

INSPECTOR NOTES: APPLICABLE SECTIONS FROM BOTH IP 60851 AND IP 86001 WERE PERFORMED DURING THE INSPECTION WITH RESULTS DOCUMENTED BELOW:

IP 60851

02.01 Determine whether the licensee's or CoC holder's QA program implementing procedures are in place and used effectively.

Pearson:

The inspector reviewed select portions of the following NAC Quality Assurance Manual sections: 2.0, "Quality Assurance Program"; 4.0, "Procurement Document Control"; 5.0, "Procedures, Instructions, and Drawings"; 6.0, "Document Control"; 9.0, "Control of Special Processes"; 12.0, "Control of Measuring and Test Equipment"; and 17.0, "Records," as well as portions of the corresponding NAC Quality Procedures (QPs).

The inspector's review, in addition to information gathered during interviews with personnel responsible for procedure control, records control, training, as well as the interviews with management personnel responsible for development provided sufficient evidence that NAC's Quality Assurance Program was fully implemented and was being effectively used.

02.02.a Determine whether a method exists to ensure that design changes initiated by the vendor or CoC holder are communicated to the licensee.

Pearson:

The inspector witnessed the process for distribution of a variety of documents and discussed the method used to notify all of the appropriate parties of changes with document control personnel. The method in use was verified to be acceptable for communicating changes to licensees.

02.02.b Determine whether the licensee was notified of the design changes in a timely manner to minimize production or operations impacts.

Desai:

The inspectors reviewed NAC design QPs and confirmed that a mechanism existed to notify the licensee of design changes such that impact to operations was minimal.

02.02.c Determine whether the licensee has reviewed and/or approved these design changes that were approved by the vendor or CoC holder.

Desai:

The inspectors reviewed inspection guidelines in NUREG/CR-6314, Quality Assurance Inspections for Shipping and Storage Containers, to determine licensee compliance with 10 CFR 71 and 72. Specifically, Appendix B, Inspection Element -2, Design Controls, of the NUREG was used to determine acceptable implementation of the QA program. In part, the inspector reviewed and discussed, with NAC, the following QA program implementing procedures:

- QP 3-1, "Control of Design Inputs"
- QP 3-2, "Preparation and Checking of Design Calculations"
- QP 3-3, "Preparation and Checking of Design and/or License Drawings, Specifications, and Technical Reports"
- QP 3-4, "Design Verification"
- QP 3-7, "License Document Configuration Control"

- QP 3-8, “10 CFR 72-48 Determinations for Changes to NAC Dry Storage Cask Systems”

The inspectors also reviewed the following Design Change Request (DCRs) to determine if the appropriate reviews were performed and that the drawing changes were in fact completed and the appropriate drawings updated to correctly reflect the intended change:

- DCR 790-002-6A, Drawing for NAC-UMS
- DCR 790-042-2B, Drawing for TSC UP-ENDER NAC UMS
- DCR 790-060-18A, Drawing for Assembly, Standard Transfer Cask (TFR) NAC-UMS
- DCR 790-081-9C, Drawing for PWR Fuel Tube, NAC-UMS

Based on the review of the NAC QPs as well as discussing the understanding of the QPs with the NAC staff, the inspectors concluded that NAC’s QA program implementing procedures were properly documented and effectively used to control NAC designs according to the criteria detailed in NUREG/CR 6314. Further, the inspectors determined that a method exists to ensure that design changes initiated by NAC are communicated to the licensee in a timely manner. For the DCRs reviewed, the inspector determined that the changes were appropriately reviewed, controlled and documented.

02.05 Determine whether the licensee, vendor, and fabricator personnel have established and effective method for tracking, evaluating, and dispositioning changes or modifications to the DCSS component design.

Desai:

The inspector reviewed Corrective Action Report (CAR) 02-03 (Design Input) that was conducted by NAC. This root cause analysis (RCA) involved an instance where certain specific design inputs were not complete nor accurate to portray the fuel design for a part 50 licensee. The inspector determined that the RCA was thorough and resulted in several enhancements to NAC procedures. Specifically, the inspectors verified that QP- 3-1, “Control of Design Input”, had been updated to incorporate changes recommended by the RCA.

02.06 For selected design changes, determine whether the applicable documentation is complete including relevant 10 CFR 50.59 or 72.48 evaluations.

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Wharton:

The inspector reviewed Quality Procedure (QP) 3-3, “Preparation and Checking of Design and /or Licensing Drawings, Specifications and Technical Reports”; QP 3-7, “License Document Configuration Control”; and QP 3-8, “10 CFR 72.48 Determination For Changes to NAC Dry Storage Cask Systems”. These NAC documents described in adequate detail and clarity the process for controlling document configuration and 72.48 changes/modifications to dry storage system designs. The procedures reflected a thorough approach to reviewing and implementing the change control process for license drawings, design specifications, and technical information. The 72.48 determination checklist was revised 2003 improve its functionality by clarifying required actions and process approvals. The revision also raised the procedure hierarchy from a Project Instruction, PI-EDS-02, “10 CFR 72.48 Related Determinations for NAC-MPC and NAC-UMS Projects,” to the current Quality Procedure, QP 3-8. Only authorized NAC personnel can approve the 72.48 Determination form. This formal authorization was

gained by completion of the LeBlond & Associates 50.59/72.48 classroom training course. A statement specifying the approval authorization was noted on every 72.48 Determination.

