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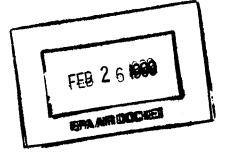
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REPORT

EPA INSPECTION NO. EPA-INEEL-7.98-8 OF IDAHO NATIONAL ENGINEERING AND ENVIRONMENTAL LABORATORY JULY 28-30, 1998

U. S. ENVIRONMENTAL PROTECTION AGENCY Office of Radiation and Indoor Air Center for the Waste Isolation Pilot Plant 401 M. Street, S. W. Washington, DC 20460

February 1999



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1.0 EXECUTIVE SUMMARY

In accordance with 40 CFR § 194.8(a)(2), the U.S. Environmental Protection Agency (EPA) conducted an inspection on July 29-30, 1998, of the U.S. Department of Energy (DOE) Audit A-98-31 of the Idaho National Engineering and Environmental Laboratory (INEEL) quality assurance program for transuranic waste characterization activities.

EPA evaluated INEEL's quality assurance program plan (QAPP), in accordance with 40 CFR § 194.8(a)(1), and found that it establishes the applicable Nuclear Quality Assurance (NQA) requirements of 40 CFR §194.22(a)(1) for the items and activities of 40 CFR §§194.22(a)(2)(i), 194.24(c)(3), and 194.24(c)(5). EPA also conducted an inspection, in accordance with Section 194.8(a)(2), of DOE's audit of the INEEL quality assurance program. During the inspection, EPA: 1) verified proper execution of the INEEL quality assurance program; 2) verified the DOE audit was performed in compliance with NQA-1, Element 18, entitled "Audits;" and 3) independently verified the implementation of certain NQA requirements by the INEEL quality assurance program. The inspection resulted in three findings, two concerns, and two observations concerning the INEEL quality assurance program. A finding is a determination that a specific item or activity does not meet a requirement under 40 CFR 194.8(a) or fails to meet an INEEL procedural requirement. The three findings had relatively minor and isolated consequences; therefore, EPA finds that INEEL has properly established and executed a quality assurance (QA) program for the Waste Isolation Pilot Plant (WIPP).

NQA-1, element 18, states that "Conditions adverse to quality *shall be ...corrected*." Thus, the EPA requires the resolution of all findings, including findings of insignificant conditions adverse to quality. Two of the minor findings were corrected during the audit. Correction of the third minor finding will be verified during a follow-up audit.

2.0 PURPOSE

In accordance with 40 CFR 194, Appendix A, Condition 2, DOE shall not allow any waste generator site (other than the Los Alamos National Laboratory) to ship waste for disposal at the WIPP until EPA determines that the site has properly established and executed a quality assurance program for waste characterization activities and assumptions. EPA will determine compliance of site-specific quality assurance programs at waste generator sites, including INEEL, using the process set forth in Section 194.8(a).

Section 194.22(a)(1) requires DOE to adhere to a quality assurance program that implements the following: 1) American Society of Mechanical Engineers (ASME) NQA-1-1989 edition; 2) ASME NQA-2a-1990 addenda, Part 2.7, to ASME NQA-2-1989 edition; and 3) ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c) and Section 17.1). EPA verified that DOE established these requirements in the Quality Assurance Program Document (QAPD) included in the Compliance Certification Application (CCA) submitted to EPA for the WIPP. The QAPD is the documented quality assurance program plan for the WIPP project, as a whole, to comply with the NQA requirements. The QAPD is implemented by DOE's Carlsbad Area Office (CAO), which has the authority to audit all other organizations associated with waste disposal at the WIPP to ensure that their lower-tier quality assurance programs establish and implement the applicable requirements of the QAPD. Each DOE generator site (including INEEL), which will characterize and ship waste for disposal in the WIPP, must prepare a site certification Quality Assurance Plan (QAP) that, together with its Quality Assurance Project Plan (QAPjP), will constitute the site-specific quality assurance program plan.

EPA annually audits DOE's quality assurance program at CAO (see EPA Air Docket No. A-93-02, Document Nos. II-A-43 and IV-A-4) and has determined that, to date, CAO has properly adhered to a quality assurance program that implements the NQA standards. EPA determined in its WIPP Certification Decision that the QAPD, as it applies to waste characterization, conforms with the NQA requirements and that DOE's quality assurance organization can properly perform audits to internally check the quality assurance programs of the waste generator sites. 63 Fed. Reg. 27354. However, as required by Sections 194.22 and 194.24, DOE was required to establish and execute required quality assurance programs to waste characterization activities and assumptions and to demonstrate implementation of a system of controls to measure and track important waste components. At the time of EPA's proposed certification decision, the Los Alamos National Laboratory (LANL) was the only site to demonstrate the establishment and execution of the required quality assurance programs and the implementation of the required system of controls for specific waste streams. Therefore, as described in the final WIPP certification, before other waste may be shipped for disposal at the WIPP, EPA must separately approve the quality assurance programs for other generator sites (Condition 2) and the waste characterization system of controls for other waste streams (Condition 3).

As set forth at Section 194.8(a)(1) and (2), EPA will verify the establishment and proper execution of site-specific quality assurance programs. At waste generator sites, EPA may either conduct its own audits or inspect audits conducted by DOE. The difference between an audit and an inspection lies in the role that EPA performs. During an audit, EPA assumes all responsibilities associated with assessing a generator site's quality assurance program, while in an inspection, EPA performs oversight of DOE's quality assurance checks of the generator site's quality assurance program.

EPA conducted an inspection on July 29-30, 1998, of DOE's audit of the INEEL quality assurance program for waste characterization activities. DOE's audit encompassed only the waste characterization activities associated with the proposed disposal of transuranic wastes at the WIPP. EPA conducted the following activities:

 In accordance with §194.8(a)(1), the EPA inspection team evaluated the INEEL quality assurance program plan to verify the establishment of applicable NQA requirements of §194.22(a)(1) for the items and activities of §§194.22(a)(2)(i), 194.24(c)(3), and 194.24(c)(5).

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- 2) In accordance with §194.8(a)(2), the EPA QA team performed the following activities to verify the proper execution of the site-specific quality assurance program plan for INEEL:
 - a) Inspected the DOE audit of the INEEL quality assurance program;
 - b) Witnessed the DOE audit team properly implementing NQA-1, Element 18 requirements for the performance of audits; and,
 - c) Conducted an independent assessment of several selected NQA requirements applicable to waste characterization activities.

3.0 SCOPE

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The scope of the inspection covered all aspects of the CAO's Audit A-98-31, which was performed on July 29-30, 1998. In addition, the EPA QA team reviewed the records of three earlier CAO audits (A-97-02, A-98-05, and A-98-07) of the INEEL quality assurance program. The purpose of the earlier three CAO audits was to determine whether INEEL had established compliant QA programs and was capable of properly characterizing TRU waste for purposes of Section 194.24(c).¹ EPA conducted an inspection of the earlier audits at the CAO on July 6-8, 1998, to determine whether these audits complied with the requirements of 40 CFR 194.8(a)(1) and (2).² The dates of performance for the earlier CAO audits were as follows:

- Audit A-97-02, conducted April 21-25, 1997
- Audit A-98-05, conducted February 23-26, 1998
- Audit A-98-07, conducted January 12-15, 1998

The activities performed by EPA's QA team included, but were not limited to, interviews with the auditors and the assessment of DOE audit reports, corrective action reports, audit

<sup>CAO conducted a separate certification process to determine whether INEEL met
DOE standards for shipment of TRU waste to WIPP. These DOE certification
standards included QA and waste characterization requirements. Upon
determining that INEEL met DOE waste generator site certification standards,
CAO requested that EPA conduct an inspection under Section 194.8 of CAO's
Audit A-98-31 to determine whether INEEL met EPA's requirements under
Sections 194.22 and 194.24.</sup>

EPA's inspection of CAO's earlier INEEL audits provided useful information on INEEL's prior establishment and execution of the requisite QA program. EPA's approval determination under Section 194.8(a), however, is based solely on the inspection of the CAO's Audit A-98-31.

checklists and all applicable DOE audit working papers. The EPA QA team assessed the adequacy of the CAO's certification audits in accordance with the requirements of 40 CFR 194.8(a)(1) and (2), as discussed above in Section 2.0 of this report.

In addition to conducting an inspection of the CAO's Audit A-98-31 and conducting an inspection of CAO's earlier INEEL audits, EPA also conducted an independent audit of five NQA-1 elements and NQA-2, Part 2.7 to independently ensure the implementation of the INEEL quality assurance program. The NQA elements chosen by EPA to inspect were:

- NQA-1, Element 2, Quality Assurance Program
- NQA-1, Element 4, Procurement Document Control
- NQA-1, Element 5, Instructions, Procedures and Drawings
- NQA-1, Element 6, Document Control
- NQA-1, Element 7, Control of Purchased Items and Services
- NQA-2, Part 2.7, Computer Software

EPA's inspection of the CAO's Audit A-98-31 also served to independently verify the establishment and proper execution of NQA requirements for process knowledge and controls at INEEL, as required by 40 CFR 194, Appendix A, Condition 2. In accordance with \S 194.24(c)(3) and 194.24(c)(5), DOE shall provide information in the CCA which demonstrates that the waste characterization activities, including process knowledge and process controls, respectively, conform with the quality assurance requirements found in \S 194.22.³

4.0 **DEFINITIONS**

Finding or *Nonconformance*: A determination that a specific item or activity does not meet a requirement under 40 CFR 194.8(a), or that this activity failed to properly execute a procedural requirement. A finding requires a response.

Concern: A judgment that may or may not be a compliance failure, and depending on the magnitude of the issue, may or may not require a response.

Observation: A comment based on an inspector's judgment that does not require a response.

³ Process knowledge includes acceptable knowledge (AK) used in waste characterization, while process controls include, but are not limited to measurement, sampling, chain of custody records, record keeping systems, waste loading schemes used, and other documentation.

5.0 QA INSPECTION TEAM, OBSERVERS, AND PARTICIPANTS

Inspection Team Member	Position	Affiliation
Mr. Mike Eagle	QA Team Leader	EPA ORIA
Ms. Caroline Laikin	QA Inspector	EPA ORIA
Mr. Gary Walvatne	QA Inspector	EPA Support Contractor
Ms. Angela Jones	QA Inspector	EPA Support Contractor
Ms. Ivy Porpotage	QA nspector	EPA Support Contractor
Mr. Raymond Wood	QA Inspector	EPA Support Contractor

The EPA QA inspection team consisted of two EPA Office of Radiation and Indoor Air (ORIA) employees and four EPA support contractors.

Numerous CAO and INEEL personnel, including both DOE staff and contractors, participated in the July 29-30, 1998 inspection. The CAO was supported by the CAO Technical Assistance Contractor (CTAC). Mr. Mark Italiano, CAO quality assurance engineer, and Mr. Steve Calvert, CTAC lead auditor, served as DOE's primary points of contact with the EPA inspection team. DOE INEEL Office is supported by several support contractors, including Lockheed Martin Idaho Technologies Company (LMITCO), Wastren, and Argonne National Laboratory-West (ANL-W). In addition, a total of five observers attended Audit A-98-31, including one from the New Mexico Environmental Evaluation Group (EEG), two from DOE Rocky Flats Environmental Technology Site (RFETS), and two from British Nuclear Fuels, Limited (BNFL).

The EPA QA team conducted its activities on July 6-8 and July 29-30, 1998. During July 6-8, 1998, the EPA QA team reviewed the records of DOE Audits A-97-02, A-98-05, and A-98-07 in Carlsbad, New Mexico. At this time, the team also reviewed the flow down of the NQA requirements from the CAO QAP to the INEEL QA Program and the CAO checklist to be used during their audit of INEEL. A list of the CAO personnel who participated in the inspection of these documents and audit records is presented in Attachment 1.

On July 29-30, 1998, DOE conducted Audit A-98-31, which was inspected by EPA. A list of the CAO and INEEL personnel who participated in EPA's inspection of Audit A-98-31 is provided in Attachment 2.

6.0 PERFORMANCE OF THE INSPECTION

EPA conducted an inspection of DOE Audit A-98-31 of the INEEL quality assurance program for waste characterization activities, reviewed the records of three earlier CAO audits (A-97-02, A-98-05, and A-98-07) of the INEEL quality assurance program, and conducted an

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independent audit of several NQA criteria. All inspection activities encompassed only the waste characterization activities associated with the proposed disposal of transuranic wastes at the WIPP. The EPA inspection team conducted the following activities:

 In accordance with 40 CFR 194.8(a)(1), evaluated the INEEL quality assurance program plan to verify the establishment of applicable NQA requirements as set forth at Section 194.22(a)(1) for the items and activities of Sections 194.22(a)(2)(i), 194.24(c)(3), and 194.24(c)(5). P 12

- 2) In accordance with §194.8(a)(2), the EPA QA team performed the following activities to verify the proper execution of the site-specific quality assurance program plan for INEEL:
 - a) Inspected the performance of the CAO's Audit A-98-31 of the INEEL quality assurance program;
 - b) Verified that the CAO audit team properly implemented NQA-1, Element 18 requirements during the performance of Audit A-98-31; and,
 - c) Conducted an independent assessment of six selected NQA requirements.

The EPA QA inspection team found, through objective evidence obtained during personnel interviews and document reviews, that the CAO's audits A-97-02, A-98-05, and A-98-07 verified the prior establishment of the INEEL quality assurance program. EPA's inspection of the CAO's Audit A-98-31 substantiated the proper establishment of the INEEL quality assurance program plan. EPA also found that these four audits verified that INEEL has properly executed its quality assurance program for the items and activities of 40 CFR 194.22(a)(2)(i), 194.24(c)(3) and 194.24(c)(5) for waste characterization activities and assumptions. Section 6.1 presents EPA's assessment of the CAO's certification activities to determine if CAO conducted its audits in accordance with NQA-1 requirements.

The EPA inspection team selected five NQA-1 requirements and NQA-2, Part 2.7 for independent assessment to ensure the proper execution of the INEEL quality assurance program. The NQA elements, including supplemental requirements, are: NQA-1, Element 2, Quality Assurance Program; NQA-1, Element 4, Procurement Document Control; NQA-1, Element 5, Instructions, Procedures and Drawings; NQA-1, Element 6, Document Control; NQA-1, Element 7, Control of Purchased Items and Services; and, NQA-2, Part 2.7, Computer Software. In particular, the EPA inspection team interviewed appropriate INEEL personnel, and reviewed the CAO's audit checklists, audit reports, corrective action reports (CARs) and all associated audit working papers to ensure that the selected NQA requirements were adequately addressed in the CAO's certification audits. This assessment is discussed below in detail in Section 6.2.

6.1 Implementation of Element 18 of NQA-1

EPA verified that the CAO's audits of INEEL were conducted in accordance with element 18 of NQA-1. EPA determined that CAO's audits of INEEL's quality assurance program were well planned and that CAO auditors developed and completed checklists for each activity associated with the INEEL quality assurance program. The checklists were developed based on the requirements of the top-tier document, the CAO QAPD, and the lower-tier documents comprising the site-specific quality assurance program plan, i.e., the INEEL QAP and QAPjP. P 13

The EPA QA team reviewed the reports for Audits A-97-02, A-98-05, and A-98-07 and verified that audit results are documented, reported to, and reviewed by responsible management. The CAO auditing team is comprised of qualified auditors who are independent of INEEL quality assurance activities. The EPA QA team reviewed all of the audit findings, CARs and corresponding corrective actions. The checklist for EPA's inspection of the CAO's audits is provided as Attachment 3 of this report; this checklist is based on the audit performance requirements of NQA-1, Element 18, Audits.

6.2 Performance of the Independent Assessment

The EPA QA team selected five NQA-1 elements and NQA-2, Part 2.7 for an assessment that was performed independent of CAO's Audit A-98-31. The objective of this independent . assessment was to ensure the proper execution of the INEEL quality assurance program; it supplements the CAO's audit inspected by the EPA QA team and recognizes EPA's authority to conduct audits of the sites without CAO participation. The team assessed the implementation of the NQA elements, including supplemental requirements, through interviews with INEEL personnel and review of documents and records. EPA's assessment of each of the NQA elements is presented below. This assessment also served to verify the results of the CAO's Audit A-98-31 and the three prior CAO certification audits considered by EPA's inspection. The checklists for the five NQA-1 elements and NQA-2, Part 2.7 are presented as Attachment 4 of this report.

6.2.1 NQA-1, Element 2, Quality Assurance Program

The QA team evaluated INEEL's training of nondestructive examination personnel as required by Supplementary Requirement 2S-2. EPA found that the requirements of Supplement 2S-2 were established and properly executed within the INEEL quality assurance program.

6.2.2 NQA-1, Element 4, Procurement Document Control

The QA team examined Requisition 50 of procurement package K97-519746, Pajarito Scientific Corp., QL2 for SWEPP hardware upgrade, dated February 4, 1997. The EPA examined this particular requisition as a sample of INEEL procurement documents. The requirements of Element 4 were established and properly executed for the referenced package. This sample document may not be fully representative of all INEEL procurement documents, and

therefore the examination of this sample alone is not sufficient to determine the proper implementation of element 4 for all INEEL procurement documents. This EPA-only examination provides an additional check to the EPA inspection of the CAO's audit of procurement documents at INEEL.

6.2.3 NQA-1 Element 5, Instructions, Procedures, and Drawings

NQA-1, Element 5 requires that activities affecting quality must be prescribed by and performed in accordance with documented instructions, procedures or drawings. The following observation was identified by the EPA's QA inspection team:

• The INEEL practices observed during the inspection include the use of an internal pulser to provide a check on the measurement system's energy calibration and resolution for each drum assayed. This practice is technically acceptable; however, the QAPP language in Section 9.3.1, pages 11-12, does not address this practice.

Since adequacy of the element was established, and the practice was technically adequate and improved upon procedural requirements, the observation discussed above does not significantly affect waste isolation at the WIPP. Therefore, EPA found that this element was established and properly executed within the INEEL quality assurance program.

6.2.4 NQA-1 Element 6, Document Control

The QA inspection team identified one finding and two concerns associated with Element 6, Document Control. Element 6 states: The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel. The following document control issues were identified:

- NDE Examiner Certification/Recertification Forms for 2 of 4 forms reviewed had incorrect expiration dates. *This finding was corrected during the inspection*.
- The delegation of approval signatures is not documented in the RWMC document control files. The RWMC has developed a draft matrix of primary and alternate reviewers for procedures, however, RWMC management had not finalized approval of the use of this matrix by the completion of the inspection. *This concern required a response. See Section 7.2.1 below.*
- INEEL RWMC Management Control Procedure, MCP-1805, paragraph 4.3.15.2 requires the RWMC Safe Operations Review Committee chairperson to "ensure that reviews and approvals of RWMC documents are documented on the document action request (DAR). However, the DARs for several revisions of

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Technical Procedure, TPR-1735 do not include approval signatures of the reviewers. Rather, the DARs include the following statement: "Please see attachments for additional signatures." The DARs do not actually have attachments, but the signatures of the reviewers are provided on the RWMC Review Sheets, which are provided throughout each revision review package. Although the reviewers' signatures are provided on the review sheets, the audit team is concerned that the signatures are not documented on a DAR as required by MCP-1805. This concern does not require a response.

Since the finding is judged to be an isolated instance of nonconformance to document control procedures and was easily corrected, EPA finds that this NQA element was established and properly executed within the INEEL quality assurance program.

6.2.5 NQA-1 Element 7, Control of Purchased Items and Services

The EPA QA team examined Requisition 50 of procurement package K97-519746, Pajarito Scientific Corp., QL2 for SWEPP hardware upgrade, dated February 4, 1997. EPA found that this element was established and properly executed within the INEEL quality assurance program.

6.2.6 NQA-2, Part 2.7, Computer Software

The EPA QA team identified the following two findings and one observation associated with software.

- NQA-2, Part 2.7 and chapter 6 of the CAO QAPD require, for the production software, that documentation be current with the software. The documentation for the SWEPP Gamma Ray Spectrometer System version 3.0 was still in draft form and had not been issued. *This finding required a response. See Section 7.1.2 below.*
- The Software Inventory List (SIL) does not match the Softwate Release Notice for the SWEPP Assay System (SAS). The SIL indicated the installed version should be V2.0a. The Software Release Notice indicates the version should be V2.2. After checking the installed version, the SIL was corrected to read V2.2. This finding was corrected during the inspection.
- The EPA QA team observed that MCP-1803 does not clearly identify:
 - Actions taken when installing new or revised software, to ensure the production installation date matches the software release date;

- The criteria used by the software configuration control board (SCCB) to determine when a stand alone validation and verification plan is required; and,
- What software falls under software configuration management (SCM) and why if not.

None of the issues discussed above significantly affect the establishment and implementation of Part 2.7; therefore, EPA found that Part 2.7 was established and properly executed within the INEEL quality assurance program.

