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Part II

Environmental Protection Agency

40 CFR Part 194

**Criteria for the Certification and
Recertification of the Waster Isolation
Pilot Plant's Compliance With the
Disposal Regulations; Alternative
Provisions; Proposed Rule**

**ENVIRONMENTAL PROTECTION
AGENCY**
40 CFR Part 194

[FRL-7255-4]

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: Proposed rule.

SUMMARY: The Environmental Protection Agency ("EPA," or "the Agency" or "we") is proposing to revise the "Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's Compliance with the Disposal Regulations," which are used to determine whether the Department of Energy's Waste Isolation Pilot Plant ("WIPP") will comply with EPA's "Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes." The following proposed revisions are included in today's action: 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 transuranic sites; changes to allow for the submission of copies of compliance applications and reference materials in alternative format; and replacement of the term "process knowledge" with "acceptable knowledge." The proposed changes do not lessen the requirements for complying with the Compliance Criteria. Moreover, these changes will have no effect on the technical approach that EPA employs when conducting independent inspections of the waste characterization capabilities at DOE waste generator sites. EPA is conducting this proposed action in accordance with the procedures for substituting alternative provisions of the Compliance Criteria. Today's notice marks the beginning of a 120-day public comment period on this proposed action.

DATES: EPA requests comments on all aspects of these proposed revisions. If you wish to submit comments on this proposal, you must do so by December 9, 2002.

ADDRESSES: Send your comments to: Air Docket, Room M-1500, U.S. Environmental Protection Agency, 401 M Street, SW., Mail Code 6102, Washington, DC 20460, Attention

Docket ID No. OAR-2002-0005. Comments may be submitted electronically, by mail, by facsimile, or through hand delivery/courier. Follow the detailed instructions as provided in Section B of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Agnes Ortiz; telephone number: (202) 564-9310; postal address: Radiation Protection Division, Mail Code 6608J, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC, 20460.

SUPPLEMENTARY INFORMATION:

General Information

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

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 Docket, Room M-1500, U.S. Environmental Protection Agency, 401 M Street, SW., Mail Code 6102, Washington, DC 20460. This Docket Facility is open from 8:30am-5 pm, Monday through Friday, excluding legal holidays. The Air Docket telephone number is 202-260-7548.

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 submit or 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. Once in the system, select "search," then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's

policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. 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 Section B under General Information. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

For additional information about EPA's electronic public docket visit EPA Dockets online or see 67 FR 38102, May 31, 2002.

B. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, by facsimile, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted

within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. However, late comments may be considered if time permits. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Section C under General Information. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. Electronically

If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet home page, select "Information Sources," "Dockets," and "EPA Dockets." Once in the system, select "search," and then key in Docket ID No. OAR-2002-0005. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

Comments may be sent by electronic mail (e-mail) to a-and-r-docket@epa.gov Attention Docket ID No. OAR-2002-0005. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-

mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Section A under General Information. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. By Mail

Send your comments to: Air Docket, Room M-1500, U.S. Environmental Protection Agency, 401 M Street, SW., Mail Code 6102, Washington, DC 20460, Attention Docket ID No. OAR-2002-0005.

3. By Hand Delivery or Courier

Deliver your comments to: Air Docket, Room M-1500, U.S. Environmental Protection Agency, 401 M Street, SW., Mail Code 6102, Washington, DC 20460, Attention Docket ID No. OAR-2002-0005. Such deliveries are only accepted during the Docket's normal hours of operation as identified in Section A under General Information.

4. By Facsimile

Fax your comments to: (202) 260-4400, Attention Docket ID. No. OAR-2002-0005.

C. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior

notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

D. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

Abbreviations Used in This Document

AK—Acceptable knowledge
 Am—Americium
 APA—Administrative Procedure Act
 ASME—American Society of Mechanical Engineers
 BID—Background information document
 CAR—Corrective Action Required
 CARD—Compliance Application Review Document
 CBFO—Carlsbad Field Office
 CCA—Compliance Certification Application
 CFR—Code of Federal Regulations
 CH—Contact handled
 Cs—Cesium
 DOE—Department of Energy
 EEG—Environmental Evaluation Group
 EPA—Environmental Protection Agency
 INEEL—Idaho National Energy and Engineering Laboratory
 LANL—Los Alamos National Laboratory
 NDA—Nondestructive Assay
 NPRM—Notice of Proposed Rulemaking
 NTS—Nevada Test Site
 NQA—Nuclear Quality Assurance
 ORNL—Oak Ridge National Laboratory
 PK—Process knowledge
 Pu—Plutonium
 QA—Quality assurance
 QAPP—Quality Assurance Project Plan
 QAPjP—Quality Assurance Project Plan
 RC—Radiochemistry
 RCRA—Resource Conservation Recovery Act
 RFETS—Rocky Flats Environmental Technology Site
 RTR—Real-time radiography
 SRS—Savannah River Site

Sr—Strontium
 TRU—Transuranic
 U—Uranium
 VE—Visual inspection
 WAC—Waste Acceptance Criteria
 WAP—Waste Acceptance plan
 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 WIPP?

The Waste Isolation Pilot Plant ("WIPP") is a disposal system for transuranic radioactive waste. Developed by the Department of Energy ("DOE" or "the Department"), the WIPP is located near Carlsbad in southeastern

New Mexico. Transuranic (TRU) radioactive wastes are 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.

Development and construction of the WIPP was authorized under Section 213 of the Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1980 (Public Law No. 96-164, 93 U.S. Stat. 1259, 1265). WIPP was authorized as a defense activity of the Department of Energy to demonstrate the safe disposal of radioactive wastes resulting from the defense activities and programs of the United States. Pursuant to Section 7 of the WIPP Land Withdrawal Act (Public Law No. 102-579, as amended by Public Law No. 104-201) (WIPP LWA), disposal operations at WIPP are limited to a total volume of 6.2 million cubic feet of transuranic radioactive waste. Section 2(18) of the WIPP LWA defines TRU waste as waste containing more than 100 nanocuries of alpha-emitting transuranic isotopes per gram of waste, with half-lives greater than 20 years. This definition excludes high-level radioactive waste, waste determined by DOE with the concurrence of EPA to not need such isolation, or waste that the Nuclear Regulatory Commission has approved for disposal on a case-by-case basis, consistent with NRC regulations.

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.

Section 8(c) of the WIPP LWA required EPA to promulgate criteria, pursuant to Section 4 of the Administrative Procedure Act (APA), for EPA's certification of the WIPP's compliance with the radioactive waste disposal regulations at 40 CFR Part 191. On February 9, 1996, EPA published the final "Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance With the 40 CFR Part 191 Disposal Regulations" (61 FR 5224) (Compliance Criteria). Section

8(d) of the WIPP LWA set forth specific procedures governing the certification of the WIPP. Section 8(d)(1) required DOE to submit a complete compliance application by October 31, 1996. Section 8(d)(1) also provided that EPA had the authority to request any additional information necessary for the Agency's determination of compliance. Section 8(d)(2) required that EPA complete its certification decision within one year of receipt of the DOE's application. (EPA clarified at § 194.11 of the Compliance Criteria that, consistent with legislative intent, EPA's certification decision would be due within one year of receipt of a complete compliance application.) EPA determined DOE's compliance application to be complete on May 22, 1997 (62 FR 27996).

EPA determined on May 18, 1998, that DOE had demonstrated that the WIPP will comply 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 and once a 30-day statutory waiting period had elapsed. EPA based its decision on a thorough review of all the information submitted by DOE, independent technical analyses, and all significant public comments submitted during a nominal 120-day comment period. EPA's certification, however, was subject to four specific conditions. Thus, EPA amended the WIPP compliance criteria at 40 CFR part 194 to include an appendix setting forth the four conditions on the certification of compliance. These conditions related to (1) design of the panel closure system (which is intended over the long term to block brine flow between waste panels in the WIPP); (2) and (3) activities conducted at waste generator sites that produce the transuranic waste proposed for disposal in the WIPP (specifically with respect to quality assurance and waste characterization); and (4) passive institutional controls.

Subsequent to the initial certification, EPA continues to have an oversight role at the WIPP. First, Section 9 of the WIPP LWA requires that DOE submit biennial documentation of continued compliance with specified laws, regulations, and permit requirements. Second, § 194.4 of the Compliance Criteria requires that DOE submit periodic reports on any activities or conditions at the WIPP that differ significantly from the information contained in the most recent compliance application. EPA may also, at any time, request additional information from DOE regarding the

WIPP to determine if regulatory action is required concerning the certification. Third, Section 8(f) of the WIPP LWA requires at least five years after the initial certification and every five years thereafter, that DOE submit to EPA and the State of New Mexico documentation of continued compliance with the Part 191 radioactive waste disposal regulations. In accordance with § 194.64 of the Compliance Criteria, documentation of continued compliance will be made available in EPA's dockets, and the public will be provided at least a 30-day period during which to submit comments. EPA's decision on recertification will be announced in the **Federal Register**.

