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**PROPOSED CHANGES TO EPA'S TRANSURANIC WASTE CHARACTERIZATION
APPROVAL PROCESS (10.0)**

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ABSTRACT

This paper describes the changes to the waste characterization (WC) approval process proposed in August 2002 by the U.S. Environmental Protection Agency (EPA or the Agency or we). EPA regulates the disposal of transuranic (TRU) waste at the Waste Isolation Pilot Plant (WIPP) repository in Carlsbad, New Mexico. EPA regulations require that waste generator/storage sites seek EPA approval of WC processes used to characterize TRU waste destined for disposal at WIPP. The regulations also require that EPA verify, through site inspections, characterization of each waste stream or group of waste streams proposed for disposal at the WIPP. As part of verification, the Agency inspects equipment, procedures, and interviews personnel to determine if the processes used by a site can adequately characterize the waste in order to meet the waste acceptance criteria for WIPP.

The paper discusses EPA's mandate, current regulations, inspection experience, and proposed changes. We expect that the proposed changes will provide equivalent or improved oversight. Also, they would give EPA greater flexibility in scheduling and conducting inspections, and should clarify the regulatory process of inspections for both Department of Energy (DOE) and the public.

WHY MUST EPA APPROVE TRU WASTE CHARACTERIZATION?

To meet the statutory mandate of the WIPP Land Withdrawal Act, in 1996, the EPA finalized compliance criteria for the WIPP (40 CFR Part 194) including requirements for characterizing TRU waste destined for disposal at the WIPP facility (1). In 1998, EPA established a process to approve WC processes implemented at DOE TRU waste sites, as a condition to certify WIPP's compliance with EPA's compliance criteria for disposal of TRU waste (40 CFR 194, Appendix A, Condition 3) (2). The waste inventory for TRU waste volume and content that DOE used in its performance assessment (PA) became the basis for the EPA's compliance decision and de facto upper limits on certain waste components, requiring DOE to demonstrate that it could control and track the waste disposed into the WIPP repository.

When developing the 1998 regulatory requirements, the Agency evaluated the Los Alamos National Laboratory (LANL)'s ability to characterize the specified waste components (identified from the performance assessment as components of concern) according to the DOE-developed Waste Acceptance Criteria (WAC), Waste Analysis Plan (WAP), and Quality Assurance Program Plan (QAPP). These documents formed the basis for EPA's certification decision

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regarding the overall acceptability of DOE's waste characterization program. Sites use these procedures to demonstrate their ability to characterize their waste and obtain EPA approval for shipment and disposal of TRU waste at the WIPP repository. To date several DOE sites have successfully demonstrated their ability to characterize contact-handled TRU debris waste consisting of rags and wipes, laboratory equipment, protective clothing, etc.

WHAT ARE THE WASTE CHARACTERIZATION REQUIREMENTS?

Section 194.8 establishes a process to review and approve WIPP-related waste characterization activities at DOE TRU waste sites around the United States. The process (Condition 3 of the Compliance Criteria) was added to the final certification decision because, at that time, DOE was able to characterize adequately only the TRU debris waste generated at LANL. In other words, with Condition 3, the Agency made sure that the sites demonstrate to EPA that it can characterize each of their TRU waste streams according to the DOE-developed WAC and comply fully with the waste characterization requirements in §194.24(c). According to §194.8, at each waste generator/storage site, we must inspect and approve the process used to characterize each waste stream or group of waste streams shipped to the WIPP for disposal. Also, as regulator, we verify that the TRU waste proposed for WIPP disposal does not exceed the regulatory limits adapted from the Compliance Certification Application (CCA) (3). These limits are based on DOE's PA supporting the CCA and our own analysis showing that several TRU waste components, if not controlled, could potentially enhance release to groundwater and the surface. In its 1998 Certification Decision, the EPA established that TRU waste sites must measure and track the following TRU waste components: ten radionuclides (^{241}Am , ^{137}Cs , ^{238}Pu , ^{239}Pu , ^{240}Pu , ^{242}Pu , ^{90}Sr , ^{233}U , ^{234}U , and ^{238}U), cellulose, plastics, and rubber (CPR). EPA established regulatory limits only for these ten radionuclides because of their prevalence in the waste and the health and environmental risks they pose.

