

July 27, 2004

MEMORANDUM TO: Chairman Diaz

FROM: Hubert T. Bell /RA/
Inspector General

SUBJECT: NRC'S OVERSIGHT OF THE QUALITY ASSURANCE
PROGRAMS RELATED TO THE MANUFACTURE OF
HOLTEC INTERNATIONAL DRY CASK STORAGE SYSTEMS

Attached is an Office of the Inspector General (OIG), U.S. Nuclear Regulatory Commission (NRC) Special Inquiry that addresses concerns with the NRC's oversight of quality assurance programs related to the manufacture of Holtec International dry cask storage systems.

Please call me if you have any questions regarding this Special Inquiry. This report is furnished for whatever action you deem appropriate. Please notify this office within 120 days of what action, if any, you take based on the results of this special inquiry.

Attachment: As stated

cc w/attachment:
Commissioner McGaffigan
Commissioner Merrifield
L. Reyes, EDO

OFFICE OF THE INSPECTOR GENERAL SPECIAL INQUIRY



**NRC'S OVERSIGHT OF THE QUALITY ASSURANCE
PROGRAMS RELATED TO THE MANUFACTURE OF
HOLTEC INTERNATIONAL DRY CASK STORAGE SYSTEMS**

Case No. 03-03S

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BASIS AND SCOPE

The Office of the Inspector General (OIG), U.S. Nuclear Regulatory Commission (NRC), initiated this inquiry in response to concerns that NRC failed to provide adequate oversight of the manufacture of Holtec International dry cask storage systems used by nuclear power plants to store spent nuclear fuel. Oscar Shirani,¹ an auditor formerly employed by the Exelon Corporation (Exelon), raised these concerns. Exelon is an NRC licensee that uses the Holtec dry cask storage systems at its Dresden Nuclear Power Generating Station.²

Shirani's concerns were based on the results of an audit conducted by the Nuclear Procurement Issues Committee (NUPIC), a nuclear industry group composed of representatives from all domestic and several international nuclear utilities. NUPIC utilizes personnel from member utilities to conduct performance evaluations of nuclear industry suppliers and vendors. Shirani was the lead auditor for the 2000 NUPIC audit which assessed the quality assurance (QA) program used to ensure that spent nuclear fuel dry cask storage systems designed by Holtec and fabricated by U.S. Tool and Die (US T&D) met their design requirements. This QA program was developed and implemented by US T&D as required by Federal regulations. According to Shirani, the 2000 NUPIC audit identified significant problems within the QA program for the fabrication of these dry casks. Shirani believed that these problems could result in the fabrication of defective casks and could affect the safe storage of spent nuclear fuel.³

In November 2001, after learning that he was going to be terminated by Exelon, Shirani contacted the NRC Region III office and raised concerns about the QA program for the fabrication of Holtec dry casks. His concerns included issues identified during the 2000 NUPIC audit. NRC assessed and responded formally to these concerns, but Shirani was dissatisfied with NRC's assessment and in July 2003 raised his concerns to OIG. During his meeting with OIG, Shirani stated that as a consequence of his experiences, he generally questioned NRC's ability to oversee nuclear industry QA programs. In particular, he pointed to a July 1999 NRC inspection of the US T&D QA program which failed to identify problems similar to those identified in the 2000 NUPIC audit. Additionally, Shirani asserted that NRC failed to adequately address the concerns he reported to the agency in November 2001.

In response to these two concerns, this Special Inquiry:

- Reviewed the NRC's July 1999 US T&D inspection in light of the 2000 NUPIC audit and other NRC and NUPIC reviews of Holtec's and US T&D's QA programs for the fabrication of dry cask storage systems.
- Reviewed NRC's handling of the technical concerns related to the QA oversight of dry cask storage systems reported by Shirani to the agency in November 2001.

¹ MD 8.8 indicates that NRC will not routinely release the identity of an alleged. However, Shirani agreed to the release of his name in connection with his safety concerns pertaining to dry cask fabrication.

² As an NRC licensee, Exelon is required, under 10 CFR Part 50, Appendix B, Section VII, to assess the quality controls of equipment providers to ensure the purchased items meet requirements.

³ Shirani also alleged that Exelon's follow-up actions concerning the audit findings were inadequate and that in December 2001 Exelon terminated his employment for raising these issues. OIG did not address these issues in this report. NRC's Office of Investigations investigated Shirani's allegations regarding his dismissal (OI Case 3-2001-055).

BACKGROUND

Dry Casks

Spent fuel is composed of the remains of nuclear fuel that had been used to generate nuclear energy. This highly radioactive waste must be stored in a manner that prevents leakage of radioactivity into the environment. Nuclear power plants have stored this spent fuel in water pools at the reactor site. Periodically, about one-third of the nuclear fuel in an operating reactor needs to be unloaded and replaced with fresh fuel, which creates a routine need for additional storage space. In the late 1970s and early 1980s, the need for alternative storage capability began to grow when pools at many nuclear reactors began to fill up with stored spent fuel. Utilities began looking at options for increasing spent fuel storage capacity.

In 1982, Congress passed the Nuclear Waste Policy Act, which, in part, directed NRC to approve a means for achieving interim dry storage of spent fuel at power plants until a permanent, centralized high-level nuclear waste repository could be developed.⁴ Consequently, NRC promulgated its regulations to authorize nuclear power plant licensees to store spent fuel at reactor sites in NRC-approved dry storage casks.⁵

To date, NRC has approved 14 cask designs for use under a general NRC license, and these designs are listed in Title 10 of the Code of Federal Regulations, Part 72.214 (10 CFR Part 72.214). Casks typically consist of a sealed metal cylinder containing the spent fuel enclosed within a metal or concrete outer shell. These systems are designed to resist floods, tornados, missiles, temperature extremes, and other unusual scenarios.

NRC's design approval – also known as a Certificate of Compliance (CoC) – places responsibility on the dry cask vendor to establish a quality assurance (QA) program to oversee all aspects of cask fabrication to ensure its casks are constructed as designed and will perform satisfactorily. This QA program pertains to all steps related to production of a cask, including design, testing, and fabrication.

NRC Spent Fuel Project Office

NRC's Spent Fuel Project Office (SFPO), within the agency's Office of Nuclear Materials Safety and Safeguards (NMSS), is the primary office responsible for overseeing the storage of spent nuclear fuel. Among its responsibilities, SFPO:

- Develops and implements the agency's regulatory, licensing, and inspection program for the storage of nuclear reactor spent fuel.
- Develops policy, regulations, and guidance for designers, users, and fabricators of NRC-certified dry spent fuel storage casks.

⁴ The Department of Energy's Yucca Mountain Project is an effort to establish the Nation's first long-term repository for high-level nuclear waste.