II. What Is the Purpose of Today's Proposed Action?

EPA proposes to revise certain provisions of the Compliance Criteria at 40 CFR part 194. Specifically, EPA is proposing to (1) revise the process for establishing "alternative provisions" in § 194.6; (2) revise the approval process in § 194.8 for waste characterization processes at TRU waste generator sites for disposal at WIPP; (3) revise the requirements in §§ 194.12 and 194.13 for submission of compliance applications and reference materials; and (4) change the term "process knowledge" to "acceptable knowledge" in § 194.24(c)(3). The proposed revisions are intended to ensure that 40 CFR Part 194 remains comprehensive, appropriate, and based upon current knowledge and information. The Agency solicits comments on this proposal.

Section 194.6 of the Compliance Criteria imposes specific requirements for substitution of "alternative provisions" of the Criteria. Such alternative provisions must be promulgated pursuant to Section 4 of the APA. Also, in proposing the alternative provisions EPA must describe how the proposed changes comport with the radioactive waste disposal regulations at 40 CFR part 191, the reasons why the existing provisions appear inappropriate, and the costs, risks, and benefits of compliance with the new provisions. Finally, EPA must provide for a public comment period of 120 days and hearings in New Mexico, and fully consider the public comments that are received. Today's Notice of Proposed Rulemaking (NPRM) is organized so that, for each of the proposed revisions, the preamble addresses the following topics: A. What are the current requirements?; B. What are the proposed changes?; and C. How has EPA addressed the Alternative Provision Analysis required by § 194.6?

III. How Is EPA Revising the Process for Establishing Alternative Provisions in § 194.6?

A. What Are the Current Requirements in § 194.6?

Section 194.6 establishes procedures applicable to substitution of alternative provisions of the Compliance Criteria. As discussed above, such substitutions require notice and comment rulemaking, pursuant to Section 4 of the APA. In addition, § 194.6 stipulates that EPA's NPRM address specific aspects of the proposed substitution, include a public comment period of at least 120 days, and public hearings in New Mexico.

B. What Changes Are Proposed for § 194.6?

EPA is proposing to revise § 194.6 to add a rulemaking process for substituting "minor alternative provisions" of the Compliance Criteria. The process for substituting "minor alternative provisions" would include: (1) Rulemaking pursuant to Section 4 of the APA; (2) publication of the proposed changes in the **Federal Register**, together with information describing how the changes conform with the disposal regulations, the reasons why the changes are needed, and the benefits of compliance with the minor changes; (3) a public comment period of at least 30 days; and (4) publication in the **Federal Register** of the final notice after public comments received have been fully considered. EPA is also proposing to add the following definition of "minor alternative provision" to § 194.2: "minor alternative provision means an alternative provision to the Compliance Criteria that clarifies a regulatory provision, or does not substantively alter the existing regulatory requirement."

C. How Has EPA Addressed the Alternative Provision Analysis Required by § 194.6?

The Agency wants to have the ability to make insignificant changes to the Compliance Criteria in an expedited time frame to facilitate WIPP's continued compliance with our regulations. The provisions for substituting minor alternative provisions could, for example, be used to modify the Compliance Criteria to change regulatory terminology to more clearly express the Agency's intended meaning or to clarify expectations. Substitution of "minor alternative provisions" would not in any way substantively modify the Compliance Criteria requirements.

1. Why Do the Existing Provisions in § 194.6 Appear Inappropriate?

In certain specific contexts, discussed below, EPA considers the existing provisions to be inappropriate because they are unnecessarily stringent. When § 194.6 was promulgated, EPA was beginning the process of formal regulation of the WIPP. EPA had not yet even received the DOE's compliance certification application. EPA now has engaged in close regulatory oversight of the WIPP for over six years. EPA has engaged in post-certification oversight of the WIPP for almost four years. During that time, EPA has gained substantial experience and insight into this regulatory process. While § 194.6, as originally drafted, was intended to address all changes to the Compliance Criteria, EPA now realizes that there may be modifications to the Compliance Criteria that, while useful, are not sufficiently significant to require the stringent procedures currently set forth in § 194.6. EPA's oversight experience indicates that minor revisions to the Compliance Criteria requirements may improve implementation and consistency in regulatory compliance.

EPA believes that today's proposal includes several examples of minor revisions that would be appropriately addressed by a less stringent process than currently available under § 194.6. For example, EPA is proposing to replace the term "process knowledge" in § 194.24(c)(3) with the term "acceptable knowledge" (*see* section VI of the preamble). This minor revision is intended to acknowledge that "acceptable knowledge" is the term EPA has used consistently since the WIPP was certified. EPA is also proposing to permit DOE to submit fewer printed recertification compliance applications than currently required in the Compliance Criteria. These proposed revisions do not substantively alter the intent or the approach to verifying compliance with the waste characterization requirements in any way, but improve the clarity of and more clearly reflect the intent of the Compliance Criteria. Such minor revisions should not require a 120-day public comment period, nor necessitate a public hearing.

We propose that a 30-day comment period is sufficient for the public to provide the Agency with relevant input on such minor revisions of the Compliance Criteria. In addition to the publication of the NPRM in the **Federal Register**, EPA intends to announce the proposal on the Agency's website and place all relevant supporting materials in the Agency's public docket. For all

substitutions of alternative provisions that are not minor alternative provisions, as defined in this document (for example, the addition, deletion, or significant revision of a requirement), EPA will continue to comply with the current requirements of § 194.6.

EPA defines a "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. For example, today's proposed revisions to §§ 194.2, 194.12, 194.13, and 194.24(c)(3) are examples of minor changes. The proposed revisions to §§ 194.6 and 194.8(b), however, are examples of non-minor alternative provisions.

2. How Do the Proposed Changes in § 194.6 Comport with 40 CFR part 191?

The proposed changes for § 194.6 comport fully with the radioactive waste disposal regulations at 40 CFR part 191. The WIPP must comply with EPA's radioactive waste disposal regulations located at Subparts B and C of 40 CFR part 191. These regulations limit the amount of radioactive materials that may escape from a disposal facility, and are intended to protect individuals and ground water resources from dangerous levels of radioactive contamination. The Compliance Criteria implement and interpret the general disposal regulations specifically for the WIPP, and constitute the basis on which EPA's certification decision was made. Section 194.6 was included in the Compliance Criteria to ensure that any amendments to the Criteria would be effected through the same rigorous rulemaking procedure under which the original Criteria were promulgated. The proposed amendment to § 194.6 would not substantively alter the scope of those requirements. The Compliance Criteria would continue to include the current process established in § 194.6 to revise 40 CFR part 191. The principle difference between the existing and proposed new provisions is the addition of a revision process for minor changes. This new revision process would not substantively affect the Compliance Criteria's implementation of 40 CFR part 191.

3. What Are the Costs, Risks, and Benefits of Compliance with the New Provisions in § 194.6?

As part of our implementation efforts for the 1998 certification decision, we will continue to develop revisions to the Compliance Criteria, as we deem

necessary, based on lessons learned from our oversight experience. This is our first revision to the Compliance Criteria since the initial certification decision in 1998.

There will be no increased costs for EPA as a result of the proposed revision. Rather, EPA believes that it is reasonable to expect significant savings over the period of active regulation of the WIPP. The proposed revision will shorten rulemakings where appropriate and eliminate a requirement for public hearings in instances where the impact of changes would be small and public interest may reasonably be expected to be low. Moreover, EPA does not expect DOE to incur additional costs, since the implementation of § 194.6 is solely EPA's responsibility.

EPA does not anticipate any increased risks related to the implementation of the proposed revision. Rather, we anticipate that EPA's regulatory activities will become more efficient, and that EPA will be able to implement necessary minor revisions to the Compliance Criteria that are designed to improve implementation and consistency in regulatory compliance.

The benefits of the proposed revision to § 194.6 are several. First, the Agency, would be able to make minor revisions to the Compliance Criteria in a timely fashion. Making these types of revisions in a shorter timeframe will enhance compliance with 40 CFR part 191. Second, the public will continue to have an opportunity to review and comment on proposed minor revisions. Third, the Agency will continue to hold public hearings in New Mexico for major revisions to the Compliance Criteria. Fourth, DOE will be able to implement minor revisions faster, therefore, this proposed revision will contribute to safer and more cost effective disposal of radioactive wastes.