The TRU waste generator/storage sites must seek EPA approval of their WC program implemented to characterize their TRU waste (grouped into three main categories: debris, solids, soil) and only upon obtaining the EPA approval can they send the approved TRU waste streams for WIPP disposal. (See discussion of the approval process below.) Also, the TRU sites must report to WIPP waste characterization information for the EPA-approved waste destined for the disposal at WIPP. The WIPP must maintain and use the site-provided waste characterization information to demonstrate that the cumulative totals of the TRU waste emplaced in the repository are below the total activity and total quantities permitted by the Land Withdrawal Act of 1992 (4).

WHAT IS THE EXISTING APPROVAL PROCESS (194.8)?

EPA approval of TRU waste sites' WC program involves site inspections (see detailed discussion on inspections below) to determine whether the site:

X Has properly trained and qualified staff;

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- X Implements waste characterization procedures appropriately; and
- X Calibrates and maintains equipment used for identifying and quantifying the 10 radionuclides and CPR contents.

We must approve the “system of controls” for waste characterization that is identified in 40 CFR 194.24(c)(4). Section 194.8(b)(1) of the WIPP Compliance Criteria requires EPA approve a system of controls for each waste stream (such as inorganic sludge) or group of waste streams (such as debris waste). During inspection, if we find deficiencies in WC activities (such as inadequate documentation for Acceptable Knowledge (AK) reports, use of improperly calibrated radioassay equipment) or have concerns related to the process, procedures, or personnel, EPA inspectors discuss their findings with the DOE auditors and notify the site management. Depending on the severity of the deficiency, EPA may not approve the site’s waste characterization activities, and may require additional inspections to verify that the site has appropriately addressed the problem. Upon receiving the EPA approval, a site can ship the waste for disposal at WIPP.

What Is the Inspection Process?

The formal approval inspection required under §194.8 can include an assessment of the entire waste characterization program implemented at a site, an evaluation of a specific radioassay equipment or radiography method used for analyzing specified CH TRU waste type (for example, debris, solids). These approval inspections, commonly known as §194.8 or “dot eight” inspections require a **Federal Register** (FR) notice announcing an upcoming inspection, docketing the site’s waste characterization plan, quality assurance project plan, and any other relevant reports, and opening a 30-day public comment period.

We determined that on-site inspections of the processes used to characterize TRU waste was the best mechanism for determining the adequacy of personnel, procedures, and equipment used in waste characterization. Therefore, at 40 CFR 194.8, the Agency laid out the responsibilities of TRU waste sites and the role of EPA. EPA modeled its approach for implementing Condition 3 of the Certification Decision (that is, the waste characterization condition) after Element 8 of NQA-1 (1989)(5). During the site inspection, the Agency assesses whether the waste characterization data meet the data quality objectives developed by DOE and approved by EPA. To do this, EPA inspectors review:

- X Qualifications of the personnel generating data and conduct interviews;
- X Procedures used to obtain/compile data;
- X Capabilities of equipment used to identify and quantify the specified radionuclides in waste containers;
- X Selected radiography and visual examination records to determine that containers do not contain prohibited items and non-radiological waste contents are properly reported; and
- X Software and algorithms used to track the data from generator/storage site to the WIPP to

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- ensure they provide “active” cumulative totals for regulated waste components;
- X Replicate tests of previously measured waste drums to assess that the precision of the data measured by NDA equipment is within acceptable limits.

