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Prepped by Keeia Richards

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#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

August 20, 2002

OFFICE OF AIR AND RADIATION

Dr. Ines Triay, Manager Carlsbad Field Office U.S. Department of Energy P.O. Box 3090 Carlsbad, NM 88221-3090

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Dear Dr. Triay:

The U.S. Environmental Protection Agency (EPA) conducted an inspection from August 6-7, 2002, of the Idaho National Engineering and Environmental Laboratory (INEEL) quality assurance (QA) program for the Waste Isolation Pilot Plant (WIPP) to confirm continued compliance in accordance with §194.8(a)(4). The investigation of the activities selected for the EPA inspection sample showed that:

1) changes to INEEL's QA Plan do not diminish the establishment of applicable Nuclear Quality Assurance (NQA) standards, and

2) INEEL's QA Officer continues to have sufficient authority, qualifications, organizational freedom, resources, and access to work areas to properly assure the quality of the characterization of transuranic (TRU) waste.

Concurrently during the EPA inspection, the QA Organization of DOE's Carlsbad Field Office (CBFO) conducted an audit to also assess INEEL's continued proper execution of a QA Program. DOE's audit sample showed that INEEL's QA Program has been properly maintained. The EPA inspectors verified that CBFO conducted the audit in accordance with the NQA standards.

EPA did not identify any findings during its inspection. No response is required from DOE's Carlsbad Field Office to this letter or the enclosed inspection report.

This letter and the report will be placed in EPA Air Docket No. A-98-49. Please contact Mike Eagle at (202) 564-9376 if you have questions regarding the report.

Sincerely,

the for

Frank Marcinowski Acting Director, Radiation Protection Division

cc: Ava Holland (CBFO) (w/enclosure) Matthew Silva (EEG) (w/enclosure) WIPP docket (w/enclosure)

# **DOCKET NO: II-A1-36**

### EPA INSPECTION OF THE IDAHO NATIONAL ENGINEERING AND ENVIRONMENTAL LABORATORY QUALITY ASSURANCE PROGRAM FOR THE WASTE ISOLATION PILOT PLANT August 6-7, 2002

## U. S. ENVIRONMENTAL PROTECTION AGENCY Office of Radiation and Indoor Air Center for Federal Regulations 1200 Pennsylvania Ave., N.W. Washington, DC 20460

August 2002

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Technical Support for this document was provided by Trinity Engineering Associates and its subcontractors under EPA Contract 68-D-00-210.

#### **1.0 EXECUTIVE SUMMARY**

The U.S. Environmental Protection Agency (EPA or Agency) conducted an inspection from August 6-7, 2002 of the Idaho National Engineering and Environmental Laboratory (INEEL) quality assurance (QA) program for the Waste Isolation Pilot Plant (WIPP) to confirm continued compliance in accordance with §194.8(a)(4). The investigation of the activities selected for the EPA inspection sample showed that:

- 1) changes to INEEL's QA Plan do not diminish the establishment of applicable Nuclear Quality Assurance (NQA) standards, and
- 2) INEEL's QA Officer continues to have sufficient authority, qualifications, organizational freedom, resources, and access to work areas to properly assure the quality of the characterization of transuranic (TRU) waste.

Concurrently during the EPA inspection, the QA Organization of DOE's Carlsbad Field Office (CBFO) conducted an audit to also assess INEEL's continued proper execution of a QA Program. DOE's audit sample showed that INEEL's QA Program has been properly maintained. The EPA inspectors verified that CBFO conducted the audit in accordance with the NQA standards.

This EPA inspection report will be made available to the public through the Agency's public dockets

INEEL, located in eastern Idaho approximately 65 miles east of Idaho Falls, Idaho, is a 889 square-mile area managed by the DOE. INEEL is a storage facility for defense-generated TRU-waste. TRU-wastes at INEEL are destined for disposal at the WIPP, the geologic repository for the disposal of the nation's TRU-wastes. EPA requires that INEEL properly execute a QA Program to oversee INEEL's characterization of TRU-waste.

