UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 3, 2020

EA-20-066

Mr. Kent S. Cole
President and CEO
NAC International
3930 East Jones Bridge Road,
Suite 200
Norcross, Georgia 30092

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT 07201015/2020-201, NAC INTERNATIONAL

Dear Mr. Cole:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) announced routine inspection at your NAC International (NAC) corporate office in Norcross, Georgia during February 24-27, 2020. The inspection assessed the adequacy of NAC's design activities for spent fuel storage casks with regard to the applicable requirements of Title 10 of the *Code of Federal Regulations* (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." The staff examined activities conducted under your NRC approved Quality Assurance (QA) program to determine whether NAC implemented the requirements associated with the Commission's rules and regulations and with the conditions of applicable certificates of compliance (CoCs). The inspection consisted of an examination of selected procedures and representative records, observations of activities, and interviews with personnel. The lead inspector discussed the preliminary inspection findings with NAC at the conclusion of the on-site portion of the inspection during a debrief, and in a subsequent telephonic exit meeting on July 22, 2020.

Based on the information developed during the inspection, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web Site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

The apparent violations involve: (1) NAC's implementation of a design change for the MAGNASTOR™ CC5 spent fuel cask without ensuring that design control measures were commensurate with those applied to the original design, as required by 10 CFR 72.146(c), "Design control;" and (2) NAC's failure to obtain a CoC amendment pursuant to 10 CFR 72.244 prior to implementing a proposed design change for the MAGNASTOR CC5 cask that resulted in a departure from the method of evaluation described in the FSAR (updated), as required by 10 CFR 72.48(c)(2)(viii), "Changes, tests, and experiments." The apparent violations, and associated inspection report, are listed in Enclosures 1 and 2, respectively. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with members of your staff at the inspection exit meeting on July 22, 2020.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in this inspection report within 30 days of the date of this letter, (2) request to participate in a Pre-decisional Enforcement Conference (PEC), or (3) request to participate in an Alternative Dispute Resolution (ADR) mediation session. These options are discussed further in subsequent paragraphs in this letter.

If you choose to provide a written response, it should be clearly marked as a “Response to Apparent Violations in NRC ISFSI Inspection Report 07201015/2020-201; EA-20-066” and should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response.

Additionally, your response should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a pre-decisional enforcement conference.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The conference will include an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. The information should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. This information may reference or include previously docketed correspondence. In presenting any corrective actions, you should be aware that the promptness and comprehensiveness of the actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed (Enclosure 3) excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in assessing adequate corrective actions. Following the PEC, you will be advised by separate correspondence of the results of our deliberations on this matter. If a PEC is held, it will be open for public observation and the NRC may issue a press release to announce the time and date of the conference.

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC process employs is mediation. Mediation is a voluntary, informal process in which a trained neutral third party (the “mediator”) works with parties to help them reach resolution. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. If the parties agree to use ADR, they select a mutually agreeable neutral mediator from ICR, who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues,

clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's alternative dispute resolution program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html, as well as NRC brochure NUREG/BR-0317, “Enforcement Alternative Dispute Resolution Program,” Revision 2 (Agencywide Documents Access and Management System (ADAMS) Accession ML18122A101). Please contact the Institute on Conflict Resolution at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through alternative dispute resolution.

If you choose to pursue ADR, the ADR will be closed to the public; however, the NRC may issue a meeting notice and/or press release to announce the time and date of this closed mediation. In addition, if the mediation is successful, NRC typically issues a Confirmatory Order to document the agreement. The Confirmatory Order is typically publicly available.

If you decide to participate in a PEC or pursue ADR, please contact Ms. Leira Cuadrado, Chief, Inspection and Oversight Branch, via e-mail at Leira.Cuadrado@nrc.gov within 10 days of the date of this letter. A PEC should be held within 30 days of the date of this letter and an ADR mediation session within 45 days of the date of this letter. If you do not contact us regarding your participation in either a PEC or ADR within the time specified above and the NRC has not granted an extension of the contact time, we will make an enforcement decision based on available information.

In addition, please be advised that the number and characterization of apparent violations described in the enclosures may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC’s Agencywide Documents Access and Management System, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Any information forwarded to NRC should be clearly labeled on the first page with the case reference number: EA-20-066, and should be sent to the NRC’s Document Control Center (Ref: 10 CFR 30.6 Communications, https://www.nrc.gov/reading-rm/doc-collections/cfr/part030/part030-0006.html), with a copy mailed to, Andrea Kock, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738.

Should you have any questions, please contact Ms. Leira Cuadrado, via e-mail at Leira.Cuadrado@nrc.gov.

Sincerely,

Christopher M. Regan

Digitally signed by Christopher M. Regan
Date: 2020.09.04 09:14:11 -04'00'

For A. Kock

Andrea Kock, Director
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 72-1015

Enclosures:
1. Apparent Violations Being Considered for Escalated Enforcement
2. Inspection Report 07201015/2020-201
3. NRC Information Notice 96-28

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT 07201015/2020-201, NAC INTERNATIONAL

DOCUMENT DATE: September 3, 2020

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ADAMS Accession Number: ML20225A032 *via email

OFFICE	NMSS/DFM	NMSS/DFM	NMSS/DFM	NMSS/DFM (prior to	NMSS/EC
NAME	JWoodfield*	WWheatley*	LCuadrado*	CRegan* for AKock	RSun*
DATE	8/14/20	8/20/20	8/14/20	8/14/20	8/18/20
OFFICE	OE	OGC	NMSS/DFM		
NAME	JPeralta*	LBaer*	CRegan* for AKock		
DATE	8/27/20	8/28/20	9/3/20		

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APPARENT VIOLATIONS BEING CONSIDERED FOR ESCALATED ENFORCEMENT

Apparent Violation A:

10 CFR 72.146(c), “Design control,” requires, in part, that a certificate holder shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval.