⁵ The terms "cask" and "cask system" are equivalent and are used interchangeably in this report.

- Conducts inspections of the implementation of QA programs by users, vendors, and fabricators of NRC-certified dry spent fuel storage casks.

Applicable Regulatory Guidance

Federal requirements relevant to dry cask storage of spent nuclear fuel are contained in 10 CFR Part 72, 10 CFR Part 50, and 10 CFR Part 21. These requirements govern the components of a QA program which every CoC holder and every power and fuel-processing plant must possess, and they require companies involved in nuclear related activities (e.g., dry cask vendors and fabricators) to notify NRC if they discover defects within their facilities or components that violate NRC regulations or orders, or pose a substantial safety hazard.

NRC licensees using dry casks and dry cask CoC holders must follow the requirements in 10 CFR Part 72, *Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste*. Subpart G, *Quality Assurance*, outlines QA program elements with which these licensees and CoC holders must comply. According to Subpart G, the QA program must include measures to ensure that design requirements are met; that contractors and subcontractors provide their own QA programs; that QA activities and instructions, drawings, and procedures are followed; and that changes to QA procedures are reviewed and approved by authorized personnel. The QA program must also include a corrective action component to identify problems and their causes and ensure that corrective measures are taken, documented, and reported to the appropriate management levels. Subpart G specifies that licensees and CoC holders are simultaneously responsible for meeting these QA requirements through the oversight of their contractors and subcontractors.

10 CFR Part 72, Subpart L, *Approval of Spent Fuel Casks*, addresses the regulatory requirements with which dry cask design CoC holders must comply. Subpart L requires these CoC holders to permit NRC to (1) inspect the premises and facilities where a spent fuel storage cask is designed, fabricated, and tested; (2) review records pertaining to the design, fabrication, and testing of dry casks; and (3) perform tests to ensure that regulatory requirements are met.

QA program guidance directed specifically at licensees is contained in 10 CFR Part 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*. This appendix specifies the QA program which every power and fuel-processing plant must possess and closely mirrors the requirements outlined in 10 CFR Part 72, Subpart G. The regulations mandate that licensee QA programs address all structures and systems with safety significance, which would include a dry cask storage system once delivered and in use at a plant.

10 CFR Part 21, *Reporting of Defects and Noncompliance*, requires companies involved in constructing, owning, operating or supplying components or activities which are licensed or regulated by the NRC to notify NRC upon discovery of defects within nuclear facilities or basic components that violate NRC regulations or orders and could create a “substantial safety hazard.”⁶ Firms licensed and regulated under 10 CFR Part 72 (e.g., dry cask design CoC holders) are included among the list of entities required to submit defect reports under this regulation.

⁶ Substantial safety hazard means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to the public health and safety by the facility or component.

NRC inspectors conduct inspections to ensure that regulated activities are conducted in accordance with applicable requirements. The NRC Inspection Manual provides the overarching guidance for these inspections and includes numerous focused inspection procedures which address all aspects of the NRC regulated nuclear industry. Ten of the inspection procedures relate primarily to the interim storage of spent nuclear fuel and dry casks. Particularly relevant to Holtec and US T&D activities is Inspection Procedure 60852, *ISFS/ Component Fabrication by Outside Fabricators*. This procedure provides specific inspection guidance to allow inspectors to determine if a fabricator is manufacturing dry casks in accordance with the requirements in 10 CFR Part 72 and reporting defects as required under 10 CFR Part 21. NRC review of the applicable QA programs, activities, and documents is an integral portion of this inspection procedure.

Holtec International and U.S. Tool and Die

Holtec International (Holtec) is an energy-related technology company that designs and sells equipment and provides consulting services to the energy industry. More than 70 percent of the company's products are destined for nuclear power plants. Holtec's Spent Fuel Systems Division (SFSD) designs and oversees fabrication of items used in the storage of spent fuel, including dry cask storage systems. Holtec holds CoCs for two dry cask storage systems: (1) the Holtec International Storage, Transportation and Repository (HI-STAR) 100, and (2) the Holtec International Storage, Transportation Operation Reinforced Module (HI-STORM) 100. Many of the fabrication activities for Holtec designed items are conducted by contractors. Holtec's contractor for cask construction is U.S. Tool and Die (US T&D). As a CoC holder, Holtec has an NRC-approved QA program and is responsible for overseeing the fabrication of its casks at US T&D. This oversight responsibility includes ensuring that US T&D's internal QA program and processes are consistent with Holtec's NRC-approved QA program.

Exelon Corporation

Exelon Corporation⁷ (Exelon), an NRC licensee, uses Holtec casks at its Dresden Nuclear Generating Station to store spent nuclear fuel. To date, Exelon has loaded 21 dry casks at the Dresden site. Per 10 CFR Part 50, Exelon is responsible for ensuring that all safety-related components will perform appropriately. This extends to its use of dry cask systems to store spent fuel at its power plants. As a result, Exelon's own NRC-approved QA program must monitor the QA programs of its vendors and suppliers and any of their subcontractors.

Nuclear Procurement Issues Committee (NUPIC)

In 1989, a group of nuclear utilities formed NUPIC to represent all domestic and several international nuclear utilities operating nuclear power plants. A primary goal was to provide a cost-effective, cooperative program to evaluate the performance of vendors and suppliers furnishing safety-related items and services to the nuclear industry. NUPIC conducts joint audits and surveys utilizing accepted industry standards to evaluate these items and services. NUPIC audit teams are composed of representatives from member utilities, each of which is responsible for ensuring the quality and integrity of the items they procure. These joint audits obviate the need for each member utility to conduct individual audits on items and services used by multiple nuclear power companies.

⁷ Exelon Corporation was formed by a merger in October 2000. One of the entities merged was ComEd, for which Shirani worked. The name, Exelon, is used exclusively in this report to represent Exelon and the preceding entities.

DETAILS

I. OVERVIEW OF SHIRANI'S CONCERNS

During an interview of Oscar Shirani conducted by OIG in July 2003, OIG learned that during June 19-23 and July 5-7, 2000, NUPIC conducted an audit of US T&D to assess the adequacy, effectiveness, and implementation of the company's QA program. Exelon, a user of dry casks designed by Holtec and fabricated by US T&D, was the lead utility for the audit, and Shirani, an auditor then employed by Exelon, was the lead auditor. He was assisted on this audit by five auditors and two technical specialists.

Shirani told OIG that the NUPIC audit identified nine findings which indicated that the Holtec casks fabricated by US T&D might not match their NRC-approved design specifications. For example, Shirani noted that US T&D had purchased many items and parts from suppliers that had not been audited. As a consequence, Shirani believed that the quality and precision of these components could not be trusted and this called into question the overall integrity of the casks. Shirani believed that the NUPIC audit findings were so significant that Exelon should have issued a Stop Work Order (SWO) against US T&D and Holtec until these problems could be corrected. Shirani was disappointed that despite his recommendations to his supervisor, Exelon did not issue an SWO.