The inspector reviewed selected screenings (3) and all the 72.48 evaluations (12) performed since 2002. The results of the screenings and evaluations were either design change requests (DCR), design change request for licensing documents (DCR(L)), nonconformance reports (NCR), or vendor nonconformance reports (VNCR) with documented dispositions. The 72.48 Determination Checklist (PI-EDS-02) and the revised 72.48 Determination form (QP 3.8) were well designed, clearly worded, and adequately detailed to assess the appropriateness of the applicability, screening and evaluation. The evaluations addressed the 10 CFR 72.48 criteria for determining that no prior NRC approval was required to implement the proposed change. The inspector also interviewed three NAC cask system users regarding 72.48 configuration controls. NAC completes a Compatibility Impact Assessment (CIA) review form for each 72.48 determination to evaluate and track interrelated changes. A bimonthly CIA review meeting is conducted with appropriate NAC users to identify generic changes to storage cask systems. The results of the meetings are formally transmitted to the appropriate NAC cask system users.

The inspector also reviewed all 72.48 training materials and records. The records included documentation of training completed by the authorized licensing approvers provided by LeBlond & Associates. The applicant also maintained records of NAC provided training on 72.48 requirements. These records document that several training sessions have been conducted; on May 15, 2001, March 1, and April 11, 2002, February 20, and June 17, 2003. A review of the training materials and inspector interviews with the authorized approvers, and other licensing personnel indicated adequate knowledge of requirements and implementation procedures.

The inspector found the NAC 72.48 change process to be in accordance with regulatory requirements, procedural sound and effectively implemented.

IP86001:

02.03 Verify that provisions are in place for reporting defects which could cause a substantial safety hazard, as required by 10 CFR Part 21.

Temps:

With respect to reportability under the provision of 10 CFR Part 21, NAC uses QP 16-2, "Reporting of Potential Significant Deficiencies and Defects, and Regulatory Reporting," to address this requirement. The inspector verified that the procedure and Part 21 postings were visibly located in accessible locations at NAC's office and that purchase orders invoked Part 21 requirements where appropriate. In instances where a supplier was unable to implement Part 21 requirements, the purchase orders specified NAC's responsibility for such reportability.

02.05 Review selected drawings, procedures and records, and observe selected activities being performed to determine that the fabrication, test, and maintenance activities meet SARP design commitments and requirements documented in the CoC.

Pearson:

The inspector interviewed specific NAC personnel and reviewed selected portions of the NAC Quality Manual as well as selected portions of NAC QPs; QP4-1, "Procurement Document Control," QP 5-1, "Preparation and Control of Quality Procedures," QP 5-2, "Preparation and Control of Project Instructions," QP 5-3, "Preparation and Control of Procedures, Instructions,

and Drawings,” QP 6-1 “Controlled Document Distribution,” QP 17-1 “Identification, Transmittal, Storage and Maintenance of Quality Records,” and QP 17-2 “Electronic Records Storage and Maintenance.” Some of the personnel interviewed, performed activities that required the use of a computerized program currently in use at NAC for document control and records management control. Multiple demonstrations of the efficiency of document control at NAC were provided for the inspector. The inspector witnessed the performance of the computerized system in the dissemination of a variety documents to various personnel within the organization and discussed the method for supply of the same documents, as needed, by entities outside the NAC organization.

The inspectors verified from various interviews, observation of activities, as well as the review of multiple documents listed in various other inspector notes that documented requirements of NAC QPs that the NAC Quality Program activities ensured the inclusion of CoC requirements.

Desai:

The inspector reviewed and discussed the completed procedure for the annual maintenance of a transportation package, NAC-LWT-Number 7, used for the legal weight truck shipping containers. The inspectors confirmed that all the requirements of the procedure were appropriately documented as complete and were within the required maintenance interval.

02.06 Observe activities affecting safety aspects of the packaging (such as fabrication, assembly, and testing) to verify that they are performed in accordance with approved methods, procedures, and specifications.

Temps:

The inspector reviewed document 790-S-05, “Procurement/Fabrication Specification, NAC-UMS Transportable Storage Canisters, Basket Assemblies and Fuel Cans.” This is a NAC document that spells out in detail a variety of controls and requirements regarding fabrication and procurement controls for the NAC-UMS system. The inspector determined that the document thoroughly addressed a variety of issues including, but not limited to, such issues as document controls, codes and standards, graded approach to quality and quality categories, materials fabrication, inspection and examination of welds, acceptance testing, and handling/shipment of completed units.

