the fungicide spiroxamine (8-(1,1-dimethylethyl)-N-ethyl-N-propyl-1,4-dioxaspiro[4,5]decane-2-methanamine) and its metabolites containing the N-ethyl-N-propyl-1,2-dihydroxy-3-aminopropane moiety, calculated as parent equivalent, in or on the following raw agricultural commodities:

Commodity	Parts per million
Banana (import)	3.0
Grape (import)	1.0
Hop, dried cones	50

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 04–16216 Filed 7–15–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 194

[FRL–7787–6]

RIN 2060–AJ07

Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's Compliance With the Disposal Regulations; Alternative Provisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (''EPA'' or ''the Agency'' or ''we'') is finalizing changes to the ''Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's Compliance with the Disposal Regulations,'' (''Compliance Criteria'') proposed August 9, 2002 (67 FR 51930–51946). Today, after considering public comments received in response to the proposed changes, we finalize the following actions: Addition of a mechanism to address minor changes to the provisions of the Compliance Criteria; changes to the approval process for waste characterization programs at Department of Energy (DOE) transuranic (TRU) waste sites; changes to the number of copies of compliance applications and reference materials submitted to EPA; and replacement of the term ''process knowledge'' with ''acceptable knowledge.'' Today's action will maintain or improve our oversight at WIPP to ensure safe disposal of waste. Moreover, these changes do not modify the technical approach that EPA employs when conducting independent inspections of the waste characterization capabilities at DOE waste generator/storage sites. EPA is conducting this action in accordance with the procedures for substituting alternative provisions in the Compliance Criteria.

DATES: This final rule is effective October 14, 2004.

FOR FURTHER INFORMATION CONTACT: Ray Lee; telephone number: (202) 343–9463; postal address: Radiation Protection Division, Mail Code 6608J, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

I. General Information

A. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. OAR–2002–0005. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at: Air and Radiation Docket and Information Center, Room B–108, U.S. Environmental Protection Agency, 301 Constitution Ave., NW., Washington, DC. This Docket Facility is open from 8:30 a.m.–4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (202) 566–1742.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''Federal Register'' listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. Once in the system, select ''search,'' then key in the appropriate docket identification number (OAR–2002–0005 for this action).

Abbreviations Used in This Document

AK—Acceptable Knowledge
ANL–E—Argonne National Laboratory-East
APA—Administrative Procedure Act
BID—Background Information Document
CBFO—Carlsbad Field Office
CFR—Code of Federal Regulations
CH—Contact Handled
DOE—Department of Energy
EPA—Environmental Protection Agency
INEEL—Idaho National Energy and Engineering Laboratory
LANL—Los Alamos National Laboratory
NDA—Nondestructive Assay
NPRM—Notice of Proposed Rulemaking
NRC—Nuclear Regulatory Commission
NTS—Nevada Test Site
ORNL—Oak Ridge National Laboratory
PK—Process knowledge
RFETS—Rocky Flats Environmental Technology Site
RTR—Real-time radiography
SRS—Savannah River Site
TRU—Transuranic
VE—Visual inspection
WC—Waste characterization
WIPP—Waste Isolation Pilot Plant
WIPP LWA—WIPP Land Withdrawal Act
WWIS—WIPP Waste Information System

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I. What Is the WIPP?

The Waste Isolation Pilot Plant (''WIPP'') is a disposal system for transuranic (TRU) radioactive waste. Developed by the Department of Energy (''DOE'' or ''the Department''), the WIPP is located near Carlsbad in southeastern New Mexico. TRU waste is emplaced 2,150 feet underground in an ancient layer of salt that will eventually ''creep'' and encapsulate the waste containers. The WIPP has a total capacity of 6.2 million cubic feet of TRU waste. Most TRU waste proposed for disposal at WIPP consists of items that have become contaminated as a result of activities associated with the production of nuclear weapons (or with the cleanup of nuclear weapons production facilities), such as, rags, equipment, tools, protective gear, and sludges. Some TRU waste is contaminated with hazardous wastes regulated under the Resource Conservation and Recovery Act (42 U.S.C. 6901–6992k) (''RCRA''). The waste proposed for disposal at WIPP is currently stored at Federal facilities across the United States, including locations in Colorado, Idaho, New Mexico, Nevada, Ohio, South Carolina, Tennessee, and Washington.

The WIPP must meet EPA's generic disposal standards at 40 CFR part 191 for high-level and TRU radioactive waste. These standards establish numeric limits to ensure that the WIPP effectively contains radioactive waste. To determine whether the WIPP performs well enough to meet these disposal standards, EPA issued the WIPP Compliance Criteria (40 CFR part 194) in 1997. The Compliance Criteria interpret and implement the disposal standards specifically for the WIPP site. They describe what information DOE must provide, how EPA evaluates the WIPP's performance, and provides ongoing independent oversight.

Using the process outlined in the WIPP Compliance Criteria, EPA determined on May 18, 1998, that DOE had demonstrated that the WIPP complied with EPA's radioactive waste disposal regulations at subparts B and C of 40 CFR part 191. EPA's certification determination permitted the WIPP to begin accepting transuranic waste for disposal, provided that other applicable environmental regulations were met. Also, the disposal of TRU waste at WIPP is conditioned on the EPA determination that activities conducted at waste generator sites appropriately comply with the quality assurance (QA) and waste characterization (WC) requirements established at § 194.22 and § 194.24, respectively. (For a detailed discussion on all of the proposed changes, see 67 FR 51930–51946; August 9, 2002.)

II. What Changes Did EPA Propose?

On August 9, 2002, EPA proposed to revise certain provisions of the Compliance Criteria at 40 CFR part 194. Specifically, EPA proposed to revise the following: (1) Process for establishing ''alternative provisions'' in § 194.6; (2) approval process in § 194.8 for waste characterization processes at TRU waste generator/storage sites used to characterize TRU waste prior to its disposal at WIPP; (3) requirements in §§ 194.12 and 194.13 for submission of compliance applications and reference material; and (4) replace the term ''process knowledge'' with ''acceptable knowledge'' in §§ 194.2 and 194.24(c)(3). The proposed revisions intend to ensure that 40 CFR part 194 remains comprehensive, appropriate, and is based upon current knowledge and information. The Agency solicited comments on this proposal over a period of 120 days. In addition, in September 2002, EPA held public hearings at Albuquerque and Santa Fe, New Mexico. The transcripts of the hearings have been placed in the EPA Docket supporting this final action (EDOCKET ID#: OAR–2002–0005).

A. Proposed Changes to § 194.6—Process for Adding Minor Alternative Provisions

Section 194.6 establishes procedures applicable to substitution of alternative provisions for any of the Compliance Criteria. Such substitutions require a notice-and-comment rulemaking in accordance with § 194.6(a). In addition, § 194.6 stipulates that EPA's notice of proposed rulemaking (NPRM) addresses specific aspects of the proposed substitution, includes a public comment period of at least 120 days, and public hearings in New Mexico.

Based on EPA's oversight experience at the WIPP and TRU waste generator/storage sites, EPA proposed to revise § 194.6 to add a rulemaking process for substituting ''minor alternative provisions'' of the Compliance Criteria. The proposed changes for § 194.6 comport fully with the radioactive waste disposal regulations at 40 CFR part 191 and would not substantively alter the scope of the TRU waste disposal requirements. EPA also proposed to add to § 194.2 the definition of ''minor alternative provision'' to be a provision that clarifies a regulatory provision without substantively altering the existing regulatory requirement. Thus, revisions that do not alter the intent or the approach to verifying compliance of an existing regulatory requirement would be considered ''minor alternative provisions.''