#### 2.0 BACKGROUND

#### 2.1 Regulatory Background

In accordance with 40 CFR 194.8(a), the Agency will determine compliance with requirements for site-specific QA Programs, including the INEEL's QA Program. In July 1998, the Agency conducted an initial inspection to verify the proper execution of the INEEL QA Program, as required under §194.8(a)(2). In accordance with §194.8(a)(3), EPA determined that the INEEL QA Program complied with the requisite QA requirements for a TRU-waste generator site. Subsequent to the initial determination of compliance, the Agency conducted annual inspections to verify continued compliance. The inspection documented by this report was to confirm continued compliance in 2002, in accordance with §194.8(a)(4). A summary of the history of inspections of INEEL's QA Program is listed in Table 1.

At §194.22(a)(1), EPA requires DOE to adhere to a QA Program that invokes the following QA standards: 1) 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). The Agency verified that DOE established these NQA standards in the Quality Assurance Program Document (QAPD) included in the Compliance Certification Application (CCA) for the WIPP. The QAPD is the documented QA Plan for the WIPP project, as a whole, to establish the NQA standards. The QAPD is maintained by the QA Organization of DOE's Carlsbad Field Office (CBFO), which has the authority to audit all other organizations associated with TRU-waste disposal at the WIPP to ensure that their lower-tier QA Programs establish and implement the applicable requirements of the QAPD. The DOE generator sites, which will characterize waste for disposal in the WIPP, must prepare site-specific QA Plans that establish the applicable NQA requirements.

The EPA annually audits DOE's QA Program at CBFO (reference EPA Air Docket No. A-93-02, Document Nos. II-A-43 and IV-A-4, and EPA Air Docket No. A-98-49, Document No. II-A-1-4) and has found that DOE properly adheres to a QA Program that implements the NQA standards. The Agency determined in its WIPP Certification Decision (63 FR 27354, May 18, 1998) that the CBFO QAPD is in conformance with the NQA standards and that the DOE's quality assurance organization can properly perform audit activities to internally check the QA Programs of the waste generator sites.

The Agency's inspection conducted in concurrence with CBFO Audit A-02-27 was performed under the authority of §194.8(a)(4), which addresses recertification of generator site's QA Program. The Agency 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 QA Program, while in an

inspection, the Agency also performs some oversight of DOE's quality assurance checks of a QA Program. The table below presents a summary of EPA inspections to-date of INEEL's QA Program.

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| Table 1: Summary of EPA Inspections of INEEL's QA Program |                          |  |  |  |  |  |  |
|---|--------------------------|--|--|--|--|--|--|
| Activity  | Date                     | Purpose  |  |  |  |  |  |
| Inspection  | July 29-30, 1998         | Inspection and independent assessment of initial CBFO<br>Certification Audit A-98-31 of QA program for<br>conformance with 40 CFR 194.22(a).   |  |  |  |  |  |
| Inspection  | May 18-20, 1999          | Inspection of DOE Audit A-99-08 for maintenance of WIPP support QA program; DOE issued 18 corrective action reports and, as a result, delayed recertification.   |  |  |  |  |  |
| Inspection  | July 27-28, 1999         | Follow-up to Audit A-99-08; Inspection of DOE Audit<br>A-99-23 to verify appropriateness and proper<br>implementation of corrective actions for 8 of 18<br>corrective action reports resulting from Audit A-99-08;<br>temporary authorization to ship waste. |  |  |  |  |  |
| Inspection  | April 24-27, 2000        | Inspection and independent assessment of initial CBFO<br>Certification Audit A-00-06 of QA program for<br>conformance with 40 CFR 194.22(a).   |  |  |  |  |  |
| Inspection  | May 17, 2000             | Follow-up to Audit A-00-06; inspection of close-out of 3 corrective action reports.  |  |  |  |  |  |
| Surveillance  | May 1, 2001              | Conducted concurrently with DOE Surveillance S-01-06 to confirm maintenance of QA program in conformance with 40 CFR 194.22(a).  |  |  |  |  |  |
| Inspection  | July 30 - August 2, 2001 | Conducted concurrently with DOE Audit A-01-14 to<br>confirm sufficiency of INEEL QA Organization in<br>conformance with 40 CFR 194.22(a).  |  |  |  |  |  |
| Inspection  | August 6-7, 2002         | Conducted concurrently with DOE Audit A-02-27 to confirm sufficiency of INEEL QA Organization in conformance with 40 CFR 194.22(a).  |  |  |  |  |  |