IV. How Is EPA Revising the Approval Process for Waste Shipment From Waste Generator Sites for Disposal at WIPP in § 194.8(b)?

A. What Are the Current Requirements in § 194.8(b)?

Section 194.8(b) describes the process by which EPA reviews and approves WIPP-related waste characterization activities¹ at DOE transuranic waste

¹The term "waste characterization," as we use it with regard to the WIPP repository and the numerous waste generator sites, encompasses a wide array of activities, all of which serve to determine what is inside any given container of transuranic waste and to control that container until DOE places it in the WIPP for disposal. Stated generally, the Compliance Criteria for waste characterization in § 194.24 require DOE to: Determine which waste components (such as

sites. At present, for each waste stream or group of waste streams² other than those approved in our final certification decision, DOE must provide information on how a waste site uses process knowledge³ to characterize those streams (§ 194.8(b)(1)(i)). The DOE also must implement a system of controls⁴ that confirms that the total quantity of important waste components⁵ in the WIPP does not exceed limits established by the final Certification Decision (§ 194.8(b)(1)(ii)). In order to show EPA that the system of controls is effective, DOE must demonstrate each TRU waste site's measurement techniques and control methods, and must demonstrate that data about waste components are properly transferred from the waste sites to the WIPP Waste Information System (WWIS).⁶

To evaluate compliance with the above-mentioned requirements, we must inspect and approve each DOE transuranic waste site that wishes to ship waste to the WIPP for disposal. We must inspect the site's use of process

ferrous metals) and characteristics (e.g., acidity) are relevant to the WIPP's performance; show how they affect performance; and identify and track significant waste components as they are placed in the WIPP. The last of these activities is the subject of § 194.8(b). The waste characterization requirements are discussed in great detail in the preamble to the May 18, 1998, Certification Decision final rule. (63 FR 27389-27393)

²The term "waste stream" means wastes derived from a single process or activity that are similar in material, physical form, isotopic makeup, and hazardous constituents. (Certification Decision proposed rule 62 FR 58813.)

³Process knowledge ("PK") refers to knowledge of waste characteristics derived from information generated contemporaneously with the waste on the materials or processes used to generate the waste. This information may include administrative, procurement, and quality control documentation associated with the generating process, or past sampling or analytical data. Usually, the major elements of process knowledge include information about the process used to generate the waste, material inputs to the process, and the time period during which the waste was generated. (Certification Decision final rule 63 FR 27390.)

⁴The system of controls for waste characterization includes, but is not limited to: Measurement, sampling, chain of custody records, record keeping systems, waste loading schemes used, and other documentation. 40 CFR 194.24(c)(4).

⁵The term "waste component" means "an ingredient of the total inventory of the waste that influences a waste characteristic". 40 CFR 194.2. The term "waste characteristic" means "a property of the waste that has an impact on the containment of waste in the disposal system". 40 CFR 194.2. The important waste components with regard to the WIPP's compliance are radionuclides, ferrous and nonferrous metals, organic materials such as paper and rubber, and free water.

⁶The WWIS is described in Chapter 4 (page 4-35) of the WIPP Compliance Certification Application as "a computerized data management system used * * * to gather, store, and process information pertaining to transuranic (TRU) waste destined for or disposed at the WIPP." [Air Docket A-93-02, Item II-G-1.]

knowledge and witness a demonstration of waste characterization processes for each waste stream, or group of waste streams, that the site intends to ship. If a site receives our approval to ship a single waste stream, that site cannot ship a different waste stream until we perform an additional inspection under authority of § 194.8(b). EPA imposed these requirements as a condition of the certification to ensure full compliance with the waste characterization regulations at § 194.24(c).

Once DOE has submitted waste characterization program plans for a given site, we place the plans in our docket and publish one or more notices in the **Federal Register** that announce the availability of the plans and our intent to inspect the site on a specific date (§ 194.8(b)(2)). We also open a comment period of at least 30 days for others to comment on the waste site's plans. After the inspection, we notify DOE of our compliance determination by letter, and place the letter and the report of the inspection in our docket (§ 194.8(b)(3)). Finally, we perform follow-up inspections at a site to verify the continuing compliance of approved waste characterization programs (§ 194.8(b)(4)).

The following two subsections explain the purpose of the requirements described above and the basic elements of a waste characterization inspection.

1. What Is the Purpose of EPA's Waste Characterization Inspections?

The purpose of EPA inspections at DOE sites is to verify that TRU waste sites are characterizing and tracking the waste such that EPA is confident that 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 set forth at § 194.8(b) establish a process by which EPA determines whether DOE is in compliance with Condition 3 of the Certification Decision. Condition 3 states, "[t]he Secretary [of Energy] shall not allow shipment of any waste from any additional LANL [Los Alamos National Laboratory] waste stream(s) or from any waste generator site other than LANL for disposal at the WIPP until the Agency has approved the processes for characterizing those waste streams for shipment using the process set forth in § 194.8." (40 CFR part 194, Appendix A.) Accordingly, § 194.8(b) sets forth procedural requirements for EPA's approval of DOE TRU waste sites to ship specific waste streams or groups of waste streams to WIPP.

The basis for applying Condition 3 to the WIPP project is rooted in our

rationale for the waste characterization criteria in § 194.24. We developed these criteria because, "in order to make meaningful predictions about the performance of the WIPP over long periods of time, it is necessary to have a good understanding of the characteristics of the waste proposed to be emplaced in the disposal system." (Compliance Criteria proposed rule, 60 FR 5771). We required DOE to show, in its compliance application for the WIPP, that a "system of controls" was in place to ensure that "the actual characteristics of waste will be identified before the waste is emplaced in the WIPP." (60 FR 5772).

The DOE developed an extensive set of technical and quality assurance requirements with which all transuranic waste sites must comply before shipping waste to the WIPP for disposal. At the time of application, DOE had incorporated these requirements into such documents as the Quality Assurance Program Plan (QAPP), Waste Acceptance Criteria (WAC), and Quality Assurance Project Plan (QAPjP). However, DOE did not submit the necessary information about all transuranic waste site programs in the application. At the time that DOE submitted the CCA, most sites had not begun the complex process of complying with the WIPP waste characterization requirements and the information therefore was not available to EPA during the certification process. (Certification Decision proposed rule 62 FR 58813-58814).

Consequently, we were not able to determine during the certification rulemaking that the technical and quality assurance requirements for waste characterization activities had been established and properly executed at all transuranic waste sites. LANL was the only transuranic waste site to demonstrate during the certification rulemaking that it could meet the waste characterization requirements for certain wastes. Therefore, as stated in Condition 3 of the certification, EPA only authorized DOE to ship legacy debris waste from LANL to the WIPP. DOE was not authorized to ship other than legacy debris waste from LANL, or any waste streams from other TRU waste sites, until DOE had demonstrated the ability to properly characterize these wastes.

DOE's Carlsbad Field Office (CBFO), which operates the WIPP, is responsible for maintaining compliance with EPA's waste characterization requirements. DOE transuranic waste sites vary considerably with regard to the types of waste they characterize and the manner in which they implement the program

requirements of CBFO. Therefore, confirmation that waste characterization is adequate must take place where waste characterization occurs, that is, at the transuranic waste sites themselves. (Certification Decision final rule, 63 FR 27392). Inspections of waste characterization programs at individual sites are the best way for us to verify that the sites have identified the actual characteristics of the waste.

During inspections, we have access to the site personnel who perform the work, to the facilities and equipment used at the site, and to the operators' extensive documentation. Direct observation of the site's activities greatly increases our confidence in their effectiveness. Confidence in the results of waste characterization is particularly important at this early stage of disposal, when DOE is characterizing waste that TRU waste sites packaged years before the establishment of the WIPP Compliance Criteria.⁷

2. What Are the Elements of an EPA Waste Characterization Inspection?

After EPA determines that an inspection is necessary, we define the scope of the inspection based on information provided by DOE. We then prepare, and share with DOE, a checklist for each of the activities that we will inspect. During the inspection, our evaluation of a site's waste characterization activities typically involves the activities listed below. EPA inspectors may or may not perform these and other activities depending on the scope of the inspection.