B. Proposed Changes to § 194.8(b)—Waste Generator Site Inspection and Approval Process

The information outlined in § 194.8 describes the process by which EPA inspects and approves waste characterization (WC) activities at TRU waste sites. (For a detailed discussion, see 67 FR 51934–38.) Previously, every time a TRU waste site sought approval of its WC processes or TRU waste stream(s), EPA was required to conduct a site inspection under the authority of § 194.8. The § 194.8 process required EPA to issue a **Federal Register** notice announcing an inspection, open a 30-day public comment period, and docket WC-related material provided by the site for public review. The same process was required to approve all subsequent expansions of the WC program to new processes or waste streams at a site. Instead, we proposed that EPA will conduct only a single baseline site inspection under § 194.8 to determine whether a given site can adequately characterize TRU waste and comply with the regulatory requirements imposed on the TRU waste destined for the disposal at WIPP. Also, we proposed that all additional inspections at an approved site would be conducted under authority of § 194.24(h) (not under § 194.8) to approve changes or expansions to the WC processes and waste streams approved during the initial site approval referred to as the ''Baseline Compliance Decision.'' (See discussion in IV.B below.) The second key change we proposed was giving the opportunity for public comment on EPA's proposed approval of the site's waste characterization program. The proposed approval and accompanying inspection report would discuss inspection results and the waste characterization program documentation provided by the site. In addition, we proposed that the Agency would issue a final approval decision only after consideration of the public comments received in response to the proposed site approval.

EPA will issue a single **Federal Register** notice after each of the initial baseline inspections. The public will be asked to comment on the proposed approval and reporting requirements for each of the waste generator sites. The results of all EPA site inspections (under § 194.8 *and* § 194.24) and other

relevant information/updates will be made available to the public in EPA's dockets, WIPP Web site, and other means. We determined that the revised process provides equivalent or improved oversight, more control over schedule, better prioritization of technical issues and distinctions, and flexibility to address relative levels of experience or expertise at various DOE sites.

C. Proposed Changes to §§ 194.12 and 194.13—Number and Form of DOE Compliance Applications and Reference Materials

Section 194.12 of the Compliance Criteria requires DOE to submit 30 copies of the compliance applications and any accompanying materials to the Administrator in printed form. This provision also applies to the compliance applications periodically submitted by DOE for re-certification of compliance. Section 194.13 requires that 10 printed copies of referenced materials be submitted to the Administrator, unless such materials are generally available.

We proposed to revise § 194.12 to change the number of printed copies of compliance applications and reference materials that DOE must submit to EPA. We proposed to reduce the number of hard copies from 30 to 5 (one original and four printed copies). In addition, the proposed revisions § 194.12 required that DOE submit 10 complete compliance applications by alternative means (*e.g.,* compact disk) or other approved format. Also, the Agency proposed to revise § 194.13 by changing the number of copies in printed form of the reference materials from 10 to 5 and to require DOE to submit 10 copies of reference materials by alternative means (*e.g.*, compact disk) or other approved format. We determined that the proposed revisions for §§ 194.12 and 194.13 would (a) improve the Agency's evaluation process and reduce costs associated with the review of compliance applications and reference materials; (b) enhance the public's access to information via Internet ability to participate more actively in the public comment process; and (c) reduce the number of copies in printed form that must be submitted, thereby reducing paper usage.

D. Proposed Changes to §§ 194.2 and 194.24(c)(3)—Terminology Related to Waste Characterization

The Agency proposed to revise § 194.24(c)(3) by replacing the term ''process knowledge'' with the term ''acceptable knowledge.'' The term ''acceptable knowledge'' has been used by EPA and DOE since the Department submitted the Compliance Certification Application, during both the certification rulemaking and subsequent site inspections. For consistency, the Agency also proposed to add the definition of ''acceptable knowledge'' to § 194.2.

III. What Is EPA's Final Action in Consideration of Public Comments?

Over the 120-day comment period for the proposed rule, EPA received 17 sets of comments (7 from the public hearings, 4 from EDOCKET, and 6 through e-mail/regular mail). During the two public hearings held in Albuquerque and Santa Fe, New Mexico, 7 individuals presented their views related to the proposal. This preamble responds to all major comments.

The Response to Comments Document placed in the docket (EDOCKET ID#: OAR–2002–0005 discusses individual comments that EPA received and EPA's responses to those comments. Below we discuss changes that we made in response to the public comment and the rationale for today's final action.

A. Summary of Comments and Final Changes to § 194.6—Process for Adding Minor Alternative Provisions

In the proposed rule, we discussed why EPA considers that the existing provisions specific to minor revisions are unnecessarily stringent and why the change is necessary (67 FR 51933–34). EPA's oversight experience indicates that minor revisions to the Compliance Criteria requirements may improve implementation and consistency in regulatory compliance. Also, we acknowledged that for all alternative provisions that do not meet the proposed definition of ''minor alternative provisions,'' the Agency will continue to comply with the current requirements of § 194.6.

EPA proposed ''minor alternative provision'' as an alternative provision that ''clarifies a regulatory provision, or does not substantively alter the existing regulatory requirement.'' Thus, revisions that do not alter the intent or the approach to verifying compliance of an existing regulatory requirement are considered to constitute minor alternative provisions. As examples, we cited the proposed revisions to §§ 194.2, 194.12, 194.13, and 194.24(c)(3) as minor revisions which the commenters supported (see Response to Comments Document, EDOCKET ID#: OAR–2002–0005). Some commenters suggested an alternate definition to better clarify the intent. In today's action, we have added additional language to the definition to emphasize that a ''minor alternative provision'' would *only* clarify an existing regulatory provision and not substantially alter the regulatory requirements. The EPA is finalizing this definition for ''minor alternative provision'' which comports fully with the radioactive waste disposal regulations at 40 CFR part 191. In addition, this definition does not substantively alter the scope of the Compliance Criteria. More substantial revisions to 40 CFR part 194 would continue to follow the process laid out originally in § 194.6 and now contained at § 194.6(a). We believe this change will make EPA's regulatory activities more efficient and improve the implementation of minor revisions to the Compliance Criteria.

We proposed that a 30-day comment period is sufficient for the public to provide the Agency with relevant input on such minor revisions to the Compliance Criteria. In addition to the publication of a proposed rule in the **Federal Register** for minor provisions, EPA committed to announce the proposal on the Agency's Web site and place all relevant supporting materials in the Agency's public docket. Public comments expressed concern that a 30-day comment period is too short a time to comment on EPA's proposals concerning minor revisions to the Compliance Criteria. The streamlined process for minor provisions is intended to apply to changes that provide clarification and are uncontroversial or purely administrative—not highly technical or complex actions. Therefore, the Agency believes that in most cases a 30-day comment period will be sufficient and has retained this minimum requirement in the final rule. The Agency retains discretion to extend the comment period when deemed necessary.

B. Summary of Comments and Final Changes to § 194.8(b)—Waste Generator Site Inspection and Approval Process

1. Background

As discussed in the proposed rule, the purpose of EPA inspections at DOE sites is to verify that TRU waste sites are characterizing and tracking waste to ensure the volume and characteristics of the wastes conform with the requirements of the WIPP LWA and the specific conditions of the Certification Decision. The requirements at § 194.8(b) establish a process by which EPA determines whether DOE complies with Condition 3 of the Certification Decision. This requires that the Agency approve the programs for characterizing TRU waste streams using the process set

forth in § 194.8. (See 40 CFR part 194, appendix A.) Section 194.8 requires that, prior to sending waste from a generator site for disposal at WIPP, DOE must implement and obtain EPA approval of the ''system of controls'' (that is, personnel, equipment, and procedures) used at the site to characterize the waste and measure the waste contents determined to be significant (*i.e.*, ten significant radionuclides, ferrous and non-ferrous metals, cellulosics, plastics and paper) (63 FR 27392, May 18, 1998). Before approving DOE sites' waste characterization activities, EPA must inspect individual sites to verify that the sites have adequately implemented the proposed characterization programs.

