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QUALITY ASSURANCE AUDIT FOR RADIOACTIVE MATERIAL TRANSPORTATION PACKAGING

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ABSTRACT

As directed by the Manager, Packaging Certification Program (PCP) of the DOE Office of Safety Management and Operations, Environmental Management, two packaging QA audits were conducted to evaluate implementation of the QA program requirements for Type B radioactive and fissile material transportation packagings in Subpart H of 10 CFR Part 71 and DOE O 460.1B. The audit team evaluated the implementation of the requirements in the Operating Procedures, Acceptance Tests and Maintenance Program, and Quality Assurance in Chapters 7, 8, and 9, respectively, of the two Safety Analysis Reports for Packaging. In addition, source verification was performed at two contractor sites to evaluate important-to-safety welds and associated nondestructive examination. During the audits and source verification, the PCP staff interviewed key personnel; reviewed numerous records and documents; and observed critical welds, helium leak testing, and ultrasonic and liquid penetrant examination.

INTRODUCTION

A quality assurance (QA) audit is considered to be an effective management evaluation tool. The purpose of conducting a QA audit is to verify implementation of a QA program. The results of the audit provide the status of compliance with the prescribed QA program for the auditee's management and the sponsor, such as the U.S. Department of Energy (DOE). In the case of Type B radioactive and fissile material transportation packaging, the licensee, certificate holder, or an applicant for a Certificate of Compliance (CoC) shall have a QA program in compliance with Subpart H, Part 71, Title 10 of the Code of Federal Regulations (10 CFR Part 71), *Packaging and Transportation of Radioactive Material*,[1] and the DOE Order 460.1B, *Packaging and Transportation Safety*.[2] The requirements for a QA program are that the licensee, certificate holder, or applicant for a CoC must establish, maintain, and implement an effective QA program. The audit team may evaluate each of the 18 criteria for compliance with Subpart H of 10 CFR Part 71, which may be full or partial in scope, depending on the nature of the work.

Fissile and radioactive materials are generally transported in two types of packages: Type A and Type B. The Type A package is restricted to carrying less than Type A quantities of radioactive material, as identified in 10 CFR 71, Appendix A. Type A packages are usually small and require little shielding. Type B and fissile material packages are used to transport greater that Type A quantities, i.e., highly radioactive materials, spent nuclear fuel, and high level waste. The Department of Transportation regulation 49 CFR 173.7(d) specifies that Type B packagings can be certified by DOE as long as they are evaluated by packaging standards equivalent to those in 10 CFR 71. The U.S. Nuclear Regulatory

Commission's evaluation is based on 49 CFR Part 173, *Shippers – General Requirements for Shipments and Packagings*,[3] and 10 CFR Part 71, *Packaging and Transportation of Radioactive Material*. The DOE Order 460.1B, dated April 4, 2003, specifies that an application for fissile or Type B package certification must include a Safety Analysis Report for Packaging (SARP) that demonstrates that the packaging conforms with the standards of 10 CFR Part 71, Subparts E, F, G, and H, and any other applicable standards that the Assistant Secretary for Environmental Management or a Secretarial Officer/Deputy Administrator in the National Nuclear Security Administration may determine applicable for granting a CoC. Relative to quality assurance, the basis of reviewing and approving QA programs and performing audits by the Office of Environmental Management (EM-60), through the Headquarters Certifying Official, is codified in DOE O 460.1B, 5.a.(1)(f).

As directed by the Manager, Packaging Certification Program (PCP) of the DOE Office of Safety Management and Operations, Environmental Management, the PCP staff conducted packaging QA audits at two sites (referred to hereafter as Facility A and B) and source verification of important-to-safety welds at two other sites (Facility C and D) in 2006 and 2007. The purpose of the two packaging QA audits was to verify that Facilities A and B have a packaging QA program in compliance with 10 CFR Subpart H and DOE O 460.1B. The purpose of source verification was to observe three critical welds and associated nondestructive examinations of the welds at Facilities C and D.

The PCP Manager appointed the lead auditor and additional auditors based on the scope of the audit from one of the three national laboratories: Argonne National Laboratory, Lawrence Livermore National Laboratory, and Savannah River National Laboratory. The lead auditor selected subject matter experts, e.g., welding, for the audit team to evaluate packaging quality assurance and technical matters.

Audit Description

There are three basic forms of quality assurance audits: system audit, process audit, and product audit.