7.0 SUMMARY OF FINDINGS, OBSERVATIONS, AND CONCERNS

The EPA QA inspection team's activities provided objective evidence in support of DOE's compliance with the requirements of Sections 194.22 and 194.24. The EPA QA inspection team found that 1) INEEL has established a quality assurance program plan that implements the NQA requirements of \$194.22(a)(1) for the items and activities of \$194.22(a)(2)(i), 194.24(c)(3), and 194.24(c)(5); and 2) INEEL has properly executed its quality assurance program plan.

In addition, the EPA inspection team collected objective evidence that the CAO performed Audits A-97-02, A-98-05, and A-98-07 in accordance with NQA-1, Element 18, Audits, and followed up on corrective action as necessary. EPA performed oversight of DOE's quality assurance checks of the INEEL quality assurance program during the CAO's Audit A-98-31; reviewed documents and records associated with the CAO's Audits A-97-02, A-98-05, and A-98-07, which were performed previously; and conducted an independent assessment of a selected sample of NQA-required activities.

The EPA QA inspection resulted in three findings, two concerns, and two observations concerning the INEEL quality assurance program. A finding is a determination that a specific item or activity does not meet a requirement under 40 CFR 194.8(a) or fails to meet an INEEL procedural requirement. The three findings had relatively minor and isolated consequences; therefore, EPA finds that INEEL has properly established and executed a QA program for the WIPP. Since audits sample the universe of activities, procedures and documents available, the following findings, observations, and concerns do not indicate to EPA that previous audits were improperly executed.

A post-inspection meeting (also referred to as the post-audit meeting for the CAO's Audit A-98-31) was held on July 30, 1998 to inform the CAO and INEEL personnel of the inspection results. Attachment 2 identifies the individuals who attended this meeting.

7.1 Findings

EPA identified three findings during its independent assessment of a portion of the INEEL quality assurance program. As defined in Section 4.0, a finding is a determination that a specific activity does not meet a requirement under 40 CFR 194.8(a), or that this activity failed to properly execute a procedural requirement. A finding requires a response.

7.1.1 Finding No. 1

NDE Examiner Certification/Recertification Forms for 2 of 4 forms reviewed had incorrect expiration dates.

This finding was corrected by INEEL during the inspection.

7.1.2 <u>Finding No. 2</u>

NQA-2 Part 2.7 and chapter 6 of the CAO QAPD require for production software, that documentation be current with the software. The documentation for the SWEPP Gamma Ray Spectrometer System version 3.0 was still in draft form and had not been issued.

This finding required a response. EPA received an adequate response from CAO on February 11, 1999 (Attachment 6). EPA will verify the response during a follow-up quality assurance audit at INEEL, currently planned for April 1999.

7.1.3 <u>Finding No. 3</u>

The Software Inventory List (SIL) does not match the Software Release Notice for the SWEPP Assay System (SAS). The SIL indicated the installed version should be V2.0a. The Software Release Notice indicates the version should be V2.2. After checking the installed version, the SIL was corrected to read V2.2.

This finding was corrected by INEEL during the inspection.

7.2 Concerns

EPA identified two concerns during the inspection of the CAO's audits of the INEEL quality assurance program. As defined in Section 4.0, a concern is a judgment that may or may not be a compliance failure, and depending on the magnitude of the issue, may or may not require a response.

7.2.1 <u>Concern No. 1</u>

The delegation of approval signatures is not documented in the RWMC document control files. The RWMC has developed a draft matrix of primary and alternate reviewers for procedures; however, RWMC management had not finalized the use of this matrix. P.18

This concern required a response. EPA received an adequate response from CAO on February 11, 1999. EPA will verify the response during a follow-up quality assurance audit at INEEL, currently planned for April 1999.

7.2.2 <u>Concern No. 2</u>

INEEL RWMC management Control Procedure MCP-1805, Paragraph 4.3.15.2 requires the RWMC Safe Operations Review Committee Chairperson to "Ensure that reviews and approvals of RWMC documents are documented on the DAR" (Document Action Request). However, the DARs for several revisions of technical procedure TPR-1735 do not include approval signatures of the reviewers. Rather, the DARs include the following statement: "Please see attachments for additional signatures." The DARs do not actually have attachments, but the signatures of the reviewers are provided on the RWMC Review Sheets, which are provided throughout each revision review package. Although the reviewers' signatures are provided on the Review Sheets, the audit team is concerned that the signatures are not documented on a DAR as required by MCP-1805.

This concern does not require a response.

7.3 Observations

EPA identified two observations during the inspection of the CAO's audits of the INEEL quality assurance program. As defined in Section 4.0, an observation is a comment based on an inspector's judgment that does not require a response.

7.3.1 Observation No. 1

INEEL practices observed include the use of an internal pulser to provide a check on the measurement system's energy calibration and resolution for each drum assayed. This practice is technically acceptable, however, the QAPP language at Section 9.3.1, pages 11-12, does not directly address this practice.

7.3.2. Observation No. 2

MCP-1803 does not clearly identify: 1) the actions taken when installing new or revised software to ensure the production installation date matches the software release date; 2) the criteria used by the software configuration control board (SCCB) to determine when a stand-alone validation and verification plan is required; and, 3) what software falls under software configuration management (SCM) and why if not.

8.0 **REFERENCES**

The documents reviewed by the EPA QA team are listed in Attachment 5 of this report.

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CAO PERSONNEL PARTICIPATING IN THE INSPECTION OF CAO AUDITS A-97-02, A-98-05, A-98-07

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CAO PERSONNEL PARTICIPATING IN THE INSPECTION OF CAO AUDITS A-97-02, A-98-05, A-98-07

Name	Title or Area of Responsibility	Pre- Inspection Meeting	Inspection Interview	Post- Inspection Meeting
D. Brown	CAO Quality Assurance Manager		. 🗶	×
S. Calvert	CTAC Lead Auditior	×	×	×

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CAO AND INEEL PERSONNEL PARTICIPATING IN THE INSPECTION OF AUDIT A-98-31

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CAO AND INEEL PERSONNEL PARTICIPATING IN THE INSPECTION OF AUDIT A-98-31

Name	Title or Area of Responsibility	Pre- Inspection Meeting	Inspection Interview	Post- Inspection Meeting
R. Arbon	RWMC Site Project Manager	×		×
D. Baxter	EIOCS Work Leader			×
G. Beaudoleil	DOE-ID	×		
D. Blattner	RWMC DCC/Off. Spec.		×	
D. Bryngelson	ANL-W Project Engineer	×		×
V. Bynum	SAIC Tech. Specialist	×		×
S. Calvert	CTAC Auditor	×	×	×
J. Channell	NM EEG (Observer)	×		×
T. Clements, Jr.	Mgr, INEEL TRU Program			×
P. Contreras	RWMC Facility Engineer			×
К. Соор	CTAC Tech Specialist	×		×
R. David	RWMC Document Control	×	×	
K. Davis	RTR System Engineer	×		×
S. Davis	CTAC QA Auditor	×		×
L. Dell	CTAC Auditor	×		×
M. Doherty	CTAC Tech. Specialist	×		×
D. Dreher	RFETS Safeguards (Observer)	×		
E. Dumas	LMITCO QA&O	×	×	×
F. Dunhour	CTAC Auditor	×		×
A. Flores	RWMC Review Coord.		×	
B. Ford	3100 Project Manager			×

CAO AND INEEL PERSONNEL PARTICIPATING IN THE INSPECTION OF AUDIT A-98-31

Name	Title or Area of Responsibility	Pre- Inspection Meeting	Inspection Interview	Post- Inspection Meeting
H. Francis	BNFL Operations (Observer)	×		
L. Fritz	DOE-ID	×		
G. Gardner	RFETS Safeguards (Observer)	×		
J. Gilman	RWMC Doc. Control/ Records			X
S. Hailey	SPO SDVO/AK Expert	×	×	×
D. Hartley	RWMC Site Project Officer		×	
G. Hayes	Site QA Officer		×	×
R. Kendrick	Training Coordinator		×	χ -
M. Maier	BNFL QA Mgr. (Observer)	×		
J. May	CTAC QA Auditor	×		×
D. Menkhaus	RWMC	×		×
J. Messenger	ANL-W Tech. Coordinator	×	<u> </u>	
K. Peters	Wastren AK Support	×		
T. Preston	LMITCO Quality Engineer	×	×	×
P. Rodriguez	CTAC QA Auditor	×	×	×
M. Sharp	RWMC Document Control	×	×	×
H. Sherick	Control Account Manager			×
B. Stroud	CAO Waste Cert. Manager			×
G. Tedford	WCO RWMC	×	×	×
G. Twedell	RWMC Physist	×	×	×
V. Wenczel	Process Quality Engineer	×	×	
J. Wells	DOE-ID	×		

ATTACHMENT 3.

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Checklist: EPA Inspection of CAO Audit

NQA-1 CHECKLIST

ELEMENT: <u>18</u> TITLE: <u>Audits</u>

	the reference document adequately define, describe, ress, or satisfy the following:	Yes	No	Applicable Procedure & Para.		
Basic Requirements						
1.	Are planned and scheduled audits performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness?	~		CAO Audit Schedule		
2.	Are audits performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited?	~		Audit Plans . A-97-02, A-98-05, A-98-07		
3.	Are audit results documented and reported to and reviewed by responsible management? Is follow-up action taken where indicated?	~	· ·	Audit Reports A-97-02, A-98-05, A-98-07		
Supp	lementary Requirement (18S-1)			· · · · · · · · · · · · · · · · · · ·		
1.	Are internal or external quality assurance audits scheduled to provide coverage and coordination with ongoing quality assurance program activities?	~		Audit Agendas A-97-02, A-98-05, A-98-07		
2.	Are audit plans developed and documented for each audit?	~		Audit Plans A-97-02, A-98-05, A-98-07		
3.	Does the auditing organization select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit? In the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team.	~		Auditor Qualification Notebook		
4.	Is the audit team identified prior to the beginning of each audit, with one individual appointed lead auditor?	~		Audit Plans A-97-02, A-98-05, A-98-07		
5.	Are audits performed in accordance with written procedures or checklists?			Audit checklist for each procedure		
6.	Are the elements that have been selected for audits evaluated against specified requirements?	~		Audit checklist for each procedure		
7.	Are audits results documented by auditing personnel and reviewed by management having responsibility for the area audited?	~		Audit Reports A-97-02, A-98-05, A-98-07		
8.	Is the audit report signed by the lead auditor prior to issuance?	~		Audit Reports A-97-02, A-98-05, A-98-07		

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NQA-1 CHECKLIST

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ELEMENT: <u>18</u> TITLE: <u>Audits</u>

1	the reference document adequately define, describe, ess, or satisfy the following:	Yes	(es No	Applicable Procedure & Para. Audit Reports A-97-02, A-98-05, A-98-07
9.	 Does the audit report include: description of the audit scope; identification of the auditors; identification of persons contacted during audit activities; summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited; and description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization? 			
10.	Does the management of the audited organization or activity investigate adverse audit findings, schedule corrective action (including measures to prevent recurrence), and notify the appropriate organization in writing of action taken or planned?	•		Follow-up on CARS, Audit Reports A-97-02, A-98-05, A-98-07
11.	Is follow-up action taken to verify that corrective action is accomplished as scheduled?	~		Follow-up on CARS, Audit Reports A-97-02, A-98-05, A-98-07
12.	Do audit records include audit plans, audit reports, written replies, and the record of completion of corrective action?	~		Audit Working Papers: A-97-02, A-98-05, A-98-07

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Checklist: EPA's Audit of INEEL

NQA-1 CHECKLIST

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REQUIREMENT: _____ TITLE: ___Quality Assurance Program___

	es the reference document adequately define. describe, ress, or satisfy the following:	Yes	No	Applicable Procedure & Para.		
Basic Requirements						
1.	Is a documented quality assurance program planned, implemented, and maintained in accordance with NQA-1?			Not evaluated during this inspection.		
2.	Does the quality assurance program identify the activities and items to which it applies?			Not evaluated during this inspection.		
3.	Does the quality assurance program provide control over activities affecting quality to an extent consistent with their importance?			Not evaluated during this inspection.		
4.	Was the quality assurance program established at the earliest time consistent with the schedule for accomplishing the activities?			Not evaluated during this inspection.		
5.	Does the quality assurance program provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions, which include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied?			Not evaluated during this inspection.		
6.	Does the quality assurance program provide for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of quality?			Not evaluated during this inspection.		
7.	Does the quality assurance program provide for indoctrination and training of personnel performing activities affecting quality?			Not evaluated during this inspection.		
8.	Does the management of the organizations implementing the quality assurance program regularly assess the adequacy of that part of the program for which they are responsible and assure its effective implementation?			Not evaluated during this inspection.		
<u>Sup</u>	plementary Requirements (2S-1)					
1.	Does the responsible organization designate those activities that require qualified inspection and test personnel and minimum requirements for such personnel?			Not evaluated during this inspection.		
2.	Has the responsible organization established written procedures for the qualification of inspection and test personnel to assure that only qualified personnel are permitted to perform inspection and test activities?			Not evaluated during this inspection.		
3.	Do personnel selected for performing inspection and test activities have the experience or training commensurate with the scope, complexity, or special nature of the activities?			Not evaluated during this inspection.		

	s the reference document adequately define, describe, ress, or satisfy the following:	Yes	No	Applicable Procedure & Para.
4.	Have provisions been made for the indoctrination of personnel regarding the technical objectives and requirements of the applicable codes and standards and the quality assurance program elements that are to be employed?			Not evaluated during this inspection.
5.	Has the need for a formal training program been determined? Are training activities, including on-the-job training, conducted to qualify personnel who perform inspections and tests?			Not evaluated during this inspection.
6.	Are the capabilities of a candidate for certification initially determined by a suitable evaluation of the candidate's education, experience, training, and either test results or capability demonstration?			Not evaluated during this inspection.
7.	Is the job performance of inspection and test personnel reevaluated at periodic intervals not to exceed 3 years?			Not evaluated during this inspection.
8.	If it is determined at any time that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, is that person removed from that activity until such time as the required capability has been demonstrated?			Not evaluated during this inspection.
9.	Is a person reevaluated for a required inspection or test capability if activities have not been performed in his/her qualified area for a period of 1 year?			Not evaluated during this inspection.
10.	 Is the qualification of personnel certified in writing in an appropriate form, including: employer's name; identification of person being certified; activities certified to perform; basis used for certification, including: education, experience, indoctrination, and training; test results, where applicable; results of capability demonstration; results of periodic evaluation; results of physical examinations, when required; signature of employer's designated representative who is responsible for such certification; and date of certification and date of certification expiration? 			Not evaluated during this inspection.
11.	Has the responsible organization identified any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination?			Not evaluated during this inspection.
12.	Does the employer establish and maintain records of personnel			Not evaluated during this inspection.

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Does the reference document adequately define, describe, address, or satisfy the following:		Yes	No	Applicable Procedure & Para.
1.	Does the quality assurance program provide for the qualification of nondestructive examination personnel to the American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980?	~		Training Implenentation Matrix PLN-127, Rev.2 January 1998 pgs B8-B11
2.	Has the responsible organization established written procedures for the control and administration of NDE personnel training, examination, and certification?	~		Training Implementation Matrix PLN-127, Rev.2 January 1998 Sec. 3, pgs 5-7
3.	Does the employer establish and maintain records of personnel qualification?	~		Reviewed training records of Julie Teton, Darrin Davis, Shawn Heath, Kris Hughes
<u>Sur</u>	plementary Requirements (2S-3)			
1.	Has the responsible auditing organization established the qualifications for audit personnel and the requirements for the use of technical specialists to accomplish the auditing of quality assurance programs?			Not evaluated during this inspection.
2.	 Is the competence of audit personnel developed by one ormore of the following methods: orientation to provide a working knowledge and understanding of NQA-1 and the auditing organization's procedures for implementing audits and reporting results; training programs to provide general and specialized training in audit performance; and on-the-job training, guidance, and counseling under the direct supervision of a lead auditor. 			Not evaluated during - this inspection.
3.	Does a prospective lead auditor have the capability to communicate effectively, both in writing and orally? Has the lead auditor's employer attested to these skills in writing?			Not evaluated during this inspection.

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	s the reference document adequately define, describe, ress, or satisfy the following:	Yes	No	Applicable Procedure & Para.
4.	 Are prospective lead auditors trained, as necessary, to assure their competence in auditing skills, including training in the following areas: Knowledge and understanding of NQA-1 and other nuclear-related codes, standards, regulations, and regulatory guides; General structure of quality assurance programs as a whole and applicable elements as defined by NQA-1; Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings; Audit planning in the quality-related functions for the following activities: design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility; and on-the-job training to include applicable elements of the audit program? 			Not evaluated during this inspection.
5.	Is a prospective lead auditor required to have participated in a minimum of five quality assurance audits within a period of time not to exceed three years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within one year prior to qualification?			Not evaluated during this inspection.
6.	Is a prospective lead auditor required to pass an examination which evaluates his/her comprehension of and ability to apply the body of knowledge identified under the training requirements (listed under question 4 above)?			Not evaluated during this inspection.
7.	 Do lead auditors maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; or participation in training program(s)? 			Not evaluated during this inspection.
8.	Does management conduct documented annual assessments of lead auditors to extend their qualification, require retraining, or require requalification?			Not evaluated during this inspection.
9.	Are lead auditors who fail to maintain their proficiency for a period of 2 years or more required to requalify?			Not evaluated during this inspection.
10.	Is the employer responsible for training auditors?			Not evaluated during this inspection.
11.	Does the responsible auditing organization select and assign personnel who are independent of any direct responsibility for performance of the activities which they will audit?			Not evaluated during this inspection.

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	Does the reference document adequately define, describe, address, or satisfy the following:		No	Applicable Procedure & Para.
1.	Does the quality assurance program provide for the qualification of nondestructive examination personnel to the American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980?	r		Training Implenentation Matrix PLN-127, Rev.2 January 1998 pgs B8-B11
2.	Has the responsible organization established written procedures for the control and administration of NDE personnel training, examination, and certification?	~		Training Implementation Matrix PLN-127, Rev.2 January 1998 Sec. 3, pgs 5-7
3.	Does the employer establish and maintain records of personnel qualification?	~		Reviewed training records of Julie Teton, Darrin Davis, Shawn Heath, Kris Hughes
<u>Sur</u>	plementary Requirements (2S-3)			
1.	Has the responsible auditing organization established the qualifications for audit personnel and the requirements for the use of technical specialists to accomplish the auditing of quality assurance programs?			Not evaluated during this inspection.
2.	 Is the competence of audit personnel developed by one or more of the following methods: orientation to provide a working knowledge and understanding of NQA-1 and the auditing organization's procedures for implementing audits and reporting results; training programs to provide general and specialized training in audit performance; and on-the-job training, guidance, and counseling under the direct supervision of a lead auditor. 			Not evaluated during this inspection.
3.	Does a prospective lead auditor have the capability to communicate effectively, both in writing and orally? Has the lead auditor's employer attested to these skills in writing?			Not evaluated during this inspection.

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Doe add	s the reference document adequately define, describe, ress, or satisfy the following:	Yes	No	Applicable Procedure & Para.
4.	 Are prospective lead auditors trained, as necessary, to assure their competence in auditing skills, including training in the following areas: Knowledge and understanding of NQA-1 and other nuclear-related codes, standards, regulations, and regulatory guides; General structure of quality assurance programs as a whole and applicable elements as defined by NQA-1; Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings; Audit planning in the quality-related functions for the following activities: design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility; and on-the-job training to include applicable elements of the audit program? 			Not evaluated during this inspection.
5.	Is a prospective lead auditor required to have participated in a minimum of five quality assurance audits within a period of time not to exceed three years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within one year prior to qualification?			Not evaluated during this inspection.
6.	Is a prospective lead auditor required to pass an examination which evaluates his/her comprehension of and ability to apply the body of knowledge identified under the training requirements (listed under question 4 above)?			Not evaluated during this inspection.
7.	 Do lead auditors maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; or participation in training program(s)? 			Not evaluated during this inspection.
8.	Does management conduct documented annual assessments of lead auditors to extend their qualification, require retraining, or require requalification?			Not evaluated during this inspection.
9.	Are lead auditors who fail to maintain their proficiency for a period of 2 years or more required to requalify?			Not evaluated during this inspection.
10.	Is the employer responsible for training auditors?			Not evaluated during this inspection.
Н.	Does the responsible auditing organization select and assign personnel who are independent of any direct responsibility for performance of the activities which they will audit?			Not evaluated during this inspection.