#### 2.2 INEEL Background

INEEL has approximately 65,000 m<sup>3</sup> of TRU waste in inventory, which is the largest inventory of TRU waste of any DOE site. The principal radionuclides in INEEL's TRU waste are plutonium and americium. Much of the TRU waste at INEEL consists of plutonium-contaminated protective clothing, filters, containers, and tools. Inventoried TRU waste at INEEL is contained in approximately 130,000 55-gallon drums and 11,000 boxes, or 310,000 55-gallon equivalents. Most of this TRU waste is stored above ground at the Radioactive Waste Management Complex (RWMC), with a small amount stored at the Argonne National Laboratory-West (ANL-W). In addition to stored TRU waste, approximately 57,500 m<sup>3</sup> of TRU waste is buried at the Subsurface Disposal Area of the RWMC. Most of the buried waste was generated at the Rocky Flats plants near Denver, Colorado and buried prior to 1970.

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Transuranic wastes stored at INEEL are destined for disposal at the WIPP, the geologic repository for the disposal of the Nation's TRU wastes. CBFO is responsible for the management of the WIPP and for assuring that generator sites, such as INEEL, have quality assurance programs that provide adequate oversight of TRU waste characterization activities.

#### 3.0 PURPOSE AND SCOPE

Section 194.22(a)(1) requires that the WIPP site establish and implement the requirements of: 1) 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). The purpose of the EPA inspection was to confirm the continued compliance of the INEEL QA program with the above requirements in accordance with §194.8(a)(4).

Section 194.22(a)(2) requires that the INEEL's 3,100 m<sup>3</sup> project properly execute a QA program for all items and activities that are important to the containment of TRU-waste in the WIPP. The scope of this EPA inspection is limited to the QA program's oversight of items and activities that are important to the containment of TRU-waste at the WIPP. The EPA confirmed that only the TRU-waste characterization items and activities of the 3,100 m<sup>3</sup> project are important to containment.

#### 4.0 **DEFINITIONS**

*Finding:* A determination that a specific item or activity does not meet a requirement under applicable elements of the nuclear quality assurance standards. A finding requires a response.

*Concern:* A judgment that a finding may occur in the future, and depending on the magnitude of the issue, may or may not require a response.

# 5.0 INSPECTION TEAM AND PARTICIPANTS

The inspection team consisted of one representative of the EPA and one support contractor.

Inspection Team Member Posi

Position

**Affiliation** 

Mike Eagle Bill Vocke Inspection Team Leader Inspector

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Mr. Jeff May, CBFO Technical Assistance Contractor (CTAC) lead auditor, served as the inspection team's point of contact with INEEL. A list of the INEEL personnel who were contacted during the EPA inspection is presented in Attachment 1.

#### 6.0 PERFORMANCE OF THE INSPECTION

In accordance with §194.8 (a)(4), the EPA performed an independent inspection of the QA Program at the INEEL Site. The EPA's inspection sample was as follows:

- 1) interviewed INEEL's Site QA Officer to verify conformance with NQA-1, Element 1, *Organization*;
- 2) reviewed all changes to INEEL's QA Plan to verify that the changes do not diminish the establishment of the NQA standards; and
- 3) witnessed CBFO Audit A-02-27 to verify conformance with NQA-1, Element 18, Audits.