- Review procedures, records of the maintenance and calibration of equipment and instruments, and personnel training files.
- Interview responsible personnel (such as equipment operators) and site managers overseeing program implementation.
- Observe analytical testing of waste drums selected by EPA inspectors to ensure that approved procedures are followed and an instrument is capable of analyzing a given waste stream.
- Observe equipment operation to determine whether the operator has deviated from the procedures and why and how the deviation may have affected the waste characterization.
- Review waste stream data reports.
- Track waste characterization data through various phases of its generation and confirmation and eventual inclusion in the WWIS.

⁷ EPA specifically addressed public comments concerning the importance of Condition 3 in EPA's Response to Comments Document for the Certification Decision. See EPA Air Docket A-93-02, Item V-C-1, pages 2-5 to 2-9.

The inspectors' determinations are recorded in the checklist for each activity that we inspect. At the end of each inspection, we prepare an inspection report. The completed checklists are included in the inspection report. The inspection report also describes any findings or concerns that the inspectors identified, and states whether EPA requires a response showing how any unresolved finding or concern was resolved.⁸ It is sometimes necessary to return to a site to confirm the adequate resolution of a finding. After a site is approved, EPA may review the site's progress on issues that we identified previously during a subsequent compliance inspection.

B. What Are the Proposed Changes to § 194.8(b)?

Section 194.8 will continue to describe the process by which EPA will inspect and approve waste characterization activities at TRU waste sites. However, we are proposing to alter the process so that the individual waste generator sites will only need one § 194.8 approval from EPA to conduct waste characterization activities related to all on-site waste streams. This single § 194.8 approval will, however, 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. The second key change is that the opportunity for public comment will come after EPA has completed its inspection, but before EPA has approved the site. Therefore, EPA will request public comment on the Agency's inspection report and proposed compliance decision for a site under § 194.8. The revised process by which the Agency will verify compliance with Condition 3 of the certification is described below, followed by an explanation of the two principal procedural changes that result from the revisions.

Under today's proposal, first, we require DOE to 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 WIPP will not exceed the upper limiting value or fall below the lower limiting value described in the introductory text of paragraph (c) of

§ 194.24. Waste characterization processes 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).

Second, DOE must notify EPA in writing that a waste characterization program at a transuranic waste site is prepared to characterize waste destined for disposal at the WIPP. The Department will also send documents that explain the site's system of controls for waste characterization, including the use of acceptable knowledge, as described in § 194.24(c)(4).

Third, EPA will conduct a baseline inspection of the waste characterization program at the site to verify that an adequate system of controls has been established in plans and technical procedures, and that those plans and procedures are adequately implemented. The inspection will include a demonstration by DOE of the following: collection and appropriate use of acceptable knowledge data; destructive and nondestructive techniques for measuring waste components identified in accordance with § 194.24(b)(2), performed on the wastes proposed for disposal; verification of the qualifications of the personnel responsible for performing waste characterization activities; and the validation, control, and transmittal to the WIPP Waste Information System database of waste characterization data, in accordance with § 194.24(c)(4). It may be necessary to conduct follow-up inspection activities or continuation of the baseline inspection in order to obtain additional information and/or confirm the implementation of corrective actions.

Fourth, EPA will announce in the **Federal Register** our proposed Baseline Compliance Decision to accept the site's compliance with § 194.24(c)(4). In the notice, we will solicit public comment on the relevant inspection report(s) and all supporting materials that we rely upon in making our proposed Baseline Compliance Decision. These materials will be placed in the public docket described in § 194.67. The notice will describe any limitations on approved waste streams or waste characterization processes and identify (through tier designations) what changes to the approved waste characterization process must be reported to and approved by EPA before they can be implemented. EPA will designate significant changes as Tier 1; minor changes will be

designated as Tier 2. The notice will open a 30-day public comment period on the proposed compliance decision.

Fifth, after the end of the public comment period our written final Baseline Compliance Decision will be conveyed in a letter from the Administrator's authorized representative to DOE. DOE will comply with any reporting requirements identified in the Baseline Compliance Decision and the accompanying inspection report. A section summarizing significant comments and issues arising from comments received on the compliance decision, as well as the Administrator's response to those comments and issues, will be included in our final inspection report and will be made available to the public through our public docket. A copy of our compliance decision letter will also be placed in the docket.

Last, after a site receives our Baseline Compliance Decision, EPA will conduct inspections under § 194.24(h) to confirm the continued compliance of the programs approved and/or to verify the adequacy of any tier-assigned changes to the waste characterization processes not authorized by our Baseline Compliance Decision. DOE must report to EPA any changes as identified in the inspection report of our Baseline Compliance Decision. The reporting will inform EPA's decision whether to perform follow-up inspections. The results of EPA's inspections will be made available to the public through the public docket. If we determine that the system of controls used by the site is not adequate to characterize certain waste streams, then the site may not dispose of materials from those waste streams at the WIPP until the Agency's findings have been adequately resolved.

1. Changes to the Scope of EPA Approvals of Waste Characterization Programs

Under the proposed new provisions, EPA will issue a proposed Baseline Compliance Decision that describes what we inspected and found to be technically adequate and also identifies DOE's subsequent reporting requirements for the waste characterization program in question. The various elements of the waste characterization program will be tiered, and the basis for the tiering will be described in the inspection report that accompanies the proposed Baseline Compliance Decision.

The proposed tiering approach is a mechanism by which EPA can specify which changes to an approved waste characterization program require EPA approval before waste characterized by

⁸In the context of its 194.8 inspections, EPA has defined a finding as "a determination that a specific item or activity is not in compliance with 40 CFR part 194." Similarly, EPA has defined a concern as "an opinion that a specific item or activity may lead to noncompliance with 40 CFR part 194 at a future time".

that program is disposed of in the WIPP. TRU waste sites would have a clear understanding of which changes must be approved by EPA prior to shipment and disposal. The tiering of elements of the system of controls for waste characterization will vary depending on the type of analytical systems that a site has demonstrated, the types of retrievably-stored waste at a site, and the type and quality of information the site has compiled to describe waste contents. The proposed tiered approach applies only to waste characterization activities subject to § 194.8(b) requirements.

We propose to institute two tiering levels. Tier 1 designation will be given to activities for which changes have a potentially significant impact on compliance with EPA regulations, such as changes that directly affect measurements and/or estimates of isotopes and other limited waste components. Tier 1 activities are those for which EPA approval would be necessary prior to shipment and disposal of waste. For example, EPA approval would be necessary if a site introduced a new radioassay technique, because radioassay is a critical element of the system of waste characterization controls. Technical areas that are likely to be subject to Tier 1 designation are acceptable knowledge and radioassay. DOE will be required to submit documentation to EPA in advance that describes planned changes to Tier 1 activities. This documentation will inform EPA's decision regarding which actions, such as performance of an inspection, are necessary in order to approve the changes.

Tier 2 activities are those for which EPA approval would not be necessary prior to shipment and disposal of waste. An approved site could implement changes to elements of the waste characterization program with Tier 2 designation without first being inspected or approved by EPA. However, DOE must report changes in the manner prescribed by EPA in the Baseline Compliance Decision. DOE's reporting of changes to Tier 2 activities will assist EPA with the planning of follow-up inspections at sites.

Tier 2 designation will be given to activities that have a minor impact on compliance with the WIPP Compliance Criteria or are sufficiently standardized that they would not be expected to change significantly. For example, the actual operation of radiographic equipment does not vary greatly from machine to machine or from site to site. Also, minor revisions to procedures are a regular part of operations and usually serve to clarify or improve work

processes. Technical areas that are likely to be subject to Tier 2 designation are radiography and visual examination. The required reporting by DOE of Tier 2 changes will enable EPA to monitor the overall waste characterization program at a site and develop targeted inspection plans for continuing compliance inspections.

When we approve a waste characterization program, we will assign tiering designations based chiefly on the following topics: the extent to which a process was demonstrated at the time of our § 194.8(b) inspection(s); quality of documentation; the range of possible waste streams at a site; the demonstrated proficiency of waste characterization personnel; and the site's compliance with DOE's waste acceptance criteria for the WIPP, as reviewed and approved by EPA. Our inspection report will describe EPA's requirements for reporting of changes to waste characterization activities, including the scope and frequency of reporting.

Sites that have not been authorized by EPA to ship waste to the WIPP under the current provisions of § 194.8(b) will be subject to the new process immediately after we issue the final version of this rule. For sites that already have received EPA's approval to ship certain waste streams, we are proposing to reinspect those sites using the revised process. In other words, we will perform a full-scope inspection at approved sites (Hanford Site, Idaho National Energy and Environment Laboratory, Los Alamos National Laboratory, Rocky Flats Environmental Technology Site, and the Savannah River Site) in order to reset the Baseline Compliance Decision based on current activities at the sites. We will place our proposed compliance decision for each approved site in our docket and open comment on it. TRU waste sites with an approved waste characterization program may continue to ship waste within the scope of the existing approval while the baseline inspection process is taking place, provided that they continue to operate in accordance with the WIPP Compliance Criteria.