2. Baseline Inspection Process

Under the revised inspection and approval process, EPA proposed the following changes (67 FR 51934–41; August 9, 2002):

- Conduct a baseline inspection at all TRU waste generator/storage sites once in accordance with the § 194.8 requirements and approve different WC program components based on the site's demonstration of its capabilities;
- Issue a **Federal Register** notice discussing § 194.8 inspection results and EPA's proposed ''Baseline Compliance Decision.'' The notice will specify what subsequent WC program changes or expansion must undergo further EPA inspection or approval under § 194.24 by assigning ''tiering'' designations to these activities. The notice will provide in detail the reasons for supporting the approval of individual WC program components, tier assignments and accompanying reporting requirements, and any limitations.
- Seek public comment on the proposed Baseline Compliance Decision (*i.e.,* comment on which activities should be assigned to each tier) and place the supporting documents in the public docket as described in § 194.67; and
- Evaluate and approve, if necessary, changes to the approved WC program activities at all sites. Inspections necessary for evaluation and/or approval of the changes will be conducted under authority of § 194.24(h), not under § 194.8. (No change in the continued compliance inspections at sites approved per the Baseline Compliance Decision.)

Today, we are finalizing the above aspects of our proposed inspection and approval process. We believe that these changes will not in any way compromise EPA's ability to oversee TRU waste sites' compliance with § 194.24 requirements. Also, these changes will clearly delineate the reasons for and the timing of the approval of different WC program component changes and the waste streams that must be approved by EPA. These changes will give TRU waste sites flexibility to seek limited or broader approval during the initial inspection by demonstrating that their WC programs can appropriately characterize a limited number or wide spectrum of TRU wastes. EPA, under its continued compliance authority, will verify that all sites characterize TRU wastes using only the EPA-approved WC programs.

We believe these changes will not lessen, but rather strengthen our ability to oversee DOE's TRU waste characterization activities and monitor sites' compliance with Condition 3 of the WIPP Certification Decision. The new process will not alter our authority or a site's ability to limit or expand the scope of WC program components. Rather, it will enable us to determine independently whether a subsequent inspection is necessary, when it should occur or whether a decision to allow a site to implement a change without EPA's approval is appropriate.

Many commenters were very concerned that the revised approval scheme would reduce the frequency of EPA inspections or even that once approved, sites might be able to operate WC programs indefinitely with little or no EPA oversight. They also expressed concern that the proposed tiering process allows undue discretion by DOE in determining what WC program changes at generator sites are significant. The comments indicate that EPA did not make sufficiently clear the nature and purpose of the proposed changes to the inspections process. In response, we find that it is necessary to further clarify and elaborate on the revised approval process and its implementation.

EPA does not believe that the proposed changes would reduce either the number of inspections nor the level of oversight and enforcement at DOE sites. The changes will modify the EPA inspection and approval procedures, but will not necessarily affect the frequency or number of times a site will be inspected. Under 40 CFR part 194, EPA may inspect DOE TRU sites' waste characterization activities using the inspection authority under § 194.8 and § 194.24. The new process provides that the individual waste generator sites will need only one § 194.8 approval from EPA to conduct WC activities. However, this single § 194.8 approval will specify any limitations on the approval that will necessitate additional inspections by EPA. Any such additional inspections will be conducted under authority of § 194.24(h), not under § 194.8. Limitations on the initial § 194.8 approval may relate to waste streams, waste categories, processes, or other factors deemed important by EPA and will specify what WC program expansions or changes must undergo further EPA inspection or approval under § 194.24. Furthermore, EPA's proposed Baseline Compliance Decision, including any proposed limitations, will be subject to public comment.

The Agency does not agree that it is necessary to require a re-evaluation of EPA's site-specific Baseline Compliance Decisions at a set interval. As discussed in the preamble to the proposed rule and reiterated above, EPA will conduct additional site inspections under § 194.24 to verify continued compliance with the baseline approval in accordance with the tiering designations or as otherwise deemed necessary. Since 1998, EPA has inspected WC programs at TRU waste sites under § 194.24 on an approximately annual basis. We are likely to maintain at least the same frequency for future continued compliance inspections under § 194.24 and may inspect more frequently as certain activities warrant. A reduced frequency of inspections might also be warranted if, for example, a site has no characterization activity over a period of time. The final rule offers flexibility in scheduling inspections as necessary while not diminishing in any way the effectiveness of our inspections program.

Generally, the Agency has conducted continuing compliance inspections to coincide with DOE's annual recertification audits. In its comments, DOE has requested that EPA continue to conduct the baseline inspections at the approved sites when DOE performs these audits. However, since the site inspections EPA would conduct to derive the Baseline Compliance Decision would be more detailed than DOE's annual recertification audits, these inspections will be scheduled by EPA and may or may not coincide with the DOE's recertification audits.

Because EPA expects to continue to inspect sites regularly, we do not believe it is necessary to specify an expiration date for the baseline compliance approval. Through ongoing compliance inspections (prompted by tiered activities/changes at the site or at EPA's own discretion under § 194.24), EPA will validate that approved processes and equipment continue to be adequately implemented. The baseline approval will remain valid so long as

the site continues to demonstrate appropriate use of approved processes.

Table 1 provides a comparison of the previous site inspection/approval process and the new Baseline Compliance Decision process. By adopting the WC program approval process we are finalizing today, EPA will achieve the following goals:

1. Maintain or improve oversight;
2. Improve public involvement and allow direct input in approval decisions;
3. Allow greater discretion in establishing technical priorities and accommodating varying degrees of WC experience at generator sites; and
4. Reduce regulatory burden by limiting **Federal Register** announcements under § 194.8 that the Agency must issue, and allow greater flexibility in scheduling inspections.

TABLE 1.—CURRENT APPROVAL AND BASELINE COMPLIANCE DECISION PROCESSES

Activity	Current inspection/ approval process	Baseline compliance decision process	Comment
Regulatory driver for waste characterization inspection.	§ 194.8	§ 194.8	Meet Condition 3 of the WIPP Certification Decision.
Notifying EPA of its readiness	Yes	Only new sites seeking initial approval.	EPA will inform each site with an approved WC program the timing for the inspection.
Announce inspection in **Federal Register** notice.	Every time a site seeks EPA approval to use a new or modified WC process or to ship any new TRU waste stream or a group of waste streams for disposal.	—Only for Baseline inspection to approve site-specific WC program. —No FR announcements for all followup tier-designated approvals.	
Report information specific to WC processes.	DOE must provide waste characterization plan and quality assurance program plan for each initial approval.	—For the Baseline inspection EPA will tell sites the type of information needed. —For followup inspections sites will provide information specified under each of the WC process tiers.	
Assign tiers based on adequacies and limitations of WC processes demonstrated.	No	Yes	Will require a thorough, detailed review to identify situations that would require EPA approval.
Require followup/additional inspections before approval.	Rarely	Possible	If the potential application of different WC components covers a wide spectrum of TRU waste streams.
Seeking public comment on the inspection results and pending approval.	No	Yes.	
Issuing a site approval decision	30 days after the announcement of the inspection in the FEDERAL REGISTER.	After the end of public comment period allowed to respond to the pending site approval decision announced in the FEDERAL REGISTER.	Increased public involvement; transparent decision process.
Require additional § 194.8 inspections.	For any new WC equipment/process or a waste stream approval.	No	The need for additional § 194.8 inspections negated by tiering signifying the need for approval under § 194.24.
Inspect sites for continued compliance under § 194.24 and issuing a letter and an inspection report.	Yes	Yes	To ensure that site is using previously approved WC program components to characterize and quantify TRU waste contents.
Inspect sites to evaluate changes to the approved WC processes.	When the site informs EPA of the need.	Identified by EPA as part of the tiering assignments.	Eliminates interpretation and/or guess work by site for the need for EPA approval.