The EPA did not identify any finding or concerns. Checklists for elements 1 and 18 are presented in Attachment 2 of this report. The following discussions provide more information on the EPA's performance of the inspection.

#### 6.1 Interview of INEEL's QA Personnel

EPA interviewed Tim Preston, INEEL's Site QA Officer (SQAO), and Mr. Tom Fallon, Environmental Operations QA Manager, to determine if the QA organization has sufficient resources, authority, independence, and access to work areas to perform their assigned functions.

#### Mr. Tim Preston, SQAO

Mr. Preston serves as the SQAO for the 3,100m<sup>3</sup> project, including all facilities that support the RWMC TRU waste management activities. Mr. Preston reports to Mr. Tom Fallon (Environmental QA Operations Manager), who in turn reports to Mr. Lance Monney (Director of QA). Mr. Preston has communication lines with Mr. Thomas Monk, the Site Project Manager. Mr. Preston's QA activities include providing adequate support and planning to ensure that the following activities are completed properly:

- Repeat of the data generation level review, validation, and verification process
- Plan and conduct scheduled surveillances
- Direct formal annual audit process
- Track NCRs and Deficiency Reports

Mr. Preston currently supervises a QA staff of six full-time and one part-time employees. INEEL has plans to gradually reduce the number of QA staff as the 3,100 m<sup>3</sup> project scales back operation. The 3,100 m<sup>3</sup> project expects to complete operations by mid November 2002.

Mr. Preston has the authority to stop work based upon identification of quality problems. He indicated that the organizations with the quality problems have issued work stand-downs on their own accord once he identifies a condition adverse to quality. One such example was when an incorrect TRUPACT II Payload was shipped. EPA reviewed the files for this occurrence and determined that the QA Officer had worked effectively with the responsible organization to identify quality problems, recommend and implement solutions, and assure that the deficiency was resolved before the work resumed. Mr. Preston indicated that between Mr. Monk and himself, the QA and Project staff are encouraged to bring nonconformances and deficiencies to their attention.

Mr. Preston is comfortable that he has sufficient authority, organizational freedom, and management access to perform the duties of his position.

#### Mr. Tom Fallon, Environmental QA Operations Manager

Mr. Fallon is responsible for providing qualified quality professionals to the 3,100m<sup>3</sup> project and other INEEL projects. He provides professional training and, where applicable, certified individuals to perform QA-related activities. In this position, he provides oversight of the QA program and ensures that the program has adequate authority and resources to perform its functions. Mr. Fallon receives daily briefings from Mr. Preston during the work day, or during their daily commute to and from the site. Based on the interview, EPA determined that Mr. Fallon has provided Mr. Preston with sufficient authority and resources to properly implement the INEEL 3,100m<sup>3</sup> project QA program.

#### 6.2 Review of QA Plan

The INEEL QA Plan is titled the *INEEL TRU Waste Characterization, Certification, and Transportation Quality Program Plan*, (PLN-182) Revision 7, dated 05/17/02. The EPA reviewed the QA Plan to verify that changes to the plan did not diminish the establishment of a NQA program for the INEEL 3,100 m<sup>3</sup> project. EPA determined that the major changes were associated with WAC and TRAMPAC requirements, which are outside the scope of the EPA inspection. Other modifications reflected organizational changes and references to CBFO source documents. Therefore, EPA determined that the changes to the QA Plan did not diminish the establishment of a NQA program for the INEEL 3,100 m<sup>3</sup> project.

#### 6.3 Witness of CBFO Audit A-02-27

EPA inspected the planning and performance of Audit A-02-27 to determine conformance with NQA-1, Element 18, *Audits*. EPA inspectors determined that the requirements of NQA-1 Element 18 were adequately met by CBFO's QA Organization and appropriately implemented

during its audit of INEEL. The EPA checklist for inspection of CBFO's Audit A-02-27 is included in Attachment 2.