1. System Audit – "A structured activity performed to verify that one or more portions of a quality program are appropriate and being implemented effectively in accordance with agreed-to standards of performance."[4]

2. Process Audit – "The evaluation of a process operation against established instructions and standards. The process audit measures conformance of the processed item or activity to established standards. It also measures the effectiveness of process instructions. The audit is a check for adequacy and effectiveness of the process controls over the equipment and operators as established by procedures, work instructions, and process specification."[4]

3. Product Audit – "The examination, inspection, or test of a product which has been accepted previously for the characteristics being audited. Such an audit is a re-inspection and retesting of the product which has already been accepted or a review of documented evidence of acceptance. It is an indicator of quality going to the customer."[4]

The objective of a system audit is to verify that contractual QA program requirements have been established, maintained, and implemented. This may mean that all 18 criteria from Subpart H of 10 CFR Part 71 are evaluated or a portion of the 18 criteria is evaluated. Should an organization be responsible for design, fabrication, assembly, testing, maintenance, repair, modification, and use of the proposed packaging, they are responsible for establishing an 18-criteria QA program in compliance with Subpart H of 10 CFR Part 71. Should an organization only be responsible for use of the packaging, the organization is only required to develop a QA program based on the appropriate criteria from Subpart H of 10 CFR Part 71.

The objective of a process audit is to verify that select activities have been implemented in accordance with technical and quality assurance requirements that have been specified in the SARP and the American Society of Mechanical Engineers (ASME) Boiling and Pressure Vessel (B&PV) Code, Section II[5] and Section III,[6] e.g., welds and final nondestructive examinations that are considered critical and important to safety. For purposes of this paper, the two source verifications at the contractors' facilities are considered to be process audits.

The objective of a product audit is to verify that a finished product is in compliance with all drawings, specifications, and procedure requirements. In this type of audit, physical characteristics (e.g., dimensions) are measured and verified for compliance with fabrication requirements.

Audit Result Description

Key terms regarding the audit results are as follows:

1. Finding – Nonconformance or discrepancy from a requirement – Subpart H of 10 CFR Part 71 and Chapters 7, 8, and 9 of the SARP. A finding is a condition that has a significant adverse effect on the quality of an item, component, assembly, or activity. When a nonconformance or discrepancy has been identified, the audited organization is required to respond to the finding with a corrective action. Depending on the nature of the finding, a follow-up audit may be necessary.

2. Observation – A concern or issue identified by the audit team that does not violate current requirements, but that has the potential of becoming a discrepancy in the future, if not addressed. An observation should be considered an opportunity for improvement by the audited organization.

3. Good Practice – An exemplary practice that exceeds typical expectations.

PACKAGING QUALITY ASSURANCE AUDITS

Facility A

The scope of the audit at Facility A was to verify that it has a written QA program that incorporates the requirements from the QA chapter in the SARP for fissile material and Type B packaging, and that the QA program is in compliance with DOE 0 460.1 B and Subpart H of 10 CFR Part 71. The Nuclear Regulatory Commission's Regulatory Guide 7.10, *Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*,[7] and ASME NQA-l, *Quality Assurance Program Requirements for Nuclear Facilities*,[8] were used as guidance documents for methods of implementation of Subpart H of 10 CFR Part 71. The audit also included an evaluation to determine whether the requirements specified in the Operating Procedures and the Acceptance Tests and Maintenance Program (Chapters 7 and 8 of the SARP packaging, respectively) have been effectively implemented via site-specific procedures.

The audit resulted in no findings, two observations, and one good practice. The two observations were that final approval is needed prior to release of a procedural document and use of a color-coded form prohibits a black-and-white scan of the document from being legible. The need for final procedure approval had been identified by a previous internal audit. The facility initiated corrective action prior to the audit team's departure. In addition, the facility's radioactive material group was commended for identifying corrosion of the lead shield subassembly and reporting the nonconformance to the DOE package regulator and the DOE complex users. The facility's industrial hygiene group determined that no respirable hazard was associated with the corrosion, but the evaluation recommended that good

housekeeping and dedicated or disposable gloves should be used to minimize the potential spread of lead contamination. During a subsequent evaluation to determine the effects of corrosion on the packaging itself, the design agency determined that a DOE "lessons learned" should be issued because this packaging is widely used in the DOE complex. The DOE subsequently issued the lessons learned. Due to the design agency's proactive action, possible harm to personnel safety and degradation of the packaging performance was mitigated.

In summary, the audit team interviewed key personnel, reviewed numerous records and documents, and witnessed helium leak testing of the packaging at Facility A. The audit team determined that the QA program identified in Chapter 9 of the SARP is being implemented and is in compliance with 10 CFR Part 71, Subpart H. In addition, the audit team determined that the packaging user has developed acceptable procedures that effectively implement the requirements specified in the SARP for Operating Procedures (Chapter 7), Acceptance Tests and Maintenance Program (Chapter 8), and Quality Assurance (Chapter 9) for the packaging.