When inspecting a waste generator site to render a Baseline Compliance Decision, EPA inspectors will evaluate each WC program component (equipment, procedure, and personnel training/experience) for its adequacy and appropriateness in characterizing TRU waste destined for WIPP disposal. The elements of this inspection will be the same as those followed in the current site inspection process discussed in the proposal (67 FR 51935–36). Depending on the site's demonstration of WC capabilities, the baseline inspection could cover a broad spectrum of WC processes and waste streams or could be limited to specific equipment or one waste stream. During the inspection a site must demonstrate its capabilities to characterize TRU waste(s) using appropriate equipment, procedures, and personnel and comply with the regulatory limits under § 194.24. The site also must demonstrate how the WC information is compiled and tracked using the EPA-approved WIPP Waste Information System (WWIS).

Under today's rule, EPA's baseline approval will specify any limitations on the approval. It will also specify what subsequent WC program changes or expansion must undergo further EPA inspection or approval under § 194.24 by assigning ''tiers'' to each of these activities. The tiering will be based on the following: Which WC processes the site has demonstrated to be suitable to and capable of characterizing a given

TRU waste type and the historical knowledge about the physical and radiological waste characteristics. EPA *will assign* the tiering designations. This eliminates the possibility of misinterpretation on DOE's part and the possibility of EPA not agreeing with DOE's selection of a tier. In addition, the public will have the opportunity to comment on which activities should be assigned to each tier.

EPA would like to further clarify the details of the tiers. Tier 1 waste characterization activities at a site will have more stringent reporting requirements. These activities will require notification by DOE and approval by EPA *prior* to shipment of waste to the WIPP. We expect to conduct site inspections as part of our decision-making process for many Tier 1 activities. Tier 2 activities will have more moderate reporting requirements and EPA may approve changes to certain activities without a follow-up inspection (*i.e.,* desktop review and approval of certain technical documents). These activities will require a notification by DOE to EPA on the specific changes; however, waste can be shipped to the WIPP without prior Agency approval. For Tier 2 notifications, EPA will review the documentation provided by DOE and reply only if additional information or analysis is needed. Other changes (*i.e.,* if no tier is specified) will be captured in DOE's annual change reports or continuing compliance inspections under § 194.24.

DOE will report any changes in equipment, processes, or personnel, based on their tier level, and certain changes must be reported to EPA before the sites are allowed to ship waste using the waste characterization activities in question. EPA will then decide whether or not a follow-up inspection is necessary to confirm and verify the adequacy of any changes to the site's waste characterization program. EPA may also conduct unannounced site inspections of a tiered activity if EPA determines a need based on the available information. Below are examples of how the tiers may be assigned:

- In its baseline inspection by EPA, a site (''Site 1'' in this example) demonstrates that it can quantify 10 WIPP-tracked radionuclides *only* in homogeneous organic solids using a particular piece of radioassay equipment (''Equipment A'' in this example). The baseline approval for Site 1 is issued and the non-destructive assay (NDA) equipment is approved with the limitation that it may be used to characterize *only* homogeneous solids. As part of the baseline approval, the change to use Equipment A on a new waste stream is designated a Tier 1 change. Therefore, if Site 1 would like to use Equipment A to characterize inorganic sludge then an additional EPA approval will be necessary.
- Site 1 would now like to use a different piece of equipment (''Equipment B'' in this example) to characterize the same waste stream that they are already approved for (in this case, homogeneous solids). Equipment B is nearly identical to Equipment A in specifications and operating controls. As part of the baseline approval, EPA specifies that using equivalent equipment to characterize an approved waste stream is a Tier 2 change. Therefore, Site 1 notifies EPA of its plans, provides documentation to EPA that Equipment A and B are equivalent, and can install and operate the new equipment without prior approval by the Agency.

For both Tier 1 and 2 changes, DOE *must* submit to EPA information discussing the relevant program changes for our evaluation. Prior to approval, Tier 1 changes may require an inspection to obtain objective evidence demonstrating a site's WC program adequacy and WC data showing compliance with the WIPP compliance criteria at 40 CFR 194. EPA will docket and post information from these § 194.24 inspections on the WIPP Web site for public review. Generally, Tier 2 changes would not require inspections, provided that EPA is satisfied with the information submitted by DOE regarding the changes. EPA's approval letter discussing Tier 1 or Tier 2 changes would explain how the available information was sufficient to justify a decision, or what additional information was collected during an inspection, if one was conducted. Also, EPA will docket and post on the WIPP Web site the Tier 2 approval letter and DOE submission for public review.

Major sites with an approved waste characterization program (Hanford, LANL, INEEL, RFETS, and SRS) and those requiring EPA approval (such as Oak Ridge National Laboratory) will be subject to a mandatory inspection to render the site-specific Baseline Compliance Decision and accompanying tiers. A few commenters misconstrued that once the Agency renders a Baseline Compliance Decision specific to the DOE's Central Characterization Project (CCP), the CCP can apply the approved WC activities at any TRU site. Commenters are incorrect with their understanding of the limitations of EPA's CCP approval. Currently, EPA inspects and approves the CCP program at each site and the approval is site-specific whenever a site hires CCP to characterize their TRU waste. EPA has followed this approach and has approved the CCP WC activities at the SRS, ANL–E, and NTS. Once today's rule becomes effective, EPA will inspect the above major sites with approved WC programs, sites with the approved CCP WC activities, and the remaining TRU waste generator/storage sites and render a Baseline Compliance Decision specific to each individual site. Each TRU site with an approved WC program may continue to dispose of their approved TRU waste streams at the WIPP. All TRU waste sites remain subject to applicable Federal and State regulations governing packaging, transportation, and disposal regulations for TRU waste.

Once the Baseline Compliance Decision has been made and tiers have been assigned at each site, the EPA may decide to revise the tiering designations, based on a variety of factors. Some sites may have a harder time converting to the more robust inspections regime, and certain aspects of their WC program that were strong in the past may need more intense scrutiny. Conversely, certain sites will undoubtedly improve their overall performance as they become accustomed to the new system, and certain aspects of their WC program will subsequently require less attention.

The decision to revise tiers at a site will be made through continued compliance inspections under the authority of § 194.24(h), as previously discussed. The Agency will announce the proposed tier changes and the reasoning behind them in the site's inspection report, which will be posted on the WIPP Web site and docketed in accordance with § 194.67. If the tier change is an elevation in stringency from Tier 2 to Tier 1 (*i.e.,* additional DOE reporting requirements for that particular waste characterization component or activity), the change will be effective immediately and the site will be expected to operate under the more stringent requirements without delay. If, however, the change is a ''downgrade'' in stringency from Tier 1 to Tier 2, the inspection report will solicit comments from the public, for a minimum of 30 days, to let them raise any concerns they might have. The site will continue to operate under the more stringent tier designation until public comment can be considered.

The site inspections necessary to develop the Baseline Compliance Decision have three components which we will include in our inspection report: (a) Description of what we inspected and found to be technically

adequate; (b) tiering of WC elements and the basis for the tiering assignment; and (c) identification of site's subsequent reporting requirements for the specific WC elements. Currently, EPA inspection reports describe what we inspect, what we determine to be technically adequate, what we identify as deficiencies and whether any corrective action is required before EPA approval. Under the new process, we will continue to complete a report containing these elements. In addition, the inspection will allow us to determine WC component modifications requiring EPA approval.

The results of all EPA site inspections (and their accompanying inspection reports), under § 194.8 *and* § 194.24, will be made available to the public in EPA's dockets, WIPP Web site, and other means. If, at any time, we determine that the system of controls at a site is not adequate to characterize certain waste streams, EPA retains authority to direct that the site may not dispose of material from those waste streams or processes at the WIPP until the Agency's findings have been adequately resolved.

3. Opportunity for Public Comment & Length of Public Comment Periods

As previously discussed, the Agency aims to improve public participation by providing an opportunity to comment on EPA inspection reports and proposed approval decision in addition to DOE program documents and other information. Thus, the public would be well informed about the inspection that was performed, which decisions are proposed and why, and can provide comments related to the approval and tiering process.