The inspection involves review of the following elements of the sites’ TRU waste characterization program:

- X Nondestructive assay (NDA) – use of gamma spectroscopy and a passive and/or active neutron assay system to measure the quantity of 10 WIPP-tracked isotopes
- X Acceptable knowledge (AK) - historical records, test results, and personnel interviews to compile waste specific data used to determine radiological and non-radiological waste contents
- X Visual examination (VE) - actually opening waste containers and sifting through the contents
- X Nondestructive examination (NDE) - radiographic evaluation of waste containers to estimate quantities of non-radiological components and make certain that prohibited items (aerosol cans, explosive and flammable material, free liquid) are absent
- X Data validation and tracking - authentication of the data for verifying the waste that would be received by the WIPP for disposal and review of waste information system maintaining cumulative totals for the TRU waste components within regulatory limits.

These elements constitute the “system of controls” for waste characterization that is identified in 40 CFR 194.24(c)(4). Section 194.8(b)(1) of the WIPP Compliance Criteria requires EPA to approve a system of controls for each waste stream (such as inorganic sludge) or group of waste streams (such as debris waste). EPA inspectors prepare checklists to evaluate each of the above elements and its application when characterizing TRU waste. This evaluation leads inspectors to identify deficiencies and ascertain the site’s ability to characterize TRU waste adequately. In addition, EPA reviews the results of previous CBFO audits and corrective actions requested by CBFO (this background information suggests potential areas of inquiry during interviews). At the end of the inspection, EPA provides feedback on any quality improving results that could improve the AK or radiography and/or radioassay methodologies.

After inspection, EPA issues an inspection report and, if appropriate, a letter of approval. If we find deficiencies in WC processes, the site does not receive EPA approval requiring the site to address the deficiencies and EPA to conduct follow-up inspection. DOE notifies EPA when the corrective actions taken by sites fully address EPA findings. During the follow-up inspection, we verify that the site has taken appropriate corrective action(s) and reevaluate the waste characterization element(s). The Agency cannot issue its decision before the end of the 30-day comment period and must consider public comments submitted responding to the FR notice and/or docketed material. Follow-up inspections are conducted under §194.24 and do not require public notice and comment. Under §194.24, EPA also conducts continuing compliance inspections to determine that the sites approved for characterizing their TRU waste continue to

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do so using approved processes and equipment, following the approved procedures, and do not send unapproved waste to the WIPP for disposal.

What Do We Emphasize During Inspections?

At present, for each waste stream or group of waste streams other than that approved in the final certification decision (namely, a TRU debris waste from LANL), the site must provide information on how a site uses process knowledge to characterize its waste (§194.8(b)(1)(i)). Under §194.8 inspection authority, we:

- X Evaluate its compliance with the waste characterization requirements;
- X Review the site's implementation documents as discussed in its CCA;
- X Review the site's implementation procedures derived from the WAP, the WAC, and the Certification Plan;
- X Make sure that the site has implemented a tracking system to confirm that the total quantity of the regulated waste components in the waste does not exceed the established limits (§194.8(b)(1)(ii)); and
- X Verify that waste component data are properly transferred to the WIPP Waste Information System (WWIS) maintained at the WIPP.

The EPA-developed inspection report emphasizes which components of the WC program the site has adequately implemented and whether the data quality objectives have been met. The report also discusses which WC program elements were unsatisfactory, whether the site failed to demonstrate adequate implementation of the specific program elements.

The approval letter states whether the waste can be disposed of at the WIPP. Alternatively, we notify the sites of the decision of non-approval, the reasons for denial, and what the site must do to gain approval. Once a site receives approval to ship a single waste stream or group of waste streams, that site cannot ship a different waste stream until we perform an additional inspection under authority of section 194.8(b). In addition, if the site makes changes in its approved characterization programs, those changes will trigger additional inspections and approvals.

WHAT HAVE WE LEARNED FROM INSPECTIONS?