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	s the reference document adequately define, describe, ress, or satisfy the following:	Yes	No	Applicable Procedure & Para.
12.	Does the lead auditor, prior to commencing the audit, concur that assigned audit personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited?			Not evaluated during this inspection.
13.	Is the employer responsible for the development and administration of the examination for a lead auditor? The employer may delegate this activity to an independent certifying, but shall retain responsibility for conformance of the examination and its administration to NQA-1.			Not evaluated during this inspection.
14.	Does the employer establish and maintain records of personnel qualifications for auditors and lead auditors performing audits?			Not evaluated during this inspection.
15.	 Does the employer certify each lead auditor as being qualified to lead audits, including documentation of the following by the certification: employer's name; lead auditor's name; date of certification or recertification; basis of qualification (i.e., education, experience, communication skills, training, examination, etc.); and signature of employer's designated representative who is responsible for such certification? 			Not evaluated during this inspection.
16.	Are the records for each lead auditor maintained and updated annually?			Not evaluated during this inspection.
Sup	blementary Requirements (2S-4)			
۱.	Are personnel identified for indoctrination or training?			Not evaluated during this inspection.
2.	 Is the extent of indoctrination and training commensurate with the following: the scope, complexity, and nature of the activity; and the education, experience, and proficiency of the person? 			Not evaluated during this inspection.
3.	 Are personnel indoctrinated in the following subjects as they relate to a particular function: general criteria, including applicable codes, standards, and company procedures; applicable quality assurance program elements; and job responsibilities and authority? 			Not evaluated during this inspection.
1.	 Is training provided, if needed, to: achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities? 			Not evaluated during this inspection.

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Does the reference document adequately define, describe, address, or satisfy the following:		Yes	No	Applicable Procedure & Para.	
5.	Do records of the implementation of indoctrination and training take the form of: attendance sheets, training logs, or personnel training records?			Not evaluated during this inspection.	

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NQA-1 CHECKLIST

ELEMENT: _____ TITLE: <u>Procurement Document Control</u>

	es the reference document adequately define, describe, dress, or satisfy the following:	Yes	No	Applicable Procedure & Para.	
Basic Requirements					
1.	Are procurement documents required to reference or to include design bases or quality requirements?	~		MCP-590 Rev. 6 Pg. B1	
2.	Do procurement documents require Suppliers to have a QA program consistent with the requirements of NQA-1?	~		MCP-590 Rev. 6 Pg. B1	
<u>Sur</u>	oplementary Requirements (4S-1)				
1.	 Do procurement documents include the following provisions as deemed necessary by the Purchaser: Scope of work, Technical requirements, QA Program requirements, Right of access, Documentation requirements, Requirement for documenting nonconformances, and Spare and replacement parts? 			Not evaluated during this inspection.	
2.	Is the review of procurement documentation documented?			Not evaluated during this inspection.	
3.	How are changes to procurement documents reviewed and approve?		-	Not evaluated during this inspection.	

NQA-1 CHECKLIST

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ELEMENT: 5 TITLE: Instructions, Procedures, and Drawings

	es the reference document adequately define, describe, ress, or satisfy the following:	Yes	No	Applicable Procedure & Para.
Bas	ic Requirements			
1.	Are activities affecting quality prescribed by and performed in accordance with documented instructions, procedures, or drawings?	~		MCP-1805, Rev. 6; Sec. 2 MCP-2522, Rev. 3; Sec. 3 MCP-100, Rev.3; All
2.	Do the above referenced documents include or reference appropriate quantitative or qualitative acceptance criteria?	2		MCP-1805, Rev. 6; Appendix A MCP-2522, Rev. 3; Appendix D MCP-100, Rev.3; Appendix C

NQA-1 CHECKLIST

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ELEMENT: 6 TITLE: Document Control

	es the reference document adequately define, describe, dress, or satisfy the following:	Yes	No	Applicable Procedure & Para.
<u>Bas</u>	sic Requirements			
1.	Is the preparation, issue and change of documents, which specify quality requirements or prescribe activities affecting quality, controlled?	~		MCP-1805, Rev. 6; All MCP-2522, Rev. 3; All MCP-100, Rev. 3; All MCP-2526, Rev. 4; All
2.	Are such documents, including changes thereto, reviewed for adequacy and approved for release by authorized personnel?	~		MCP-1805, Rev. 6: All MCP-2522, Rev. 3: All MCP-100, Rev. 3: All MCP-2526, Rev. 4: All
Sup	oplementary Requirements (6S-1)			
1.	Are documents controlled to assure that correct and applicable documents are available at the location where they are to be used?			Not evaluated during this inspection.
2.	 Does the document control system provide for: identification of documents to be controlled and their specified distribution; identification of personnel, positions, or organizations responsible for preparing, reviewing, approving, and issuing documents; and review of documents for adequacy, completeness, and correctness prior to approval and issuance? 			Not evaluated during this inspection.
3.	Are major changes to documents reviewed and approved by the same organization that performed the original review?			Not evaluated during this inspection.
4.	Are minor changes to documents defined (i.e., those changes that do not require a review as a major change). Are the persons who can authorize a minor change clearly delineated?			Not evaluated during this inspection.

NQA-1 CHECKLIST

	Does the reference document adequately define, describe, address, or satisfy the following:			Applicable Procedure & Para.		
Basic	Basic Requirements					
1. [by an and the supplier, Source inspection or audit, and 	~		MCP-591, Rev. 4 Sec. 2, pg. 1 Sec. 4.1, pg. 2 Sec. 4.4, pg. 7 MCP-2482 TPR-4960		
Supple	ementary Requirements (7S-1)					
1. C	how it is to be accomplished, and			Not evaluated during this inspection.		
2. D	 control; selection of procurement sources; bid evaluation and award; Purchaser control of Supplier performance; verification (surveillance, inspection, or audit) activities by Purchaser, including notification for hold and witness points; control of nonconformances; corrective action; acceptance of item or service; and 			Not evaluated during this inspection.		
so fo	capability, of providing an identical or similar product which performs satisfactorily in actual use;			Not evaluated during this inspection.		

Doe add	s the reference document adequately define, describe, ress, or satisfy the following:	Yes	No	Applicable Procedure & Para.
4.	 Are the following items considered in bid evaluations: technical considerations, quality assurance requirements, Supplier's personnel, Supplier's production capability, Supplier's past performance, alternates, and exceptions? 			Not evaluated during this inspection.
5.	 Are the following items considered in a Supplier's performance evaluation: establishing an understanding between Purchaser and Supplier of the provisions and specifications of the procurement documents, requiring the Supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements, reviewing Supplier documents which are generated or processed during activities fulfilling procurement requirements, identifying and processing necessary change information, establishing method of document information exchange between Purchaser and Supplier, and establishing the extent of source surveillance and inspection activities? 			Not evaluated during this inspection.
ő.	Are verification activities of Supplier's planned and verified and documented by qualified personnel?			Not evaluated during this inspection.
7.	Are Supplier-generated documents controlled, handled, and approved in accordance with established methods?			Not evaluated during this inspection.
3.	Are measures established, implemented, and documented to control changes to procurement documents?			Not evaluated during this inspection.
9.	Are methods established for the acceptance of an item or service being furnished by a Supplier?			Not evaluated during this inspection.
10.	Is the Supplier required to verify that the item or services being furnished complies with the procurement requirements?			Not evaluated during this inspection.
1.	 Are one or more of the following methods used to accept an item or related services from a Supplier: Supplier certificate of conformance, source verification, receiving inspection, or post-installation test? 			Not evaluated during this inspection.
	e: Specific requirements for each of the above is addressed in plementary Requirements 7S-1, Paragraph 8.2.			

Does the reference document adequately define, describe, address, or satisfy the following:		Yes	No	Applicable Procedure & Para.
12.	 Are one or more of the following methods used to accept purchased <u>services</u>: technical verification of data produced; surveillance and/or audit of the activity; or review of objective evidence for conformance to the procurement document requirements such as certifications, stress reports, etc? 			Not evaluated during this inspection.
13.	 Does the Purchaser and Supplier have documented methods for disposition of items and services that do not meet procurement document requirements? Do these methods contain provisions for: Evaluation of nonconforming items; Submittal of nonconformance notice to Purchaser by Supplier as directed by the Purchaser. This submittal shall include Supplier-recommended disposition (e.g., use-as-is or repair) and technical justification. Nonconformances to the procurement requirements or Purchaser-approved documents which consist of one or more of the following shall be submitted to the Purchaser for approval of the recommended disposition: technical or material requirement is violated; requirement in Supplier documents, which has been approved by the Purchaser, is violated; nonconformance cannot be corrected by continuation of the original manufacturing process or by rework; or the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired; Purchaser disposition of Supplier recommendation; and Maintenance of records of Supplier-submitted nonconformances. 			Not evaluated during this inspection.

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NQA-2.7 CHECKLIST

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REQUIREMENT: 2.7

TITLE: Computer Software

	es the reference document adequately define, describe, dress, or satisfy the following:	Yes	No	Applicable Procedure & Para.	
Basic Requirements					
1.	Is the application of specific requirements for software prescribed in plans for software quality assurance and documented in policies and procedures?			MCP-1803, Rev. 6 Paragraph 2.1, Software Quality Assurance Requirements: INEL/INT-98-00430, SWEPP Gamma Ray Spectrometer System Software V 3.0 (SGRS); INEL/EXT- 97-00363, SWEPP Assay System V2.1 (SAS)	
2.	Is software development traceable and performed in a planned and orderly manner?	~		MCP-1803, Rev. 6, Paragraph 2.2.5 SAS VVP, DD, QAP, UD, RD	
3.	Is software specified, documented, and reviewed for functionality, performance, design constraints, attributes, and external interfaces?		~	MCP-1803 Rev. 6, Section 2.2.5 SGRS test plan report SAS test plan report SGRS Document Action Request (DAR) # EO-RS-4307 SGRS DAR # EO-RS- 4306 SGRS installed software is V3.0; the documentation for V3.0 is not out yet but has a DAR written to release it from draft form.	
4.	Does the software design phase have verification and validation activities, which include generations of test plans based on the requirements and generation of design-based test cases, and the review of the software design to ensure that the requirements are addressed?	~		MCP-1803 Rev. 6, Section 2.2.53, App. C software change verification SGRS V3.0 test plan and report, 5/98 INEL-ext-97-00364, Rev. 0, SAS software design description V2.1, 5/97	

5.	Do the implementation activities include a verification phase which examines the source code listings ?		Not evaluated during this inspection.
6.	Does the testing phase include a validation of the code to assure adherence to the requirements, and to assure that the software produces correct results for test cases?		MCP-1803 Rev. 6 Section 2.2.5.3 MCP-1812 SGRS V3.0 test plan and report, 5/98 INEL-EPT-97-00350, Rev. 0, SAS Software Test Plan and Report
7.	Does the installation and checkout phase for the software include execution of tests for installation and integration, and documentation of the approval of the software for operational use?	~	MCP-1803, Rev. 6, Section 2.2.53, App. C, Software Change Verification SGRS V3.0 test plan and report, 5/98 DAR EO-RS-4307 INEL-EPT-97-00350, Rev. 0, SAS Software Test Plan and Report
8.	Are software modifications approved, documented, verified, validated, and controlled in a manner consistent with their importance?		Not evaluated during this inspection.
9.	Are there procedures for preventing the use of retired software?		Not evaluated during - this inspection.
10.	Are verification and validation activities planned and performed for each system configuration that may impact the software? Do these procedures ensure that the software performs all intended functions and that the software does not perform any unintended functions?		MCP-1803 Rev. 6. Section 2.2.53 SGRS V3.0 test plan and report, 5/98 DAR EO-RS-4307 SAS-0030, 5/6/98, system change request SAS-0030, 5/6/98, system change verification

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11.	 Is a labeling system for configuration items implemented that: uniquely identifies each configuration item, identifies change to configuration items by revision, and provides the ability to uniquely identify each configuration of the revised software available for use? 		MCP-1803, Rev. 6, App. D, Software Inventory and Classification MCS-1781, Section 4.3.3.2, System Labeling SGRS System Backup V 3.0 SAS System Backup, V2.1 Software Inventory List does not match the software release notice for SAS. SIL says V2.1, V3.0 is already installed. Corrected during inspection.
12.	Are changes to software formally documented with a description of the change, the rationale for the change, and identification of the affected baselines?		Not evaluated during this inspection.
13.	Is there a plan for assuring software quality assurance?	~	MCP-1803, Rev. 6 Paragraph 2.1, Software Quality Assurance Requirements: INEL/INT-98-00430, SWEPP Gamma Ray Spectrometer System Software V 3.0 (SGRS); INEL/EXT- 97-00363, SWEPP Assay System V2.1 (SAS)
14.	 Does the software documentation address: functionality, performance, design constraints imposed on implementation phase activities, attributes, and external interfaces? 		MCP-1803, Rev. 6. Section 9, Software Documentation DAR EO-RS-4306 INEEL/INT-95-0053, Rev. 0, SGRS System Software Design Description INEL-EXT-97-0063 Rev. 1, SAS V 2.1 Software Req. Specification
15.	Does the program provide for the qualification of audit personnel?	~	Not evaluated during this inspection.

ATTACHMENT 5

REFERENCES

1.	DOE Carlsbad Area Office. CAO file for Audit Report A-97-02.
2.	DOE Carlsbad Area Office. CAO file for Audit Report A-98-05.
3.	DOE Carlsbad Area Office. CAO file for Audit Report A-98-07.
4.	DOE Idaho National Engineering and Environmental Laboratory. MCP-100, Rev. 3, Developing Procedures.
5.	DOE Idaho National Engineering and Environmental Laboratory. MCP-147, Rev. 3, Vendor Assessment.
6.	DOE Idaho National Engineering and Environmental Laboratory. MCP-590, Rev. 6, Procurement Quality Requirements.
7.	DOE Idaho National Engineering and Environmental Laboratory. MCP-591, Rev. 4, Evaluated Supplier Program.
8.	DOE Idaho National Engineering and Environmental Laboratory. MCP-592, Rev. 2, ⁻ Acqusition of Goods and Services.
9.	DOE Idaho National Engineering and Environmental Laboratory. MCP-1803, Rev. 6. Configuration Control of RWMC Hardware/Software.
10.	DOE Idaho National Engineering and Environmental Laboratory. MCP-1805, Rev. 6, Document Preparation, Review, Control, and Release.
11.	DOE Idaho National Engineering and Environmental Laboratory. MCP-2387, Rev. 1, Quality Engineering Review.
12.	DOE Idaho National Engineering and Environmental Laboratory. MCP-2482, Rev. 3, Inspection for Comformance.
13.	DOE Idaho National Engineering and Environmental Laboratory. MCP-2522, Rev. 3, Preparation and Control of Management Control Procedures.
14.	DOE Idaho National Engineering and Environmental Laboratory. MCP-2526, Rev. 4, Control of QAPPs and FIPs.
15.	DOE Idaho National Engineering and Environmental Laboratory. PLN-127, Rev. 2, Training Implementation Matrix.

16. DOE Idaho National Engineering and Environmental Laboratory. TRP-4960, Rev. 2, Receiving Inspection.

- DOE Idaho National Engineering and Environmental Laboratory. Requisition 50, Package K97-519746, Pajarito Scientific Corp. QL2 for SWEEP hardware upgrade, February 4, 1997.
- 18. DOE Idaho National Engineering and Environmental Laboratory. Training Records for Julie Teton, Darrin Davis, Shawn Heath, and Kris Hughes.
- 19. DOE Idaho National Engineering and Environmental Laboratory. INEL/INT-98-00430, SWEPP Gamma Ray Spectrometer System Software V 3.0.
- 20. DOE Idaho National Engineering and Environmental Laboratory. INEL/EXT-97-00363, SWEPP Assay System V2.1.

HTTACHMENT 6



Department of Energy

Carlsbad Area Office P. O. Box 3090 Carlsbad, New Mexico 88221

February 11, 1999

Mr. Mike Eagle Office of Radiation and Indoor Air Environmental Protection Agency MS 6602J 401 M Street, S. W. Washington, D.C. 20460

Dear Mr. Eagle:

The Carlsbad Area Office (CAO) has reviewed Finding 2 and Concern 1 that were discussed in the exit meeting during the Environmental Protection Agency (EPA) inspection performed at the Idaho Engineering and Environmental Laboratory (INEEL) on July 29 and 30, 1998.

Finding 2 relates to a software issue and was identified as CAR 98-070 by CAO. The INEEL response has been received and the proposed corrective action to formally issue the current software version was found to be acceptable. Follow-up verification of the corrective actions will be performed during CAO's April 1999 annual recertification audit.

Concern 1 relates to a matrix that is being used by the Radiological Waste Management Complex (RWMC) document control department for determining procedure reviewers. Use of the matrix does not violate the CAO Quality Assurance Program Document (QAPD). The matrix is used as an informal tool by the RWMC document control department to expedite their review process. The RWMC's document control was evaluated and found to be in compliance with applicable INEEL procedure requirements. Regardless, RWMC is in the process of having the procedure review matrix approved by the TRU waste Site Project Manager.

If you have any questions or need additional information, please contact me at (505) 234-7484.

Sincerely,

marca Stalians

Marc A. Italiano Acting Quality Assurance Manager

cc:

G. Basalilvaso, CAO S. Vega, CAO L. Fritz, ID J. Wells, ID T. Clements, INEEL/LMITCO G. Hayes, INEEL/LMITCO

CAO 99-0535 UFC 2300



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SECTION 2: WASTE CHARACTERIZATION

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Section 2: Waste Characterization

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Attachment C	Memorandum by Butch Stroud, dated November 13, 1998
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1.0 EXECUTIVE SUMMARY

In accordance with 40 CFR § 194.8, on July 28-30, 1998, the Environmental Protection Agency (EPA or the Agency) conducted EPA inspection No. EPA-INEEL-7.98.8 at the Idaho National Engineering and Environmental Laboratory (INEEL) to verify that waste proposed for disposal in the Waste Isolation Pilot Plant (WIPP) could be characterized in accordance with 40 CFR § 194.24(c)(4). EPA must verify compliance with 40 CFR 194.24 before waste may be shipped to the WIPP for disposal, as specified in Condition 3 of the Agency's certification of the WIPP's compliance with disposal regulations for transuranic (TRU) radioactive waste. 63 Fed. Reg. 27354, 27405 (May 18, 1998). The waste proposed for disposal at the time of EPA's inspection of INEEL was contact-handled (CH), retrievably stored waste that originated at the Rocky Flats Environmental Technology Site (RFETS) near Boulder, Colorado. P 51

The EPA inspection team determined that INEEL's waste characterization program can adequately characterize the proposed waste in accordance with 40 CFR 194.24(c)(4). The EPA inspection team identified one finding and seven concerns. The finding, that the requirement to quantify and report ²³⁴U had not been clearly defined for INEEL and other sites by the U.S. Department of Energy Carlsbad Area Office, was adequately addressed following the inspection.

2.0 PURPOSE OF INSPECTIONS

On May 18, 1998, EPA certified that the WIPP will comply with the radioactive waste disposal regulations at 40 CFR 191. 63 Fed. Reg. 27354. EPA's certification of the WIPP contains the following condition (Condition 3): "The Secretary shall not allow shipment of any waste from any additional [Los Alamos National Laboratories (LANL)] 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." In accordance with Section 194.8(b)(2), EPA approves waste characterization activities at Department of Energy (DOE or the Department) waste generator sites either by conducting a waste characterization audit or an inspection of a DOE waste characterization audit.

The approval process described at 40 CFR 194.8 requires the Department to provide EPA with two types of information: (1) information on process knowledge¹ for waste streams proposed for disposal at WIPP, and (2) information on the system of controls in place at the generator site that is used to confirm that the total amount of each waste component that will be

¹- Process knowledge refers to knowledge of waste characteristics derived from information 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 and analytic. 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. In the context of these reports specifically and waste characterization generally, EPA uses the term "acceptable knowledge" synonymously with "process knowledge."

emplaced in the WIPP will not exceed limits identified in the WIPP Compliance Certification Application (CCA). After reviewing these materials, an EPA audit or inspection team visits the site to verify that process knowledge and other elements of the system of controls are technically adequate and being implemented properly. Specifically, the EPA audit or inspection team verifies compliance with 40 CFR 194.24(c)(4), which states:

(c) For each waste component identified and assessed pursuant to paragraph (b) of [40 CFR 194.24], the Department shall specify the limiting value (expressed as an upper or lower limit of mass, volume, curies, concentration, etc.), and the associated uncertainty (i.e., margin of error) for each limiting value, of the total inventory of such waste proposed for disposal in the [WIPP]. Any compliance application shall:

* * *

Provide information which demonstrates that a system of controls has been and will continue to be implemented 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 this section. The system of controls shall include, but shall not be limited to: Measurement; sampling; chain of custody records, record keeping systems, waste loading schemes used; and other documentation.

In other words, the purpose of inspections is to verify that DOE waste generator sites, which characterize TRU waste prior to shipment to the WIPP, are characterizing and tracking the waste in such a manner that EPA is confident that the waste will not exceed the approved limits.

3.0 PURPOSE OF THIS REPORT

This waste characterization inspection report documents the basis for EPA's approval decision by explaining the results of the July 28-30, 1998, inspection in terms of findings or concerns. The report, when applicable, provides objective evidence of findings (nonconformances) in the form of documentation. The report also describes any tests or demonstrations completed during the course of the inspection. The completed checklists attached to the report show the documents (principally procedures) that the EPA inspection team reviewed. If you wish to see any items identified in the attached checklists, please contact:

Quality Assurance Manager USDOE/Carlsbad Area Office P.O. Box 3090 Carlsbad, NM 88221

EPA's decision to approve or disapprove the system of controls (processes) used to characterize one or more waste streams at a site is conveyed to the DOE separately by letter. 40 CFR § 194.8(b)(3). This report identifies and explains the basis for EPA's decision as contained in the letter. EPA's approval or disapproval extends only to the processes reviewed during the inspection and identified in this report and its attachments. Only waste that can be adequately characterized using processes verified by EPA through audits or inspections may be shipped to the WIPP for disposal. Also, approved processes could be used to characterize not just existing waste, but also waste that will be generated in the future.