After completing the baseline § 194.8 inspections to determine capabilities and adequacy of WC program at each TRU site, EPA will prepare an inspection report discussing the inspection process and the findings and/or concerns. The site-specific inspection report will discuss various WC process-specific tiers and their basis. They will also contain subsequent reporting requirements for the WC program components. Using this information, we will issue the proposed Baseline Compliance Decision in the **Federal Register** for public comment (see discussion for the public comment period below). In addition, we will make available in the EPA Docket our inspection report and the site-specific waste characterization documents for public review. Most commenters responding to this issue supported the proposal. One commenter contended that this would result in unnecessary operational delays and costs. As discussed in the Response to Comments Document (See EDOCKET ID#: OAR–2002–0005), EPA does not agree with the reasoning as the approved TRU sites can continue to dispose of their approved waste streams at the WIPP.

Today, we are finalizing a 45-day comment period when seeking public comment related to EPA's site-specific Baseline Compliance Decision and associated tier assignments. Several commenters stated that a 30-day comment period is not adequate, especially considering the amount and nature of the technical material kept in the docket and commenters' other work priorities. As discussed in the Response to Comments Document (EDOCKET ID#: OAR–2002–0005), the public-notice-and-approval process described in § 194.8(b) has not yielded the level of comment that we anticipated.

Over the past 4 years, EPA has made every effort to inform public of EPA inspections when necessary by issuing a **Federal Register** notice and posting updates on the EPA's WIPP Web site. DOE documents and other material related to these inspections has also been docketed at each of our docket locations. However, we recognize that the highly technical nature of the documents available for comment may have discouraged public participation. In recognition of this, the changes to the site approval process include significant changes to the public comment process. The changes allow for comment not only on DOE's technical documents, but also on EPA's proposed decision on site approval. The public will also be able to comment directly on the proposed tiering designations (and associated level of EPA review and approval) for subsequent changes or expansions of the WC program at a given site. A minimum 45-day comment period will be opened for the proposed Baseline Compliance Decisions at each site. As a general rule, EPA will allow 45 days for receiving public comment and may provide additional time on a case-by-case basis when needed. Thus, the public will have an opportunity to review and comment on EPA's proposed Baseline Compliance Decisions and inspection reports prior to site approvals.

The Agency also acknowledges that the **Federal Register** is not the only effective tool for providing information to the public. Under these revisions, EPA will issue a **Federal Register** notice for the initial Baseline Compliance Decision at each site. EPA also expects to use e-mail, web updates, and other more user-friendly communication tools to notify stakeholders of the occurrence and results of baseline approvals and subsequent ongoing inspections.

As discussed previously (see Section III.B.2), if EPA deems that a change in tiering designation (from Tier 1 to Tier 2) at a site is warranted, the Agency will announce the proposed changes and the reasoning behind them in the site's inspection report, which will be posted on the WIPP Web site and placed in the dockets. EPA will also open a minimum 30-day comment period on the proposed change. However, where circumstances warrant, EPA will consider a longer comment period.

4. Time Frame and Effective Date

Although today's actions will be effective on October 14, 2004, EPA expects that the baseline compliance inspections and approval process will be more wide-ranging than the current inspection regime since it will not be limited by waste stream designations and will explicitly address future expansions of the characterization program. The first approvals conducted under the new process are likely to be highly detailed and very intensive, since EPA will need to work with DOE and stakeholders to ensure that the full range of waste characterization activities is identified and placed in appropriate reporting/approval tiers. The final rule provides important flexibility to ensure that EPA can effectively implement—and that the public can fully understand and participate in—the new process. First, the final rule does not establish a time period within which EPA must ''convert'' sites to the new inspections and approval process. DOE sites with approved waste characterization programs will be allowed to continue operations under the existing inspection and approval process based on waste streams; the waste stream system, while less flexible than the newly revised process, remains rigorous and can continue to provide effective oversight during the transition period. We expect to review approved programs and issue new baseline approval decisions for those sites within approximately two years. However, the Agency retains the discretion to take longer (if warranted) by the complexity of technical issues or the scope of more comprehensive inspections. Similarly, we decline to limit the length of the comment period on proposed baseline approval decisions. We believe that limiting the available comment period would be counterproductive for both EPA and the public in adjusting to the new process, and could constrain discussion if unanticipated or especially complex issues arise.

5. Consideration of Resources

A few commenters endorsed the proposed changes to § 194.8, but did not necessarily agree with EPA's resource rationale. The Agency believes that the proposed changes are fully justifiable on a technical basis, as outlined above in Section III.B.2. While resource consideration is a valid factor, the discussion of resources in the preamble to the proposal may have been misleading in regard to its relative importance. The revised process provides equivalent or improved oversight, more control over schedule, better prioritization of technical issues and distinctions, and flexibility to address relative levels of experience or expertise at various DOE sites.

6. Compliance of Waste Generator Sites and the WIPP Facility

Some commenters expressed concern about the reference in the proposed § 194.8(b)(3)(i) to § 194.48(b)(1) and (2). They suggested that the provisions of § 194.4 are specific to the WIPP site itself and are not appropriate responses to noncompliance at a waste generator site. The Agency disagrees with those statements. Section 194.8(b)(4)(i) provides that EPA may suspend shipments of TRU waste from an approved TRU waste site if EPA subsequently determines that waste characterization programs or processes are not adequately established or implemented. In addition, if necessary, EPA may take action under § 194.4(b)(1) or (2). Section 194.4(b)(1) provides that EPA may suspend, modify, or revoke the certification of the WIPP. Suspension may be at the discretion of EPA; modification or revocation will be conducted by rule pursuant to 5 U.S.C. 553. Section 194.8(b)(3)(i) provides that EPA may request that DOE provide information to enable EPA to determine whether suspension, modification, or revocation of the certification is warranted. DOE's inability to properly establish, maintain, or implement adequate waste characterization activities at a waste generator site could lead to circumstances that necessitate consideration of suspension, modification, or revocation of the WIPP certification. Poorly and/or inadequately characterized waste when emplaced in the repository could be relevant to determining the long-term performance of the WIPP. Therefore, EPA disagrees that the provisions of § 194.4(b) are specific only to the WIPP facility, and can never be relevant to activities at a waste generator site.

C. Summary of Comments and Final Changes to §§ 194.12 and 194.13—Number and Form of DOE Compliance Applications and Reference Materials

EPA proposed to revise § 194.12 by changing the number of copies of compliance applications in printed form from 30 to 5 (one original and four printed copies). In addition, the Agency proposed to revise § 194.12 by requiring that DOE submit 10 complete compliance applications in alternative format (*e.g.,* compact disk) or other approved format. (For a detailed discussion, see 67 FR 51941–42.)

Also, the Agency proposed to revise § 194.13 by changing the number of copies in printed form of the reference materials from 10 to 5 and to require DOE to submit 10 copies of reference materials in alternative format (*e.g.,* compact disk) or other approved format.

Public comments were supportive of these proposed actions and therefore, we are finalizing the proposed requirements under § 194.12 and § 194.13. Commenters requested clarification that EPA's WIPP dockets would continue to be provided paper copies of application materials for public review. In accordance with § 194.67, the paper copies of compliance applications and related materials will be placed in the official docket in Washington, DC, and at the four informational dockets in New Mexico.

D. Summary of Comments and Final Changes to §§ 194.2 and 194.24(c)(3)—Terminology Related to Waste Characterization

Section 194.24, waste characterization, generally requires DOE to identify, quantify, and track the chemical, physical, and radiological components of the waste destined for disposal at WIPP that may influence disposal system performance. Section 194.24(c)(3) requires DOE to demonstrate that the use of process knowledge to quantify waste components conforms with the quality assurance (QA) requirements outlined in § 194.22. To demonstrate compliance, DOE must have information and documentation to substantiate that process knowledge data acquired and used during waste characterization activities are in compliance with the QA requirements.