Shirani said that on September 5, 2000, US T&D responded to the NUPIC audit and addressed the causes and provided corrective actions for each finding. Exelon was responsible for reviewing US T&D's proposed corrective actions. Shirani told OIG that he signed Exelon's response, dated October 19, 2000, to US T&D which stated that the proposed corrective actions were reasonable; however, he told OIG he did so only because of pressure from his supervisors. Additionally, he said he agreed to sign the October 19 letter because the letter kept the NUPIC audit findings open until their resolution could be verified. Shirani also claimed to OIG that he was prevented by his supervisor from conducting any follow-up review of US T&D to ensure that the audit findings were properly addressed. He felt that having served as the lead auditor on the original NUPIC audit, he should have been the person who reviewed and verified US T&D's corrective actions.

Shirani related that in December 2000, he agreed to a transfer from the section that provided QA oversight of Exelon suppliers into a financial audit position. In October 2001, Shirani learned that his employment with Exelon would be terminated, effective December 2001. In November 2001, Shirani formally came to NRC Region III with concerns about Exelon's, Holtec's, and US T&D's QA programs. Shirani stated that the NRC responded formally to these concerns, but he was dissatisfied with NRC's responses and subsequently contacted OIG.

Shirani told OIG that the 2000 NUPIC audit identified significant safety issues related to the QA oversight of the manufacture of the spent nuclear fuel dry cask storage systems. He said that the problems were extensive and recurring. Shirani noted that in June and July 1999, NRC conducted an inspection of the US T&D QA program but failed to uncover any of the same deficiencies identified during the 2000 NUPIC audit. Shirani characterized NRC as "sleeping" during its 1999 inspection, and he felt that NRC should have identified similar weaknesses at US T&D as those discovered by NUPIC. According to Shirani, he was more rigorous than NRC inspectors in evaluating US T&D against the relevant industry and regulatory standards.

Shirani also told OIG that although Region III made reasonable attempts to capture his concerns pertaining to the QA programs at Holtec and US T&D when he reported them in November 2001, the agency failed to fully understand his issues and came to the wrong conclusions. Shirani said he disagreed with NRC's response to his concerns, which, in his view, was evidence of the NRC staff's inability to properly regulate the nuclear industry. Shirani maintained that his NUPIC audit findings were based on criteria established in the applicable industry codes and in NRC regulations. According to Shirani, NRC inspectors lacked an understanding of these codes and regulations and the expertise necessary to address his technical issues. Shirani stated to OIG that he did not accept NRC's conclusions because they conflicted with his perception of conditions at US T&D and because he could not verify how NRC reached its conclusions.

II. OIG REVIEW OF NRC INSPECTIONS OF US T&D/HOLTEC QA PROGRAMS

Because of Shirani's contention that the 2000 NUPIC audit findings were indicative of extensive, recurring deficiencies in the Holtec QA program that the NRC should have identified during its inspections, OIG reviewed:

- NRC's 1999 inspection of US T&D's QA program.
- NUPIC's 2000 audit of US T&D's QA program.
- Other NRC and NUPIC inspections of Holtec and US T&D QA programs conducted prior to and following the 2000 NUPIC audit. (NRC conducted three inspections related to Holtec and US T&D dry cask QA programs between July 2000 and February 2002. In addition to the 2000 audit, NUPIC conducted three audits related to US T&D's QA program between 1996 and 2002.)

July 1999 NRC Inspection of US T&D

From June 28 to July 2, 1999, three NRC Headquarters SFPO inspectors conducted an inspection of US T&D's facility to determine whether:

- US T&D was fabricating the dry cask storage systems in accordance with 10 CFR Part 72 regulations for spent fuel storage systems and the NRC-approved QA program for Holtec.
- Manufacturing defects were being reported as required under 10 CFR Part 21.
- Holtec's QA oversight of US T&D cask fabrication activities was effective.

The resulting NRC inspection report (IR 72-1008/99-201), dated August 2, 1999, indicated that inspectors reviewed US T&D management controls, design controls, and fabrication controls. With regard to management controls, NRC inspectors reviewed US T&D QA program goals, objectives, and practices. They also reviewed the effectiveness of the QA program in controlling quality-related documentation, including inspection of engineering drawings and change notices, and inspection and test procedures. Inspectors reviewed the nonconformance⁸ control program to assess the effectiveness of measures established to control materials, parts, and components that did not conform to design requirements. To assess design controls, inspectors reviewed design development and modifications, including reviews of engineering changes, design reviews, and document changes. NRC inspectors also reviewed fabrication controls to determine if all phases of the fabrication process were properly controlled, implemented, and verifiable, to include material procurement, fabrication, and assembly. This included a review of nuclear industry codes, standards, and drawings to assess if fabrication procedures were followed; a review of inspection and test acceptance criteria and test conditions; and a review to determine if tools and equipment were properly calibrated and met standards.

While the 1999 NRC inspection report identified no violations of NRC regulations, it documented several observations. For example, the report noted that in the area of fabrication and assembly, US T&D did not complete one logbook entry regarding the issuance of welding

⁸ Nonconforming items are those which do not exactly conform to design specifications.

material as required by US T&D's quality control procedures. In response to NRC's observation, US T&D entered the item into its corrective action system, provided additional training to the individual who did not complete the log, and updated the log entry. Another observation questioned the independence of Holtec's QA auditing personnel. The inspection report noted that the last three annual internal audits of Holtec's QA program were performed by US T&D and that the last three annual audits of US T&D's QA program were performed by Holtec. The report also indicated that Holtec and US T&D agreed to cease conducting audits of each other's QA programs to ensure independence of the audit process.

Another observation in the 1999 NRC inspection noted a lack of clarity in Holtec's requirements for US T&D concerning the retention of fabrication drawings. In response, Holtec agreed to update the applicable procurement specification to clarify these requirements.

Overall, the NRC inspection report concluded that US T&D's QA program was adequately implemented and that Holtec's oversight of US T&D's cask fabrication activities was adequate.

NRC Inspector Comments

Two of the SPFO inspectors involved in the 1999 NRC inspection of US T&D told OIG that each inspection team member was assigned to sample particular key areas or processes to determine US T&D's compliance with NRC regulations. To do so, they reviewed US T&D's procedures and inspection records, observed work practices, and interviewed personnel in key areas to determine the company's compliance with NRC requirements. The inspectors told OIG that while the inspection focused on a sampling of US T&D activities, the results were indicative of the company's overall compliance with NRC regulations.