4.0 SCOPE OF INSPECTION

The scope of EPA Inspection No. EPA-INEEL-7.98-8 incorporated:

- technical adequacy of process (acceptable) knowledge (AK) used for characterization of the waste streams at INEEL proposed for disposal at the WIPP (graphite and inorganic sludges)
- technical adequacy of the system of controls used to characterize Waste Material Parameters (WMPs) and radionuclides, including nondestructive assay (NDA) using a Cambera IQ2 modified to use 4 detectors, acceptable knowledge (AK) for graphite and inorganic sludges, real-time radiography (RTR), visual examination (VE), and data tracking via the WIPP . Waste Information System (WWIS).

At the time of the inspection, the procedures and activities reviewed by EPA were used to characterize contact-handled, retrievably stored waste generated by the Rocky Flats Environmental Technology Site and stored at INEEL.

5.0 DEFINITIONS

- *Finding*: A determination that a specific item or activity has a negative effect on compliance with 40 CFR 194.24(c)(4). A finding requires a response from the DOE Carlsbad Area Office (CAO).
- Concern: A judgment that a specific item or activity may or may not be a compliance failure, and depending on the magnitude of the issue, may or may not require a response.

6.0 INSPECTION TEAM

The members of the EPA waste characterization inspection team are identified below. (The members of the quality assurance audit team are identified separately in the quality assurance report.) In addition, a total of five observers attended DOE Audit A-98-31, including one from

Inspection Team Member	Position	Affiliation
Mr. Charles Byrum	Inspection Team Leader	EPA
Ms. Connie Walker	Inspector	EPA Support Contractor
Mr. Bill Vocke	Inspector	EPA Support Contractor
Mr. Ray Wood	Inspector	EPA Support Contractor
Mr. Don Hammer	Inspector	EPA Support Contractor
Mr. Howard Finkel	Inspector	EPA Support Contractor
Mr. Patrick Kelly	Inspector	EPA Support Contractor
Observers		
Mr. J. Francis Hodson		BNFL
Mr. Michael Mailh		BNFL
Mr. Jim Channell		EEG
Mr. Gary Gardner		RFETS
Mr. David Dreher		RFETS

the New Mexico Environmental Evaluation Group (EEG), two from DOE Rocky Flats Environmental Technology Site (RFETS), and two from British Nuclear Fuels Limited (BNFL).

Numerous DOE Carlsbad Area Office (CAO) and INEEL personnel, including both DOE staff and support contractors, participated in the July 29-30, 1998 inspection and performed a separate DOE audit. The CAO was supported by the CAO Technical Assistance Contractor (CTAC). Mr. Mark Italiano, CAO lead auditor, Mr. Butch Stroud, site certification manager, and Mr. Steve Calvert, CTAC lead auditor, served as DOE's primary points of contact with the EPA inspection team. The DOE INEEL Office is supported by several support contractors, including Lockheed Martin Idaho Technologies Company (LMITCO), Wastren, and Argonne National Laboratory-West (ANL-W).

7.0 PERFORMANCE OF THE INSPECTION

EPA inspection No. EPA-INEEL-7.98.8 involved the following elements of INEEL's TRU waste characterization program: nondestructive assay (NDA) using a Cambera IQ2 modified to use four detectors located in the Stored Waste Examination Pilot Plant (SWEPP) facility, acceptable knowledge (AK) for graphite and inorganic sludges, visual examination (VE), real-time radiography (RTR), data transfer using the WIPP Waste Information System (WWIS), and

data tracking and validation. These elements constitute the "system of controls" for waste characterization that is identified in 40 CFR 194.24(c)(4). The inspection was conducted in the following steps:

- 1) preparation of draft checklists prior to the inspection based upon CCA documents and public comment
- review of the results of CAO's Audits A-98-05 and A-98-07² and corrective actions requested by CAO (this background information suggests potential areas of inquiry during interviews and tests)
- 3) review of site procedures and other information, and modification of EPA checklists, if necessary, to incorporate site-specific information
- 4) on-site verification of the technical adequacy or qualifications of personnel, procedures, and equipment by means of interviews, demonstrations, and tests, and completion of checklists.

The inspection began with a brief presentation by CAO about the scope and results of previous CAO audits of INEEL. CAO representatives discussed planning for their waste characterization technical inspection and identified reference tools for the use of the EPA team (including a completed CAO checklist with DOE technical requirements that were addressed by INEEL procedures).

The following subsections address each technical area in turn. Each subsection identifies key documents that the EPA inspection team reviewed, key site personnel who were interviewed, key tests or demonstrations that were performed, and any findings or concerns. The checklists attached to this report (Attachments A1 - A5) reveal in greater detail the scope of EPA's inquiries and the specific items and activities reviewed.

7.1 Acceptable Knowledge (AK)

As part of the inspection, EPA reviewed the elements of the AK process listed below. The checklist at Attachment A.1 identifies the objective evidence reviewed by EPA in these areas.

- Overall procedural technical sufficiency and scope, with emphasis on the ability to track the AK waste characterization process for containers and waste streams
- Characterization of waste material parameters and radionuclides as required by 40 CFR
 194.24

² A-98-05 and A-98-07 are audit tracking numbers assigned by CAO and are not related to EPA's tracking numbers for its own inspections.

• Compilation of AK information and use of supplemental information

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- Confirmation of AK and resolution of discrepancies
- Technical adequacy of AK characterization results
- Preparation of the AK summary
- Preparation and technical adequacy sufficiency of required procedures (e.g., a consistent definition of waste streams)
- Reassignment of any waste stream based on an analysis of AK and discrepancies.

During the inspection, EPA inspectors verified the following technical elements of INEEL's AK characterization program (see also Attachment A.1):

1) The definition of Item Description Codes (IDCs) and their relationship to waste streams is documented and technically appropriate.

EPA examined procedures INEL-96/0280 and EDF-922, which discuss waste stream determination and the relationship of waste streams to item description codes. EPA found that, in many cases, grouping waste by IDC instead of by waste stream could result in a smaller grouping. IDCs are grouped by radionuclide content as well as other waste stream criteria (i.e., physical and chemical characteristics). EPA determined that INEEL appropriately identified waste streams via IDCs in their AK characterization process.

2) A technically adequate process was used to define the approximately 21 categories of waste described in the AK Summary Document (INEL-96/0280).

The AK Summary Document (INEL 96/0280) identified 21 separate waste categories but did not specify how these categories were devised. EPA therefore discussed the origin of waste groupings in the AK Summary Document with INEEL support contractors Mr. Kevin Peters (WASTREN) and Ms. Sheila Halley (Lockhead-Martin Idaho Technology Company (LMITCO) DOE's Management and Operating contractor for the INEEL site). On the basis of this interview, EPA found that INEEL's approach to grouping waste in the AK summary (e.g., by physical characteristics) was technically sound. However, since the 21 groupings identified in INEL 96/0280 should not be construed as equivalent to waste streams, EPA inspectors also found that the document would benefit from an explanation of the categorization process as distinct from the identification of individual waste streams. 3) A link exists between the defined IDCs and the Waste Material Parameters (WMPs).

EPA examined document no. WM-F1-82-021 and cross-referenced IDCs to the Baseline Inventory Report (BIR) using Table 1 of this document. EPA found that IDCs can be crossreferenced to waste material parameters, though there is no specific table or listing in the AK Summary Document (INEL-96/0280) that includes this information. P.57

4) An adequate process exists for INEEL to update the AK Summary in the event that discrepancies are found during confirmatory testing.

EPA found that MCP-2988 inappropriately states that the AK Summary Document (INEL-96/0280) will not be updated on a regular basis as additional AK information is obtained (e.g., headspace gas data, NDA results). Ms. Sheila Halley (LMITCO) agreed that this periodic editing should be done, and procedure MCP-2988 was revised during the inspection to remove the sentence stating that this update would not take place.

5) An adequate process has been implemented to provide the waste material parameters to the operators performing RTR, VE, and data validation (MCP-2989 4.4.3).

EPA interviewed Ms. Halley to confirm whether personnel performing RTR, VE, and NDA are given AK information prior to the actual performance of these characterization - techniques, as required in MCP-2989. Ms. Halley stated that in fact these data are not shared so as not to bias the RTR/VE analysis. EPA considers this approach acceptable, but the procedure should be revised to reflect actual practice.

6) The Acceptable Knowledge Source Document Review Summary contains all necessary information and is traceable to the source (MCP-2989 4.2.1).

References C090 and P112 in the AK Summary Document (INEL-96/0280) were examined to determine whether information in them was traceable to the AK Summary Document. EPA found that information contained in these documents were directly traceable to the AK Summary Document.

7) Traceability exists for the graphite waste stream from the Waste Stream Profile Form to the source documents.

EPA examined data files for three individual containers—RF001210371, RF001210876, and RF001210673—to determine whether the information is traceable to the AK Summary Document. For each container, EPA reviewed data characterization information (specifically, batch reports) pertinent to AK, including Site Validation D Officer checklists (MCP 2536), Appendix C (MCP-2988) discrepancy resolution checklists, waste stream summaries, MCP-1815 lists, and discrepancy reports. In addition, container data were tracked to AK Summary Document Appendix B, wherein the generation building and,

ultimately, waste material parameter and radionuclide content data were cross-referenced. EPA concluded that acceptable knowledge information is traceable to the container. EPA also concluded that individual estimates of radionuclide content and waste material parameter content can be derived based on acceptable knowledge.

 A current listing of drums processed through Stored Waste Examination Pilot Plant (SWEPP) is being maintained, and the percent changes in the Material Parameter Categories (MPCs) are being calculated and are technically adequate (MCP-2988 Appendix E).

EPA reviewed current listings of drums that present, for each drum, its number, barcode, IDC, material parameter change, and hazardous waste ID. Percent changes in material parameter categories are documented. EPA concluded that the requirements for drum tracking and calculation of percent changes in the material parameters are being conducted as described in MCP-2988.

As a result of the inspection, EPA inspectors identified the following three concerns:

- INEL 96/0280 includes 21 separate waste categories, but specifically how these categories were devised is not included in this document. EPA is concerned that these categories could be confused with waste streams.
- Procedure MCP-2988 inappropriately states that the Acceptable Knowledge Summary Document (INEL-96/0280) will not be updated as new acceptable knowledge information is acquired. This concern was resolved during the inspection when INEEL personnel revised Procedure MCP-2988 to remove the inappropriate statement.
- Procedure MCP-2989, Section 4.4.3 states that RTR and VE operators must be given AK information prior to RTR/VE analysis. However, EPA is concerned that actual practice does not reflect this requirement.

EPA does not require a response to these concerns. DOE should communicate these concerns to the site, and should reexamine these issues in future audits or inspections. EPA concluded that the elements of INEEL's AK program that the inspection team examined, as identified in Attachment A.1, are technically adequate.

7.2 Nondestructive Assay (NDA)

As part of the inspection, EPA reviewed the elements of the NDA process listed below. The checklist at Attachment A.2 identifies the objective evidence examined by EPA in these areas.

- Operator and technical staff training and qualification
- Performance Demonstration Program (PDP) participation

- Data handling processes, including data reporting, validation, and review
- AK use and reporting for NDA
- NDA methods and procedures, including a technical assessment of the INEEL NDA systems consisting of a Canberra IQ-2 gamma scan system modified to use four detectors (Segmented Gamma Ray Scanner (SGRS)), and a passive-active neutron counter (PAN).

During the inspection, EPA inspectors verified the following technical elements of INEEL's NDA program (see also Attachment A.2):

1) Comprehensive analysis of isotopes

EPA examined a Gamma Ray Spectroscopy Report dated July 8, 1998, the SWEPP assay system gamma ray isotopic library, and a barrel summary report for uranium, plutonium, and americium dated July 29, 1998. EPA also observed the operation of the gamma and neutron assay systems. EPA was not shown evidence that INEEL was quantifying isotopic quantities of Uranium-234 (²³⁴U) in the waste. Interviews of INEEL staff with regard to applicable procedures revealed that the requirement for quantifying ²³⁴U had not been defined for INEEL by CAO. Appendix WCL of the CCA identifies ²³⁴U as an isotope that must be quantified and reported. Technical requirements established by CAO must flow from higher-tier documents into lower-tier site procedures. EPA issued a finding to CAO instead of INEEL, since CAO is responsible for ensuring proper flow-down of technical requirements.

EPA considered the question of whether INEEL and other sites are quantifying ²³⁴U to be significant because quantification and tracking of specific radioisotopes is key to DOE's demonstration of conformance with established waste limits. Following EPA's inspection, CAO corrected the quality assurance finding with a memorandum from E. Kent Hunter (Attachment B) to waste generator sites (including INEEL) identifying the specific radionuclides (including ²³⁴U) that must be quantified and reported during the waste characterization process. This memorandum correctly identifies the radioisotopes identified in DOE's CCA, upon which EPA's certification is based. EPA additionally requested that CAO provide evidence that INEEL was in fact examining waste drums for the presence of the required radioisotopes. In response, CAO sent a memorandum from Butch Stroud (Attachment C) that identifies evidence that INEEL and other sites have adequately evaluated all required radioisotopes. Based on this memorandum and evidence reviewed during the inspection, EPA is satisfied that the technical finding has been adequately resolved. Available evidence, including AK information reviewed by EPA, shows that only trace amounts of ²³⁴U have been found in the drums measured to date by INEEL.

2) Integration with Acceptable Knowledge (AK)

EPA examined the use of AK information in the NDA process and the feedback of assay results to the AK database. INEEL NDA procedures (TPRs 1573, 1588, and 1726) indicate that, in general, default weapons grade isotopic ratios are being used to quantify the plutonium measurements. EPA found that the waste that has been assayed to date or will be assayed in the near future originated at the Rocky Flats Environmental Technology Site. EPA determined, based on a review of the calculated Total Measurement Uncertainty (TMU), that the AK information for this waste is of sufficient quality that the use of default isotopic ratios involves lower measurement uncertainty than would be the case with isotopic ratios produced by the gamma assay system. The SGRS system confirmed that the isotopic ratios are weapons grade plutonium and indicated the presence of other isotopes in the waste. Instances where the SGRS did not confirm the plutonium content as being weapons grade plutonium were resolved during level 1 data review. EPA agreed with INEEL that the use of AK for determining the plutonium isotopic ratios for the Rocky Flats waste streams is appropriate, provided the AK information is adequate. However, total measurement uncertainty and bias must be determined for waste streams other than those with strong AK information (such as inorganic sludges and graphite waste). INEEL was not prepared at the time of the inspection to perform NDA on waste categories other than inorganic sludges and graphite waste.

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3) Determinations of Minimum Detectable Concentrations (MDC)

EPA examined INEEL's determination of Minimum Detectable Concentration (MDC) for their assay systems. INEEL Engineering Design File (EDF) 1035 describes the site's approach for determining MDC for inorganic sludges. G. Twedell of INEEL stated that a Nonconformance Report (NCR) had been written against the MDC process, and closing the NCR includes reviewing the effect on previously assayed drums with matrices other than organic sludge. EPA agrees that assay systems should not be used for segregating non-TRU waste from TRU waste for these matrices, until such time as INEEL has completed their MDC determination for matrices other than that of organic sludge.

4) System calibration

Calibration of the INEEL SWEPP PAN system is controlled by three Radioactive Waste Management Complex (RWMC) documents: EDF-973, Zero Matrix Calibration of the SWEPP PAN System; EDF-609, Modeling and Verification of Monte Carlo Neutron Photon (MCNP) Calculations; and EDF-921 (Rev. 1), Input Preparation and Post Processes for SWEPP and PAN Assay System. The original calibration for the PAN system was performed at Los Alamos National Laboratories (LANL) in 1985. LANL developed a method whereby the calibration of response vs. source was performed on an empty drum, with calibration sources mounted in the center of the drum. Empirical correction factors were then developed to describe changes in the response based on changes in the properties of the waste matrix. These correction factors ideally modify the system response such that the modified response is equivalent to the empty drum response. INEEL performed a full recalibration of the PAN system in June 1997, following replacement of the neutron generator and the system front-end electronics. This calibration was performed using Nuclear Accident Dosimetry (NAD) foils and Zero Power Physics Reactor (ZPPR) plates as sources. The MCNP code was used to develop self-shielding and neutron leakage factors for the calibration. EPA found that INEEL's calibration program conforms to the requirements in the TRU Quality Assurance Program Plan (QAPP).

5) Performance of Quality Control Checks

EPA examined performance of quality control (QC) checks by directly observing the operation of the NDA systems and observing the tracking of the QC information in the software. In addition, EPA reviewed the Gamma Ray Summary Report Dated 3-21-98 through 7-25-98, and EDF-959, Control Charts. INEEL uses a method different from that assumed during authorship of the TRU QAPP for performing instrument performance checks. Section 9.3 of the QAPP states that "... instrument performance checks shall be performed and documented at least twice per shift." This requirement suggests that a radioactive source of known energy and activity will be measured to ensure that the channel energy calibration and activity response have not changed. Rather than measure a well-characterized radioactive source twice per shift, INEEL continuously injects a known signal into the system electronics during the measurement and checks the validity of the known signal against a well characterized radioactive source once per week. The injected signal (called a pulser) method was said to be equivalent in effect to the QAPP requirement for performance checks twice per shift.

EPA concurred with INEEL on this matter, but found that the pulser method does not appear to test the entire detector system twice per shift, since the signal is injected behind the detectors themselves into the system electronics. From a technical perspective, EPA believes the use of a well characterized radioactive source once per week during the pulser check is sufficient to identify drift in the detector electronics. However, the intent of the QAPP requirement was to perform an independent check of the entire detector system twice per shift, therefore, INEEL should produce documentation describing how their use of the pulser method is equivalent to the intent of the QAPP.

EPA inspectors also reviewed the NDA level 1 data validation and CAO audit reports and checklists for audits A-97-02 and A-98-05. Level 1 data validation process reviews were coordinated with the EPA WWIS inspection activities, which focused on level 2 data validation. EPA determined that the level 1 data review and validation process at INEEL met all applicable requirements.

As a result of the inspection, EPA inspectors identified the following finding:

• The requirement to quantify and report ²³⁴U in Appendix WCL of the WIPP CCA was not clearly defined for sites by CAO. This finding was resolved by memoranda from CAO that (1) expressly identified ²³⁴U and other radionuclides that must be either quantified or justified as absent on the basis of AK information, and (2) identified evidence that INEEL has been evaluating waste drums for ²³⁴U and other required radioisotopes.

EPA also identified the following concern:

• The use of the pulser for meeting the twice per shift performance check requirement is not in conformance with the requirement of the TRU QAPP.

EPA does not require a response to this concern. DOE should communicate this concern to the site, and should reexamine the issue in future audits or inspections.

EPA concluded that the elements of INEEL's NDA program that the inspection team examined, as identified in Attachment A.2, are technically adequate. INEEL's nondestructive assay program is implemented and effective for inorganic sludges and graphite waste streams from the Rocky Flats site. The NDA program that EPA inspected is also applicable to additional Rocky Flats retrievably stored waste streams for which adequate AK information describing the plutonium isotopic ratios and matrix characterizations is available, provided that INEEL can document the applicability of the TMU and bias methods, system calibration, and MDC to these waste streams. INEEL has yet to demonstrate that NDA systems can perform assays of waste streams that are not accompanied by AK information that provides a high level of confidence in descriptions of isotopic content and waste matrix properties.

7.3 Visual Examination (VE)

As part of the inspection, EPA reviewed the elements of INEEL's visual examination (VE) process listed below. The checklist at Attachment A.3 identifies the objective evidence examined by EPA in these areas.

- Miscertification rate determination and use
- Container selection
- VE procedures, equipment, and records (particularly videotaping of visual examination and documentation of results)
- Waste segregation

Determination of waste material parameters.

EPA randomly selected batch data reports and reviewed them to verify that they contained all necessary technical information. EPA inspectors also interviewed VE operators and viewed videotapes showing VE of the waste drums identified in the selected batch reports (see Attachment A.3). During the inspection, EPA inspectors verified the following technical elements of INEEL's VE process (see also Attachment A.3): P.63

1) The INEEL Visual Examination Plan and Decision Record for each container contains appropriate information.

The EPA inspector reviewed the Visual Examination Plan and Decision Records for a sample of containers to verify that all necessary information has been entered by the Visual Examination Expert examination. EPA inspectors verified the adequacy of this element by reviewing data package number 022238 and 023970.

2) Data generation level reporting, verification, and validation are adequately performed.

The EPA inspector verified that the data generation level reporting, verification, and validation is performed by an independent Visual Examination Expert, a technical supervisor, and the site data generation level QA officer. The EPA inspector reviewed four data packages for these elements, including data package 005695.