Facility B

The audit scope for Facility B was basically the same as for Facility A with the exception of the design control criterion. Facility B does not have any direct design responsibility for the packaging. The packagings were processed as government-furnished items with receipt inspection consisting of checking for shipping damage. Relative to the audit evaluation, design control was limited to confirming that procedural controls are in place so that the facility can perform design control on future fissile material or Type B packagings, if necessary. Should there be a nonconformance concerning the design, fabrication, testing, operations, or acceptance testing and maintenance, Facility B must receive approval of the nonconformance by the design agency. Other than the design control aspect, the scope of the audit also included an evaluation to determine whether the requirements specified in the Operating Procedures and Acceptance Tests and Maintenance Program (Chapters 7 and 8 of the SARP packaging, respectively) have been effectively implemented via site-specific procedures.

The audit resulted in three findings and six observations. The three findings were as follows:

1. Revise packaging loading and unloading to be in compliance with Chapter 7 of the SARP.

2. Perform independent QA audits of fissile material and Type B packagings in accordance with Subpart H of 10 CFR Part 71.

3. The loading and unloading shipping procedures either fail to include the appropriate Certificate of Compliance (CoC) revision level or fail to include any revision level.

The six observations were as follows:

1-3. Need to revise user procedures to be consistent with Chapter 7 and 8 of the SARP.

4. Recommendation to revise radiation limits for oxides to be consistent with 10 CFR 71.47.

5. The need for a crosswalk between Subpart H 10 CFR Part 71 and DOE O 414.1C[9] in Table 4 of *Transportation and Packaging Program Quality Assurance Program Plan, HNF-25689*, Revision 2.[10]

6. The need to identify inspection, test, and operating status of each packaging in accordance with 10 CFR 71.129.

In summary, the audit team interviewed key personnel, reviewed numerous records and documents, and witnessed loading of the packaging. The audit team determined that the QA program identified in Chapter 9 of the SARP will be in compliance with 10 CFR Part 71, Subpart H, after appropriate corrective actions have been implemented. In addition, Chapters 7 and 8 will be in compliance after corrective actions have been incorporated into the user's procedures for loading and unloading.

SOURCE VERIFICATION

Facility C

The PCP staff, Office of Safety Management and Operations (EM-60), conducted a source verification of select critical operations at Facility C. Weld integrity of the Debris Bed Experiments (DBE) Canisters is critical to maintain safety and meet the federal regulatory requirements for transport of radioactive and fissile materials. Source verification needs to be conducted at intervals consistent with the importance and complexity of the item or service that includes monitoring, witnessing, or observing selected activities. In 10 CFR Part 71.115, *Control of Purchased Material, Equipment, and Services*, the licensee, certificate holder, and applicant for a CoC are required to establish measures to assure that purchased material, equipment, and services conform to procurement documents. One method used to assure that purchased material conforms to procurement requirements is to perform oversight and inspection at the contractor's facility. Source verification provides the objective evidence that procurement requirements have been satisfied.

Prior to the site visit, the PCP staff reviewed the furnished documents on the certified material test reports (CMTRs), welding procedures, procedure qualification, and nondestructive examination (NDE) procedures for ultrasonic and liquid penetrant examination. During the facility visit, the team observed critical welding operations on the canister (bottom plate to canister weld and the top flange to canister weld), observed NDE of the critical welds, and reviewed certified material test reports. The welding observation focused on whether the welding process was conducted in accordance with the established procedures and within the requirements of the specifications. Specifically, the team observed the following activities:

- Gas tungsten arc tack welding and root pass of the canister bottom assembly
- Final flux core gas metal arc welding of a typical canister flange
- Grinding of a typical canister flange end
- Liquid penetrant examination of a typical final bottom (end) cap weld
- Ultrasonic inspection of a typical final bottom (end) cap weld

A summary of the observations follows:

1. There was one area noted in the procedure observation. The welding operation for the gas tungsten arc weld of the root pass for the bottom assembly weld requires a full penetration one-sided weld. This operation requires inert gas shielding and gas backing. The Welding Procedure Specification (WPS) indicates that argon (welding grade) is used as shielding gas; no requirement is specified for the gas backing composition except its flow rate. Even though this is a non-essential variable for the welding procedure as required by ASME Section IX[11] (QW-256 and QW-408.5), the PCP staff recommended that the WPS specify that the gas backing composition to reflect what was actually being used, i.e., welding grade argon, with an oxygen probe used to determine whether the oxygen level is less than 2% in the canister before initiation of welding.