For example, one inspector recalled that he assessed the material control process by (a) observing an individual perform welding work, (b) reviewing training and qualification records for the individual to determine if the individual was qualified to perform the work, (c) reviewing records to ensure the individual's equipment was appropriately calibrated and tested, and (d) checking records to ensure that appropriate materials were being used. The inspector recalled identifying an instance in which a log entry had not been completed for a particular welding material. The inspector noted that although the correct welding material was used, it had not been documented appropriately. The inspector said he checked other similar log entries to determine if this failure to document the use of the welding material was an isolated instance or a recurring problem. According to the inspector, he confirmed that the failure to complete the paperwork as specified in US T&D's procedures was an isolated case that did not call into question the integrity of the casks. Although this issue was not a violation of NRC regulations or something that would affect the safety or integrity of the casks, the inspector said that because he had noted this weakness, he included it in the inspection report as an observation.

Two of the NRC inspectors who conducted the US T&D inspection told OIG that throughout the inspection process the inspectors discussed what they were finding. Neither of the inspectors recalled any dissension or disagreement among the NRC inspection team members about the inspection results. Both inspectors told OIG that they believed the NRC inspection report accurately captured the results of the 1999 US T&D inspection, and each recalled having a favorable impression of US T&D's overall activities.

NUPIC's 2000 Audit of US T&D

Approximately 1 year after NRC's 1999 inspection of US T&D, NUPIC conducted an audit of the adequacy, effectiveness, and implementation of US T&D's QA program for its wet and dry spent fuel storage fabrication activities. The audit spanned 8 days in June and July 2000 (June 19-23 and July 5-7), and the audit team, led by Shirani, comprised six auditors (including Shirani) and two technical specialists from five different NRC licensee utilities.

In its executive summary, the August 4, 2000, NUPIC report (SR-2000-257) noted that US T&D had established a "fairly acceptable" QA program but that "enormous improvement" was needed in the areas of special processes and the corrective action program. The audit report, signed by Shirani, identified nine findings which are summarized below.

Organization/Program

1. US T&D's organization chart was not consistent with the identified positions and/or authority and responsibilities depicted in US T&D's Quality Assurance Manual.

QA Records

2. This finding identified a lack of procedures related to the storage of QA documents. Some documents were not maintained in a fireproof container.

Corrective Action

3. US T&D did not take adequate corrective action relative to one corrective action report and failed to identify a solution that would prevent recurrence of the problem. This finding was closed during the audit.

Training/Certification

4. There was a lack of procedures concerning documentation of training records, which resulted in the use of different forms and missing documentation pertaining to some training.

Calibration

5. Calibration of the temperature in two rod ovens was about 3 months overdue. During the audit, the as-found temperatures were acceptable.

Special Processes

6. Eleven items were identified that pertained to (a) US T&D's use of nonconformance reports to control welding applications where no approved procedure existed, and (b) documentation of welding procedures that was either ineffective, incorrectly completed, or raised questions concerning safety issues. Although the audit indicated the condition of the casks appeared to be of "high quality," these two problem areas were deemed significant.

Procurement/External Audit

7. Issues were identified that pertained to audits of vendors, e.g., some audit due dates had passed without an audit being conducted, some external audits of vendors were not comprehensive, and no audits were scheduled or planned for some vendors. In one case, a vendor that provided safety-related thread gauges to US T&D was not on the company's approved vendor list and had not been audited.

Corrective Action

8. A corrective action report was issued on a particular fabrication issue. This report indicated the issue was of an isolated nature and was intended to prevent recurrence. Nonetheless, four subsequent reports were found on the same issue suggesting the corrective action program was ineffective.

Test/Inspection

9. US T&D did not initiate a nonconformance report when a pressure test was performed using an uncalibrated gauge, US T&D did not satisfy a test requirement, and responsible personnel did not review and approve the test report.

US T&D responded to the NUPIC audit report in a letter dated September 5, 2000, and addressed the causes and provided corrective actions for each of the audit findings. An Exelon letter dated October 19, 2000, advised US T&D that the company's planned corrective actions were acceptable. The Exelon letter was prepared and signed by Shirani and stated, "Your response to the Nine (9) Audit Findings sounds reasonable." The letter also noted that the findings would remain open until the corrective actions specified by US T&D were verified by the NUPIC designated resident inspector at the US T&D facility. The letter also invited US T&D to contact Shirani in the event of questions.

Subsequently, in a letter to Exelon dated February 21, 2001^[1], the NUPIC designated resident inspector (employed by Entergy Operations, Inc., and assigned to work at US T&D) indicated that surveillance activities of the corrective actions were conducted from December 2, 2000, through February 15, 2001. This letter indicated that the corrective actions were completed satisfactorily and that the 2000 NUPIC audit findings should be closed. On February 22, 2001, Exelon concurred with the inspector's recommendation and closed the findings.

OIG Interviews NUPIC Auditors

According to an auditor who worked with Shirani on the 2000 NUPIC audit, none of the nine findings from the 2000 NUPIC audit were reason to question the integrity of the dry casks produced by US T&D. This auditor, who also worked on a similar NUPIC audit in 2002, was employed by Energy Northwest, another nuclear power utility that used Holtec dry cask storage systems. The auditor had 20 years of experience and estimated that he had participated in about 200 audits as a team member and about 100 as a team leader. The auditor told OIG that no one on the audit team, including Shirani, appeared to consider the audit findings to meet the criteria of a "significant condition adverse to quality" at the time of the audit.⁹ He noted that there were requirements in the NUPIC Joint Audit Procedure guidance to immediately notify NUPIC member companies who used the products being audited if a problem of safety significance was identified. The auditor said that there were no discussions among the 2000 NUPIC audit team members, including Shirani, during which anyone expressed a need to make such notifications and no such notifications were made.

The auditor explained to OIG that a utility could impose an SWO in response to safety significant issues identified by NUPIC audits, but the findings reported in the 2000 NUPIC audit did not warrant such an action. He said there was nothing especially significant about the NUPIC audit findings, and he considered many to be "paperwork deficiencies." He said the findings reflected the "growing pains" of a company that had recently experienced a rapid

⁹ NUPIC Joint Audit Procedure guidance document indicates that conditions meeting this term are those that "have the net result of placing the product's ability to function in its intended application in question."

growth in its business. He noted that neither the 2000 or 2002 NUPIC audits in which he participated called into question the overall integrity of earlier NUPIC audits or NRC inspections.

A second auditor who participated in the 2000 NUPIC audit told OIG that about half of the nine findings would have been better viewed as observations, rather than findings. This auditor, who was employed by Alliant Energy, had approximately 15 years of auditing experience at the time of the NUPIC audit, and had participated in “hundreds” of audits, including at least 30 NUPIC audits. He noted that none of the 2000 NUPIC audit findings called the integrity of the casks into question but that these findings demonstrated weaknesses in the paperwork and administration associated with the QA process. According to the auditor, the finding pertaining to the handling of nonconformance reports was the most significant; however, the overall QA program was adequately implemented.