3) Visual examination container selection verification and substitution forms contain appropriate information.

The EPA inspector reviewed completed selection verification and substitution forms to ensure that the information contained is appropriate and that the containers are appropriate for visual examination.

4) Visual examination operators record the fill height (percent full) prior to unloading the drum.

For this activity, the EPA Inspector reviewed videotapes of waste containers previously examined. The EPA Inspector reviewed the videotape recorded for drum 005695, as well as for two additional drums, 022238 and 007085. EPA found that while the percent full for the drums was recorded in documentation, the procedure was not recorded on the videotape.

5) Each layer of confinement (bag) is weighed prior to opening and removing contents.

Each individual waste container can be unique, and depending on the waste stream, internal confinement layers (inner bags containing waste) may be present. The EPA Inspector asked to review the weighing of these confinement layers during the visual examination by reviewing a videotape showing this activity. However, there were no layers of internal confinement in

the drum videotapes examined at INEEL. In addition, the weighing of the individual confinement layers at INEEL was not routinely videotaped as part of the visual examination record.

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6) Operators use weight reference tables to estimate weight, and glove box aid is posted and updated as necessary.

VE operators are required to maintain reference tables to aid them in developing weight estimates and assigning wastes to waste material parameters. The EPA Inspector ensured, through inspection, that these tables are completed and readily available for use by the Visual Examiner.

7) An evaluation of the accuracy of the TRUCON Code, matrix parameter category, and IDC (as appropriate) has been performed.

The EPA Inspector reviewed data reports, including the Decision Report to ensure that information on the TRUCON Code, IDC, and waste matrix codes are included and appropriate. EPA examined information presented in the visual examination record and confirmed that appropriate characterization took place.

8) The location and amount of liquid are recorded.

EPA examined the visual examination tapes to determine whether the VE staff identified liquids encountered, at any time, and whether a description of the location, container, and estimated volume of the detected liquid is made. No liquids were identified in the containers examined on visual examination tapes observed at INEEL.

9) The empty weight of the container and liners is recorded.

The EPA Inspector reviewed the waste material parameter summary for all drums reviewed to ensure that they were complete. This included ensuring that the weight of all waste items, liners, and the empty waste container have been measured and recorded accurately.

10) Decision making criteria for VE are documented in the operating procedure.

The EPA inspector reviewed the site's procedures to ensure that guidance is provided on how to handle materials that interfere with the examination such as metal containers, discolored plastic bags, stabilized wastes such as cement, etc. Also, the site's VE procedure must ensure that prohibited items are identified and that proper steps are taken to isolate the particular waste container. At INEEL, the EPA Inspector reviewed INEEL procedure HFEF-OI-6890 and Argonne National Laboratory-West procedure 2546 and verified that the information was complete for containers 023970 and 022238.

11) Video equipment resolution is checked daily.

The EPA Inspector verified that the video camera used to videotape visual examinations are checked daily to ensure that the camera's resolution is correct. In cases where review of visual examination of actual drums is not feasible, it is important that this resolution check be conducted. P 65

12) The INEEL Visual Examination Plan and decision record are completed as required.

See Item 1 above.

13) All necessary equipment is available and exams are conducted in adequate radiation control facilities.

The EPA Inspector verified through inspection that all the necessary equipment was available and those exams are conducted in radiation control facilities.

As a result of the inspection, EPA inspectors identified the following concerns:

- Full drum height (percent full), bag weighing, core extrusion, and video equipment checks performed during visual examination were not recorded on videotape.
- Daily video check results were not included on visual examination forms.

EPA does not require a response to these concerns. EPA concluded that the elements of INEEL's visual examination process that the inspection team examined, as identified in Attachment A.3, are technically adequate.

7.4 Radiography

As part of the inspection, EPA reviewed the elements of INEEL's real-time radiography (RTR) process listed below. The checklist at Attachment A.4 identifies the objective evidence examined by EPA in these areas.

- Waste material parameter identification
- Radiography equipment
- Record of Variance contents
- Test Drum analysis
- Radiography test data reports

Radiography procedures and operator responsibilities.

During the inspection, EPA inspectors verified the following technical elements of INEEL's RTR process (see also Attachment A.4):

<u>P.66</u>

- 1) The system is designed to resolve a 2-2T hole in a steel block.
- 2) RTR is recorded on audio/video tape.
- 3) Start of shift operations are documented.
- 4) The daily image check is performed adequately.
- 5) Liquids are located and recorded.
- 6) Container contents (detailed inventory) are adequately described on audio recordings and in written records, including an estimation of items' weights.
- 7) The fill height (percent full) and shape of the waste are recorded on audio and in written form.
- 8) The operator jogs the container to identify liquids.
- 9) The operator records parameter weights and matrix parameter category.
- 10) RTR results in both a audio/video recording and a written record of the examination.
- 11) Current copies of applicable procedures (e.g., WM-P1-82-021, INEL CH Stored TRU Waste Cert. Program, INEL-96/0280, and INEL/EXT-97-00105) are present and available to the RTR operator.
- 12) Independent replicate scans and replicate observations of the video output are conducted once per batch.
- 13) Periodic tape reviews are made by an independent RTR operator (1 in 10) and a supervisor.
- 14) Batch reports receive data generation level review and verification.
- 15) RTR operators are adequately trained.
- 16) Each operator periodically and adequately scans the training drum.

17) The test drum contains the required elements, packed at varying densities.

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18) A report comparing RTR and VE is prepared.

EPA randomly selected and reviewed batch data reports to verify that they contained all necessary technical information. EPA inspectors also observed RTR of waste drums and viewed videotapes of the waste drums identified in the selected batch reports (see Attachment A.4). As a result of the inspection, EPA inspectors identified no findings or concerns. EPA concluded that the elements of INEEL's RTR process that the inspection team examined, as identified in Attachment A.4, are technically adequate.

7.5 WIPP Waste Information System (WWIS) and Data Transfer

As part of the inspection, EPA reviewed the elements of INEEL's process for data transfer to the WWIS that are listed below. The checklist at Attachment A.5 identifies the objective evidence examined by EPA in these areas.

- WWIS data review and nonconformance identification
- WWIS input data/collection forms
- WWIS checklist data verification
- WWIS field population and edit/limit checks
- WWIS-WIPP data transfer and verification

During the inspection, EPA inspectors verified the following technical elements of INEEL's data transfer process (see also Attachment A.5):

- 1) Personnel performing data entry and verification are authorized to use the system and have adequate training.
- 2) The appropriate checklists were used for data input into the WWIS.

3) Data can be successfully transmitted to the WIPP.

EPA inspectors reviewed a batch file (970018) and drum file (022022), which compile all waste characterization information to be submitted to WIPP via the WWIS. The drum file contains the WWIS checklist that is used to input data manually into WWIS. These data are validated prior to completion of the checklist, and the information on the checklist is verified before data entry is approved. EPA found that the checklist contains all of the data elements required for submittal of characterization, certification, and shipment data to WIPP.

Data are verified during data entry. The verifier proofs all data for each screen before the data entry person moves to the next screen prior to submittal to WIPP for approval. EPA found the system to be adequate for entering data into the WWIS system prior to submittal to WIPP for approval.

EPA next observed a demonstration of data submittal for the characterization module to WIPP via the WWIS. The site successfully demonstrated that characterization data could be submitted to WIPP via the WWIS. The site had not yet submitted certification or shipment data to the WIPP for the following reason: the WWIS system includes the weight of waste packaging materials in the weight of the waste, which causes the weight of the drum to exceed limitations imposed by CAO. Site personnel stated that they were working with DOE CAO to address this issue with the WWIS system.

4) The Waste Container Data Report is compared to the data entry checklist.

EPA reviewed data packages used to track characterization data. Specifically, EPA reviewed a package for NDA and RTR (Batch report 970018). The report was complete and adequate to verify and validate generation level data used for input into the WWIS checklist.

5) The following documents are maintained:

- electronic e-mail notifications
- training roster and briefing materials
- WWIS checklists
- WWIS Access Request form
- WWIS Waste Container Data Report
- WWIS Shipment Summary Report.

As a result of the inspection, EPA inspectors identified the following concern:

• waste containers fail the weight limits established by CAO.

EPA does not require a response to this concern. DOE should communicate this concern to the site, and should reexamine the issue in future audits or inspections. EPA concluded that the elements of INEEL's WWIS process that the inspection team examined, as identified in Attachment A.5, are technically adequate.

8.0 **RESPONSE TO COMMENTS**

EPA received no comments from the public on items announced in the <u>Federal Register</u> on June 24, 1998.

9.0 SUMMARY OF RESULTS

The EPA inspection team concluded that the elements of INEEL's waste characterization program reviewed by inspectors were technically adequate. The inspection team identified one significant finding that was subsequently resolved and seven concerns. DOE should communicate these concerns to the site, and should reexamine the issues in future audits or inspections. P.69

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9.1 Findings

• The requirement to quantify and report ²³⁴U in Appendix WCL of the WIPP CCA was not clearly defined for sites by CAO. This finding was resolved by memoranda from CAO that (1) expressly identified ²³⁴U and other radionuclides that must be either quantified or justified as absent on the basis of acceptable knowledge information, and (2) identified evidence that INEEL has been evaluating waste drums for ²³⁴U and other required radioisotopes.

9.2 Concerns

- Procedure MCP-2988 inappropriately states that the Acceptable Knowledge Summary Document (INEL-96/0280) will not be updated as new acceptable knowledge information is acquired. This concern was resolved during the inspection when INEEL personnel revised Procedure MCP-2988 to remove the inappropriate statement occur.
- INEL 96/0280 includes 21 separate waste categories, but specifically how these categories were devised is not included in this document. Consequently, it is possible that these categories could be confused with waste streams.
- Procedure MCP-2989, Section 4.4.3 states that RTR and VE operators must be given AK information prior to RTR/VE analysis, but actual practice does not reflect this requirement.
- The use of the pulser for meeting the twice per shift performance check requirement may not be in conformance with the requirement of the TRU QAPP.
- Full drum height (percent full), bag weighing, core extrusion, and video equipment checks performed during visual examination were not recorded on videotape.
- Daily video check results were not included on visual examination forms.
- Waste containers fail the weight limits established by CAO for individual containers.

Attachment A.1 Acceptable Knowledge (AK) Checklist Idaho National Engineering and Environmental Laboratory July 28-30, 1998

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Question	Procedure Documented			Comment
	Location	Adequate? Y/N (Why)		(e.g., any change in procedures since last audit, etc.)
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Has the generator developed procedures whereby a logica sequence of acceptable knowledge information that progresses from general facility to more detailed waste stream-specific information can be acquired? Is AK documentation traceable to the drum level?	MCP 2989 Sec. 1	See Comment		See below Verification Items 6 and 7
QAPP, Section 4.3	QAPjP			
Does the site have sufficient procedures and processes to ensure that the Acceptable Knowledge process is adequately and consistently implemented?	MCP 2988, 2989 QAPjP, INEL 96/0280	Y		
QAPP, Section 4.2				
Does the generator site's TRU waste management program have procedures to determine: waste categorization schemes(e.g. consistent definitions of waste streams) and terminology; breakdown of the types and quantities of TRU waste generated/stored at the site; how waste is tracked and managed at the generator site (including historical and current operations?)	INEL 96/0280 MCP 2988, 2989	See Comment		See below Verification Items 1, 2, and
QAPP, Sections 4.2 and 4.3.1				
Do generator procedures ensure that acceptable knowledge information will be collected for: Arm ²⁴¹ , Pu ²³⁸ , Pu ²³⁹ , Pu ²⁴⁰ , Pu ²⁴² , U ²³³ , U ²³⁴ , U ²³⁸ , Sr ⁹⁰ , Cs ¹³⁷ + unexpected radionuclides ferrous metals (in containers) cellulosics, plastics, rubber nonferrous metals (in containers) 40 CFR §194:24(c)	eMCP 2989 p. 3, Sec. 3	Not sufficient; doesn't specify, but INEL 96/0280 collects sufficient info.		TECH-17 refs. EDF 840 (for unexpected radionuclide) Does not specify radionuclides However, INEL-96/9280 lists radionuclides. See below Verification Items 6 and 7.

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INEEL AK Checklist (Continued)

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Question	Procedure Documented		Comment			
	Location	Adequate? Y/N (Why)	(e.g., any change in procedures since last audit, etc.)			
ACCEPTABLE KNOWLEDGE PROCEDURES; GENERAL CONTENT REQUIREMENTS						
Are there AK procedures for: <u>Compliing</u> AK documentation into an auditable record; the process should include review of AK information to determine the waste material parameters and radionuclides present and source info discrepancy resolution. <u>Confirming</u> AK information with other analytical results. This will be done by comparing AK characterization data with that obtained through NDA, radiography, and/or visual examination, including discrepancy resolution. If data consistentl indicate discrepancies between NDA and radiographic/VE waste material parameter/radionuclide data, generator sites must reevaluate the processes that generate waste and modify it's acceptable knowledge characterization (o provide an explanation in it's AK record, available fo EPA inspector review). <u>Auditing</u> of AK records. QAPP, Section 4.2	r	See Comment	2989-2 states INEL-96/ 0280 is evidence of 2989 implementation; AK compilation via IDCs, for confirmatory analysis see below Verification Items 3, 4, and 5			

INEEL AK Checklist (Continued)

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	Procedure Documented		Comment	
Question	Location	Adequate? Y/N (Why)	(e.g., any change in procedures since last audit, etc.)	
 Do procedures indicate that: Acceptable knowledge information is compiled in an auditable record, including a road map for all applicable information. A reference list is provided that identifies documents databases, Quality Assurance protocols, and other sources of information that support the acceptable knowledge information. The overview of the facility and TRU waste management operations in the context of the facility mission is correlated to specific waste stream information. p.3 Correlations between waste streams, with regard to time of generation, waste generating processes, and site-specific facilities shall be clearly described. For newly generated wastes, the rate and quantity of waste to be generated shall be defined. Segnegation of nonconforming waste RCRA-16 INEL procedure? QAPP Sec. 4.4.2 	S	See Comment	2989-3 refers to AK Source document review summary forms, which documen individual elements examined. 2989-6-id's roadmap as INEL-96/0280. NOTE: Roadmap only applies to RFETS waste. See below Verification Item 1.	

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INEEL AK Checklist (Continued)

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	Procedure ['] Documented			Comment
Question	Location	Adequate? Y/N (Why)		(e.g., any change in procedures since last audit, etc.)
Do procedures indicate that the following information will be included in the acceptable knowledge record. Map of the site with the areas and facilities involved in TRU waste generation, treatment, and storage identified	QAPjP Sec., 4.3; MCP-2989 p. 3	Υ.		2989-1 references 0280 <u>and</u> INEL-96-0345 (site cert. plan) INEL-96/0280 includes RFETS- specific information. Does not apply to non- RFETS waste at INEEL.
 Facility mission description as related to TRU waste generation and management (e.g., nuclear weapons research may involve metallurgy, radiochemistry, ar nuclear physics operations that result in specific waste streams) 	đ			
 Description of the operations that generate TRU waste at the site (e.g., plutonium recovery, weapons design, or weapons fabrication), including a description of the waste generating processes. Doe the process RCRA-20 (process flow diagram only) information include. 	S			
Area(s) and building(s) from which the waste stream was or is generated Waste stream volume and time period of generation (e.g., 100 standard waste boxes of retrievable stored waste				
generated from June 1977 through December 1977) Waste generating process described for each building (e.g., batch waste stream generated during decommissioning				
operations of glove boxes) Process flow diagrams (e.g., a diagram illustrating glove boxes from a specific building to a size reduction facility to a container storage area)				
Material inputs or other information that identifies the chemical and radionuclide content of the waste stream and the physical waste form (e.g., glove box materials, chemicals and radionuclides				
handled during glove box operations, if applicable)		·		

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	Procedure	e Documented	Comment
Question	Location	Adequate? Y/N (Why)	(e.g., any change in procedures since last audit, etc.)
 Types and quantities of TRU waste generated, including historical generation through future projections Correlation of waste streams generated from the same building and process, as appropriate (e.g., sludge, combustibles, metals, and glass) QAPP, Sections 4.3.1, 4.3.2 	As above		
 Do procedures commit to collect the following supplemental information, as available? Process design documents (e.g., Title II Design) Standard operating procedures that may include a list of raw materials or reagents, a description of the process or experiment generating the waste, and a description of wastes generated and how the wastes are managed at the point of generation Preliminary and final safety analysis reports and technical safety requirements Waste packaging logs Test plans or research project reports that describe reagents and other raw materials used in experiments Site databases (e.g., chemical inventory database for Superfund Amendments and Reauthorization Act Title III requirements) Information from site personnel (e.g., documented interviews) Standard industry documents (e.g., vendor information) 	Soc 433	See Comment	CAO TECH-11 requires all "reasonable sources" to be examined this would include supplemental information. Not required in QAPP.
 Previous analytical data relevant to the waste stream including results from fingerprint analyses, spot checks, or routine verification sampling Material Safety Data Sheets, product labels, or other product package information Sampling and analysis data from comparable or surrogate waste streams (e.g., equivalent nonradioactive materials) Laboratory notebooks that detail the research processes and raw materials used in an experiment QAPP; Section 4.3.3 		· .	

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	Procedure	bocumented	Comment
Question	Location	Adequate? Y/N (Why)	(e.g., any change in procedures since last audit, etc.)
Do procedures indicate that radiography or visual examination and NDA information used to confirm the matr parameter category and waste material parameters identifie using AK? QAPP, Section 4.2.2.1		Y	Confirmation is done. See below Verification (tem 4
Do site documents/procedures confirm that the facility will provide a summary to DOE-that summarizes all information collected, <u>including basis and rationale for all waste stream</u> <u>designations?</u> Is an example of this <u>summary available for</u> <u>EPA review?</u> OAPP, Section 4.5	in MCP-2988,	See Comment	RCRA-12 references INEL-96/0345 and MCP-2842 2989-4 states info is in a "single document" -INEL-96/0280 -A. See below Verification Item 2.
Do site procedures indicate that if the required AK information is not available for a retrievably stored waste stream, additional information will be collected before waste can be shipped? QAPP, Section 4.3	-Not in QAPjP - Fig. 1 MCP 2989	See Comment	AK info available for all waste included inspected procedures (ie. Rocky Flats waste only)

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	Procedure	e Documented	Comment
Question	Location	Adequate? Y/N (Why)	(e.g., any change in procedures since last audit, etc.)
	SPECIFIC	PROCEDURES	
 Have the following procedures been prepared: Procedure(s) to <u>assemble</u> acceptable knowledge records, including the origin of the documentation, how it will be used, and any limitations associated with the information (e.g., identify the purpose and scope of a study that included limited sampling and analysis data Appendix B- no limitations noted). Procedure(s) to <u>compile</u> the required acceptable knowledge record. The procedure must describe the sites must assemble and evaluate available documentation in the following priority: Section 4.1 2989 a) relevant information from published documents and controlled databases, b) unpublished documents and controlled databases, b) unpublished documents and controlled waste. Procedure(s) for <u>defining and consistently assigning</u> a waste stream and for assigning a Waste Matrix Code to waste streams Procedure(s) to <u>identify the physical form</u> (i.e. summary waste category group) of the waste Procedure(s) for <u>determining waste material parameters</u> (i.e., physical waste form and properties present in a waste stream Where are these exactly 4.4.3 - but very general. Specify sources etc. Procedure(s) to determine radionuclides present 	d 1.	See Comment	See below Verification Items 2, 3, 4 and 8.

