant must include information regarding the reason for the failure or breakdown and also include what procedures or equipment improvements have been made to protect against future breakdowns; and

(v) Such other information that the Regional Administrator considers necessary.

(f) Samples Undergoing Treatability Studies at Laboratories and Testing Facilities. Samples undergoing treatability studies and the laboratory or testing facility conducting such treatability studies (to the extent such facilities are not otherwise subject to RCRA requirements) are not subject to any requirement of this Part. Part 124, Parts 262-268, 286, and 270, or to the notification requirements of Section 3010 of RCRA provided that the conditions of paragraphs (f)(1) through (11) of this section are met. A mobile treatment unit (MTU) may qualify as a testing facility subject to paragraphs (f)(1) through (11) of this section. Where a group of MTUs are located at the same site, the limitations specified in (f)(1) through (11) of this section apply to the entire group of MTUs collectively as if the group were one MTU.

(1) No less than 45 days before conducting treatability studies, the facility notifies the Regional Administrator, or State Director (if located in an authorized State), in writing that it intends to conduct treatability studies under this paragraph.

(2) The laboratory or testing facility conducting the treatability study has an EPA identification number.

(3) No more than a total of 250 kg of "as received" hazardous waste is subjected to initiation of treatment in all treatability studies in any single day. "As received" waste refers to the waste as received in the shipment from the generator or sample collector.

(4) The quantity of "as received" hazardous waste stored at the facility for the purpose of evaluation in treatability studies does not exceed 1000 kg, the total of which can include 500 kg of soils, water, or debris contaminated with acute hazardous waste or 1 kg of acute hazardous waste. This quantity limitation does not include:

(i) Treatability study residues; and

(ii) Treatment materials (including nonhazardous solid waste) added to "as received" hazardous waste.

(5) No more than 90 days have elapsed since the treatability study for the sample was completed, or no more than one year has elapsed since the generator or sample collector shipped the waste stream which have been sent for or undergone treatability studies.

(6) The treatability study does not involve the placement of hazardous waste on the land or open burning of hazardous waste.

(7) The facility maintains records for 3 years following completion of each study that show compliance with the treatment rate limits and the storage time and quantity limits. The following specific information must be included for each treatability study conducted:

(i) The name, address, and EPA identification number of the generator or sample collector of each waste sample.

(ii) The date the shipment was received.

(iii) The quantity of waste accepted.

(iv) The quantity of "as received" waste in storage each day.

(v) The date the treatment study was initiated and the amount of "as received" waste introduced to treatment each day.

(vi) The date the treatability study was concluded.

(vii) The date any unused sample or residues generated from the treatability study were returned to the generator or sample collector or, if sent to a designated facility, the name of the facility and the EPA identification number.

(8) The facility keeps, on-site, a copy of the treatability study contract and all shipping papers associated with the transport of treatability study samples to and from the facility for a period ending 3 years from the completion date of each treatability study.

(9) The facility prepares and submits a report to the Regional Administrator, or State Director (if located in an authorized State), by March 15 of each year that estimates the number of studies and the amount of waste expected to be used in treatability studies during the current year, and includes the following information for the previous calendar year:

(i) The name, address, and EPA identification number of the facility conducting the treatability studies:

(ii) The types (by process) of treatability studies conducted:

(iii) The names and addresses of persons for whom studies have been conducted (including their EPA identification numbers):

(iv) The total quantity of waste in storage each day:

(v) The quantity and types of waste subjected to treatability studies:

(vi) When each treatability study was conducted:

(vii) The final disposition of residues and unused sample from each treatability study.

(10) The facility determines whether any unused sample or residues generated by the treatability study are hazardous waste under §261.3 and, if so, are subject to Parts 262 through 268, Part 270 of this Chapter, unless the residues and unused samples are returned to the sample originator under the § 261.4(e) exemption.

(11) The facility notifies the Regional Administrator, or State Director (if located in an authorized State), by letter when the facility is no longer planning to conduct any treatability studies at the site.

(Approved by the Office of Management and Budget under control number 2050-0098)

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