The inspector also reviewed two randomly sampled completed fabrication data packages, one for fabrication of a unit at Hitachi-Zosen and the other unit at Ionics. The inspector verified that the processes documented in the data packages conformed to the 790-S-05 specification requirements and that the packages were complete. NCRs, if any, generated during the fabrication of each unit were included in the package for easy reference. Use of calibrated equipment was noted and the travelers contained various hold and witness points, as well as signature blocks for verification of any required NDE. Proper controls for the documentation of temporary attachment points were also included in the documents. All required signatures were in the data packages and no discrepancies were identified in either of the reviewed packages.

02.07 Review selected drawings and records, and interview selected personnel, to verify that the procurement specifications for materials, equipment, and services received by the QA Program holder meet the design requirements.

Temps:

The inspector reviewed NAC’s QPs governing procurement activities. These included QPs:

QP 4-1, "Procurement Document Control"
QP 7-1, "Control of Purchased Items and Services"

NAC's qualified vendors list (QVL) was also reviewed.

The above procedures and the QVL were determined to meet the 10 CFR 72.148 and 72.154 requirements in the areas of procurement document control and control of purchased material, equipment, and services. One minor issue was identified with the maintenance of the QVL with respect to the currency of the listing of supplier's NAC approved QA programs; the issue was immediately addressed by NAC through issuance of written guidance in a newly developed procedure, SP (Standard Practice)-406, "Development and Use of the NAC Qualified Vendors List."

The inspector reviewed several procurement documents from suppliers listed on the QVL for various important-to-safety (ITS) Class A, B or C, materials and services. No concerns were identified.

Pearson:

The inspector reviewed the NAC QVL and 2 vendor audits. One audit, 03-E-01, was performed on Ionics Incorporated from 4/1-4/03. The second audit, 03-E-02, was performed on the Northeast Technology Corporation from 8/26-27/03.

The inspector noted that both of these audits were performed according to detailed checklists and in accordance with the requirements of the NAC Quality Manual, and the associated NAC QPs.

02.08 Review selected records and interview selected personnel to verify that a nonconformance control program is effectively implemented, and that corrective actions for identified deficiencies are technically sound and completed in a timely manner.

Temps:

The inspector reviewed the NAC QAM and verified that Sections 15 and 16, respectively, addressed control of non-conforming items and corrective actions. The following quality procedures (QPs) are used by NAC in implementing their QAM commitments in this area:

QP 15-1, "Control of Nonconforming Items"
QP 15-2, "Vendor Nonconformance Reports"
QP 16-1, "Corrective Action Reports"

10 CFR 72.170 addresses the requirements for certificate holders in controlling nonconforming items and 10 CFR 72.172 requires a corrective action system be in place to address conditions adverse to quality as well as significant conditions adverse to quality. The inspector determined that NAC's QPs address the regulatory requirements. With respect to the corrective action program, the inspector noted that NAC's system is structured such that conditions adverse to quality are addressed through the use of non-conformance reports (NCRs) and vendor non-conformance reports (VNCRs) whereas significant conditions adverse to quality are addressed through the issuance of corrective action reports (CARs). Under NAC's program, NCRs and VNCRs can always be upgraded to CARs if the condition warrants.

A sample of NCRs, VNCRs, and CARs were reviewed by the inspector and the resolution of the

issues identified in them were assessed to be appropriate to the nature of the concern identified in the reports. NAC QA has appropriate measures in place for the tracking and trending of the reports and for ensuring proper report closure timeliness.

02.09 Review selected records and procedures, interview selected personnel, and observe selected activities affecting the safety aspects of the packaging to verify that individuals performing activities affecting quality are properly trained and qualified, and to verify that management and QA staff are cognizant and provide appropriate oversight.

Pearson:

The inspector reviewed training, qualification and certification records for two of seven active lead auditors and found them to be well qualified and experienced. The inspector also reviewed the qualification records for a mechanical inspector, a civil Inspector, a shield material inspector, and an NDE inspector and found all to be acceptably qualified and experienced. Interviews with Management Staff indicate that they are cognizant of current quality activities as well as sensitive to the needs of the NAC workforce. In addition to the above, though not a formal part of the NAC quality program, the inspector recognized the direction provided in the NAC Standard Practice; "Strategic Business Units (SBU) Training Programs."

02.10 Verify that audits of the QA Program and activities affecting the safety aspects of the packaging are scheduled, have been performed as scheduled, and that identified deficiencies have been satisfactorily resolved in a timely manner.

Pearson:

The inspector reviewed the NAC Quality Manual, Section 18.0, "Audits" as well as select portions of the following NAC QPs: 18-1, "Qualification and Certification of Quality Assurance Audit Personnel;" 18-2, "Audits, Surveys, and Corrective Action;" 18-3, "Quality Assurance Surveillance." In addition, the inspector reviewed the 2003 and 2004 NAC Audit schedules. The inspector also reviewed 2 internal audits; 03-I-02, 03-I-01 as well as a management audit, 03-M-01. The inspector noted that the audits had multiple appropriate audit finding reports as well as multiple observations. The management audit was well written and provided many suggestions to NAC for possible improvements.

The inspector determined that audits are occurring on schedule and are performed with detailed audit checklists on the appropriate criteria.

Note format based on 86001 - Issue Date 02/07/02