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	Procedure	Documented	Comme	
Question	Location	Adequate? Y/N (Why)	(e.g., any change in since last au	
 Procedure(s) for resolving discrepancies in acceptable knowledge documentation. Also to resolve discrepancies between AK and VE/RTR and NDA results, and to confirm AK information with radionuclide and waste material parameter results. Do procedures state that if data consistently indicate discrepancies between NDA/radiographic/VE waste material parameter and radionuclide analytical data and that acquired through AK, generator sites will reevaluate the processes that generate waste and modify it's AK characterization Procedure(s) describing management controls used to ensure nonconforming items are identified and managed 2988 4.3; need to see MCP-2530, 2536 QAPP; Sections 4.2, 4.4.5 		As Above	As Above	
CONFIRMATIO	N OF ACCEPTABL	E KNOWLEDGE & I	RE-EVALUATION	
destructive examination, and/or visual examination? Are these procedures developed for both retrievably stored and newly generated waste? Do these procedures include reevaluating acceptable knowledge if radiography or NDA visual examination identify it to be a different waste matrix codes? Does this procedure cescribe how the waste is reassigned, acceptable knowledge reevaluation?	Sec. 4.2, 2988 Sec. 22. MCP 2536	See Comment	Reconciliation was fou unsatisfactory. by DOI QAPP TECH-8, TECH-9 Confirmatory procedur below Verification Item	E in 1/98 audit es in 2546: See
QAPP, Section 4.4.5				
Does the generator site have written procedures to document the confirmation of acceptable knowledge information with visual examination prior to or during waste packaging for newly generated waste or retrievably stored waste that is repackaged? QAPP: Section 4.2.2.1	N/A			

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	Procedure D	Jocumented		Comment
Question	Location	Adequate? Y/N (Why)		(e.g., any change in procedures since last audit, etc.)
 Do site procedures ensure that the following steps are followed if wastes are reassigned to a different waste matrix code based on visual examination or radiography: Review existing information based on the container identification number and document all differences it hazardous waste code assignments Reassess and document all analytical data associated with the waste Reevaluate waste material parameter determination and document any changes Reevaluate the radionuclide content and document any changes Verify and document that the reassigned waste matrix code was generated within the specified time period, area and buildings, waste generating process, and that the process material inputs are consistent with the waste material parameters identified during radiography or visual examination Record all changes to acceptable knowledge record if discrepancies exist in the acceptable knowledge information for the reassigned waste matrix code, complete a nonconformance report, document the segregation of this container, and define the corrective actions necessary to fully characterize the waste 	4.4.5 of QAPjP	See Comment		See below Verification Items 4 and 8
	SHIPMENT	EXCLUSIONS		· .
Has a waste stream been revoked based on acceptable knowledge information or reassessment as part of reconfirmation? Are there procedures in place for shipmer revocation and do these include notification procedures for when a container is revoked? QAPP, Section 4.5	N/A t			
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	· · · · · · · · · · · · · · · · · · ·		Procedure	Docum	ented		Commo (e.g., any change i	
	Que	estion	Location		equate? N (Why)		since last au	
knowledge inform reassessed the m waste, and resubr Until discreparicie	ation; has aterials an nitted was s are resol P is prohit	discrepancies with acceptable the site increased sampling, d processes that generate the te stream profile information? lve, shipment of the waste bited as per the QAPP.	N/A	See C	omment		Packaging configuration examined in verification increased sampling no because site is not at below Verification Item	on inspection; ot performed this point yet. See
			<u></u>	VERIFIC				<u>- 1991 - 1991 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 199</u>
Item No.		Characteris	tic(s)			Objective Evic	lence	EPA Determination
1	Ve de de	erify that the definition of IDCs aste streams is documented an erify that a technically adequate efine the approximately 21 cate escribe the waste in the AK Sur 5/0280)	nd technically approp e process was utilize gories of waste use	priate ed to d to	IDCs may t a/b or differ and 320a/b material for material for Example: E 922 reg. gro BIR# in tab of ID in BIR waste strea Waste grou concern ex equivalent	ent superscripts; eg · IDC definition is g ms; waste streams m :DF-922 Table A-1. puping IDCs. Table le A-1 = BIR-ID = IN .) Can therefore tra ims and waste mate upings logical but no pressed to clarify th	are not by nuclear Waste stream on p 1= waste streams. I - WXXV.XXC (portion ice A-1 to BIR for erial parameters. It well documented - at groupings are not roupings intended to	Satisfactory Concern
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Item No.	Characteristic(s)	Objective Evidence	EPA Determination			
3	Verify that a link exists between the defined IDCs and the Waste Material Parameters.	Waste stream summary includes current ranges of WMPs based on elements, historic analysis. Periodically update, but do not link to BIR WMPs; however, this can be done easily using EDF- 922. Table A-1.	Satisfactory			
4	Verify that a process exists for INEEL to update the AK Summary in the event that discrepancies are found during confirmatory testing (note: MCP-2988 indicates that the AK Summary Report will not be revised).	Concern expressed that updating of INEL 96-0280 would not be done. Have agreed to change the text o the procedure to remove sentence in question MCP-2988 presents process.	Concern, corrected during inspection.			
5	Verify that a technically appropriate process has been implemented to provide the waste material parameters to the operators performing RTR, VE and data validation (MCP- 2989 4.4.3).	Section A.2 of 4 4.3 MCP-2989 does not reflect actual practice; sharing of AK information with RTR operator prior to Radiography is not done, as stated in procedure. Inconsistency not significant at this time.	Concern			
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Item No.	Characteristic(s)	Objective Evidence	EPA Determination				
6	Verify that the Acceptable Knowledge Source Document Review Summary contains all of the necessary information and is traceable to the source (MCP-2989 4.2.1)	Examined References C090 and P112 (from INEL- 96/0280). References continue the same summary data presented in Appendix A of 0280; document contents were traceable to the source	EPA's Determination: Satisfactory				
7	Verify that technical traceability exists for the graphite waste stream from the Waste Stream Profile Form to the Source Documents.	Traceability analysis for containers RF 001210876. RF 001210371; possible to trace from container back to WSDF to source documents to determine WMPs and radionuclides	Satisfactory				
8	Verify that a current listing of drums processed through SWEPP is being maintained, and the percent changes in the MPSs are being calculated and are technically acceptable (MCP-2988 Appendix E).	EXCEL spreadsheet in FOXPRO that maintains the drum information. Reviewed spreadsheet that records Drum number, barcode, IDC, MPS change, and Haz. waste number change. Percent changes in MPS - there is a field that presents the required MCP, etc.	Satisfactory				
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Attachment A.2 NDA Checklist Idaho National Engineering and Environmental Laboratory July 28-30, 1998

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Procedure I	Documented		Comment (e.g. any change in procedures
Location	Adequate? <u>Y/N (Why)</u>		since last audit, etc.)
PDP PROGRAM			
▶ N/A,			no NDA subcontractors
·			
QAPjP 2.2	Y		
QAPjP section 2.3	Y		
QAPjP section 2 .3	Y		Scoring report for passing cycle 4, verbal from INEEL that SWEPP passed cycles 1-3
	Location <u>PDP PROGRAM</u> p N/A, QAPjP 2.2 QAPjP section 2.3 QAPjP section 2	PDP PROGRAM PARTICIPATION PDP PROGRAM PARTICIPATION N/A, QAPjP 2.2 Y QAPjP section Y QAPjP section 2 Y	Location Adequate? Y/N (Why) PDP PROGRAM PARTICIPATION PN/A, QAPjP 2.2 Y QAPjP section 2.3 QAPjP section 2

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Question	Procedure (Documented	Comment (e.g. any change in procedures
	Location	Adequate? Y/N (Wby)	since last audit, etc.)
	DATA H		
 Raw test data meet the following requirements: signed and dated by the person generating data recorded clearly and legibly in field or lab records, including sample id numbers all changes to data are lined out and initialed, dated by changer, and include justification for change data is transferred and reduced from field or lab records completely and accurately field and lab records are maintained in permanent files electronic and video data must be stored such that the container, sample, and any QC data are readily available 	NDA Drum Data report for drum RF001211254	Y	
QAPP. Section 3.1			
100% data receives a technical review performed by qualified independent personnel	TPR-1726 4.4	Y	
QAPP, Section 3.1			
Technical reviews of data include the subjects in Section 3.1.1 of QAPP	EDF-840, Rev.1, all	Y	
QAPP, Section 3.1			
Documents verifying compliance with Table 9-1 QAO's calculate precision and accuracy using QAPP equations 3 2 and 3-3 (precision), and 3-5 (accuracy). See also QAPP 9,6 QAPP. Section 3.2		Y	
Site project manager performs data reconciliation prior to data being transmitted by the WWIS to WIDD for shipment certification	N/A		By WWIS Inspection
QAPP, Section 3.3			

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Question	Procedure I	, Documented		Comment (e.g. any change in procedures		
	Location	Adequate? Y/N (Why)		since last audit, etc.)		
WWIS data entry procedure accounts for all radionuclides identified on the radioassay results data sheets (not limited to Pu alone)				By WWIS Inspection		
QAPP, Section 3.4						
The WWIS client includes fields for all data listed in QAPP Table 3-2, (first 6 report elements), and has the ability to handle multiple other radionuclides	N/A			By WWIS Inspection		
QAPP, Section 3.4						
ACCEPTABLE KNOWLEDGE USAGE AND COMPLETENESS						
Is acceptable knowledge (AK) being used to identify the waste stream parameters and radionuclides present? QAPP, Section 4.2	EDF-924 Rev 3, INEL 96/0280	Y				
The NDA process relies on AK to determine which radionuclides are present in the waste stream QAPP, Section 4.2	Interview w/ G Twedell of RWMC	Y		INEEL relies on AK to determine isotopic ratios.		
A process has been implemented to confirm the radionuclide content from acceptable knowledge using the results of the radioassay	EDF-840, MCP- 2988	Y		INEEL assumes default isotopics for PU as supported by AK		
QAPP, Section 4.2						
Procedures exist for handling packages for which NDA does not confirm the acceptable knowledge	EDF-840, also NCR process; MCP-2988	Y				
QAPP, Section 4.2						
100% of waste containers are to undergo NDA	QAPjP 9.1	Y				
QAPP, Section 5.0	······					

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Question	Procedure	Documented	Comment (e.g. any change in proc	edures
	Location	Adequate? Y/N (Wby)	since last audit, etc	
	NDA F	ROCESS	· · · · · · · · · · · · · · · · · · ·	
All waste containers submitted :or NDA carry a unique identifier meeting QAPP Section 6.2.1	TPR-1573 4.6.2.3, 4.8.2.3, TPR 1588 4.9.2.4	Y	TPR 1726 4.2.5.1 also requi reports require id number be	
The NDA system provides for entry of the unique containe identifier into the analysis	TPR-1573 4.6.2.3, 4.8.2.3, TPR 1588 4.9.2.4	Y	Reports require id number be	e included
All printouts and data transfers from the NDA system include the unique identifier QAPP, Section 6.2	TPR-1573 TPR 1588 appendices	Y	Confirmed by observation of reports for drum RF RF0012	
The NDA methods report all of the following per container: Individual radionuclides & activity total alpha activity total TRU activity thermal power Pu-239 fissile grams equivalent	QAPjP 9.6, TPR 1573 and TPR 1588 auto reports	N	Finding to CAO for not trans requirement to INEEL to qua report specified radionuclide U-234	ntify and
QAPP, Section 9.0 The site has successfully demonstrated their NDA methods for applicability to the waste streams being certified QAPP, Section 9.1	EDF-924 Rev 3	Y	Verified by interviews and ob of NDA systems	oservation

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Question	Procedure	Documented	Comment (e.g. any change in procedures
	Location	Adequate? Y/N (Why)	since last audit, etc.)
 The site has technically justified that the NDA methods are appropriate for the specific characteristics of the waste streams, including: inhomogenous sources heterogenous shielding internal to the container for neutron assay methods, similar ranges of neutron moderation and absorption capability to detect unexpected isotopes which could cause interference with radioassay QAPP, Section 9.1 	EDF 843 Rev 2, EDF-973 Rev 1, SGRS Library	Y	Complete documentation of applicability of the methods to certain waste streams
 NDA precision and accuracy are calculated using the methods in QAPP Section 9.6, including: at least 15 replicate counts quantities of TRU isotopes for each range in QAPP Table 9-1 removal and reinsertion of the container between each count using a verification standard that is well characterized, but not a calibration standard QAPP, Section 9.1 	QAPjP 9.1	Y	
MDC calculations use QAPP equation 9-1, or have been shown to be equivalent for the specific NDA system, for any system being used to discriminate TRU from LLW	EDF-1035	Y .	MDC defined for inorganic sludges
QAPP, Section 9.1		ļ ļ_	
Total measurement uncertainty and bias have been calculated using the methods provided in QAPP Section 9-6, and evaluated by the DOE expert review team (pg 9-17 QAPP)	TWCP MCP- 2990 and 2991	Y	Good for Rocky Flats derived waste streams only
QAPP, Section 9.1			
NDA is only being performed using methods, procedures, software and systems which have been approved by CAO QAPP, Section 9.1	All PAN and SWEPP procedures	Y	

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Question	Procedure Documented			Comment (e.g. any change in procedures	
	Location	Adequate? Y/N (Wby)		since last audit, etc.)	
All NDA data is validated according to QAPP Sections 9.6 and 3.0 prior to shipment of the waste to WIPP QAPP, Section 9.1	QAPjP 9.6	Y		MCP's 1815, 2527, 2535, 2529, 2530, 2536,2537, 2538, 2539	
If multiple systems which generate the same or comparable are certified or being certified, procedures for performing intercomparability tests on samples of containers have been developed QAPP, Section 9.1	QAPjP 9.3	Y		Only one system for gamma, one for neutron	
 Assay procedures reference one of the following: ASTM C1030-89 for PU determination using gamma-ray spectroscopy ASTM C1133-89 NDA of SNM using segmented passive gamma scanning ASTM C1207-91 NDA of Pu in scrap and waste using passive neutron coincident counting ASTM C1221-92 NDA of SNM in homogenous solutions using gamma-ray spectroscopy NRC Reg Guide 5.11, NDA of SNM in scrap and waste QAPP, Section 9.2 	QAPjP 9.4	Y	- -		
NDA SOPs require performance and background checks prior to assaying containers QAPP, Section 9.2 Background and performance checks are performed regularly, even during ongoing testing QAPP, Section 9.2	TPR-1588 4.9.1.1, TPR 1573 4.6.1, 4.8.1 TPR 1726 4.1.4, 4.1.7	Y Y			
Procedures for performance and background checks include specific quantified acceptance criteria and remedial actions QAPP, Section 9.2	TPR-1726 throughout	Y			

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Question	Procedure	Documented	Comment (e.g. any change in procedures
-	Location	Adequate? _ <u>Y/N (Why)</u>	since last audit, etc.)
Assay procedures prohibit NDA activities unless a system meets all acceptance criteria from the performance and background checks	TPR-1726	Y	
QAPP, Section 9.2			
Assay procedures require re-testing or justification of use of any containers which were tested while the system could not be shown to meet all required acceptance criteri or control checks	TPR 1726 4.2.7	Y	NCR process provides thorough review
QAPP, Section 9.2			
SOPs include detailed instructions for the operation (and limitations of operation) of computerized data acquisition systems, including required I/O	TPR 1726, 1573, 1588, QTP 011 and 004	Y	
QAPP, Section 9.2	···		
SOPs for NDA have been developed, approved, and updated in accordance with the controlling site QA plan	QAPjP 1.9.1	Y	Best detailed set of procedures seen to date at a generator site
QAPP, Section 9.2			
The QC activities applied to NDA activities are controlled by the facility QA plan	QAPjP 9.3	Y	
QAPP, Section 9.3			
Performance of SOPs and QC testing is monitored by the facility QA officer (look for source of QA authority to audit WC activities, set stop work orders; also see if regular audits have been done)	TPR-1726 throughout	Y	QA signatures both during and after procedure actions
QAPP, Section 9.3			
Non-conformance reports are initiated for any case where QC tests do not meet acceptance criteria	TPR-1726	Y	Verified by reviewing Operability Evaluation for SWEPP NCR EO 35
QAPP, Section 9.3			
The facility QA plan specifies that the QA officer and technical supervisor are responsible for implementing corrective action when acceptance criteria are not met	QAPjP 9.3	Y	
QAPP, Section 9.3			

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Question	Procedure	ocumented	Comment (e.g. any change in procedures
• 	Location	Adequate? Y/N (Why)	since last audit, etc.)
Statistical control charts, which monitor system repeatability for key parameters, are developed and maintained for each system	TPR-1573 and TPR 1588	Y	
QAPP, Section 9.3			
Statistical control charts include preset control limits, and are procedurally required to be updated at regular intervals by replicate testing	TPR-1573 and TPR 1588	Υ.	
QAPP, Section 9.3			
Replicate counts are performed at least every 20 containers or once per shift, whichever is more frequent	TPR-1726 4.2.7	Y	
QAPP, Section 9.3			
Routine instrument performance checks include measures of:	TPR 1588 and TPR 1573	Y	
 instrument efficiency as a function of energy and geometry background under circumstances similar to those existing during assay tests energy resolution for gamma systems energy calibration for gamma systems 			
QAPP, Section 9.3			
Instrument check procedures include accounting for changes in check sources over time	SWEPP Assay System software	Y	Probably done in software but not noted in the procedure
QAPP, Section 9.3			
Results of performance checks are logged, tracked, and controlled in accordance with QA procedures	TPR 1588 and TPR 1573	Y	Unclear how results are controlled stored, procedure section 6 implies logbooks. QA records not defined.
QAPP, Section 9.3			
Performance checks other than background are performed at least twice per shift	TPR 1726 4.1	Y, conditional; see comment	Concern over use of pulser and one per week check by radioactive source
QAPP, Section 9.3		L	

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Question	Procedure I	Documented	Comment (e.g. any change in procedures
	Location	Adequate? Y/N (Why)	since last audit, etc.)
NDA system operators have been trained and certified for the systems on which they are performing testing QAPP, Section 9.3	QAPjP 2 and 9.3, TPR 1726 3.2	Y	
NDA operators are re-qualified at least every two years	QAPjP 9.3	Y	
QAPP, Section 9.3 Calibration and maintenance programs for the NDA systems are controlled by procedures and spelled out in the site QAPjP	QAPjP 9.4, 9.5, TPR-1719	Y	 <u> </u>
QAPP, Section 9.4 NDA systems are calibrated for the specific analysis of interest	TPR-1719, EDF- 973 Rev 1	Y	
QAPP, Section 9.5 Calibration is performed over the ranges of parameters being measured, including: neutron moderating and absorbing parameters radiation of interest expected background signals energy geometry signal strength / count rate	MCP-2990 and EDF-924, EDF- 973	Y	
QAPP, Section 9.5 Calibration standards are traceable to NIST QAPP, Section 9.5	QAPjP 9.5, maybe EDF- RWMC-973?	Y	
Requirements for re-calibration are procedurally defined	QAPjP 9.5	Y	
QAPP, Section 9.5			
Records of calibration and calibration standards are maintained as QA records	TPR 1719	Y	
QAPP, Section 9.5			

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Question	Procedure	Documented		Comment (e.g. any change in procedures
	Location	Adequate? <u>Y/N (Why)</u>		since last audit, etc.)
Assay measurements falling outside the range of calibration applicability are required to be re-performed	EDF-840 Rev 1	Y		Verified by G. Twedell interview
QAPP, Section 9.5	<u></u>		-	
Calibrations include the determination of any required algorithmic correction factors in the system software	1719 4.2.1	Y		
QAPP, Section 9.5				
Data reduction performed by software is independently verified by qualified personnel	QAPjP 9.5	Y		Done as part of SQA program,
QAPP, Section 9.6				
Data reduction software is subject to QA controls and requirements for software traceable to ASME NQA 2.7	QAPjP 9.5	Y		Part of SQA program,
QAPP, Section 9.6				
NDA facilities maintain all raw data necessary to regenerate calculations as necessary	TPR1726, 4.3	Y		
QAPP, Section 9.6				
NDA test results are reported to the site project office on a test batch basis	QAPjP 9.6	Y		
QAPP, Section 9.6				
Test batch reports meet the requirements of QAPP, Section 9.6	QAPjP 9.6	Y		
QAPP, Section 9.6		Ì		
Contract testing facilities are providing all data specified in QAPP Section 9.6 to the site project office	N/A .			No contract testing facilities at INEEL
QAPP, Section 9.6				

Attachment A.3 Visual Examination (VE) Checklist Idaho National Engineering and Environmental Laboratory July 28-30, 1998

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	Procedure D	ocumented		Comment			
Question	Location	Adequate Y/N (Why)		(e.g. any change in procedures since last audit, etc)			
REQUIRED TECHNICAL ELEMENTS							
Does the site use the data from visual examination to check the matrix parameter category and waste material parameter weight estimates as determined by radiography? QAPP Section 5, pg. 18 of 27	HFEF-OI-6890. Appendix B	Y					
Does the site use the data obtained from the visual examination to determine, with acceptable confidence, the percentage of miscertified waste containers? QAPP Section 5, pg. 18 of 27	EDF-RWMC-363, page 4/45	Y		Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist.			
For the first year of operation, did the site use INEL's historical miscertification rate of 2% to calculate the number of waste containers that must be visually examined during the first year of program activities? QAPP Section 5, pg. 18 of 27	EDF-RWMC-363, page 4/45	Y		Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist			
Has the site established a site-specific miscertification rate? Is the site's revised miscertification rate based on the last 12 (or more) months of certification activities? QAPP Section 5, pg. 18 of 27	EDF-RWMC-363, Table 2; page 40/45; and MCP- 2546, Sect. 4, page 1/5	Y		Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist.			
Table 5-1, page 19 of 27 presents the number of waste containers requiring visual examination by miscertification rate and annual number of waste containers undergoing characterization. Is the annual number of waste containers undergoing characterization within the range used in the table (50 to 500)? Is the miscertification rate within the range presented in the table (1% to 6%)? QAPP Section 5, pg. 19 of 27	EDF-RWMC-363, Table 4, page 35/45	Y		Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist.			