The Agency proposed to revise § 194.24(c)(3) by replacing the term ''process knowledge'' with the term ''acceptable knowledge.'' The term ''acceptable knowledge'' has been the term used by EPA and DOE since DOE submitted the Compliance Certification Application, during both the certification rulemaking and subsequent site inspections. Use of the term ''acceptable knowledge'' in § 194.24(c)(3) in lieu of ''process knowledge'' will not alter our technical approach to verifying compliance during an inspection; rather, it will reflect our actual practice more accurately. (For a detailed discussion, see 67 FR 51942–43.)

For consistency with the change being proposed today for § 194.24(c)(3), the Agency also proposed to add the following definition of ''acceptable knowledge'' to § 194.2: ''*Acceptable knowledge* means any information about the process used to generate waste, material inputs to the process, and the time period during which the waste was generated, as well as data resulting from the analysis of waste conducted prior to or separate from the waste certification process authorized by EPA's Certification Decision, to show compliance with Condition 3 of the certification decision (40 CFR part 194, appendix A).''

Both of these changes as proposed were supported by commenters and therefore, we are finalizing the definition of ''acceptable knowledge'' in §§ 194.2 and 24(c)(3).

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, (58 FR 51735; October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. It has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective 90 days from publication in the **Federal Register**.

C. Regulatory Flexibility Act

Today's final rule is not subject to the RFA, which generally requires an agency to prepare a regulatory flexibility analysis for any rule that will have a significant economic impact on a substantial number of small entities. The RFA applies only to rules subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act (APA) or any other statute. This rule is not subject to notice and comment requirements under the APA or any other statute. This rule pertains to agency management or personnel, which the APA expressly exempts from notice-and-comment rulemaking requirements. 5 U.S.C. 533(a)(2).

Although this final rule is not subject to the RFA, EPA nonetheless has assessed the potential of this rule to adversely impact small entities subject to the rule. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant economic impact on a substantial number of small entities because it sets forth requirements which apply only to Federal agencies.

D. Paperwork Reduction Act

This final action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Compliance Criteria (in 40 CFR part 194) requirements are applicable only to DOE and EPA and do not establish any form of collection of information from the public. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's final rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector. This rule applies only to Federal agencies. Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA.

F. Executive Order 12898: Environmental Justice Strategy

Pursuant to Executive Order 12898 (59 FR 7629, February 16, 1994), entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' the Agency has considered environmental justice related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income, minority, and native American communities. We have complied with this mandate. However, the requirements specifically set forth by the Congress in the Waste Isolation Pilot Plant Land Withdrawal Act (Pub. L. 102–579), which prescribes EPA's role at the WIPP, did not provide authority for EPA to examine impacts in the communities in which wastes are produced, stored, and transported, and Congress did not delegate to EPA the authority to consider the issue of alternative locations for the WIPP.

During the development of the existing provisions in 40 CFR part 194, the EPA involved minority and low-income populations early in the rulemaking process. In 1993, EPA representatives met with New Mexico residents and government officials to identify the key issues that concern them, the types of information they wanted from EPA, and the best ways to communicate with different sectors of the New Mexico public. The feedback provided by this group of citizens formed the basis for EPA's WIPP communications and consultation plan. To help citizens (including a significant Hispanic population in Carlsbad and the nearby Mescalero Indian Reservation) stay abreast of EPA's WIPP-related activities, the Agency developed many informational products and services. The EPA translated into Spanish several documents regarding WIPP, including educational materials and fact sheets describing EPA's WIPP oversight role and the radioactive waste disposal standards. The EPA also established a toll-free WIPP Information Line, recorded in both English and Spanish,

providing the latest information on upcoming public meetings, publications, and other WIPP-related activities. The EPA also developed a mailing list, which includes many low-income, minority, and native American groups, to systematically provide interested parties with copies of EPA's public information documents and other materials. Even after the final rule, in 1998, EPA has continued to implement outreach services to all WIPP communities based on the needs determined during the certification.

This final action does not add or delete any certification criteria. The rule will revise the public notice process for the approval of waste characterization activities at DOE waste generator sites, which produce and store wastes destined for disposal at WIPP. Affected communities and the public in general would have the opportunity to comment on EPA's proposed waste generator site approval decision. The existing provision does not offer such opportunity. The proposed revision makes the public comment period more meaningful to all communities. The Agency also intends to continue its outreach activities to make information on waste characterization activities more accessible by using the Internet, EPA information line, and fact sheets.

G. National Technology Transfer & Advancement Act of 1995

Section 12 of the National Technology Transfer & Advancement Act of 1995 is intended to avoid ''re-inventing the wheel.'' It aims to reduce costs to the private and public sectors by requiring federal agencies to draw upon any existing, suitable technical standards used in commerce or industry. To comply with the Act, EPA must consider and use ''voluntary consensus standards,'' if available and applicable, when implementing policies and programs, unless doing so would be ''inconsistent with applicable law or otherwise impractical.'' We have determined that this regulatory action is not subject to the requirements of National Technology Transfer & Advancement Act of 1995 as this rulemaking is not setting any technical standards.

H. Executive Order 13045: Children's Health Protection

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

EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

I. Executive Order 13132: Federalism

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

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This final action revises specific portions of the Compliance Criteria in 40 CFR part 194. These criteria are applicable only to DOE (operator) and EPA (regulator) of the WIPP disposal facility. Thus, Executive Order 13132 does not apply to this rule.

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

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This final rule does not have tribal implications, as specified in Executive Order 13175. This proposed action revises specific portions of the Compliance Criteria in 40 CFR part 194. The Compliance Criteria are applicable only to Federal agencies. Thus, Executive Order 13175 does not apply to this rule.

K. Executive Order 13211: Energy Effects

This final rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355; May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

List of Subjects in 40 CFR Part 194

Environmental protection, Administrative practice and procedure, Nuclear materials, Radionuclides, Plutonium, Radiation Protection, Uranium, Transuranics, Waste Treatment and Disposal.

Dated: July 8, 2004.

Michael O. Leavitt,

Administrator.

■ For the reasons set out in the preamble, 40 CFR part 194 is amended as follows.

PART 194—CRITERIA FOR THE CERTIFICATION AND RE-CERTIFICATION OF THE WASTE ISOLATION PILOT PLANT'S COMPLIANCE WITH THE 40 CFR PART 191 DISPOSAL REGULATIONS

■ 1. The authority citation for part 194 continues to read as follows:

Authority: Pub. L. 102–579, 106 Stat. 4777, as amended by Pub. L. 104–201, 110 Stat. 2422; Reorganization Plan No. 3 of 1970, 35 FR 15623, Oct. 6, 1970, 5 U.S.C. app. 1; Atomic Energy Act of 1954, as amended, 42 U.S.C. 2011–2296 and 10101–10270.

■ 2. Section 194.2, is amended by adding definitions in alphabetical order for ''Acceptable knowledge'' and ''Minor alternative provision'' to read as follows:

§ 194.2 Definitions.

* * * * *

Acceptable knowledge means any information about the process used to generate waste, material inputs to the process, and the time period during which the waste was generated, as well as data resulting from the analysis of waste, conducted prior to or separate from the waste certification process authorized by EPA's Certification Decision, to show compliance with Condition 3 of the certification decision (appendix A of this part).

* * * * *

Minor alternative provision means an alternative provision to the Compliance

Criteria that only clarifies an existing regulatory provision, or does not substantively alter the existing regulatory requirements.

* * * * *

■ 3. Section 194.6 is revised to read as follows:

§ 194.6 Alternative provisions.