CBFO's audit of INEEL was well planned and scheduled to verify continued compliance with selected elements of the QAPD. The CBFO auditors developed and completed checklists based on the NQA standards for a sample of activities associated with the INEEL QA Program as defined in the audit plan.

The audit report for Audit A-02-27 has not been distributed, therefore, the EPA inspection team could not verify if the audit results are documented, reported to, and reviewed by responsible management. However, the inspectors conclude that the requirement will be met based on previous EPA audits of CBFO, and reviews of other CBFO audit reports. EPA may review the audit report for audit A-02-27 during future audits to verify that this requirement was satisfied.

The EPA inspectors determined that DOE's auditing team consisted of qualified auditors who are independent of INEEL. Jeff May, CTAC, served as the lead auditor for CBFO Audit A-02-27.

The EPA inspection team did not identify any findings or concerns related to this element.

The EPA witnessed a discussion between a CBFO auditor and INEEL site personnel regarding a possible non-conformance. At one point, the site personnel argued that the DOE auditor should have identified the possible non-conformance during a previous audit. The DOE auditor responded that the site personnel who perform the work are responsible for the achievement of quality and that the site must not depend upon independent verifications to achieve quality. The EPA inspectors consider this instance a demonstration of the effective maturity of the CBFO QA Program.

#### 7.0 SUMMARY OF FINDINGS AND CONCERNS

The EPA inspection team's activities provided objective evidence in support of INEEL's compliance with the requirements of §194.22.

The Agency did not identify any findings or concerns as a result of the inspection of INEEL performed in concurrence with CBFO Audit A-02-27. The EPA inspection team provided daily briefings to both CBFO and INEEL staff regarding the progress of the inspection. On August 7, 2002, EPA presented its conclusions to CBFO and INEEL at a post-audit meeting. Attachment 1 identifies the individuals who attended this meeting.

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#### 7.1 Findings

EPA did not identify any findings during its inspection of the INEEL QA Program for the TRU Waste Characterization Program. EPA did not identify any findings during its inspection of the CBFO Audit A-02-27.

#### 7.2 Concerns

EPA did not identify any concerns during its inspection of the INEEL QA Program for the TRU Waste Characterization Program. EPA did not identify any concerns during its inspection of the CBFO Audit A-02-27.

# 8.0 **REFERENCES**

The documents reviewed by the EPA inspection team are listed in Attachment 3 of this report.

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# ATTACHMENT 1

<u>P.18</u>

# CBFO AND INEEL PERSONNEL CONTACTED DURING THE EPA INSPECTION OF INEEL'S QA PROGRAM

# ATTACHMENT 1

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# CBFO AND INEEL PERSONNEL CONTACTED DURING THE EPA INSPECTION OF INEEL'S QA PROGRAM

| Name         | Organization and Position         | Interview | Exit Briefing |
|--------------|-----------------------------------|-----------|---------------|
| T. Fallon    | BBWI, Environmental QA<br>Manager | X         | X             |
| T. Preston   | BBWI, Site QA Officer             | X         | X             |
| A. Holland   | CBFO QA Manager                   | X         | X             |
| M. Navarrete | CBFO QA Specialist                | X         | Х             |
| J. May       | CBFO/CTAC Lead Auditor            | X         | X             |
| S. Calvert   | CBFO/CTAC Auditor                 | x         | Х             |