DOE has initiated an effort called the Central Characterization Project (CCP) to assist small quantity TRU waste sites with the completion of the waste characterization activities required by EPA and State agencies. Under the CCP, a single DOE contractor assumes responsibility for the characterization of a site's transuranic waste. The CCP sends a mobile waste characterization laboratory to the site to complete certain activities, such as radioassay.

EPA has approved the CCP's operation at the Savannah River Site, where it was first tested [Air Docket A-98-49, Item II-A4-19]. Under the existing provisions for § 194.8, EPA must first inspect and approve the CCP at each site, for each waste stream or group of waste streams. Under the proposed new provisions, EPA approval under § 194.8(b) will still be required for CCP operations at each site. However, once we have approved the CCP at a site, the CCP will be approved to characterize all waste streams at that site. Moreover, any subsequent inspections by EPA will be performed under § 194.24(h). The same processes described above for TRU waste sites will apply to our compliance decisions for the CCP.

2. Changes to Public Notice of Waste Characterization Inspections

Under the existing provisions of § 194.8(b), EPA opens comment on DOE waste characterization plans each time that we plan to inspect a waste characterization program at a site, if that program involves new waste streams or changes to the system of waste characterization controls. We announce comment periods and dates of inspections in the **Federal Register**. Because each site has multiple waste streams and evolving waste characterization programs, we have opened multiple comment periods on different documents for each site that we have approved to ship waste. We respond to the relevant comments that we receive in our inspection reports, and docket the inspection reports and compliance decisions.

Under the new provisions of § 194.8(b), EPA will request comment on our proposed Baseline Compliance Decision for each site, which includes the results of our inspection(s) in the form of an inspection report, and any appropriate supporting documentation, such as objective evidence in support of Agency findings. We will open comment periods only in relation to baseline inspections under § 194.8(b). We will continue to respond to the relevant comments that we receive in our inspection reports, and to docket the inspection reports and compliance decisions. The results of subsequent inspections of waste characterization programs that we perform, including for the purpose of approving Tier 1 changes, will be placed in our docket.

In addition to these steps, we plan to continue to announce our inspections and other WIPP-related activities on our WIPP home page at www.epa.gov/radiation/wipp and our WIPP Information Line (1-800-331-9477). We

encourage the public to visit our Website and to contact us with questions or information regardless of whether we have opened a public comment period. (Comments in response to an announcement in the **Federal Register** should be sent directly to the EPA docket specified in the announcement.)

C. How Has EPA Addressed the Alternative Provision Analysis Required by § 194.6?

The proposed changes to § 194.8(b) are needed to increase the options available to EPA in implementing our regulatory oversight of DOE's waste characterization program, and to simplify the public notice process.

1. How Do the Proposed Changes Comport With 40 CFR part 191?

Considered individually and as a group, the proposed changes comport fully with the radioactive waste disposal regulations at 40 CFR part 191. The inclusion of requirements for waste characterization in order to implement the disposal regulations was established by the rulemaking that resulted in the WIPP Compliance Criteria at 40 CFR part 194. Today's proposed changes do not alter the scope of the part 191 requirements. The Compliance Criteria will continue to apply waste characterization requirements to the WIPP project. The principal difference between the existing and proposed provisions is the process by which EPA verifies compliance with the provisions and notifies the public of that process. This new process will not substantively affect the Compliance Criteria's implementation of EPA's radioactive waste disposal regulations at 40 CFR part 191. Moreover, EPA believes that the proposed changes to the 194.8 approval process will allow for more meaningful public participation.

2. Why Do the Existing Provisions Appear Inappropriate?

EPA considers the existing provisions inappropriate for the reasons explicated below. EPA explained the basis for the existing provisions in the May 18, 1998, Certification Decision final rule (63 FR 27354).⁹ The importance of independently verifying the adequacy of waste characterization activities conducted by DOE has not grown any less relevant. However, our experience with site inspections since the 1998

⁹The existing provisions were designed to address the fact that at the time of certification, DOE was able to demonstrate the effectiveness of the proposed system of controls for waste characterization only for certain waste streams at Los Alamos National Laboratory [see 63 FR 27390].

certification decision has raised two key issues that we believe must be addressed through alternative provisions.

First, for a variety of reasons, the focus of the existing provisions on waste streams as the determining factor for initiation of an inspection is overly restrictive for EPA. The requirement at § 194.8(b)(1) that DOE must demonstrate the system of controls for each waste stream or group of waste streams reflects the fact that some waste streams are better documented than others. Consequently, there may be variations in how a given site uses information in the acceptable knowledge (AK) record in relation to the AK confirmatory program that DOE employs under the terms of the Certification Decision. DOE sites must report to WIPP as part of the TRU waste tracking requirement on a container basis, quantities of 10 WIPP-tracked radionuclides (americium-241, cesium-137, plutonium-238, plutonium-239, plutonium-240, plutonium-242, strontium-90, uranium-233, uranium-234, and uranium-238) disposed of at the WIPP. Reporting on a container basis may require sites to perform additional waste analysis if using the site-compiled AK is not adequate to estimate these radionuclides. Similarly, sites are responsible for reporting the quantities of cellulose, paper, and rubber (CPR) present in each waste container. During the certification rulemaking, we were concerned about the need to monitor the effect of these variances on the quality of waste characterization data. Section 194.8(b) was therefore constructed such that changes to the system of controls, in addition to the introduction of new waste streams, would be sufficient cause to require separate approval. As explained in the 194.8 BID document, EPA's regulatory experience over the past four years suggests that this narrow focus on specific waste streams is no longer necessary.

Second, the public notice process described in § 194.8(b) has not yielded the level of comment that we anticipated. As demonstrated by the quantity and type of comments we have received following publication of inspection announcements in the **Federal Register**, the process may actually be a source of confusion for the public. Each of these issues is discussed below.

a. *Why are the existing provisions overly restrictive for EPA?* EPA now has several years of experience with inspections at DOE sites where waste characterization takes place. Since certifying the WIPP in May 1998, we have completed over twenty inspections

under authority of § 194.8. We also have completed numerous other inspections of waste characterization activities under authority of §§ 194.21 and 194.24(h). We conducted the § 194.8 inspections at Los Alamos National Laboratory, Rocky Flats Environmental Technology Site, Idaho National Engineering and Environmental Laboratory, the Nevada Test Site, the Savannah River Site, and the Hanford Site. In addition, we inspected the operation of the DOE Central Characterization Program (CCP) at the Savannah River Site. We approved all of the programs we inspected except for the Nevada Test Site. We also have observed DOE audits at Lawrence Livermore Laboratory and Battelle Columbus Laboratory for the purpose of learning about the system of waste characterization controls those sites are developing.¹⁰

Based on this experience, we have determined that the existing provisions constrain EPA's ability to apply limited resources to a burgeoning waste characterization program for maximum regulatory benefit. Under the existing provisions, we must conduct a § 194.8 inspection at a site if any of the following conditions is true: the site has not previously been approved by EPA to ship waste; the site seeks approval for one or more new waste streams that will be characterized using approved processes; the site seeks approval for one or more new waste streams that will be characterized using at least one new or revised process; or the site seeks approval to introduce a new or revised process to characterize one or more previously approved waste streams.

DOE is currently engaged in waste characterization at five major sites, and plans to begin operations at four or more additional sites in the near future. The number of DOE sites that ultimately will ship waste to the WIPP could grow to approximately two dozen. There are or will be hundreds of waste streams at these sites, and the methods used to characterize them will change as sites acquire new instruments and techniques. Consequently, the expansion of DOE's national transuranic waste shipment program could lead to an indefinite expansion of EPA's inspection program. If EPA must complete a § 194.8 inspection for each

¹⁰EPA has prepared a document entitled "Background Information Document for § 194.8(b) Modification" (Air Docket OAR-2002-0005-0001), which explains in more detail the technical elements examined during waste characterization inspections, summarizes EPA's inspection experiences to date, and presents lessons learned. This document expands and complements this preamble discussion for the proposed revisions to § 194.8(b).

new waste stream, group of waste streams, or waste characterization process, the demands of this inspection regime will overwhelm our resources.