   NOTE: The PCP staff wishes to emphasize that the welders have taken the necessary precautions to ensure the weld quality of the joint, and that the composition of the gas backing for this WPS is a non-

essential variable for the welding procedure. Revision of the WPS to reflect the actual gas composition used for the weld removes any potential ambiguity and represents an opportunity for improvement.

2. With regard to the review of CMTRs, most of the materials for Category A and B items (Important-to-Safety) were purchased to conform with ASME B&PV Code, Section II, 2004 Edition and 2006 Addenda. While the review concluded that the base material for stainless steel plate, pipe, and bar material was in compliance with ASME B&PV Code, Section II, SA-240,[12] SA-312,[13] and SA-479,[14] respectively, the Code of Record specified in the SARP for the packaging is the 1998 Edition. In addition, the SARP specifies that the design of the canister is based on ASME B&PV Code, Section III, Subsection NB and Subsection NF, 1995 Edition. Although it is typical for material suppliers to provide material to the latest addenda of the ASME Code, the design organization is required to perform an engineering evaluation to determine whether the material received from a later edition of the Code complies with the Code of Record. In this case, the design organization established that material purchased to a later edition of the Code complied with the edition established in the SARP. After the discrepancy between the Code of Record and material purchased to the latest edition of the Code was identified by the PCP staff, the applicant conducted an engineering evaluation and reconciled the purchased material and the Code of Record identified in the SARP. The Code of Record was established in the SARP design, materials, fabrication, testing, operating procedures, and acceptance testing and maintenance.

In conclusion, the PCP staff has determined that fabrication of the DBE canisters is in accordance with the established requirements in Chapter 7 of the SARP requirements, including the Code of Record.

Facility D

In September 2007, the PCP staff conducted a source verification of the lid-to-top flange weld for the DBE canister at Facility D. The PCP staff had conducted a previous source verification regarding the fabrication of DBE transport canisters in May 2007. Witnessing the welding of the canister lids to the top flange of the DBE canisters after loading is a follow-up activity that completes the source verification of the transport canisters.

Prior to the visit, the PCP staff reviewed the facility's *Work Procedure for Seal Welding and NDE of DBE Canister Lid and Port Cover Plate*. During the visit, the staff observed the DBE canister lid-to-top flange welding and liquid penetrant examination of the root and final pass. In addition, the staff evaluated records for the welding procedure, welding procedure qualification, welder performance qualification, vision test for the NDE inspector, CMTR and Certificate of Conformances for 3/32-in. and 1/8-in. diameter ER308L weld filler metal for compliance with Chapter 8 of the SARP and ASME B&BV Code, Section III. The witnessing focused on whether the welding process and the liquid penetrant examination were conducted in accordance with the established procedures and within the requirements of the specifications.

Specifically, the staff observed the following activities for canister serial numbers 119-99:

-1 Final LP inspection
-2 Root and final weld and LP inspection
-3 Fit-up, tacking, and partial root pass
-6 Fit-up, tacking, and partial root pass
-7 Final weld and LP inspection
-9 Fit-up and tacking

Both the essential and non-essential variables of the welding procedure were verified. The filler metal was stamped and traceable to the heat numbers on the CMTRs. Weld fit-up, tack weld, root and final pass, and weld size were verified and found to be acceptable, along with liquid penetrant examination of the root and final pass.

In conclusion, the welding and liquid penetrant examination procedures and qualification records were appropriately implemented and documented. Manufacturing controls were in place to ensure that all welding and NDE personnel had properly controlled information on how to perform the work. The welder and NDE examiner were experienced and qualified to perform the work in accordance with the specifications. Welding materials were properly controlled and documented. Welding and NDE equipment were calibrated and appeared to be operating properly. The welder and NDE examiner used appropriate techniques in performing their respective tasks. Personnel were adequately qualified, and proof of their qualifications was verified by the PCP staff. The personnel were knowledgeable and cooperative. In summary, all observed work was being performed in accordance with SARP requirements established in Chapter 8, Acceptance Tests and Maintenance Program.

SUMMARY AND CONCLUSION

The performance of QA audits and source verification of critical activities at DOE contractor and sub-contractor sites provides valuable information to various groups within the Department of Energy: Manager, Packaging Certification Program; the Headquarters Certifying Official; and the DOE Packaging Programmatic Offices. In addition, management of the audited organization is provided with a status report that demonstrates compliance with Chapters 7, 8, and 9 of the SARP and with the QA requirements prescribed in Subpart H of 10 CFR 71. By learning the up-to-date status of the QA program, the audited organization can implement corrective actions to prevent more serious problems at a later date.

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