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ATTACHMENT 2

# INSPECTION CHECKLISTS

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# NQA-1 CHECKLIST

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ELEMENT: <u>1</u> TITLE: <u>Organization</u> INSPECTORS: <u>Mike Eagle, Bill Vocke</u>

|       | the reference document adequately define,<br>ibe, address, or satisfy the following:  | Yes | No | Applicable<br>Procedure & Para.  |
|-------|---|-----|----|--|
| Basic | Requirements  |     |    |  |
| 1.    | Are the organizational structure, functional<br>responsibilities, levels of authority, and lines of<br>communication documented for activities<br>affecting quality?  | X   |    | <ul> <li>PLN-182, Sect. 2.2 and 2.3, and Fig.</li> <li>2-1 (TWCP Organization Structure)</li> <li>3,100 m<sup>3</sup> Project Organization (org. chart), February 2002</li> </ul>  |
| 2.    | <ul> <li>Do persons or organizations responsible for performing quality assurance functions have sufficient authority, access to work areas, and organizational freedom to: <ul> <li>identify quality problems;</li> <li>initiate, recommend, or provide solutions to quality problems through designated channels;</li> <li>verify implementation of solutions; and</li> <li>assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred?</li> </ul> </li> </ul> | X   |    | PLN-182, Sect. 2.2<br>MCP-2993, all<br>3,100 m <sup>3</sup> Project Organization (org.<br>chart), February 2002<br>Matrix assignment of Data Generation<br>Level QA Representatives at waste<br>characterization activities<br>Interview of SQAO |
| 3.    | Do persons or organizations responsible for<br>performing quality assurance functions have<br>direct access to responsible management at a<br>level where appropriate action can be effected?   | X   |    | PLN-182, Sect. 2.2 and 2.3, and Fig.<br>2-1 (TWCP Organization Structure)<br>3,100 m <sup>3</sup> Project Organization (org.<br>chart), February 2002  |

|        | he reference document adequately define,<br>be, address, or satisfy the following:  | Yes | No  | Applicable<br>Procedure & Para.   |
|--------|---|-----|-----|---|
| 4.     | Do persons or organizations responsible for<br>performing quality assurance functions report<br>to a management level that provides the<br>required authority and organizational freedom,<br>including sufficient independence from cost<br>and schedule considerations?  | X   |     | <ul> <li>PLN-182, Sect. 2.2 and 2.3, and Fig.</li> <li>2-1 (TWCP Organization Structure)</li> <li>3,100 m<sup>3</sup> Project Organization (org. chart), February 2002</li> <li>Matrix assignment of Data Generation Level QA Representatives at waste characterization activities</li> </ul> |
| Supple | ementary Requirements (1S-1)  | ·   |     |   |
| 1.     | <ul> <li>Are the organizational structure and the responsibility assignments such that:</li> <li>quality is achieved and maintained by those who have been assigned responsibility for performing work, and</li> <li>quality achievement is verified by persons or organizations not directly responsible for performing the work?</li> </ul> | X   |     | PLN-182, Sect. 2.2 and 2.3.1<br>Interview of SQAO   |
| 2.     | Does the individual(s) or organization(s)<br>responsible for establishing and executing a<br>quality assurance program delegate any or all<br>of the work to others, and if so, does the<br>individual(s) or organization(s) retain<br>responsibility for the quality assurance<br>program?   | X   |     | PLN-182, Sect. 2.3.1  |
| 3.     | Is responsibility for the control of further<br>processing, delivery, installation, or operation<br>of nonconforming items designated in writing?   | X   |     | PLN-182, Sect. 4.3<br>PLN-190, Sect. B3-13  |
| 4.     | Where more than one organization is involved<br>in the execution of quality assurance activities,<br>is the responsibility and authority of each<br>organization clearly established and<br>documented?   | N/A | N/A | Not applicable. One QA organization<br>at INEEL that is matrixed throughout<br>the facility, including the RWMC.  |

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|    | the reference document adequately define,<br>ibe, address, or satisfy the following:   | Yes | No | Applicable<br>Procedure & Para.   |
|----|--|-----|----|---|
| 5. | Are the external interfaces between<br>organizations, as well as the internal interfaces<br>between organizational units, documented?<br>Are interface responsibilities defined and<br>documented? | X   |    | <ul> <li>PLN-182, Sect. 2.2 and 2.3, and Fig.</li> <li>2-1 (TWCP Organization Structure)</li> <li>3,100 m<sup>3</sup> Project Organization (org. chart), February 2002</li> </ul> |