We believe that it is appropriate to amend the Compliance Criteria to increase the flexibility of our waste characterization inspection program. At present, the most restrictive factor in the existing provisions is that § 194.8(b) requires EPA to issue approvals that are specific to individual waste streams or groups of waste streams. Our experience with DOE's waste characterization activities since 1998 has shown that there are multiple factors that must be considered when verifying technical adequacy, including but not limited to waste groupings. Moreover, for purposes of waste characterization as required under the Compliance Criteria, the applicable waste groupings at the site are often of limited relevance. Typically, DOE TRU waste sites define and delineate waste streams on the basis of factors related to hazardous components of the waste, not radiological waste components. Thus, while the waste stream groupings may have significant relevance for RCRA purposes, they are often of less relevance for purposes of waste characterization requirements conducted under authority of the WIPP LWA.

In order to approve a site's waste characterization program, we must be confident that the site is capable of identifying and reporting waste components (particularly certain radioisotopes) identified in the 1998 Certification Decision as important to compliance (*see* Compliance Application Review Document (CARD) 31, Air Docket A-93-02, Item V-B-2). As DOE stated in Chapter 4 of the Compliance Certification Application (Air Docket A-93-02, Item II-G-1), a combination of qualitative and quantitative methods would be used to identify and report waste components.

These methods are: acceptable knowledge, which provides information about waste stream contents and the processes that generated the waste; nondestructive examination of waste containers using radiographic techniques, which provides qualitative estimates of physical waste components; destructive and nondestructive examination of waste containers using radioassay techniques, which was the only quantitative means proposed by DOE to quantify radioisotopic components; destructive (visual) examination of sampled containers to confirm the results of radiography through direct observation and measurement; and data reporting via the WIPP Waste Information System

(WWIS). Confirmation of data validity at various points is an integral part of these processes.¹¹ All of these technical processes constitute the "system of controls" specified in § 194.24(c)(4).

The demonstrated effectiveness of a given element of the system of controls may or may not be constrained by the specific features of a waste stream. A TRU waste site's implementation of certain elements of the system of controls, such as the WWIS, may not change at all from one waste stream to the next. In contrast, which nondestructive assay techniques may be effective for a given waste stream depends in part on the physical form of the waste and the quality of the acceptable knowledge for that waste.

The result most often has been that we have defined limitations on approved waste streams based on the element of the system of controls whose effectiveness is tied most closely to the characteristics of individual waste streams, that is, nondestructive assay (NDA). We have limited (or narrowed) our approvals to certain NDA equipment because factors such as the calibration and physical location of an individual instrument are important to the technical adequacy of the method, and because instrument performance varies based on the radioisotopes in a waste container. DOE may only ship waste streams characterized with certain equipment; otherwise, EPA must conduct another § 194.8 inspection to approve new equipment.

Our new approach to waste characterization inspections, with the new tiering approach, will require DOE to report changes such as the introduction of new nondestructive assay equipment, but will allow EPA to determine whether an inspection is needed for the new equipment. Under Tier 2, it is possible that a "desktop" review of procedures and data packages will be sufficient to demonstrate the similarity of a new process to an approved process. Alternatively, under Tier 1, EPA will have flexibility to schedule an inspection whose scope covers multiple processes and waste streams, *etc.*¹²

¹¹ For quality assurance purposes, we verify that data validation occurs in accordance with site procedures, and that properly qualified and independent QA personnel review the data. This step takes place during a QA audit or inspection. For technical purposes, we independently verify the quality of a sample of data. This step takes place during a waste characterization inspection.

¹² Currently, EPA is able to conduct such a broad scope inspection. However, new processes and/or waste streams must be inspected under § 194.8(b), and previously approved processes and/or waste streams must be inspected under §§ 194.21 and 194.24(h). Today's proposal would allow EPA to

Ultimately, the critical factor in our decision making on the initial approval is how effectively TRU waste sites set and enforce appropriate limitations on the usage of certain techniques, and how carefully they confirm and control the results of those techniques. Issuance of our approval under § 194.8(b) means that we have found that the site developed appropriate procedures for waste characterization processes; the site properly implemented those procedures; and we are confident, based on our independent evaluation, that the data reported to the WWIS are properly controlled.

We will continue to make this assessment during the initial § 194.8 inspection(s) at a site. Under the existing provisions, introduction of any waste streams or processes outside the scope of the initial approval necessitates potentially many more § 194.8(b) inspections. The changes that we are proposing today will not alter our authority to limit the scope of any site approval. Rather, the changes will enable EPA to determine independently whether a subsequent inspection is appropriate, and when it should occur. We reserve the authority to specify any appropriate limitations on the waste streams that may be shipped and the processes that may be used to characterize waste.

b. *How can the public notice process for § 194.8 inspections be improved?* Under the existing provisions, EPA must publish a notice in the **Federal Register** announcing a scheduled inspection under authority of § 194.8(b)(2). In the same notice or a separate notice, we must solicit public comment for at least thirty days on waste characterization program plans and other documents relevant to the inspection. DOE sends these plans and other documents to EPA and we place copies in our public docket and supplemental dockets. After the comment period has ended, we notify DOE by letter of our compliance determination and place the resulting inspection reports in our dockets (§ 194.8(b)(3)).

In our 1998 Certification Decision, we explained the rationale for the process described in § 194.8(b). In particular, we explained that our compliance decision must be based on our independent inspections of waste characterization processes. Inspections involve review of many different documents, interviews with staff, and on-site demonstrations, which are then summarized and made

review new processes and waste streams under § 194.24(h) after a site has been initially approved under § 194.8(b).

public in our inspection reports [see, for example, EPA Air Docket A-93-02, Item V-C-1, pp. 2-8 to 2-11 and 6-26]. We are not able to provide all potentially relevant information in our dockets when we open a public comment period. Under the existing provisions, we open comment on the top-tier program plans that describe the fundamental requirements for and organization of waste characterization activities at a site, plus additional procedures if appropriate to the scope of the inspection.

Such documents inform our preparation for an inspection and are sufficient to allow the public to raise compliance concerns or questions, or provide additional information to EPA, so that we are aware of that information prior to reaching a compliance decision. We refrain from reaching a final compliance decision until we have reviewed and responded to public comment. Our inspection reports reference the specific materials that we reviewed at the site and contain objective evidence in support of our findings.

As mentioned above, we have completed a significant number of inspections under authority of § 194.8(b) since May 1998. We have published a total of twenty-one **Federal Register** notices related to those inspections. In response, we received only nine sets of comments, which we believe to be low. Also, several comments consisted of requests to extend a public comment period, which suggests there may be a misunderstanding of the purpose of the comment period under current procedures (that is, to comment on the waste characterization documents in the docket and/or raise concerns to EPA). Specifically, at least one of the requests argued that an extension was appropriate so that information other than the waste characterization plans and procedures could be docketed and reviewed by the public. Both of these factors indicate that the existing provisions for public notice are not optimal for either EPA or the public.

There is also evidence to suggest that the conditions that necessitate additional § 194.8 inspections at an approved site may not be widely understood, even within the DOE transuranic waste complex. The most serious example occurred in July 2001, when EPA learned that waste was shipped from DOE's Idaho site (INEEL) and disposed of in the WIPP despite having been assayed by equipment that had not approved by EPA following inspection. INEEL had received our approval to use certain waste characterization processes on certain

waste streams in 1999, but the equipment in question was not included in the previous approval. During an inspection to investigate the nonconformance, we learned that its cause was an isolated failure to follow document control procedures. Nevertheless, our interviews with site personnel and Carlsbad Field Office personnel revealed confusion over whether a § 194.8(b) inspection (including public notice) was required for the new equipment (see Air Docket A-98-49, Item II-A1-28).

In response to these issues, the new public notice process that we are proposing would change three key aspects. First, each site would be inspected only once under § 194.8(b), therefore only one comment period would be opened for each site under § 194.8. Second, EPA would solicit comment not only on DOE documentation, but also on our baseline inspection report(s) and proposed compliance decision for each site. The comment period would begin after we have completed all necessary inspections and assembled the inspection report(s). Third, the inspection report resulting from a site's § 194.8(b) baseline inspection(s) would identify and explain EPA's tier assignments for DOE reporting of changes to the approved waste characterization processes, based on the conditions and maturity of the waste characterization program particular to that site. This reporting would inform EPA that a site has implemented or is considering changes to the approved waste characterization processes. For those changes requiring EPA approval, we would perform follow-up inspections prior to allowing changes in the site's system of controls, or in the waste streams shipped from the site. We believe that this approach is more straightforward than the existing provisions and should serve to reduce any confusion about the public notice process that may exist.