The Administrator may, by rule pursuant to 5 U.S.C. 553, substitute for any of the provisions of this part alternative provisions, or minor alternative provisions, in accordance with the following procedures:

(a) Alternative provisions may be substituted after:

(1) Alternative provisions have been proposed for public comment in the **Federal Register** together with information describing how the alternative provisions comport with the disposal regulations, the reasons why the existing provisions of this part appear inappropriate, and the costs, risks and benefits of compliance in accordance with the alternative provisions;

(2) A public comment period of at least 120 days has been completed and public hearings have been held in New Mexico;

(3) The public comments received have been fully considered; and

(4) A notice of final rulemaking is published in the **Federal Register.**

(b) Minor alternative provisions may be substituted after:

(1) The minor alternative provisions have been proposed for public comment in the **Federal Register** together with information describing how they comport with the disposal regulations, the reasons why the existing provisions of this part appear inappropriate, and the benefit of compliance in accordance with the minor alternative provision;

(2) A public comment period of at least 30 days has been completed for the minor alternative provisions and the public comments received have been fully considered;

(3) A notice of final rulemaking is published in the **Federal Register** for the minor alternative provisions.

■ 4. Section 194.8 is amended:

■ a. By redesignating paragraph (b) as paragraph (c);

■ b. By adding a new paragraph (b) and revising newly designated paragraph (c) to read as follows:

§ 194.8 Approval process for waste shipment from waste generator sites for disposal at the WIPP.

* * * * *

(b) *Waste characterization programs at transuranic waste sites.* The Agency will establish compliance with Condition 3 of the certification using the following process:

(1) DOE will implement waste characterization programs and processes in accordance with § 194.24(c)(4) to confirm that the total amount of each waste component that will be emplaced in the disposal system will not exceed the upper limiting value or fall below the lower limiting value described in the introductory text of § 194.24(c). Waste characterization processes will include the collection and use of acceptable knowledge; destructive and/or nondestructive techniques for identifying and measuring waste components; and the validation, control, and transmittal to the WIPP Waste Information System database of waste characterization data, in accordance with § 194.24(c)(4).

(2) The Agency will verify the compliance of waste characterization programs and processes identified in paragraph (b)(1) of this section at sites without EPA approval prior to October 14, 2004, using the following process:

(i) DOE will notify EPA by letter that a transuranic waste site is prepared to ship waste to the WIPP and has established adequate waste characterization processes and programs. DOE also will provide the relevant waste characterization program plans and documentation. EPA may request additional information from DOE.

(ii) EPA will conduct a baseline compliance inspection at the site to verify that adequate waste characterization program plans and technical procedures have been established, and that those plans and procedures are effectively implemented. The inspection will include a demonstration or test by the site of the waste characterization processes identified in paragraph (b)(1) of this section. If an inspection does not lead to approval, we will send an inspection report to DOE identifying deficiencies and place the report in the public docket described in § 194.67. More than one inspection may be necessary to resolve compliance issues.

(iii) The Agency will announce in the **Federal Register** a proposed Baseline Compliance Decision to accept the site's compliance with § 194.24(c)(4). We will place the inspection report(s) and any supporting documentation in the public docket described in § 194.67. The site inspection report supporting the proposal will describe any limitations on approved waste streams or waste characterization processes. It will also identify (through tier designations in accordance with paragraph (b)(4) of this section) what changes to the approved waste characterization processes must be reported to and approved by EPA before they can be implemented. In the notice, we will solicit public comment (for a minimum of 45 days) on the proposed Baseline Compliance Decision, including any limitations and the tier designations for future changes or expansions to the site's waste characterization program.

(iv) Our written decision regarding compliance with the requirements for waste characterization programs and processes described in paragraph (b)(1) of this section will be conveyed in a letter from the Administrator's authorized representative to DOE. EPA will not issue a compliance decision until after the end of the public comment period described in paragraph (b)(2)(iii) of this section. EPA's compliance decision will respond to significant and timely-received comments. A copy of our compliance decision will be placed in the public docket described in § 194.67. DOE will comply with any requirements identified in the compliance decision and the accompanying inspection report.

(3) Subsequent to any positive determination of compliance as described in paragraph (b)(2)(iv) of this section, the Agency intends to conduct inspections, in accordance with § 194.24(h), to confirm the continued compliance of approved waste characterization programs and processes at transuranic waste sites. EPA will make the results of these inspections available to the public in the dockets described in § 194.67.

(4) Subsequent to any positive determination of compliance as described in paragraph (b)(2)(iv) of this section, the Department must report changes or expansions to the approved waste characterization program at a site in accordance with the tier designations established in the Baseline Compliance Decision.

(i) For changes or expansions to the waste characterization program designated as ''Tier 1,'' the Department shall provide written notification to the Agency. The Department shall not ship for disposal at WIPP any waste that has been characterized using the new or revised processes, equipment, or waste streams until EPA has provided written approval of such new or revised systems.

(ii) For changes or expansions to the waste characterization program designated as ''Tier 2,'' the Department shall provide written notification to the Agency. Waste characterized using the new or revised processes, equipment, or

waste streams may be disposed at WIPP without written EPA approval.

(iii) EPA may conduct inspections in accordance with § 194.24(h) to evaluate the implementation of Tier 1 and Tier 2 changes or expansions to the waste characterization program at a site.

(iv) Waste characterization program changes or expansions that are not identified as either ''Tier 1'' or ''Tier 2'' will not require written notification by the Department to the Agency before implementation or before shipping waste for disposal at WIPP.

(5) Subsequent to any positive determination of compliance as described in paragraph (b)(2)(iii) of this section, EPA may revise the tier designations for approving changes or expansions to the waste characterization program at a site using the following process:

(i) The Agency shall announce the proposed tier changes in a letter to the Department. The letter will describe the Agency's reasons for the proposed change in tier designation(s). The letter and any supporting inspection report(s) or other documentation will be placed in the dockets described in § 194.67.

(ii) If the revised designation entails more stringent notification and approval requirements (*e.g.,* from Tier 2 to Tier 1, or from undesignated to Tier 2), the change shall become effective immediately and the site shall operate under the more stringent requirements without delay.

(iii) If the revised designated entails less stringent notification and approval requirements, (*e.g.,* from Tier 1 to Tier 2, or from Tier 2 to undesignated), EPA will solicit comments from the public for a minimum of 30 days. The site will continue to operate under the more stringent approval requirements until the public comment period is closed and EPA notifies DOE in writing of the Agency's final decision.

(6) A waste generator site that EPA approved for characterizing and disposing transuranic waste at the WIPP under this section prior to October 14, 2004, may continue characterizing and disposing such waste at the WIPP under paragraph (c) of this section until EPA has conducted a baseline compliance inspection and provided a Baseline Compliance Decision under paragraph (b)(2) of this section.

(i) Until EPA provides a Baseline Compliance Decision for such a site, EPA may approve additional transuranic waste streams for disposal at WIPP under the provisions of paragraph (c) of this section. Prior to the effective date of EPA's Baseline Compliance Decision for such a site, EPA will continue to conduct inspections of the site in accordance with § 194.24(c).

(ii) EPA shall conduct a baseline compliance inspection and issue a Baseline Compliance Decision for such previously approved sites in accordance with the provisions of paragraph (b) of this section, except that the site shall not be required to provide written notification of readiness as described in paragraph (b)(2)(i) of this section.

(c) *Waste characterization programs at waste generator sites with prior approval.* For a waste generator site that EPA approved for characterizing and disposing transuranic waste at the WIPP under this section prior to October 14, 2004, the Agency will determine compliance with the requirements for use of process knowledge and a system of controls at waste generator sites as set in this paragraph (c). Approvals for a site to characterize and dispose of transuranic waste at WIPP will proceed according to this section only until EPA has conducted a baseline compliance inspection and provided a Baseline Compliance Decision for a site under paragraph (b)(2) of this section.

(1) For each waste stream or group of waste streams at a site, the Department must:

(i) Provide information on how process knowledge will be used for waste characterization of the waste stream(s) proposed for disposal at the WIPP; and

(ii) Implement a system of controls at the site, in accordance with § 194.24(c)(4), to confirm that the total amount of each waste component that will be emplaced in the disposal system will not exceed the upper limiting value or fall below the lower limiting value described in the introductory text of § 194.24(c). The implementation of such a system of controls shall include a demonstration that the site has procedures in place for adding data to the WIPP Waste Information System (''WWIS''), and that such information can be transmitted from that site to the WWIS database; and a demonstration that measurement techniques and control methods can be implemented in accordance with § 194.24(c)(4) for the waste stream(s) proposed for disposal at the WIPP.