# NQA-1 CHECKLIST

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### ELEMENT: <u>18</u> TITLE: <u>Audits</u> Inspectors: Mike Eagle, Bill Vocke

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| Does the reference document adequately define,<br>describe, address, or satisfy the following:  | Yes | No | Applicable<br>Procedure & Para.  |
|---|-----|----|--|
| Basic Requirements  |     |    |  |
| <ol> <li>Are planned and scheduled audits performed to<br/>verify compliance with all aspects of the quality<br/>assurance program and to determine its<br/>effectiveness?</li> </ol> | X   |    | Audit A-02-27 Audit Plan<br>CBFO Audit Schedule<br>MP 10.3, Sect. 2.0  |
| 2. Are audits performed in accordance with written<br>procedures or checklists by personnel who do not<br>have direct responsibility for performing the<br>activities being audited?  | x   |    | MP 10.3, Sect. 5.0<br>CBFO Audit A-02-27 Audit Notebook<br>Audit A-02-27 Audit Plan<br>CBFO Audit A-02-27 Checklists<br>CBFO Auditor Qualification Records |
| <ol> <li>Are audit results documented and reported to and<br/>reviewed by responsible management? Is follow-<br/>up action taken where indicated?</li> </ol>                          | X   |    | MP 10.3, Sect. 5.5<br>Results were presented to INEEL<br>management at management meetings<br>during the audit.  |
| Supplementary Requirement (18S-1)   | ·I  | L  |  |
| <ol> <li>Are internal or external quality assurance audits<br/>scheduled to provide coverage and coordination<br/>with ongoing quality assurance program activities?</li> </ol>       | X   |    | MP 10.3, Sect. 5.1   |
| 2. Are audit plans developed and documented for each audit?   | X   |    | MP 10.3, Sect. 5.3<br>CBFO Audit A-02-27 Audit Notebook<br>Audit A-02-27 Audit Plan  |

| Does the reference document adequately define, describe, address, or satisfy the following:   | Yes | No | Applicable<br>Procedure & Para.  |
|---|-----|----|--|
| 3. Does the auditing organization select and assign<br>auditors who are independent of any direct<br>responsibility for performance of the activities<br>which they will audit? In the case of internal<br>audits, personnel having direct responsibility for<br>performing the activities being audited shall not be<br>involved in the selection of the audit team. | X   |    | MP 10.3, Sect. 5.2.3<br>CBFO Auditor Qualification Records<br>CBFO auditors are from CBFO and its<br>support contractors. The audited<br>organization is INEEL, an entirely<br>separate organization. It was confirmed<br>that all the participating auditors<br>satisfied the independence requirement. |
| 4. Is the audit team identified prior to the beginning<br>of each audit, with one individual appointed lead<br>auditor?   | X   |    | Audit A-02-27 Audit Plan<br>CBFO Audit A-02-27 Audit Notebook.<br>Jeff May was appointed as Lead<br>Auditor. The Lead Auditor is certified<br>in accordance with NQA requirements<br>MP 10.3, Sect. 5.2.1 and 5.2.2  |
| 5. Are audits performed in accordance with written procedures or checklists?  | X   |    | CBFO Audit A-02-27 Checklists<br>MP 10.3, Sect. 5.3.5, 5.4<br>Observed auditors using checklists<br>during performance of the audit.   |
| 6. Are the elements that have been selected for audits<br>evaluated against specified requirements?   | X   |    | MP 10.3, Sect. 5.3.5<br>CBFO Audit A-02-27 Checklists<br>Audited elements were evaluated against<br>CBFO's QAPD and against INEEL<br>implementing procedures.  |
| 7. Are audits results documented by auditing<br>personnel and reviewed by management having<br>responsibility for the area audited?   | x   |    | MP 10.3, Sect. 5.4.7 through 5.4.14,<br>5.14.16, 5.5<br>CBFO auditors were observed<br>discussing results with INEEL<br>management during the audit.   |