3. What Are the Costs, Risks, and Benefits of Compliance With the Alternative Provisions?

Since 1998, we have conducted over twenty inspections under § 194.8(b), at an average cost of approximately \$22,350 each (this estimate includes contractor travel and technical support plus labor and travel costs of EPA personnel). These inspections were conducted to approve both new waste streams and new waste characterization processes proposed by DOE. DOE has identified 569 different waste streams as potentially eligible for disposal at the WIPP facility [Air Docket A-93-02, Item

II-G-1, Vol.s III-IV, Appendix BIR-Transuranic Baseline Inventory Report]. If we were to continue to approve site waste characterization activity on a waste stream basis, the costs and logistics of our inspection schedule would rapidly become unmanageable.

DOE incurs costs as a result of being inspected by EPA. Operations may be interrupted to some extent while key personnel respond to the inquiries of inspectors and operators respond to EPA's requirements for testing of equipment. The additional reporting requirements introduced by the proposed new provisions also represent costs to DOE. However, we do not anticipate that the long-term costs to DOE due to the proposed new provisions will be greater than at present.

The risk associated with the proposed new provisions is the same as that which exists for the existing provisions. There is always a possibility that a compliance issue may continue undetected by EPA for a period of time, leading to the improper placement of waste in the repository. With regard to this possibility, we note several important considerations. First, EPA will maintain a rigorous inspection program for WIPP waste characterization activities. Second, DOE is required to maintain an active quality assurance program that audits waste characterization programs on an annual basis for compliance with applicable regulatory requirements. Last, as the operator of the WIPP, DOE is responsible for maintaining the quality of waste characterization programs. As a regulator of the WIPP, EPA's role is to verify independently that DOE is adequately maintaining quality. The combination of DOE's internal quality assurance audits and EPA's independent regulatory inspections has proven able to identify compliance issues and correct them. Therefore, we conclude that the proposed new provisions do not carry greater risks for compliance with the disposal regulations than the existing provisions.

The benefits of the new provisions were described in the preceding section. We expect site shipment activity to increase as approved waste generator sites incorporate new waste streams to their current characterization activities and new waste generator sites seek EPA approval for their shipments for the first time. Under the proposed new provisions, EPA will have more control over our inspection schedule, which will enable us to manage limited resources for maximum regulatory benefit. The proposed changes will not alter EPA's technical approach to

inspections of the waste characterization capabilities at DOE waste generator sites. Inspections will continue to involve in-depth interviews of personnel, careful reviews of analytical procedures, and demonstrations of waste characterization techniques and equipment. We will approve only sites that can effectively characterize wastes destined for disposal at the WIPP. Once those sites are approved, we will continue to oversee their programs through ongoing inspections.

Additionally, we expect that the changes to the public notice process that we are proposing will make the comment period for inspections more relevant. The public will now have an opportunity to review and comment on EPA's proposed decisions and inspection reports prior to site approvals.

Finally, the new provisions will be beneficial to DOE because reporting requirements for DOE will be established on a site-by-site basis. It will be clearer to the sites when a particular change in their activities will trigger review, inspection, or approval on EPA's part. Also, DOE will be able to implement changes in the Tier 2 elements of their waste characterization activities without prior approval. Sites with more effective waste characterization programs, including sites that successfully demonstrate the applicability of waste characterization controls to the broadest possible spectrum of waste at the time of EPA's inspection, are likely to have more activities listed in Tier 2 than sites with less effective programs.

V. How Is EPA Revising the Submission of Compliance Applications and Reference Materials Requirements in §§ 194.12 and 194.13?

A. What Are the Current Requirements in §§ 194.12 and 194.13?

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.

B. What Are the Proposed Changes to §§ 194.12 and 194.13?

EPA proposes 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 is revising § 194.12 to require that DOE submit 10 complete compliance applications in alternative format (*e.g.*, compact disk) or other approved format.

Also, the Agency is proposing 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.

C. How Has EPA Addressed the Alternative Provision Analysis Required by § 194.6?

The proposed changes to §§ 194.12 and 194.13 are intended to minimize the number of copies in printed form that need to be submitted and to allow for the submission of compliance applications and reference materials in alternative format (*e.g.*, compact disk). The use of alternative format will facilitate compliance with 40 CFR part 194 requirements because it will expedite EPA's evaluation of the compliance application and reduce costs associated with the review of compliance applications and reference materials. Receipt of application materials in alternative format will also improve information sharing with the public by enabling the Agency to more easily make these materials available via the Internet.

1. Why Do the Existing Provisions in §§ 194.12 and 194.13 Appear Inappropriate?

The existing provisions in §§ 194.12 and 194.13 are inappropriate because EPA does not need DOE to deliver 30 printed copies of the complete compliance application, nor 10 printed copies of all reference materials. In 1996, when the Compliance Criteria were finalized, the Agency required that 30 copies of the compliance application and 10 copies of the referenced material be submitted for use in our review and evaluation activities. Printed form copies were necessary because the Agency had a limited time period for review and the complexity of the application material required many reviewers. Also, EPA placed copies of these documents in various public dockets.

EPA's requirements for the submission of compliance applications and reference materials have changed since the promulgation of the Compliance Criteria in 1996. If material is submitted in alternative format (*e.g.*, compact disk) or other approved format

instead of printed matter, it is only necessary to have 5 printed copies of the compliance application and 5 printed copies of the reference materials not included in previous compliance applications (provided that the information has remained true and accurate) for our four public dockets (including an official copy for EPA).

New advances in information management require the use of new submission methods, such as the use of alternative format (*e.g.*, compact disk). Information and data in alternative format are easier to view, share, navigate, and analyze. However, current regulatory language in §§ 194.12 and 194.13 does not allow for the submission of compliance applications and reference materials in alternative format. Therefore, today's action proposes to revise the regulatory language in these sections to require alternative format (or other approved format) submission of both compliance application (also re-certification applications) and reference materials.

2. How Do the Proposed Changes in §§ 194.12 and 194.13 Comport With 40 CFR Part 191?

The proposed changes to §§ 194.12 and 194.13 comport fully with the radioactive waste disposal regulations at 40 CFR part 191. The inclusion of submission requirements for compliance applications and reference materials in order to implement the disposal regulations was established by the rulemaking that resulted in the WIPP Compliance Criteria at 40 CFR part 194. Today's proposed changes do not alter the scope of those requirements. The Compliance Criteria would continue to apply submission requirements to the WIPP project. The principle differences between the existing and proposed new provisions are that the number of printed copies to be submitted to EPA has been reduced considerably and alternative format (or other approved format) submission of compliance applications and reference materials is now required. The proposed revisions to this part do not impact the Compliance Criteria's implementation of 40 CFR part 191.

3. What Are the Costs, Risks, and Benefits of Compliance With the New Provisions in §§ 194.12 and 194.13?

Sections 194.12 and 194.13 require DOE to submit a specified number of copies in printed form of the compliance application and reference materials. This provision also applies to the compliance applications periodically submitted by DOE for recertification of compliance. The

proposed revisions reduce the number of copies required and requires submission of compliance applications and references in alternative format (or other approved format). We do not anticipate any cost increase related to our implementation of the changes to §§ 194.12 and 194.13. These changes will improve our ability to view, share, navigate, print, and analyze submitted materials. We expect to be able to conduct our review of compliance applications in a more efficient and cost effective manner. Also, the implementation of these changes will facilitate our ability to share information with the public in a more timely fashion. As we received information and data in alternative format, it would be easier to post this information in our webpage. Similarly, we do not anticipate that DOE will experience any cost increase as a result of their compliance activities with this part because the technology to produce alternative format submittals exists and is currently in use.

We do not anticipate any significant risks related to the implementation of the proposed revisions to this part. Submission of information and data in other than paper form is a widely accepted process that will ease the transfer of information between DOE and EPA and therefore, improve compliance with 40 CFR part 194.

In summary, the benefits of the proposed revisions for §§ 194.12 and 194.13 are several. First the Agency will benefit from an improved evaluation process and reduced costs associated with the review of compliance applications and reference materials. Second, the public will be able to have better and faster access to information used in support of WIPP compliance activities. This change will improve the public's ability to participate more actively in the public comment process. Third, the proposed changes to §§ 194.12 and 194.13 are intended to reduce the number of copies in printed form that must be submitted, thereby reducing paper usage.