NRC Inspections of Holtec and US T&D QA Programs

OIG learned that, among other NRC inspection and licensing activities pertaining to Holtec and US T&D operations between May 2000 and February 2002, NRC’s SFPO conducted three inspections into the companies’ QA programs for the fabrication of dry cask systems. While the first inspection was very limited in scope, the latter two NRC inspections were overall QA program reviews that were similar in scope to NRC’s 1999 inspection of US T&D. Each of the NRC inspections was conducted prior to the SFPO’s knowledge of Shirani’s allegations.

In May 2000, NRC conducted a limited inspection at Holtec that focused on the adequacy of a neutron shielding material considered for use by Holtec in the dry cask design. NRC inspection report 71-0784/00-201, dated July 25, 2000, reflected that SFPO inspectors reviewed past tests and ongoing test data to validate use of the material, the design and the development of the shielding material, and to determine whether Holtec complied with QA requirements to report defects and noncompliance items under 10 CFR Part 21. The inspection report identified weaknesses in Holtec’s implementation of procedures for identifying and reporting potential noncompliances on safety significant projects. For example, the NRC inspection found that during testing of samples of the neutron shielding material in 1998, Holtec did not file a report with the NRC in accordance with 10 CFR Part 21 when it learned that the shielding material did not perform as required by its design specifications. NRC inspectors disagreed with Holtec’s determination that because the vendor of the neutron shielding material was ultimately rejected by Holtec as a potential supplier, no report was necessary. Despite this weakness, the report indicated that in areas of management, design, and fabrication controls with respect to the neutron shielding material, the Holtec QA program met regulatory requirements and no violations were identified.

In September 2001, inspectors from NRC’s SFPO conducted an inspection of Holtec’s fabrication and QA programs for the dry cask storage systems and Holtec’s oversight of US T&D. According to inspection report 72-1014/01-201, dated October 22, 2001, inspectors evaluated management, design, and fabrication controls; reviewed procedures and instructions, selected documents, records, and drawings; verified training and qualifications; and interviewed Holtec personnel. While the NRC inspection concluded that management controls and implementation of the QA program met regulatory requirements, the report identified five

Severity Level IV violations and one non-cited violation.¹⁰ The first Severity Level IV violation noted that at the time of the inspection, Holtec was using a revised QA program that had not yet been approved by the NRC. The other four violations included a lack of documented procedures for QA surveillances, an ineffective corrective action by Holtec regarding the incorporation of design changes on technical drawings, seven instances involving failure to follow procedures because engineering change orders were edited in ways not prescribed in Holtec procedures, and inadequate design control regarding a drawing note that allowed weld defects in excess of industry codes which did not conform to the requirements of the Holtec CoC. The non-cited violation was related to an issue identified by Holtec in which one of the procedures regarding the review of engineering drawings did not match the procedure outlined in the QA manual.

In addition, the October 2001 inspection report noted weaknesses that demonstrated that the procedural issues identified in the violations were fairly broad in scope. Further, the report noted that the team identified a weakness regarding corrective actions caused by inattention to detail and failure to follow procedures. The report reflected that design control QA activities were adequate but that the team found more problem areas than expected, particularly in the area of the adequacy of and compliance with procedures.

In a November 21, 2001, letter to NRC, Holtec agreed with NRC's five cited violations, identified the causes for each violation, described corrective measures to bring the issues into regulatory compliance, and outlined corrective actions to avoid recurrence of the violations.

In February 2002, NRC conducted an inspection of US T&D dry cask storage system fabrication activities. NRC inspection report 72-10114/02-201, dated February 27, 2002, reflected that SFPO inspectors reviewed administrative procedures and qualification and training documentation; interviewed multiple welders, quality assurance staff, and procurement personnel; and observed material tests conducted by US T&D personnel. As part of this effort, inspectors reviewed procedures for documentation of corrective action reports and nonconformance reports, reviewed vendor audits, and reviewed 19 items to determine if suppliers were listed on US T&D's approved vendors list. The report identified two Level IV violations for US T&D's failure to control conforming material. The first violation involved the failure by US T&D to tag nonconforming items appropriately to ensure they were segregated from other items until a final determination was made on their condition. The second violation involved the failure to put a hold on the casks to preclude the inadvertent use of casks whose design did not conform to certain industry specifications. These nonconformances had previously been identified as a violation in the September 2001 NRC inspection, and subsequent to the inspection, Holtec and US T&D failed to place a hold on casks whose nonconformances had not been approved by the NRC. As a result, seven of these casks were loaded with spent fuel at the Dresden plant. These findings were shared with Region III inspectors responsible for inspecting the Dresden plant for their follow-up and possible regulatory sanctions.

¹⁰ NRC's inspection program ranks violations on a scale of I to IV. Severity Level IV violations are less serious than Level I through III violations but are of more than a minor concern. Violations at Severity Level IV involve noncompliance with NRC requirements that are not considered significant based on risk. In addition, violations determined to have a very low safety significance and that do not require written responses from the licensee/certificate holder are referred to as non-cited violations. The licensee is required to maintain safety and compliance and must take steps to address corrective actions for these violations.

In an April 10, 2002, letter to NRC, Holtec identified causes of the violations, corrective actions to bring the issues back into regulatory compliance, and corrective actions designed to avoid recurrence of these violations. Among the immediate actions taken, Holtec notified all of its customers to cease loading its casks until approvals were received from NRC to allow specific variations to standard industry design codes. In February 2002, Holtec applied for these variance approvals, and in March and May 2002, NRC approved the variances. This approval was granted after SFPO staff reviewed the technical basis for the variances and found that the variances did not compromise cask design integrity.

OIG Interviews NRC Inspectors

SFPO inspectors who conducted the inspections of the Holtec QA program for dry casks from 2000 through 2002 told OIG that the violations identified during the NRC inspections did not affect the integrity of the dry casks. As an example, one inspector referenced one of the violations identified in the September 2001 inspection regarding weld authorizations that did not meet the applicable industry design codes. These codes outline specific, technical requirements that must be met in the design of various nuclear related components and devices. The inspector stated that on occasion, a device's design might include features that do not meet the code requirements. In these instances, industry codes have specific methods for obtaining exceptions, or permission, to vary from the standard requirements. The weld violation cited in the September 2001 inspection report reflected that procedures for obtaining an exception were not followed by Holtec; however, NRC inspectors reviewed the technical details associated with the variance to determine if it caused a reduction in the cask's integrity. The inspectors determined that it did not. The inspectors also monitored whether US T&D performed the proper corrective actions to address any violations identified during NRC inspections and found that the company had taken appropriate corrective actions.