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| Does the reference document adequately define, describe, address, or satisfy the following:   | Yes | No | Applicable<br>Procedure & Para.   |
|---|-----|----|---|
| 8. Is the audit report signed by the lead auditor prior<br>to issuance?   | X   |    | MP 10.3, Sect. 5.5.1<br>Based on audits and inspections of<br>previous CBFO audits, the audit reports<br>are signed by the lead auditor as<br>specified. The reports are also signed<br>by the CBFO QA Manager. The audit<br>report fore Audit A-02-27 may be<br>reviewed during a future EPA audit to<br>verify continued compliance with this<br>requirement by CBFO. |
| <ul> <li>9. Does the audit report include:</li> <li>description of the audit scope;</li> <li>identification of the auditors;</li> <li>identification of persons contacted during audit activities;</li> <li>summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited; and</li> <li>description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization?</li> </ul> | X   |    | MP 10.3, Sect. 5.5.1<br>Based on audits and inspection of<br>previous CBFO audits, the audit reports<br>contain each of these items. The audit<br>report fore Audit A-02-27 may be<br>reviewed during a future EPA audit to<br>verify continued compliance with this<br>requirement by CBFO.  |
| 10. Does the management of the audited organization<br>or activity investigate adverse audit findings,<br>schedule corrective action (including measures to<br>prevent recurrence), and notify the appropriate<br>organization in writing of action taken or<br>planned?  | X   |    | This requirement was not evaluated<br>during this inspection. Based on<br>previous inspections of INEEL, EPA<br>determined that this requirement is<br>satisfied.   |
| 11. Is follow-up action taken to verify that corrective action is accomplished as scheduled?  | X   |    | MP 3.1, Sect. 5.6,<br>TP 3.2, all sections  |

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| Does the reference document adequately define, describe, address, or satisfy the following:  | Yes | No | Applicable<br>Procedure & Para.  |
|--|-----|----|--|
| 12. Do audit records include audit plans, audit<br>reports, written replies, and the record of<br>completion of corrective action? | X   |    | MP 10.3, Sect. 6.0<br>MP 3.1, Sect. 6.0<br>Based on audits and inspection of<br>previous CBFO audits, the audit reports<br>contain each of these items. The audit<br>report fore Audit A-02-27 may be<br>reviewed during a future EPA audit to<br>verify continued compliance with this<br>requirement by CBFO |

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# ATTACHMENT 3

# REFERENCES

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#### **ATTACHMENT 3**

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#### REFERENCES

- 1. DOE Carlsbad Field Office. CD-ROM, A-02-27 INEEL, including Audit Checklists, Audit Plan, and Daily Schedule.
- DOE CBFO. Audit Team Qualification Review, Audit Number A-02-27, INEEL Recert." 7/25/02
- 3. DOE Idaho National Engineering and Environmental Laboratory. TRU Waste Characterization, Certification, and Transportation Quality Program Plan, PLN-182, Rev. 7, effective May 17, 2002.
- 4. DOE Idaho National Engineering and Environmental Laboratory. "Formal Root Cause Analsis: Incorrect TRUPACT II Payload Shipped, DR 27226, Occurrence Report ID-BBWI-RWMS-2002-2003." RWMC-02-02. April 4, 2002
- 5. DOE Idaho National Engineering and Environmental Laboratory. Control of Deficiencies and Nonconforming Items, MCP-2993, Rev. 8, effective April 3, 2001.
- 6. DOE Idaho National Engineering and Environmental Laboratory. Organization chart: 3,100 m<sup>3</sup> Project Organization, February 2002.