EPA has approved five large sites (Hanford, Los Alamos National Laboratory, Savannah River Site, Rocky Flats Environmental Technology Site, and Idaho National Environmental Engineering Laboratory) and the Central Characterization Program (a mobile characterization unit contracted for conducting WC activities at smaller sites and/or to expedite WC at larger sites). From experience inspecting these sites, we discovered areas in which we could improve the inspection and approval process for EPA, DOE and stakeholders. These improvements are incorporated in the August 2002 proposal (67 FR 51930-51946, August 9, 2002). For example, we found that for some portions of the characterization process (AK, WWIS, VE, etc.) the

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procedures and processes employed for different waste streams do not vary significantly. In other words, sites that are able to characterize one debris waste stream are able to characterize a similar waste stream with equivalent accuracy. We also learned that some sites place greater effort on some components of the characterization process than other sites, and while both sites may have an adequate process, the site placing greater effort could require less regulatory oversight.

From experience gained inspecting TRU waste generator sites we learned that after sites receive waste characterization program approval and before the annual recertification inspections (per §194.24) sites may have:

- X Made operational changes to the approved equipment (e.g., recalibration after changing of the source material);
- X Used new equipment which was deemed by the site as similar to the one already approved for characterizing TRU waste;
- X Modified an approved procedure or process (e.g., to minimize redundancy or increase efficiency); or
- X Hired new waste characterization staff.

Some of these changes (such as using an unapproved NDA system) could affect the waste characterization data quality. Importantly, the disposal of the waste containers tested using an unapproved system also represents a regulatory violation. During 2001, one of the DOE waste characterization sites did not inform either the DOE TRU waste program office or EPA of their intent to use a new piece of NDA equipment. This suggested that when such changes are made, the sites must provide timely notification to the EPA so that we could determine whether (a) the changes to WC system at the site could continue to generate data that meet the data quality objectives, and (b) the EPA approval of the modified WC process or NDA equipment which may be similar to the approved equipment is necessary. The proposed reporting requirements requires the sites to report changes similar to those mentioned above to their waste characterization process to the EPA, and the Agency will determine if an inspection is required.

WHAT ARE THE PROPOSED REGULATORY CHANGES?

On August 9, 2002, we proposed to alter the inspection and approval process. (6) The proposed changes would eliminate the requirement for EPA to conduct separate inspections, with accompanying public notice and comment for each waste stream (or group of waste streams) at a site. Instead, only one approval per site would be issued under authority of §194.8 (67 FR 51936-51937, August 9, 2002). When granting approval, we would specify any limitations that necessitate additional inspections following the initial approval. Such additional inspections would be carried out under the authority of section §194.24(h). Under the proposed TRU waste approval process, we would request public comment on our proposed site approval decision based on the inspection results. This represents a deviation from the current process where we

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request comment on the site's waste characterization plans that are placed in the public docket before inspection.

Also, the proposed changes would give flexibility to sites to gain approval of a wide range of waste characterization equipment and processes/procedures as opposed to individual waste or a group of waste streams. Sites could request to use the same suite of approved equipment and processes/procedures to characterize wastes with differing waste matrixes (homogeneous vs. heterogeneous, sludge vs. soil) without needing waste-specific approval. Sites, however, would have to demonstrate that the approved equipment and processes/procedures can appropriately characterize the full range of waste.

We believe the proposed changes will neither diminish the capacity to oversee sites' TRU waste characterization programs nor reduce the ability to evaluate DOE sites' waste characterization capabilities. As discussed below, the overall framework for the proposed changes to our inspections and approvals would continue to verify compliance with Condition 3 of the certification decision.

What Is the General Framework?

First, DOE sites would be required to implement waste characterization programs and processes in accordance with the waste characterization requirements in §194.24(c)(4) to confirm that the total amount of each waste component that would be emplaced in the WIPP would not exceed the upper limiting value or fall below the lower limiting value in accordance to §194.24(c).

Second, sites would be required to notify the Agency in writing that a site is seeking an EPA approval of its overall waste characterization program or specific component (such as radioassay equipment) to characterize waste destined for disposal at the WIPP. Sites would also send to the EPA documents explaining the site's system of controls for waste characterization.