Another NRC inspector noted that inspectors generally find violations during inspections at both vendor and fabricator facilities. He explained that all QA programs have "human failures" that could result in some items not conforming exactly to design specifications. However, according to this inspector, of greater importance was a company's corrective action program and whether the company dealt with problems in a systematic manner which, he believed, was the case at US T&D. The inspector told OIG that based on his inspections, neither Holtec nor US T&D had issues that indicated programmatic QA problems.

A different SFPO inspector told OIG that there have been only a few changes over time regarding the general design and process of fabricating dry casks. He noted there are only three companies that supply dry cask storage systems to the nuclear industry. As a result, the SFPO has identified and addressed inspection and licensing issues related to these dry casks and has inspected vendors and fabricators in a sufficient, recurring manner to provide adequate regulatory oversight of the fabrication of storage casks. He also told OIG that he was not aware of any instance where a dry cask had been placed into service and found not to perform its function of safely containing radioactive material. According to this inspector, the lack of any major issue identified during the actual use of these casks was an indicator that vendors and fabricators were being regulated properly.

One SFPO inspector told OIG that dry casks are tested during fabrication and as they are loaded with spent fuel. Loaded casks are then tested after they are positioned in the storage area at the nuclear plant. This inspector stated that the casks fabricated at the time of the 2000 NUPIC audit would certainly have been loaded since that time. He indicated that he was aware

of only one minor incident involving the integrity of a dry cask, and that incident pertained to a non-Holtec/US T&D cask.

NUPIC Audits Conducted From 1996 – 2002

OIG learned that between 1996 and 2002, NUPIC conducted four audits of the Holtec and US T&D QA programs. Of the four NUPIC audits, only the 2000 audit led by Shirani identified any findings that required follow-up. The following are summaries of the three NUPIC audits conducted in 1996, 1999, and 2002. Each of these NUPIC audits was led by a different utility, with Exelon serving as the lead in 2002.

NUPIC audit report of US T&D (VEND-96-023) dated March 25, 1996, described a limited scope audit conducted between March 7-8, 1996, which focused on US T&D products and services, including basic fabrication and welding, machining, and engineering. The audit, intended to supplement a 1994 NUPIC audit (VEND-94-062), noted that US T&D programs for submitting nonconformance reports under 10 CFR Part 21, preparing corrective action reports, and for auditing suppliers and vendors were reviewed. The audit report identified no deficiencies at US T&D, found all audited areas satisfactory and noted that the 1994 audit had also identified no findings.

NUPIC audit report of US T&D (SQL 99-093) dated December 13, 1999, reported results of an audit conducted between November 15-19, 1999, to verify compliance and implementation of NRC requirements under 10 CFR Part 50, Appendix B, which establish criteria for licensee QA programs. Although this audit focused on the fabrication of components used in “wet storage” facilities, the review covered many areas in common with the 2000 NUPIC audit. For example, welding activities, including the calibration of welding machines and the processes for issuing welding materials and equipment, were reviewed and found to be in compliance with US T&D guidance and industry standards. Additionally, the procedures for auditing suppliers and vendors, as well as the corrective action programs, were inspected and found to be satisfactory. NUPIC audit report SQL 99-093 did not document any adverse findings.

NUPIC audit report of US T&D, SR-88050-02 (18194), dated August 20, 2002, reflected that this audit was conducted between July 15-19, 2002, to “evaluate the adequacy and implementation of the US T&D programs and procedures that control the manufacture of spent fuel storage racks and dry cask storage containers.” The report noted that all areas audited were rated “satisfactory,” and the report did not list any findings or recommendations requiring a response.

NUPIC audit report SR-88050-02 also noted that the nine findings from the 2000 NUPIC audit were re-examined and that corrective actions had been effectively implemented and no recurrences were identified. For example, the report indicated that corrective action reports had been reviewed in light of Finding 8 from the 2000 audit. This review demonstrated that no additional repetitive issues similar to those previously identified had been noted, and that the corrective action process was “healthy and adequately” implemented. US T&D compliance with 10 CFR Part 21 reporting requirements was also reviewed, and the system of tagging nonconforming items until a final disposition was achieved was found acceptable. The program for auditing suppliers (some of which were conducted jointly with Holtec) was also reviewed and found complete. Additionally, cask fabrication welding activities were reviewed by the NUPIC audit team, and all the welding reviewed was verified to be performed by “suitably qualified welders in accordance with the requisite [procedures].”

III. OIG REVIEW OF NRC'S HANDLING OF SHIRANI'S TECHNICAL CONCERNS

Shirani related to OIG that after learning in October 2001 that he was going to be terminated by Exelon, he contacted NRC Region III and met with regional staff on several occasions beginning in November 2001 to provide information about safety concerns related to deficiencies he noted during his employment as an auditor with Exelon. Among these concerns were several that specifically related to the fabrication of dry cask systems by Holtec and US T&D. Shirani told OIG that because of deficiencies in the QA documentation, particularly the handling of items that did not exactly conform to design specifications, he believed that none of the cask components could be relied upon.

NRC Region III's Handling of Shirani's Allegations

OIG learned that the Region III Allegation Review Board (ARB)¹¹ met on a regular basis to monitor the progress of allegations received by the Region, including the allegations reported by Shirani. The ARB and other regional staff members selected for their technical expertise reviewed written material submitted by Shirani, along with transcripts and notes from the meetings with Shirani. The information provided by Shirani concerned a wide-ranging assortment of QA, safety, and other issues, going back several years that was derived from various audits and activities with which Shirani had been involved during his tenure with Exelon.

Region III grouped Shirani's issues into 19 separate concerns that were documented in two allegation files. Of the 19 concerns reported by Shirani, 15 related to his termination and to findings from various audits he had conducted while with Exelon. Four of the concerns related directly to the fabrication of the dry cask storage systems by US T&D. These four concerns stemmed from the 2000 NUPIC audit of US T&D's QA program, a 1999 Exelon audit of Holtec's QA Program, and information Shirani received from an Exelon resident inspector and QA personnel at US T&D. The following are summaries of Shirani's four concerns:

- (1) Holtec did not report defects involving "wide-ranging welding deficiencies" in the fabrication of the dry casks as required by 10 CFR Part 21.
- (2) Dry casks were manufactured with non-approved materials.
- (3) US T&D violated QA requirements by making repairs and accepting items "as-is" without obtaining review and approval of the designers (i.e., Holtec).
- (4) The use of nonconforming items without an engineering analysis violated QA program controls.

Shortly after each of three major meetings Shirani had with Region III staff, Region III sent Shirani letters – in November 2001, February 2002, and April 2002 – summarizing the concerns that he had brought forward. Shirani told OIG that he felt Region III had made a reasonable attempt to capture the information he had provided.