VI. How Is EPA Revising the Waste Characterization Requirements in § 194.24(c)(3)?

A. What Are the Current Waste Characterization Requirements in § 194.24(c)(3)?

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. EPA verifies compliance with this requirement through inspections, where EPA conducts proper review of such information to determine whether use of process knowledge data is appropriate and reliable.

B. What Are the Proposed Changes to § 194.24(c)(3)?

The Agency is proposing 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 consistency with the change being proposed today for § 194.24(c)(3), the Agency is also proposing 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)." ¹³

Section 194.2 is contained in Subpart A (General Provisions) of the rule, which describes the purpose and scope of the regulation, clarifies terms, specifies dates, and imparts a range of administrative information. Section 194.2 focuses on providing an

explanation of all terms and abbreviations contained in 40 CFR part 194 for clarification purposes.

C. How Has EPA Addressed the Alternative Provision Analysis Required by § 194.6?

The proposed changes for both §§ 194.2 and 194.24(c)(3) are intended to clarify exactly what information EPA requires from DOE. EPA expects that with these changes, acceptable knowledge (AK) will be more clearly identified as an integral part of the system of controls for waste characterization and will require DOE to provide information about the entire system of controls (including AK) and implement the systems at each site. Again, these proposed changes in terminology do not alter our technical approach to verifying compliance during an inspection, but will reflect our actual practice more accurately.

1. Why Do the Existing Provisions in § 194.24(c)(3) Appear Inappropriate?

We do not consider the existing provisions in § 194.24(c)(3) to be fully inappropriate because process knowledge remains a crucial component of the waste characterization system of controls. However, the Agency seeks to improve communication with DOE and the public and the use of consistent and clear language is an important factor towards meeting that goal. Section 194.24(c)(3) is used to verify compliance in the collection and appropriate use of process knowledge during waste characterization, and that the procedures adhere to the quality assurance requirements identified in § 194.22. During the EPA inspection of a TRU waste site, we review the establishment and implementation of procedures for collection and use of process knowledge, demonstration of waste characterization processes, and the qualifications and practices of technical personnel.

The term "process knowledge," as currently used by EPA in the Compliance Criteria, incorporates information about the process or operation that led to the creation of the transuranic waste.¹⁴ The term "acceptable knowledge" includes process knowledge, any data resulting from analysis of waste prior to WIPP waste characterization, and any other information about the physical form of

¹³ This definition is consistent with EPA's and DOE's use of the term "acceptable knowledge" during the WIPP certification rulemaking. See, for example: Air Docket A-93-02, Item II-G-1, page 4-45; Item V-B-2, Compliance Application Review Document (CARD) 24, page 24-1; and 63 FR 27390, footnote 32.

¹⁴ Examples of processes or operations that create transuranic waste are molding of plutonium with crucibles, laboratory analysis of radioactive samples, and chemical separation of plutonium from other materials. The number and types of processes in use at a DOE site depends on the nature and complexity of the site's mission.

the waste and its base components. The two terms are related; process knowledge is a subset of acceptable knowledge.

In Chapter 4 of the Compliance Certification Application, DOE used the term "acceptable knowledge" and explained that this term incorporates "information regarding the physical form of the waste, the base materials composing the waste, and the process that generates the waste." DOE derived this usage from an EPA document entitled, "Waste Analysis at Facilities that Generate, Treat, Store, and Dispose of Hazardous Waste: A Guidance Manual (EPA530-R-94-024, April 1994)." This guidance defines AK broadly as including process knowledge, waste analysis data from waste generators, and records of analysis performed. A hazardous waste treatment, storage, and disposal facility when accepting hazardous waste for management may test waste to confirm that the hazardous waste determination done by a generator is accurate and the facility indeed can handle that particular waste type. The referenced guidance document applies specifically to compliance with the Resource Conservation and Recovery Act; however, its definition of AK is consistent with the definition that we are proposing for use in the WIPP Compliance Criteria.

It is important that both EPA and DOE have the same understanding on the terminology applicable to the requirements in § 194.24(c)(3). The use of the term "process knowledge" in the Compliance Criteria to date has not interfered with DOE's compliance with the terms and conditions of the certification. However, EPA seeks to avoid the possibility for miscommunication now or in the future.

2. How Do the Proposed Changes in § 194.24(c)(3) Comport With 40 CFR part 191?

The proposed changes to § 194.24(c)(3) comport fully with the radioactive waste disposal regulations at 40 CFR part 191. The inclusion of requirements for waste characterization requirements in order to implement the disposal regulations was established by the rulemaking that resulted in the WIPP Compliance Criteria at 40 CFR part 194. Today's proposed changes do not alter the scope of those requirements. The Compliance Criteria would continue to apply waste characterization requirements to the WIPP project. The principle difference between the existing and proposed new provisions is the replacement of the term process knowledge with acceptable

knowledge. The use of the new term would not substantively affect the Compliance Criteria's implementation of 40 CFR part 191.

3. What Are the Costs, Risks, and Benefits of Compliance with the New Provisions in § 194.24(c)(3)?

We do not anticipate any cost increase related to our implementation of the changes to § 194.24(c)(3). EPA will continue to conduct waste characterization oversight in the same manner as before. Similarly, we do not anticipate that DOE will experience any cost increase as a result of their compliance activities with this part. Essentially, DOE will continue to comply with the requirement of this part as they previously have.

We do not anticipate any risks related to the implementation of the proposed revisions to this part. The Agency anticipates that the use of the term acceptable knowledge will serve to enhance communication with the regulated party and therefore, compliance with 40 CFR part 194.

The benefits of the proposed revisions for § 194.24(c)(3) are two-fold. First, the proposed changes will not affect the actual technical approach to verifying compliance during our independent audits and inspections of the relevant WIPP activities. Therefore, EPA will continue to enforce the waste characterization requirements in the Compliance Criteria and ensure that DOE's waste characterization programs are properly implemented. Second, the clarification of the applicable terminology will ensure that no confusion arises regarding the specific waste characterization information required for compliance.

VII. Administrative Requirements

A. Executive Order 12866

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. Pursuant to the terms of Executive Order 12866, it has been determined that this rule is not a "significant regulatory action."

B. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA") generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This proposed rule will not have a significant impact on a substantial number of small entities because it sets forth requirements which apply only to Federal agencies. Therefore, I certify that this action will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

This proposed action does not impose an information collection burden under the provisions of the Paper Reduction Act, 44 U.S.C. 3501 *et seq.* The Compliance Criteria in 40 CFR part 194 requirements are applicable only to both DOE and EPA and do not establish any form of collection of information from the public.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 ("UMRA"), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Pursuant to Title II of the UMRA, we have determined that this regulatory action is not subject to the requirements of sections 202 and 205, because this action does not contain any "federal mandates" for State, local, or tribal governments or for the private sector. This rule applies only to Federal agencies.

E. Executive Order 12898

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 proposed action does not add or delete any certification criteria. The proposal would 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.

F. 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.

G. Executive Order 13045: Children's Health Protection

This rule is not subject to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it does not involve decisions on environmental health risks or safety risks that may disproportionately affect children.

H. 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 proposed 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 proposed action revises specific portions of the Compliance Criteria in 40 CFR part 194. These criteria are applicable only to both DOE (operator) and EPA (regulator) of the WIPP disposal facility. Thus, Executive Order 13132 does not apply to this rule.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

I. 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 proposed 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.

In the spirit of Executive Order 13175, and consistent with EPA policy to promote consultation and coordination with Indian Tribal Governments, EPA specifically solicits comment on this proposed rule from Tribal officials.

J. Executive Order 13211: Energy Effects

This proposed 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 30, 2002.

Christine Todd Whitman,
Administrator.

For the reasons set out in the preamble, 40 CFR Part 194 is proposed to be amended as follows.

PART 194—CRITERIA FOR THE CERTIFICATION AND RE-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 Public Law 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 clarifies a 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 by revising paragraph (b) 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 paragraph (c) of § 194.24. 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 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 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). In the notice, we will solicit public comment on the relevant inspection report(s) and any supporting materials, which will be placed in the public docket described in § 194.67. The proposal will describe any limitations on approved waste streams or waste characterization processes and identify (through tier designations) what changes to the approved waste characterization processes must be reported to and approved by EPA before they can be implemented.

(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.

(i) If the Agency determines, at a subsequent inspection of an approved transuranic waste site, that waste characterization programs or processes are not adequately established or implemented, then we may suspend shipments and disposal of affected and potentially affected waste streams, or take other action in accordance with § 194.4(b)(1) and (2), until we determine that the deficiencies have been adequately resolved.

(ii) [Reserved]

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. 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. 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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