Third, EPA would conduct a baseline inspection of the waste characterization program at each DOE site (regardless of whether a site has been approved under the current requirements) to verify that an adequate system of controls has been established in plans and technical procedures, that the site is using approved plans and technical procedures, and that plans and procedures are adequately implemented. The inspection would include a demonstration by a site of the following waste characterization elements:

- X Collection and appropriate use of acceptable knowledge data;
- X Use of destructive and nondestructive techniques for measuring waste components identified in accordance with §194.24(b)(2);
- X Verification of the qualifications (training and experience) of the personnel responsible for performing waste characterization activities; and
- X Validation, control, and transmittal of waste characterization data to the WWIS database,

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in accordance with §194.24(c)(4).

Follow-up inspection activities or continuation of the baseline inspection may be necessary for obtaining additional information and/or confirming the implementation of corrective actions. As under the current process, we would prepare an inspection report describing the waste characterization method and procedures evaluated for the determination of whether the site can adequately characterize a particular waste, areas of nonconformance, and the timing of a response to EPA's findings/concerns if necessary. The report also would 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 would designate significant changes as Tier 1 and minor changes as Tier 2 (see tier discussion below for more detail).

Fourth, EPA would announce in the FR the proposed Baseline Compliance Decision to accept the site's compliance with §194.24(c)(4). Using the contents of the site inspection report, the Agency would develop a notice discussing our proposed decision and solicit public comment. These materials would be placed in our public docket. The notice would open a 30-day public comment period on the proposed compliance decision.

Fifth, after the end of the public comment period, the written final Baseline Compliance Decision would be conveyed in a letter from the EPA to DOE's Carlsbad Field Office. The site would be required to comply with any reporting requirements identified in the Baseline Compliance Decision and the accompanying inspection report. A copy of the compliance decision letter would also be placed the docket.

Finally, after a site receives the Baseline Compliance Decision, EPA would continue to 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 the Baseline Compliance Decision. 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 those waste streams at the WIPP until the Agency's findings have been adequately resolved.

What Is the Proposed "Tiered Approach"?

As mentioned above, EPA would issue a proposed Baseline Compliance Decision that describes what we inspected and found to be technically adequate and also identifies subsequent reporting requirements for the waste characterization program in question. The various elements of the site-specific 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 to manage changes and expansions in waste characterization activities after the Baseline Compliance Decision has been issued. The tier

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approach would be used to specify which changes to an approved waste characterization program require EPA approval prior to implementing the change, shipment, and disposal of wastes at the WIPP. EPA inspections conducted to verify continued compliance would continue under §194.24 where the entire system of controls will be evaluated regardless of the tiering designation pursuant to §194.8(b) requirements.

The proposed revisions would establish two tiering levels. Tier 1 designation would 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 would require EPA approval prior to implementing the change and shipping waste for disposal at WIPP. The site would be required to submit documentation to EPA in advance that describes planned changes to Tier 1 activities. We would evaluate this documentation to determine whether an inspection is necessary 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. However, a site would have to report changes to EPA.

Tier 2 designation would be given to activities that have a minimal impact on compliance with the WIPP Compliance Criteria or are sufficiently standardized. For example, the actual operation of radiographic equipment and audio/video recording of drum contents 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. The required reporting by a site of Tier 2 changes would enable EPA to monitor the overall waste characterization program at a site and develop targeted plans for continuing compliance inspections.

When approving a waste characterization program at individual sites, as part of the baseline compliance decision, we would assign tiering designations based on the following:

- X Extent to which a process was demonstrated at the time of our §194.8(b) inspection(s);
- X Quality of documentation;
- X The range of possible waste streams at a site;
- X Demonstrated proficiency of waste characterization personnel; and
- X Site's compliance with DOE's waste acceptance criteria for the WIPP, as reviewed and approved by EPA.

Our inspection report would describe EPA's requirements for reporting changes to waste characterization activities, including the scope and frequency of reporting.

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How Would the Proposed Changes Affect the Approved Sites?

For sites that already have received EPA's approval to ship certain waste streams, we are proposing to re-inspect those sites using the revised process. In other words, we would perform a baseline inspection at approved sites (Hanford, INEEL, LANL, RFETS, and SRS) to bring these sites on board with the §194.8(b) changes and indicate the proposed tiering designations. We would place our proposed compliance decision and accompanying §194.8(b) inspection report in our docket for public comment. TRU waste sites with an approved waste characterization program would 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.