(2) The Agency will conduct an audit or an inspection of a Department audit for the purpose of evaluating the use of process knowledge and the implementation of a system of controls for each waste stream or group of waste streams at a waste generator site. The Agency will announce a scheduled inspection or audit by the Agency with a notice in the **Federal Register.** In that or another notice, the Agency will also solicit public comment on the relevant waste characterization program plans and Department documentation, which will be placed in the dockets described in § 194.67. A public comment period of at least 30 days will be allowed.

(3) The Agency's written decision regarding compliance with the requirements for waste characterization programs described in paragraph (b)(1) of this section for one or more waste streams from a waste generator site will be conveyed in a letter from the Administrator's authorized representative to the Department. No such compliance determination shall be granted until after the end of the public comment period described in paragraph (b)(2) of this section. A copy of the Agency's compliance determination letter will be placed in the public dockets in accordance with § 194.67. The results of any inspections or audits conducted by the Agency to evaluate the plans described in paragraph (b)(1) of this section will also be placed in the dockets described in § 194.67.

(4) Subsequent to any positive determination of compliance as described in paragraph (b)(3) of this section, the Agency intends to conduct inspections, in accordance with §§ 194.21 and 194.24(h), to confirm the continued compliance of the programs approved under paragraphs (b)(2) and (b)(3) of this section. The results of such inspections will be made available to the public through the Agency's public dockets, as described in § 194.67.

■ 5. Section 194.12 is revised to read as follows:

§ 194.12 Submission of compliance applications.

Unless otherwise specified by the Administrator or the Administrator's authorized representative, 5 copies of any compliance application(s), any accompanying materials, and any amendments thereto shall be submitted in a printed form to the Administrator's authorized representative. These paper copies are intended for the official docket in Washington, DC, as well as the four informational dockets in Albuquerque and Santa Fe, New Mexico. In addition, DOE shall submit 10 copies of the complete application in alternative format (*e.g.,* compact disk) or other approved format, as specified by the Administrator's authorized representative.

■ 6. Section 194.13 is revised to read as follows:

§ 194.13 Submission of reference materials.

Information may be included by reference into compliance

applications(s), provided that the references are clear specific and that unless, otherwise specified by the Administrator or the Administrator's authorized representative, 5 copies of reference information are submitted to the Administrator's authorized representative. These paper copies are intended for the official docket in Washington, DC, as well as the four informational dockets in Albuquerque and Santa Fe, New Mexico. Reference materials that are widely available in standard text books or reference books need not to be submitted. Whenever possible, DOE shall submit 10 copies of reference materials in alternative format (*e.g.,* compact disk) or other approved format, as specified by the Administrator's authorized representative.

■ 7. Section 194.24 is amended by revising paragraph (c)(3) to read as follows:

§ 194.24 Waste characterization.

* * * * *

(c) * * *

(3) Provide information that demonstrates that the use of acceptable knowledge to quantify components in waste for disposal conforms with the quality assurance requirements of § 194.22.

* * * * *

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BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 239 and 257

[FRL–7787–3]

Adequacy of Indiana Solid Waste Landfill Permit Programs Under RCRA Subtitle D

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: Under Section 4005(c)(1)(C) of the Resource Conservation and Recovery Act (RCRA), EPA can approve state permit programs for solid waste disposal facilities that receive hazardous waste from conditionally exempt small quantity generators (CESQGs). A generator is a CESQG in a calendar month if he generates no more than 100 kilograms of hazardous waste in that month. CESQGs are subject to minimal record keeping and reporting requirements under RCRA, but must satisfy three basic regulatory requirements to remain exempt from the full scope of hazardous waste regulations that apply to other generators: compliance with hazardous waste determination requirements, compliance with storage quantity limits, and compliance with applicable hazardous waste treatment and disposal regulations. Federal regulations specify that CESQG hazardous waste must be disposed of in either: a hazardous waste landfill subject to RCRA Subtitle C; a state licensed or permitted municipal solid waste landfill (MSWLF) subject to the RCRA Subtitle D regulations; or a state licensed or permitted non-municipal, non-hazardous waste disposal unit subject to the RCRA Subtitle D regulations. This document approves Indiana's regulation that requires that CESQG hazardous waste must be disposed of in either a permitted MSWLF subject to the RCRA Subtitle D regulations, or a hazardous waste facility subject to RCRA Subtitle C.

EPA is publishing this rule to approve applicable regulations in Indiana without prior proposal because we believe this action is not controversial, and we do not expect comments that oppose it. Unless we receive written comments that oppose this approval during the comment period, the decision to approve the subject regulations in Indiana will take effect as scheduled. If we receive comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect, and a separate document in the proposed rules section of this **Federal Register** will serve as a proposal to approve the subject regulations for Indiana.

DATES: This direct final rule is effective on September 14, 2004, unless EPA receives relevant adverse written comment by August 16, 2004. If EPA receives such comment, it will publish a timely withdrawal of this direct final rule in the **Federal Register** and inform the public that this rule will not take effect.

ADDRESSES: Send written comments to Ms. Susan Mooney, Waste Management Branch (Mail Code: DW–8J), U.S. EPA Region 5, 77 West Jackson Boulevard, Chicago, IL 60604. Comments may also be submitted electronically to: *mooney.susan@epa.gov* or by facsimile at (312) 353–4788. Comments in electronic format should identify this specific notice. Documents pertaining to this regulatory docket can be viewed and copied during regular business hours at the EPA Region 5 office located at the address noted above.

FOR FURTHER INFORMATION CONTACT: For information on accessing documents or supporting materials related to this rule or for information on specific aspects of this rule, contact Susan Mooney, Waste Management Branch (Mail code: DW–8J), U.S. EPA Region 5, 77 West Jackson Boulevard, Chicago, IL 60604, phone (312) 886–3585, or by e-mail at *mooney.susan@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

Under 40 CFR 261.5, ''Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators,'' which was promulgated on March 24, 1986 (51 FR 10174), CESQG waste could be disposed of only in an EPA or State regulated hazardous, municipal, industrial or miscellaneous waste landfill. At that time, EPA had promulgated rules only for hazardous waste landfills and MSWLFs, not for industrial or miscellaneous waste landfills that accepted CESQG waste. On July 1, 1996, EPA promulgated criteria under its solid waste program at 40 CFR Part 257, subpart B, for industrial waste and other non-municipal, non-hazardous waste landfills that accept CESQG waste (61 FR 34252–34278). In the same notice, EPA also revised its hazardous waste program regulations at 40 CFR 261.5 (f)(3) and 261.5 (g)(3) to allow the disposal of CESQG waste in non-municipal, non-hazardous waste landfills that meet the requirements of 40 CFR Part 257, subpart B, as well as in hazardous waste landfills or MSWLFs that meet appropriate Federal regulations.

RCRA Section 4005 requires states to develop permitting programs or other systems of prior approval and conditions to ensure that solid waste disposal units that receive household hazardous waste or CESQG waste or both comply with the revised Federal criteria under parts 258 and 257, subpart B. To fulfill this need, EPA issued the State Implementation Rule on October 23, 1998, (63 FR 57026) to provide a process for approving state permitting programs for municipal solid waste landfills and for non-municipal solid waste landfills that receive CESQG waste.

On February 6, 2004, the Indiana Department of Environmental Management requested a review in accordance with RCRA Section 4005, of new Indiana regulations to determine whether the regulations are adequate to assure compliance with Federal disposal requirements for CESQG waste. Indiana regulation at 329 IAC 10–3–2 (c) requires CESQG waste to be disposed of in either a municipal solid waste