The Region III ARB recognized that the four concerns involving the design and fabrication of dry cask storage systems pertained to systems that were used by nuclear power plants throughout

¹¹ NRC has an Allegation Management Program for receiving, evaluating, and managing information brought to the agency about potential nuclear safety-related issues. Allegation Review Boards consist of designated individuals who monitor and approve the initiation, progress, and resolution of these issues.

the country. Because the monitoring and inspection of spent fuel system vendors and suppliers falls under the purview of SFPO, located organizationally within NMSS at NRC Headquarters, Region III forwarded the concerns in memoranda dated February 20, 2002, and April 19, 2002, to NMSS where an NMSS ARB assigned the concerns to a senior SFPO inspector. This SFPO inspector had not participated in the NRC's 1999 inspection of US T&D.

Following the transfer of these concerns to NMSS' ARB, Region III took no further action to review the four technical concerns related to the dry casks. The remaining 15 concerns were handled through the Region III allegation process.

SFPO Assesses Validity of Shirani's Concerns With Dry Cask Storage Systems

Between May 6-9, 2002, the senior SFPO inspector and another inspector conducted an inspection at Holtec to (1) determine whether Shirani's concerns were valid and (2) follow up on the five Severity Level IV findings identified during SFPO's September 2001 inspection at Holtec and the two Severity Level IV findings identified during the February 2002 SFPO inspection at US T&D. The inspection results were documented in NRC inspection report 72-1014/02-202, dated May 14, 2002, and in SFPO correspondence to Shirani dated May 28, 2002.

According to the May 2002 inspection report, all seven violations reported in the two prior NRC inspections had been adequately addressed by Holtec; therefore, these violations were closed.¹² The inspectors also concluded that none of the four concerns reported by Shirani were violations of NRC regulations or were safety significant. This evaluation of the four concerns was conveyed to Shirani in correspondence from NMSS dated May 28, 2002. Shirani's four concerns and NRC's responses are summarized below.

Concern 1: Wide-ranging welding deficiencies existed in spent fuel storage casks manufactured by Holtec and US T&D. These deficiencies demonstrated that there were fundamental flaws in the casks. Because the casks are considered components under 10 CFR Part 21, the flaws should have been reported, but neither Holtec nor Exelon reported them.

NRC Response: NRC inspectors reviewed the 2000 NUPIC audit finding concerning welding deficiencies and noted that the number of deficiencies was not excessive, given the number of NUPIC auditors and duration of the audit. The NRC inspectors noted that none of the deficiencies resulted in rework or repair of the hardware. The NRC inspectors reviewed US T&D's corrective actions taken to prevent recurrence. Inspectors noted that the corrective actions primarily involved procedure clarifications and welder retraining regarding weld documentation. Inspectors indicated that absent the identification of a defect in a basic component, there was no requirement under 10 CFR Part 21 to report weld deficiencies. The inspectors also noted that NRC performed an inspection of fabrication activities including welding at US T&D in February 2002 and that this inspection found no welding problems and considered welding activities to be adequately controlled. NRC inspectors concluded that this concern was not substantiated.

¹² The follow-up efforts are described in NRC inspection report 72-1014/02-202. All seven findings from the earlier inspections were closed based on this report. However, one additional violation of minor significance regarding weld documentation that failed to meet industry standards was noted. This violation was related to welding documentation for another Holtec project and did not involve the fabrication of dry casks.

Concern 2: Holtec spent fuel storage casks were manufactured with materials from suppliers that were not approved to supply safety-related materials. Neither Holtec nor Exelon had audited these suppliers to establish product acceptability as required under 10 CFR Part 50 and 10 CFR Part 72.

NRC Response: Inspectors reviewed the 2000 NUPIC audit that identified five apparent deficiencies involving material suppliers and reviewed US T&D corrective actions. NRC inspectors noted that none of the material supplier deficiencies resulted in invalidation of work or required repair of the hardware. Inspectors noted that the materials used for fabrication were almost exclusively provided to US T&D from Holtec using Holtec's approved suppliers. The NRC inspectors noted that a February 2002 NRC inspection reviewed the material controls program at US T&D and did not find problems with material supplier controls. While the NRC inspectors substantiated¹³ the conditions described by Shirani, they concluded there was no safety significant or regulatory issue.

Concern 3: US T&D modified spent fuel storage casks during the fabrication process by making repairs and/or accepted discrepancies "as is" without obtaining the required design review and approval from Holtec. Shirani was concerned that this was contrary to Exelon procedures.

NRC Response: NRC inspectors found that Holtec had failed to provide explicit procedures and instructions regarding certain types of fabrication discrepancies and that the Holtec deficiency form, a Supplier Manufacturing Deviation Report (SMDR), lacked a block to reflect the category "reworked." The inspectors noted that the NUPIC audit concluded that these findings had "no negative impact" on the casks and that US T&D had added the category "rework" to the SMDR form subsequent to the audit.

The NRC inspectors reviewed Holtec and US T&D procedures to determine, if required, how engineering approval was obtained when fabrication discrepancies occurred. The review did not identify any instances where procedures were not in accordance with regulatory requirements. The inspectors noted that US T&D fabrication drawings generally had tighter tolerances than those on Holtec's engineering drawings. This allowed for some margin for error on the shop floor without requiring engineering approval as long as the engineered drawing requirements were not exceeded. Therefore, in cases where only US T&D tolerances were exceeded, US T&D did not require Holtec's approval because the Holtec tolerances were not exceeded. The NRC inspectors also noted that Holtec had resolved a procedural matter involving the company's failure to forward "use-as-is" dispositions to Exelon for approval in accordance with contract requirements. The inspectors characterized this as a contract requirement dispute and not a regulatory concern. The NRC inspectors noted that the dispute had been resolved.

The inspectors examined the examples referenced in the NUPIC audit and found no instances where engineering approval was required but not obtained. Additionally, the inspectors relied on their sampling and review during NRC's February 2002 inspection at US T&D to demonstrate that there were no other instances where required approval was not obtained.

The NRC staff substantiated the conditions as described by Shirani, but determined there was no significant safety or regulatory issue that required further NRC action.

¹³ Substantiation in this context meant that NRC concluded that the conditions that Shirani described existed. However, the concerns were not found to be safety significant or a violation of regulations.

Concern 4: Holtec's QA/QC oversight over US T&D was inadequate and resulted in indeterminate cask quality and questionable structural integrity. US T&D's disposition of nonconformance conditions as "use-as-is," "rework," and "repair" was a violation of the QA program for design control as specified in 10 CFR Part 71 and 10 CFR Part 72. "Use-as-is" and "repair" dispositions are design changes and should be evaluated and documented by engineering analysis. In addition, the fabricator dispositioned many nonconformance conditions under its QA program without Holtec's consent.