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	Procedure Documented			Comment
Question	Location_	Adequate Y/N (Why)		(e.g. any change in procedures since last audit, etc)
Were waste containers randomly selected and examined? Were only waste containers certified for compliance with WIPP-WAC and TRAMPAC selected?	EDF-RWMC-363, page 40/45	Y		Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist.
QAPP Section 5, pg. 20 of 27				
Is there a definable finite population of waste containers for which the proportion miscertification rate was based or (e.g., 200 drums)?	EDF-RWMC-363, page 4/45	Y		Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist.
QAPP Section 5, pg. 20 of 27				Verified during inspection (~2500 drums in FY98).
What period of time was the miscertification rate based on? If less than 12 months of operating data were available, was the historical miscertification rate of 2% used?	EDF-RWMC-363, pages 1/45 and 3/45	Y		Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist.
QAPP Section 5, pg. 20 of 27				
Does the facility have a procedure for randomly selecting waste containers? QAPP Section 5, pg. 20 of 27	EDF-RWMC-363, page 3/45, and Appendix A	Y		Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist.
Does the facility have a replacement strategy for selecting waste containers? Was the replacement visual examination performed on the sampled containers? QAPP Section 5, pg. 20 of 27	EDF-RWMC-363, page 6/45; and Appendix A; and MCP 2546	Y		Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist.
Was the replacement strategy restricted to a waste strean or waste stream lot that, through the random selection process, happened to have container(s) identified for visual examination?	EDF-RWMC-363, page 6/45	Y		Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist.
QAPP Section 5, pg. 20 of 27				
If fewer containers were visually examined than were sampled, were the replacements selected randomly from the population of sampled containers? Were the replacement containers from a different lot?	EDF-RWMC-363, page 40/45	Y		Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist.
QAPP Section 5, pg. 20 of 27				

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	Procedure D	ocumented	Comment	
Question	Location	Adequate Y/N (Why)	(e.g. any change in procedures since last audit, etc)	
Once containers have been visually examined, was the UCL ₁₀ for the proportion miscertified calculated? QAPP Section 5, pg. 21 of 27	MCP 2546, Section 4.5, page 3/5	Y	Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist.	
Did the site take precautions to ensure that corrective actions taken after the containers were visually examined to improve certification accuracy were not used to adjust the visual examination results and the UCL ₉₀ ? QAPP Section 5, pg. 21 of 27	EDF-RWMC-363, Table 2	Y	Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist.	
Did the facility use the hypergeometric distribution for the UCL _{so} calculation? The normal distribution is not allowed. If the binomial distribution was used, was <i>N</i> larger than 500 waste containers? QAPP Section 5, pg. 21 of 27	EDF-RWMC-363, pages 36/45 - 38/45	Y	Part of DOE/CAO's audit of Section 5 of INEEL's QAPP sampling Checklist.	
Are the results of the visual examination forwarded to the radiography facility? QAPP Section 10, pg. 6 of 11	MCP 2529, Appendix H, page H1	Y		
Was the visual examination based on a semi-quantitative and/or qualitative evaluation of the waste container contents? Was the examination recorded on audio/videotape? QAPP Section 10, pg. 6 of 11	HFEF-OI-6890, Section 5.3, page 3/19, and Appendix B	Y		
Has the visual examination expert decided the extent of waste segregation necessary to achieve program objectives? QAPP Section 10, pg. 7 of 11	HFEF-OI-6890, Section 8.2.3, page 8/19	Y		

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	Procedure De	ocumented	Comment
Question	Location	Adequate Y/N (Why)	(e.g. any change in procedures since last audit, etc)
Does the site's QAPjP specify decision-making criteria for the visual examination expert to follow when determining the appropriate degrees of segregation? Does the site have SOPs to support the visual examination process? How does the visual examination expert document the basis for his/her decision?	HFEF-OI-6890, Section 8.2.3, page 8/19, and QAPjP Section 10.3	Y	
QAPP Section 10, pg: 9 of 11			
Does the visual inspector record the description of the waste container contents on any form? Does the description clearly identify the appropriate matrix parameter categories listed in the BIR? Is the information sufficient to estimate weights of waste material parameters?	HFEF-OI-6890, Appendix B	Y	Verified use of glove box aids during inspection.
QAPP Section 10, pg. 9 of 11			
If the bags are not opened, is a brief written description of the contents of the bags prepared to document the estimated amounts of each waste type in the bags?	HFEF-OI-6890, Section 8.2.3, page 8/19	Y	
QAPP Section 10, pg. 9 of 11			
Are the written records of visual examination supplemented with the audio/video recording?	HFEF-OI-6890, Sections 5.3 and 8.2.3, page 9/19	Y	
QAPP Section 10, pg. 9 of 11	0.2.0, page 5/15		
Does the site have a site-specific SOP for conducting visual examinations?	HFEF-OI-6890	Y	
Methods Manual-96, P-310.2, pg. 310.2-1			
How does the site define testing batch? Does the testing batch have less than 20 waste containers? If so, is it possible for the site to examine the number of waste containers in one day?	QAPjP Glossary and Facility Implementation Plan	Y	
Methods Manual-96, P-310.2, pg. 310.2-1		<u>_</u>	

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	Procedure De	ocumented	 Comment	
Question _	Location	Adequate Y/N (Why)	(e.g. any change in procedures since last audit, etc)	
If the site visually examines a waste container that has no undergone radiography, were the results of the visual examination placed in a separate visual examination report?	I NA	-	INEEL does not open any container prior to conducting RTR.	
Methods Manual-96, P-310.2, pg. 310.2-1				
Does the site have a SOP for handling instances when the inspector is unable to see through the inner plastic bags/packages of waste because of discoloration, grease and dust adhering to the interior surface of the bags/packages or because of sealed and taped containers within the bags/packages? Does the facility use documented acceptable knowledge to identify the matrix parameter category and estimate waste material parameter weights?	Sections 5.5, page 3/19 and 8.2.3, page 8/19, and Glove Box Aids	Y		
Methods Manual-96, P-310.2, pg. 310.2-1				
Does the visual examination expert have decision-making criteria for assessing the need to open the bags/packages in order to identify all of their contents?		Y		
Methods Manual-96, P-310.2, pg. 310.2-3				
Was the weight estimates based on the best possible values?	HFEF-OI-6890, Section 8.2.3, page 9/19	Y		
Methods Manual-96, P-310.2, pg. 310.2-3			 	
Are visual examinations conducted in areas that have adequate radiation containment facilities? Does the visua examination area have the following equipment:	-	. N	no specific listing of required equipment.	
 Drum, waste bag, and waste handling equipment? Video cameras and audio equipment? Mass balances and calibration standards? Bag opening unit? Data input station? Safety equipment? 				
Methods Manual-96, P-310.2, pg. 310.2-3				

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	Procedure D	ocumented	Comment
Question	Location	Adequate Y/N (Why)	(e.g. any change in procedures since last audit, etc)
Does the site follow all the waste container handling and chain-of-custody procedures described in Section 6.0 of the QAPP? Methods Manual-96, P-310.2, pg. 310.2-3	NA	-	CAO deleted requirement for chain- of-custody procedures on drums while they are undergoing characterization at the site.
Prior to starting the visual examination, did the visual examination expert review all documented data related to the waste container and its contents? If the visual examination expert determined in advance to open all bags/packages in a waste container of a particular TRUCON code, matrix parameter category, and/or IDC, was this decision based on documented acceptable knowledge or data from previous examinations of the waste? Did the visual examination expert document the basis for these decisions?	HFEF-OI-6890, Section 8.1.1, pages 4/19 and 5/19	¥	
Methods Manual-96, P-310.2, pg. 310.2-3			
Are there SOPs for ensuring that headspace gas sampling is conducted prior to the visual examination team's opening of the waste container?	HFEF-OI-6890, Section 8.1.1, page 4/19	Y	
Methods Manual-96, P-310.2, pg. 310.2-3			 ·
Once the lid of the waste container is removed, does the visual examination expert estimate the waste container volume utilization percentage? Methods Manual-96, P-310.2, pg. 310.2-4	HFEF-OI-6890, Section 8.2.1, page 7/19, and Appendix B	Y	
Are the number of liners and types of liners present in the waste container documented? Are the individual inner bags/packages, if present, removed from the poly liner(s)? Are all of the inner bag/packages labeled and weighed using a properly calibrated mass balance?	Sections 8.2.2/3,	- Y	
Methods Manual-96, P-310.2, pg. 310.2-4			
Is the video camera properly focused prior to the start of the visual examination of an unopened inner bag/package Is the operator's verbal description of the inner bag/package's inventory recorded?	HFEF-OI-6890, ? Section 8.1.3, page 5/19, and Appendix B	Y	
Methods Manual-96, P-310.2, pg. 310.2-4			

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	Procedure Do	ocumented	Comment
Question _	Location	Adequate Y/N (Why)	 (e.g. any change in procedures since last audit, etc)
Does the inventory include a description of all waste items residual materials, packaging materials, and/or waste material parameters contained in the inner bag/package?	, HFEF-OI-6890, Section 8.2.3, pages 8/19-11/19	Y	
Methods Manual-96, P-310.2, pg. 310.2-4			
Are the estimates of the weights of the waste items, residual materials, packaging materials and/or waste material parameters recorded on both audiotape and the visual examination data form?	HFEF-OI-6890, Section 8.2.3, pages 8/19-11/19	· Y	
Methods Manual-96, P-310.2, pg. 310.2-4			
Has the site developed reference tables to assist the operators in making weight estimates and for assigning waste to a particular wast material parameter? Does the site have a procedure for updating these reference tables as the site gains experience in conducting visual examinations?	HFEF-OI-6890, Section 5.5 and Glove Box Aid	Y	INEEL does not have a procedure for updating reference tables
Methods Manual-96, P-310.2, pg. 310.2-4			
Does the visual examination expert assess the accuracy of the TRUCON code, matrix parameter category, and/or IDC? Does the visual examination expert recommend changes? If so, are they documented?	f MCP-2546, Appendix B	Y .	
Methods Manual-96, P-310.2, pg. 310.2-4			
If it is determined that the inner bag/package needs to be opened, are all of their contents sorted, weighed, and recorded? Is an inventory of loose waste items, residual materials, packaging materials, and/or waste material parameters not contained in inner bags/packages also recorded, sorted, and weighed?	HFEF-OI-6890, Sections 5.5 page 3/19 and 8.2.3, page 9/19	Y	
Methods Manual-96, P-310.2, pg. 310.2-4			
If liquids are found, is a description of their location, container, and estimated volume recorded?	HFEF-OI-6890, Section 8.2.3, page 9/19	Y	
Methods Manual-96, P-310.2, pg. 310.2-4			5

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	Procedure Documented			Comment
Question	Location	Adequate Y/N (Why)		(e.g. any change in procedures since last audit, etc)
Is the weight of the empty container and its rigid poly liner if present, recorded and documented? Is the gross weigh of the waste container (container plus contents) recorded on the visual examination data form? Is the total number of bags/packages also recorded on the data form? Methods Manual-96, P-310.2, pc. 310.2-4		Y	· •	
Has the site established standard nomenclature, based or current site practice, to assure that all operators recognize waste by the same descriptors? Methods Manual-96, P-310.2, pg. 310.2-4		Y		

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VERIFICATION ITEMS						
Item No.	Characteristic(s)	Objective Evidence Identified by EPA	EPA Determination			
1	Verify that the SPO VEE completes page 1 of the INEEL Visual Examination Plan and Decision Record for each container to be shipped for visual examination.	new data packages 023970; page 1 - SPO VEE, page 2 - ANL-W PM and VEE; and page 3 - Operator	Satisfactory			
	Section 4.1.					
2	Verify that the data generation level reporting, verification, and validation is performed by an independent VE, technical supervisor, and data generation level QA officer.	four data packages, including 005695.	Satisfactory			
3	Verify that visual examination container selection verification and substitution forms are completed.	completed VE container selection forms.	Satisfactory			
4	Verify that the visual examination operator records the fill height (percent full) prior to unloading the drum (Section 9.2.1).	drum 005695 verified on video; also drums 022238 and 007085 (not on video).	Concern: percent full not videotaped.			
5	Verify that each layer of confinement (bag) is weighed prior to opening and removing contents (Section 9.2.3).	No debris stream available for review; examined 005695 (N/A).	Concern: weighing not videotaped.			
6	Verify that operators use weight reference tables to estimate weight. Also verify that glove box aid is posted and updated as necessary.		Satisfactory			

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	VERIFICATION ITEMS						
Item No.	Characteristic(s)	Objective Evidence Identified by EPA	EPA Determination				
7	Verify that an evaluation of the accuracy of the TRUCON Code, matrix parameter category, and IDC (as appropriate) and make recommended changes if necessary.	Decision record. Old forms had description of waste recorded. New forms provide verification (INEEL TWP VE Plan and Decision Record - 023970)	Concern: core extrusion not videotaped.				
8	Verify that the location and amount of liquid is recorded.	SWEEP Cert. Log - new form, item #3, 022238.	Satisfactory				
9	Verify that the empty weight of the container and liners is determined and recorded.	Waste material parameter summary for all four drums reviewed and found complete.	Satisfactory				
10	Verify that the "decision making criteria" for the VE is documented in the operating procedure.	HFEF-OI-6890 - ANL-W Method Procedure - 2546 contains form RWMC. Verified for drums 023970 and 022238.	Satisfactory				
11	Verify that the video equipment resolution is checked daily.	Check reportedly is conducted by not captured on video. New data forms have space for entry of daily check being conducted (023970).	Concern: check is not videotaped. Also, daily video checks should be included on VE forms.				
12	Verify that ANL-W completes the INEEL Visual Examination Plan and decision Record as required.	Verified for 022238 and 023970.	Satisfactory				
13	Verify thru observation that all the necessary equipment is available and that exams are conducted in adequate radiatio control facilities. Also verify that glove box aids are posted.	Observed VE tapes that showed all necessary nequipment present and that VE was conducted in appropriate area.	Satisfactory				

Attachment A.4 Radiography (RTR) Checklist Idaho National Engineering and Environmental Laboratory July 28-30, 1998

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Question	Procedure [Documented	0
	Location	Adequate? Y/N (Why)	Comment (e.g., any change in procedures since last audit, etc.?)
	REQUIRED TECHN	ICAL ELEMENTS	
Does the site use RTR to determine the matrix parameter category and estimate waste material parameter weights of retrievably stored waste? QAPP Section 10, pg. 1 of 1	TPR-1572, Section 4.3.7.6, page 19/26, and Appendix D	Y	Operator is prompted by data entry screen in RTR room.
 Did the radiography system consist of the following: a shielded room that is properly ventilated and lighted? an X-ray producing device? (See #13 below.) an imaging system? (See #14 below.) an enclosure for radiation protection? a waste container handling system (including a turntable dolly assembly)? an audio/video recording system? safety interlocks? an operator control and data acquisition station? QAPP Section 10, pg. 2 of 11 	TPR-1522, Section 2, pages 4/15 - 11/15	Y	
Did the X-ray producing device have controls which allow the operator to vary voltage, thereby controlling image quality? Was it possible to vary the voltage, typically between 150-400 kV, to provide an optimum degree of penetration through the waste? Was high-density material examined with the X-ray device set on the maximum voltage? Was low-density material examined at lower voltage settings to improve contrast and image definition? QAPP Section 10, pg. 2 of 11	Section 4.3.7, page 18/26, and	Ŷ	
Did the imaging system typically utilize a fluorescent screen and a low light television camera? QAPP Section 10, pg. 2 of 11	TPR-1522, Section 2.2.6, pages 8/15 - 9/15	Y	Site uses a digital RTR that has a charged coupled device (CCD)

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Location	<u></u>		
	Adequate? Y/N (Why)		Comment (e.g., any change in procedures since last audit, etc.?)
TPR-1572, Section 4.5.7, page 18/26, and TPR-1522, Section 2.2.8, page 9/15	Y		
TPR-1572, Section 4.3.3, page 15/26	Y		
TPR-1726, Section 4.2, pages 15/21 - 17/21	Y		
TPR-1572, Appendix D	Y		
N/A			Site does not allow the use of variances.
	Section 4.5.7, page 18/26, and TPR-1522, Section 2.2.8, page 9/15 TPR-1572, Section 4.3.3, page 15/26 TPR-1726, Section 4.2, pages 15/21 - 17/21 TPR-1572, Appendix D	TPR-1572, Section 4.5.7, page 18/26, and TPR-1522, Section 2.2.8, page 9/15 Y TPR-1572, page 15/26 Y TPR-1726, Section 4.2, pages 15/21 - 17/21 Y TPR-1726, Section 4.2, pages 15/21 - 17/21 Y TPR-1572, Appendix D Y	TPR-1572, Section 4.5.7, page 18/26, and TPR-1522, Section 2.2.8, page 9/15 Y TPR-1572, Section 4.3.3, page 15/26 Y TPR-1726, Section 4.2, pages 15/21 - 17/21 Y TPR-1726, Section 4.2, pages 15/21 - 17/21 Y TPR-1572, Appendix D Y

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Question	Procedure I	Documented	
· · ·	Location	Adequate? Y/N (Why)	Comment (e.g., any change in procedures since last audit, etc.?)
Was the proper waste stream assignment determined, the correct hazardous waste codes assigned, and the resolution documented?	TPR-1572, Appendix D, page D2/D16	Y	
QAPP Section 10, pg.4 of 11	-		
Were the radiography operators instructed in the specific waste generating practices and typical packaging configurations expected to be found in each matrix paramete category at the site?	TPR-1726, page 18/21 r	Y	
QAPP Section 10, pg. 4 of 11			
Did the radiography test drum include items common to the waste streams generated/stored at the site? QAPP Section 10, pg. 5 of 11	-	N	
Was the test drum divided into layers with varying packing densities or were different drums used to represent different situations that may occur during radiography examination at the site?	-	Y	Site only has one drum; varying densities within the one drum confirmed during inspection.
QAPP Section 10, pg. 5 of 11			 ,
Did the radiography test drum include the following required elements:	-	N	
 Aerosol can with puncture? Horsetail bag? Pair of coveralls? Empty bottle? Irregular shaped pieces of wood? Empty one gallon paint can? Full container? Aerosol can with fluid? One gallon bottle with three tablespoons of fluid? One gallon bottle with one cup of fluid (upside down)? Leaded glove or leaded apron? Wrench? 			
QAPP Section 10, pg.5 of 11			

Question	Procedure I	Documented		
	Location	Adequate? Y/N (Why)		Comment (e.g., any change in procedures since last audit, etc.?)
Were independent replicate scans and replicate observations of the video output of the radiography process performed under uniform conditions and procedures? Were independent replicate scans performed on one waste container per day per testing, which ever is less frequent? Were independent observations of one scan (not the replicate scan) performed once per day per testing, which ever is less frequent, by a qualified radiography operator (other than the individual who performed the first examination)?	TPR-1726, Section 4.2.5.2, page 16/21	Ŷ		
QAPP Section 10, pg. 6 of 11				
Were oversight functions including periodic audio/videotape reviews of accepted waste containers performed by qualified radiography personnel (other than the operator who dispositioned the waste container)? QAPP Section 10, pg. 6 QAPP-96,	MCP-1815, Appendix C	Y ·		
Were the matrix parameter category and waste material parameter weights verified through a comparison of radiography and visual examination results? QAPP Section 10, pg. 6 of 11	MCP-2529, Appendix H	Y		Reviewed Data Validation Checklist - Project Level.
		Y	· · ·	
Did the RTR operator have access to the visual examination results?	-	Ŷ		No requirement for RTR operator to have VE results prior to RTR (safety
QAPP Section 10, pg. 6 of 11				concerns prevent opening of drums prior to RTR).
When the RTR equipment is in use, are operational checks conducted at the beginning of each work shift? Do these checks include observation of a test pattern to ensure that the RTR system has adequate video quality?	TPR-1572, Section 4.2.5, page 8/26	Y		
QAPP Section 10, pg. 9 of 11				

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Question	Procedure [Documented		
-	Location	Adequate? Y/N (Why)		Comment (e.g., any change in procedures since last audit, etc.?)
Does the RTR testing data reports provide the following information:	TPR-1572, Appendix D	Y		
 RTR facility name testing number waste container numbers included in that testing appropriate signatures (operator, independent reviewers, technical supervisor, site project manager, site project QA officer) table of contents data review checklists for each test verifying that the data generation level review, validation, and verification has taken place? 				
QAPP Section 10, pgs. 9 and 10 of 11				
For waste containers undergoing visual examination, does the testing report sheet for each waste container also identif the matrix parameter category and waste material paramete weights as determined by visual examination?	TPR-1572, Appendix D	Y		
QAPP Section 10, pg. 10 of 11				
How does the site define testing ? Does the testing have less than 20 waste containers? If so, is it possible for the site to examine the number of waste containers in one day? Methods Manual-96,P-310.1,pg. 310.1-1	QAPjP Glossary and Facility Implementation Plan	Y		
Does the site have a SOP for handling waste containers that can not be examined due to the presence of a lead liner? Are lead-lined waste containers visually examined to determine the matrix parameter category and waste material parameter weights?	TPR-1572, Appendix D, item 2.A, page D5 of D16	Y		
Methods Manual-96,P-310.1,pg. 310.1-1				
During the RTR examination, does the operator describe the height and shape of the waste in the container so that the volume of the container and the volume utilization percentag can be determined?	Appendix D,	Y		
Methods Manual-96,P-310.1,pg. 310.1-3	·		·	