Sites that have been not authorized by EPA to ship waste to the WIPP under the current provisions of §194.8(b) would be subject to the new process after the final rule is in effect.

How Would the Proposed Revisions Improve Public Involvement?

Under the existing provisions, we publish a notice in the FR announcing the scheduled inspection under authority of §194.8(b)(2). We also solicit public comment for at least 30 days on the DOE-provided waste characterization program plans and other documents relevant to the site inspection. After the comment period has ended and when an inspection report is ready, we notify DOE by letter of our compliance determination and place the resulting inspection report in our dockets (§194.8(b)(3)).

As mentioned earlier, we completed a significant number of inspections under authority of §194.8(b) between May 1998 and September 2001. We have published over 30 FR notices related to those inspections. In response, however, we received only a handful of comments specific to the docketed material. This suggests that the existing provisions for public notice are not optimal for either EPA or the public.

In revising the public notice process, we are proposing three key changes. First, since each site would be inspected only once under §194.8(b), 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 an FR notice discussing inspection results and docketed assembled 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 based on the conditions and maturity of the waste characterization program particular to that site. The inspection report would identify what changes must be reported and/or approved by EPA. For most changes requiring EPA approval, we would perform follow-up inspections prior to allowing such changes. We believe that this approach is more straightforward than the existing provisions and should serve to reduce confusion that may exist about the public notice process.

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What Is the Public Reaction to the Proposed Changes?

At the end of 120-day comment period, EPA received comments from public interest groups, the Department of Energy, the Environmental Evaluation Group, and concerned citizens. EPA also held public hearings in Albuquerque and Santa Fe, New Mexico where commenters expressed their opinions concerning the proposed rule. The comments generally support the enhanced opportunity for public comment, although requested clarification of certain aspects, and were mixed regarding the baseline approval process. Public interest groups were concerned that EPA appeared to justify some of the proposed changes based on resource and cost considerations. EPA will evaluate and respond to all relevant public comments in developing the final rule.

When Are the Proposed Changes Expected to be Finalized?

We expect to issue a final rule before the end of this year.

CONCLUSION

EPA believes that the proposed changes would allow us to maintain our close oversight of waste characterization at TRU waste sites as long as necessary to verify that waste emplaced in the WIPP is in compliance with our regulations and commitments in the CCA. DOE should continue to maintain or even exceed the high level of rigor necessary to characterize TRU waste using the approved system of controls as well as when seeking approval of new processes or assay methods for characterizing new and/or difficult-to-characterize stored TRU waste. The continued oversight of EPA over TRU waste sites serves to promote confidence in the long-term safety of the WIPP demonstrated in the CCA-based risk assessment.

REFERENCES

1. U.S. Environmental Protection Agency. Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR part 191 Disposal Regulations: Final Rule (40 CFR 194). 61 FR 5224-5245. February 9, 1996.
2. U.S. Environmental Protection Agency. Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's Compliance with the Disposal Regulations: Certification Decision (40 CFR Part 194, Appendix A). 63 FR 27353-27406. May 18, 1998.
3. U.S. Department of Energy. 40 CFR Part 191 Compliance Certification Application for the Waste Isolation Pilot Plant, containing Volumes I – XXI and references. Carlsbad Field Office. October 1996.
4. 1992 WIPP Land Withdrawal Act, Pub. L. 102-579, as amended by the 1996 WIPP LWA Amendments, Pub. L. 104-201.
5. American Society of Mechanical Engineers. Quality Assurance Program Requirements for Nuclear Facilities, ASME NQA-1. 1989.

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6. U.S. Environmental Protection Agency. Criteria for the Certification of the Waste Isolation Pilot Plant's Compliance with the Disposal Regulations; Alternative Provisions; Proposed Rule (40 CFR 194). 67 FR 51930-51946. August 9, 2002.