NRC Response: Staff reported that these matters were addressed in the response to Concern 3, above. Inspectors identified no examples that supported Shirani's assertion that inadequate QA oversight had caused indeterminate cask quality and questionable structural integrity. Again, the staff determined that Shirani's description of the condition was accurate, but that there was no significant safety or regulatory issue that required further NRC action.

OIG Interviews Senior SFPO Inspector

The senior SFPO inspector on the SFPO inspection team during the 2001 and 2002 NRC inspections at Holtec and US T&D told OIG that he concluded that Shirani's characterization of "wide-ranging welding deficiencies" was not substantiated. The inspector noted that the deficiencies identified in the 2000 NUPIC audit were for the most part valid¹⁴ but primarily involved procedure clarifications and weld documentation problems. The inspector believed that the number of weld-related findings reported in the NUPIC audit was not excessive given the number of welding specialists involved in the 2000 audit. Additionally, the inspector pointed out that none of the weld findings contained issues that required any physical rework or repair of the hardware. The inspector also concluded that there were no physical defects in the welding of the dry casks that required Holtec to report welding deficiencies under 10 CFR Part 21.

The SFPO inspector found that Shirani's second concern about the use of materials from unapproved vendors was substantiated because US T&D had purchased thread gauges from a vendor that was not on its approved vendor list. However, subsequent to the 2000 NUPIC audit that identified this concern, US T&D had the accuracy of the gauges verified by an approved vendor, and US T&D ensured that no measurements made with the gauges could have led to conditions exceeding the design specifications. The inspector also noted that US T&D revised its purchasing procedures to prevent recurrence. The inspector told OIG that his inspection revealed that the use of unapproved vendors was not a widespread problem within US T&D. Additionally, because of US T&D's effective corrective action program, the inspector concluded that this issue was not of safety significance and required no further NRC action.

The inspector further explained to OIG that he found that the Holtec and US T&D QA programs were ensuring that design criteria and tolerances were met prior to acceptance of cask components. The inspector noted that on occasion, contractually mandated notifications about the acceptance of certain variances were not made between Exelon and Holtec. However, the inspector explained that these reporting omissions did not violate NRC regulations because engineering and QA notifications within Holtec and US T&D were being made as required. The inspector reviewed the specific examples cited by Shirani, as well as sampling and reviews

¹⁴ The May 28, 2002, NMSS response letter points out that 4 of the 11 weld deficiencies noted in the 2000 NUPIC audit were determined by US T&D not to be valid. This determination, along with the corrective actions related to the remaining seven deficiencies, was included in the US T&D response to the audit. The entire response was deemed "reasonable" by Shirani's October 19, 2000, letter.

conducted in the February 2002 NRC inspection of US T&D, and he found no instances where the notifications required by regulation had failed to occur. Therefore, the inspector concluded that no significant safety or regulatory concerns existed.

NRC's Follow-up Responses

OIG learned that following the May 28, 2002, response from NMSS to Shirani, Shirani wrote at least four letters and e-mails disputing the staff's determinations. These letters and e-mails were included in the NMSS allegation files and forwarded to the staff for their review. Because of his familiarity with the issues, the senior SFPO inspector was assigned to review the letters to determine if they contained new, relevant information that would cause a reevaluation of Shirani's concerns. The inspector told OIG that Shirani's responses simply restated the issues and did not make relevant clarifications or counterarguments.

In three written responses to Shirani, SFPO reiterated the earlier findings and included additional descriptions of the inspection activities upon which their determinations were based. SFPO's last response, dated September 23, 2002, noted that unless "NRC receives additional information that suggests that our conclusion should be altered, we plan no further action on this matter."

OIG Interviews SFPO Deputy Director

An SFPO Deputy Director, who also served as the NMSS ARB chairman, recalled reviewing Shirani's concerns when they were sent to SFPO. He noted that after reading the allegations he felt no particular urgency with regard to Shirani's concerns. The Deputy Director explained that the dry casks related to the 2000 NUPIC audit had probably already been loaded by the time NMSS received the allegation. He stated that after casks are loaded they are scanned and monitored for leaks and that NRC had direct test data indicating that none of the casks were leaking or otherwise emitting unusual radiation.

The Deputy Director indicated that he reviewed the May 14, 2002, inspection report prepared by the SFPO inspectors and that the inspection findings were discussed by the NMSS ARB before approving a response to Shirani. The Deputy Director recalled that after the ARB received a copy of Shirani's response critiquing SFPO's review of his concerns, the senior SFPO inspector indicated to the NMSS ARB that no additional, relevant information had been submitted. The Deputy Director asked another SFPO materials expert to review Shirani's letters and the senior inspector's conclusions. After reviewing the draft response, the materials expert concurred with the senior SFPO inspector.

The Deputy Director expressed strong confidence to OIG in the SFPO's ability to ensure effective regulation of the QA programs at Holtec, US T&D, and other vendors and fabricators of dry cask storage systems. The Deputy Director indicated that SFPO has a strong staff of technical experts who, in addition to conducting inspections, have conducted numerous analytical reviews to determine the ability of these casks to withstand a wide variety of threats.

FINDINGS

1. OIG's review of NRC's inspection history at Holtec and US T&D did not substantiate Shirani's concern that NRC failed to provide adequate oversight of Holtec and US T&D QA programs for the fabrication of dry cask storage systems. OIG determined that NRC conducted inspections of Holtec and US T&D QA programs in 1999, 2000, 2001, and 2002. These inspections, as well as NUPIC audits of these QA programs conducted in 1996, 1999, 2000, and 2002, disclosed a number of deficiencies. However, these examinations concluded that both QA programs were adequate and met requirements. OIG found no record that either NRC inspections or NUPIC audit reports uncovered systemic, significant problems within the Holtec or US T&D QA programs. Additionally, OIG determined that NRC verified that Holtec and US T&D took appropriate corrective actions in response to NRC inspection findings.
2. OIG determined that NRC's handling of the four concerns pertaining to dry cask integrity raised by Shirani in November 2001 was appropriate. Upon receiving Shirani's concerns questioning the adequacy of the Holtec and US T&D QA programs pertaining to dry cask fabrication, the NRC Region III office handled the concerns consistent with NRC's allegation review process. Region III documented its understanding of these concerns in letters to Shirani, and Shirani found the Region's summary of his concerns to be satisfactory. Region III appropriately forwarded Shirani's technical concerns regarding the QA oversight of the fabrication of dry cask storage systems to the SFPO at NRC Headquarters. SFPO inspectors conducted a timely inspection at Holtec into Shirani's QA concerns. The NRC inspection into Shirani's concerns found no violations of NRC regulations or safety significant deficiencies. OIG found that SFPO's examination of Shirani's concerns was sufficient to support its conclusion that the QA deficiencies pointed out by Shirani did not adversely impact the physical integrity of the Holtec dry cask storage systems.