Question	Procedure I	Documented	
	Location	Adequate? Y/N (Why)	Comment (e.g., any change in procedures since last audit, etc.?)
Upon identification of liquids, does the operator describe the location, container, and estimated volume (as a percent of the container volume and depth of liquid within the container of any liquids detected? Methods Manual-96,P-310.1,pg. 310.1-3	Appendix D, Item	Y	
Does the operator estimate the utilized waste container volume percentage using the highest point and shape of waste in a waste container? Did the site qualify when these percent values will not hold due to the presence of certain packaging materials (e.g., presence of fiber packs)? Methods Manual-96,P-310.1,pg. 310.1-5	TPR-1572, Appendix D, page D3 of D16	Ŷ	INEEL does not have fiber packs.
Is the RTR equipment tuned precisely enough to allow an operator to resolve a 2-2T hole in a steel block? Methods Manual-96,P-310.1,pg. 310.1-9	QTP-002, page 18/21	Y	The site uses standardized device provided by manufacture; sufficient resolution to resolve a 2-2T hole verified.
Are the standardized Methods Manuals, Sampling and Analysis Procedures, manuals, etc., which are used to standardize waste characterization methodologies present ir the RTR examination facility? 194.24(c)(5)	TPR-1572, Appendix D, page D1 of D16	Y	

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	VERI FIC	ATION ITEMS	
Item No.	Characteristic(s)	Objective Evidence Identified by EPA	EPA Determination
1	Verify that the system is designed to resolve a 2-2T hole in a steel block (Section 3.3	Witnessed RTR of 2-2T holes in stainless steel stock in varying thickness (Image File 2T_1In.TIF)	Satisfactory
	MM 310.1-9, 9.3.		
2	Verify that the RTR recording is on audio/video tape as stated in QAPjP Section 10.2.	Observed the Optical Disk Storage System, reviewed video disk for drum D01767, disk #R98034, side A. Observed image and heard audio.	Satisfactory
· 3	Verify that the required Start of Shift operations are documented (Section 4.2).	RTR logbook complete and correct.	Satisfactory
4	Verify that the daily image check is performed and is satisfactory (Section 4.2.5).	Documentation on TPR-1726.	Satisfactory
5	Verify that the location of liquids is recorded (Section 4.3.7.6).	Reviewed batch reports SWE970020 and SWE970026 for 4 of 15 drums and 4 of 18 drums, respectively.	Satisfactory
6	Verify that the container contents (detailed inventory) are described on the audio recording and the written record, including an estimation of the items weights (Section 4.3.7.6).	Reviewing batch reports SWE970020 and SWE970026 and RTR of drums D001040 and D001767.	Satisfactory
7 [°] .	Verify that the fill height (percent full) and shape of the waste is recorded on audio and written record (Section 4.3.7.6).	Reviewed batch reports SWE970020 and SWE970026 and RTR of drum D001040.	Satisfactory
8,	Verify that the operator is required to jog the container to identify liquids (Section 4.3.7.6).	Observed RTR of drum D001040	Satisfactory
9	Verify that the operator records parameter weights and matri parameter category.	x Reviewed batch reports SWE970020 and SWE970026 and RTR of drum D001040.	Satisfactory
10 .	Verify that this procedure will result in both audio/video - recording and a written record of the examination (Section 8)	Reviewed batch reports SWE970020 and SWE970026; RTR of drum D001040; reviewed tape for D001767.	Satisfactory
11	Verify that current copies of WM-P1-82-021, INEL CH Stored TRU Waste Cert. Program, INEL-96/0280, and INEL/EXT-97-00105 are present and available to the RTR operator during observations (Appendix C).	Documents present in the RTR operations booth.	Satisfactory
12	Verify that independent replicate scans and replicate observations of the video output are conducted once per batch.	Reviewed batch reports SWE970020 and SWE970026.	Satisfactory

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	VERIFICATION ITEMS					
Item No.	Characteristic(s)	Objective Evidence Identified by EPA	EPA Determination			
13	Verify that periodic tape reviews are made by an independer RTR operator (1 in 10) and periodic reviews are made by a supervisor.	t Reviewed batch reports SWE970020 and SWE970026.	Satisfactory			
14	Verify that batch reports receive data generation level review and verification.	Batch Reports SWE970020 and SWE970026	Satisfactory			
15	Verify that RTR operators are trained according to the requirements specified in the QAPjP.	Reviewed training implementation matrix and training file for Preston Abbott (Content Code File Training RWMC-TGRW0053).	Satisfactory			
16	Verify the content of the formal and OJT training. Verify that the operators passed a comprohensive test and a practical demonstration for the RTR subject matter expert.	Reviewed training implementation matrix and training file for Preston Abbott	Satisfactory			
17	Verify that operators are requalified every two years.	Reviewed training implementation matrix and training file for Chad Wayslow.	Satisfactory			
18	Verify that each operator periodically scans the training drun and the results are reviewed by a supervisor.	Verified for Julie Teton and Chad Wasylow.	Satisfactory			
19	Verify that test drum contains aerosol can with puncture, horsetail bag, pair of coveralls, empty bottle, irregular shape pieces of wood, empty one-gallon paint can, full container, aerosol can with fluid, one-gallon bottle with 3 tablespoons o fluid, one-gallon bottle with cup of fluid (upside down), leaded glove or apron, and wrench, all packed at varying densities.	Viewed tape MMW-Testdrum.mpg which showed all of the required items being present in the training drum.	Satisfactory			
20	Verify that a comparison report between RTR and VE was prepared.	Reviewed Comparison Reports CAF-01-98 and CAF- 03-97 for 2/19/98 and 3/11/97, respectively.	Satisfactory			

Attachment A.5 WWIS Data Entry/Data Validation Checklist Idaho National Engineering and Environmental Laboratory July 28-30, 1998

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	Procedure Documented			Comment		
Question	Location	Adequate? Y/N (Why)		Comment (e.g., any change in procedures since last audit, etc.)		
GENERAL REQUIREMENTS						
Were data package reviews completed (project level data generation)	MCP-2535, Rev. 1,	Y				
Are procedures in place and implemented for non- conforming data?	MCP-2529, Rev. 1	Y				
Were data reported from NDA, VE, and RTR reviewed, verified, and validated using appropriate procedures, i.e., evaluation of batch reports?	MCP-2517, Rev. 1	Y				
Were the appropriate checklists used for data input into WWIS?	MCP-2544, Rev. 0	Y .				
Is the information contained in the checklists for individual waste containers verified prior to entry into WWIS?	MCP-2544, Rev. 0	Y				
Are these data records maintained appropriately?	MCP-2544, Rev. 0	Y				
Does the site have appropriate security measures for accessing WWIS? Are they implemented?	MCP-2544, Rev. 0	Y				
Does the site have procedures for entering data into WWIS?	MCP-2544, Rev. 1	Y				

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INEEL WWIS Data Entry/Data Validation Checklist (Continued)

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	Procedure Documented		
Question	Location	Adequate? Y/N (Why)	Comment (e.g., any change in procedures since last audit, etc.)
Have the data entry personnel and data reviewers/verifiers been trained on WWIS using the WIPP Waste Information System User=s Manual and the appropriate site procedures?	MCP-2544, Rev. 0	Y	
Does the site conduct verification of waste characterization data entered into the WWIS, including resolution of discrepancies between WWIS data and waste data?	MCP-2544, Rev. 0	Y	
Do the data fields on the checklists correspond to the data fields required for submittal of characterization, certification, and shipping data to WWIS?	MCP-2544, Rev. 0	Y	
Are the edit/limit checks in WWIS appropriate for the site?	N/A	N/A	Inherent in the WWIS system. Verified during demonstration of WWIS data transfer.
Can the operator enter and transmit waste container characterization data to the WIPP via the WWIS?	MCP-2544, Rev. 0	Y	
Can the operator enter and transmit waste container certification data to the WIPP via the WWIS?	MCP-2544, Rev. 0	Y	Observed characterization data entry
Can the operator enter and transmit waste container shipping data to the WIPP via the WWIS?	MCP-2544, Rev. 0	Y	Observed characterization data entry
Can the operator print the appropriate reports for the data transmitted to WIPP, e.g. waste container data reports?	MCP-2544, Rev. 0	Y	
Does the site verify the accuracy of the data entered into WWIS and submitted to WIPP?	MCP-2544, Rev. 0	Y	
Does the site have appropriate recordkeeping procedures for WWIS data, including: WWIS access requests Waste container data reports Data input reports Waste shipment reports	MCP-2544, Rev. 0	Y	No quality records generated yet.
E-mail correspondence with WIPP?			

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INEEL WWIS Data Entry/Data Validation Checklist (Continued)

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	- VERIFICATION ITEMS				
Item No.	Characteristic(s)	Objective Evidence	Results		
1	Verify that personnel performing data entry and verification: - are authorized access - have received training	Reviewed training records and access logs.	Satisfactory		
2	Verify that the appropriate checklists were used for data input into WWIS.	Reviewed batch report 970018 and drum file 022022.	Satisfactory.		
3	Verify that site can transmits characterization, certification, and shipment data to WIPP.	WWIS data entry demonstration for characterization module.	Satisfactory for characterization only. Concern: Cannot due to certification module failure because of weight limit problems		
4	Verify that WWIS Waste Container Data Report is compared to the data entry checklist after submittat to WIPP	WWIS data entry demonstration	Satisfactory		
5	Verify that the following documents are maintained as quality records: - electronic e-mail notifications - training roster and briefing materials - WWIS Checklists - WWIS Access Request Form - WWIS Waste Container Data Report - WWIS Shipment Summary Report	Reviewed drum file 022022.	Satisfactory.		

ATTACHMENT B

United States Government

MAIL ROOM COPY Department of Energy

memorandum

Carlsbad Area Office Carlsbad, New Mexico 88221

DATE: August 26, 1998 REPLY TO ATTN OF: CAO:QA:RAS 98-1500 UFC 5822

8/27/98 1318 5822.00

SUBJECT: Request for Equivalency Determination-Assay Method for LECO Crucibles

Joseph A. Legare, RFFO

The CAO has received and evaluated the request of RFFO for approval to utilize acceptable knowledge (AK) coupled with confirmatory testing to satisfy the requirement for non-destructive assay (NDA) of LECO crucibles.

The CAO Quality Assurance Program Plan (QAPP) provides for previous analytical data to be utilized as acceptable knowledge (AK) in the characterization of waste to be shipped to WIPP. If such data is available, traceable, and of sufficient quality, it may be utilized in place of performing non-destructive assay (NDA) or radioassay on waste to be disposed of at WIPP. The CAO will determine its concurrence with the effectiveness of the AK process for determining the radionuclide content (in terms of both the radionuclides present, their quantites, and the total uncertainty associated with this determination) as part of the upcoming certification audit activity scheduled for RFETS residues.

With respect to documentation and disposition of radionuclides other than plutonium that could be present in the waste stream, the generator sites are reminded that as a minimum, the radionuclides specified in Appendix WCL of the WIPP Compliance Certification Application must be addressed (i.e. either quantified or demonstrated via acceptable knowledge to be absent) as part of the waste characterization activities. These radionuclides are:

²⁴¹ Am	
²³⁸ Pu	
209Pu	
240Pu	UNIQUE NO. 9803928
242Pu	
233	
2340	
238()	
[%] Sr	
¹³⁷ Cs	

Of these ten, ⁴⁰Sr, ²³³U, ¹³⁷Cs are important to and must be addressed for RH but not CH waste streams.



Joseph A. Legare

August 26, 1998

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Additionally, the generator sites must demonstrate that at least 95% of the radioactive hazard of the waste has been accounted for.

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As part of the acceptance of CAO of this alternative route to fulfilling the intent of the NDA requirements, the CAO is requiring that auditable records be maintained demonstrating through the confirmatory process that the AK for the radionuclides continues to meet the accuracy and precision QAO's for radioassay. An evaluation of the total uncertainty for the radionuclide content must also be performed and included in the auditable record.

If you have any questions, please contact Butch Stroud at 505-234-7483.

EK Huntin

E. Kent Hunter, Assistant Manager Office of Waste Disposal Operations

cc:

Cindy Baebler, DOE/CII Jerry Wells, DOE/ID Bruce LeBrun, DOE/LAAO Frank Schmaltz, DOE/MB Cathy Karney, DOE/NV Roy Kearns, DOE/OAK Gary Riner, DOE/ORO Joe Legarc, DOE/RFFO Mark French, DOE/RL Mike Mason, DOE/SRO Mike Griffin, Bechtel NV Doug Berry, BNFL/SRS Tom Baillieul, CEMP Tom Clements, INEEL/I_MITCO Ines Triay, LANL Kem Hainebach, LLNL Tom Monk. LMES Eric Pennala, MCS Gerry O'Leary, RFETS/RMRS Gerry Streier, TRUtech Tim Greager, WMH Mark Doherty. CTAC WIPP Home Page

ID:2025245061

NAT'L TRU WASTE OPS

10/23/98 12:19 FAX 15058876970 DEPT OF ENERGY

CORRECTIVE ACTION REPORT

1. CAR No.: 98-071 Rev. 1	2. Activity Report No.:	N/A (A-98-31)	3. Page 1_ of 1_		
4. Controlling Document: EPA FINAL RU	JLE	5. CAO Assessment Team Leader: Marc Italiano			
6. Responsible Organization: CAO -NTP		7. CAQ Was Discussed With: Hunter/Galbraith			
8. Requirements that were violated: CAO QAPD 2.1.1 B "Criteria describing acceptable work performance shall be defined for the worker." CAO QAPD 2.1.1 D Work shall be planned, authorized and accomplished under controlled condition using technical and QA standards and implementing procedures commensurate with applicable control levels.					
9. Conditions Adverse to Quality:					
Table 4-10 in Chapter 4 and Appendix WCL ²⁴¹ Am, ²³³ Pu, ²³⁹ Pu, ²⁴⁰ Pu, ²⁴² Pu, ²³² U, ²³⁴ U, ²³⁸	Table 4-10 in Chapter 4 and Appendix WCL of the WIPP CCA lists 10 radio-nuclides that DOE committed to track. They are ²⁴¹ Am, ²¹³ Pu, ²¹⁹ Pu, ²⁴⁰ Pu, ²⁴² Pu, ²¹³ U, ²¹⁴ U, ²¹⁴ U, ²⁰⁵ Sr, and ¹¹⁷ Cs.				
The CAO has not defined this requirement to	the waste characterization	organization.			
10. Suggested Actions (Optional): Revise the QAPP Section 9.0 to provide a list of the "nominal isotopes of interest". This revision will be made effective by distributing a memo to the affected characterization facilities until such time as the QAPP revision can be approved. Evaluate and document rationale as to the impact on current certifications.					
11. Significant Condition Adverse to Qua	lity (Yes or No)?: NO	· · ·			
12. Types of Actions: Remedial: X Investigative: X Root Cause: Actions to Preclude Recurrence:					
13. CAR Initiator: <u>M. Italiano</u>	mad Date: 1	0/23/98			
14. Response Due Date: <u>8/25/98</u>	14. Response Due Date: <u>8/25/98</u> Corrective Action Plan Required: YES				
15. Trend Cause Code:					
16. Concurrence	ader	Date			
17. Corrective Actions Proposed by the Responsible Organization (for SCQA only): Use CAR Continuation Sheet					
18. Acceptance of Proposed Corrective Actions (for SCAQ only):					
Assessment Team Leader	Date	Quality Assurance Mas	lager Date		
19. Verification of Corrective Action Completion:					
20. Verified By:Name		Date			
21. Closure:Assessment Team Le	ader	Date			

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HMEN

United States Government

memorandum

Carlsbad Area Office Carlsbad, New Mexico 88220

Department of Energy

NOV 1 3 1998

OATE

REPLY TO: CAO:OWDO:NTP:RAS 98-1467 / UFC 5822

SUBJECT: Measures used to Meet Radioassay Requirements for CCA

to: Marc Italiano, Acting Manager, QA

This is follow up information concerning my letter to you of October 23, 1998 (CAO:NTWP:RAS 98-1449/UFC 2300). That letter montions a telephone survey of three sites to determine what measures they used to meet the radioassay requirements for the Compliance Certification Application (CCA). The information provided over the phone was followed up with hardcopy material. The material provided to establish that the three certified sites are evaluating the isotopes listed in the CCA is as follows:

LANL

- 1. Procedure TWCP-DTP-1.2-029. Section 6.6 specifies gamma spectroscopy to determine the isotopic ratios. It also is used to determine what assay systems will be used to measure isotopes of plutonium and it specifically addresses ²³⁴U, ²³⁴U, and ²⁴¹Am. Section 6.7 addresses the data analysis for ²⁴²Pu (by correlation), as well as interpretation of the uranium and americium isotopic results.
- 2. A copy of a FRAM isotopic analysis report that demonstrate that each assay provides results for ²⁴¹Am, ²¹⁸Pu, ²¹⁹Pu, ²⁴⁰Pu, and ²⁴²Pu, as well as the relative masses for ²³⁴U and ²³⁸U.

RFETS

- 1. Copies of the IQ3 Library printouts that show the complete list of isotopes that are searched during gamma spectroscopy (which is performed on all drums). The library lists ²⁴¹Am, ²³²Pu, ²³²Pu, ²⁴²Pu, and ²³²U.
- 2. A facsimile message stating that RI'ETS will revise the acceptable knowledge document (RF/RMRS-97-018) to clearly specify that ²³⁴U was never used there.
- RF/RMRS-97-018, RFETS TRU Waste Acceptable Knowledge Supplemental Information. The radionuclide table provides all the uses of various isotopes found in RFETS waste. The Uranium portion of the table does not include ²³⁴U. This reference is the basis for the revision to the acceptable knowledge document.

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Marc Italiano

INEEL 📮

1. Quality Assurance Project Plan for The Transuranic Waste Characterization Program. Section 9.6 of this document specifies the assay reporting requirements which include the report provided by SORS.

.2.

- 2. A copy of an SGRS radioassay data sheet that shows ²⁴¹Am, ²³⁸Pu, ²³⁹Pu, ²⁴⁰Pu, and ²⁴²Pu, and ²⁴²Pu, ²⁴⁰Pu, ²⁴⁰
- EDF-RWMC-840, Nondestructive Assay (NDA) Data Assessment and Technical Review Process. This EDI² specifies data evaluation for all assay measurements on each drum. Section 3.3.1 addresses weapons grade plutonium, ²⁴¹Am, and uranium isotopes.
- A copy of a gamma-ray spectrometry summary report. This printout shows that ²⁴¹∧m, ²³⁶Pu, ²³⁹Pu, ²⁴⁰Pu, ²⁴⁰Pu, ²³⁴U, and ²³⁸U are evaluated for each drum. ²⁴²Pu is determined by correlation.
- 5. A copy of the library files used at SWEPP. These files are attached to e-mail messages. (They do not include ²⁴²Pu.)
- Calculation of Activities of Difficult-to-Detect Isotopes Using Bateman Equations, CVM-77-97. This report addresses the concern for ²³⁴U quantification noted during the certification audit. The report describes how INEEL intends to quantify ²³⁴U if it ever is found at significant concentrations.

The documentation provided above assures CAO that the three certified sites are investigating their waste for the seven isotopes of interest specified by the CCA for CII TRU waste.

If you have questions, please contact me at 234-7483.

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Butch Stroud, Tcam Leader National TRU Waste Program

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Lea Chism, CAO

cc:

Mike Brown, CAO Mark Doherty, CTAC Steve Calvert, CTAC

Department of Energy Carlsbad Area Office

memorandum

DATE: October 23, 1998

REPLY TO

ATTN OF: CAO:NTWP:RAS 98-1449 / UFC 2300

SUBJECT: CAR 98-071 Closure Activities TO: Marc Italiano, CAO

During Carlsbad Area Audit A-98-31, it was determined that the radioisotopes of interest for performance assessment and compliance with the Waste Isolation Pilot Plant (WIPP) Compliance Certification Application (CCA) had not been fully identified to the generator sites. A letter was sent August 26, 1998 (K. Hunter to the generator sites) identifying the requirement that there are 10 isotopes of interest to the Carlsbad Area Office (CAO) for compliance with the CCA. Of those 10, seven are specified as necessary to be addressed for contact-handled (CH) waste. This letter was the corrective action performed to close CAR 98-071, Revision 1. This letter is attached.

A telephone survey and a review of audit records was conducted to ensure that Idaho National Engineering and Environmental Laboratory (INEEL), Rocky Flats Environmental Technology Site (RFETS) and the Los Alamos National Laboratory (LANL) have been evaluating the waste for the Isotopes of interest. All three sites have done this by performing gamma spectrometry and identifying the various peaks of the seven isotopes required for contact-handled waste. Consequently, there has been no impact to the data collection activities at the sites because they have always been evaluating for all seven of the CH isotopes.

If you have questions, please contact me at 234-7483.

Robert A. Stroud, Team Leader National TRU Waste Programs

Attachment

cc w/attachment: Lea Chism, CAO Mike Brown, CAO

cc w/o attachment: Mark Doherty, CTAC Steve Calvert, CTAC

ID:2025245061