Contrary to the above, prior to December 30, 2016, the certificate holder (NAC) implemented a design change for the MAGNASTOR spent fuel cask without ensuring that design control measures were commensurate with those applied to the original design. Specifically, NAC failed to use the nonlinear LS-DYNA computer model (identified in the MAGANASTOR FSAR Sections 3.7.3.7 and 3.10.4.4 as the method of evaluation for concrete cask tip-over analysis applied to the original design) for the assessment of acceleration values for a design basis tip-over accident of the MAGNASTOR CC5 spent fuel cask.

Apparent Violation B:

10 CFR 72.48(c)(2)(viii), “Changes, tests, and experiments,” requires, in part, that a certificate holder shall obtain a CoC amendment pursuant to 72.244, prior to implementing a proposed change that would result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.

MAGNASTOR FSAR Section 3.7.3.7, “Concrete Cask Tip-Over,” states, in part, that the concrete cask tip-over analyses are performed using LS-DYNA.

Contrary to the above, on December 30, 2016, the certificate holder (NAC) failed to obtain a CoC amendment from the NRC pursuant to 10 CFR 72.244 prior to implementing a design change for the MAGNASTOR CC5 spent fuel cask that resulted in a departure from a method of evaluation described in the MAGNASTOR FSAR. Specifically, NAC failed to utilize LS-DYNA, a non-linear analysis methodology that was described in the MAGASTOR FSAR Section 3.7.3.7, when implementing a design change for the MAGNASTOR CC5 spent fuel storage cask.

U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Fuel Management

Inspection Report

Docket:	72-1015
Report:	72-1015/2020-201
Certificate Holder:	NAC International 3930 East Jones Bridge Road, Suite 200 Norcross, Georgia 30092
Inspection Dates:	February 24-27, 2020, on site
Inspection Team:	Jon Woodfield, Transportation & Storage Safety Inspector, Team Leader Earl Love, Senior Transportation & Storage Safety Inspector Jerry Tapp, Transportation & Storage Safety Inspector
Approved by:	Leira Cuadrado, Chief Inspections and Oversight Branch Division of Fuel Management Office of Nuclear Material Safety and Safeguards

U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Fuel Management

EXECUTIVE SUMMARY

NAC International
NRC Inspection Report 721015/2020-201

On February 24, 2020, to February 27, 2020, the U.S. Nuclear Regulatory Commission (NRC) staff performed an inspection at NAC International (NAC) corporate offices in Norcross, Georgia. The purpose of the inspection was to assess NAC's activities with regard to the design of spent fuel storage casks with the requirements of Title 10 of the *Code of Federal Regulations* (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." The inspection scope included reviews of NAC's implementation of the 10 CFR 72.48 change process.

Based on the results of this inspection, the NRC staff assessed that the implementation of NAC's Quality Assurance (QA) program did not meet certain NRC requirements in the areas of design control and 10 CFR 72.48 evaluations. This resulted in the identification of two apparent violations which are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The apparent violations related to performing design changes to an NRC approved design and not subjecting the changes to design control measures commensurate with those applied to the original design and implementing a proposed change that would result in a departure from a method of evaluation described in the FSAR used in establishing the design bases or in the safety analyses are further described in the applicable sections of this inspection report. Since the NRC has not made a final determination in this matter, no final action is being issued at this time.

As summarized in Table 1 below, two Apparent Escalated Violations of NRC requirements were identified.

Table 1
Summary of Inspection Findings

Regulatory Requirement 10 CFR Section	Subject	Number of Findings	Type of Finding	Report Section(s)
72.146	Design Control	1	Apparent Escalated Violation	3.3.2
72.48	Changes, tests, and experiments	1	Apparent Escalated Violation	3.3.2

REPORT DETAILS

1.0 Inspection Scope

On February 24-27, 2020, the NRC conducted an announced inspection at the corporate headquarters of NAC International (NAC) in Norcross, Georgia. The inspection focused on an assessment of NAC's activities with regard to the design of spent fuel storage casks (Table 1) in accordance with the requirements of Title 10 CFR Part 72, as well as, a review of various NAC 10 CFR 72.48 reports.

Table 1
List of NAC Dry Cask Storage Systems Models

Storage System Model	Docket / Certificate #	Amendment
NAC-UMS	07201015	7
NAC-MPC	07201025	8
MAGNASTOR	07201031	8

1.1 Inspection Procedures and Guidance Documents Used

IP 60851, Design Control of ISFSI Components
IP 60857, Review of 10 CFR 72.48 Evaluations
NUREG/CR-6314, Quality Assurance Inspections for Shipping and Storage Containers
NUREG/CR-6407, Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety
RG 3.72, Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments

1.2 List of Acronyms Used

APS	Arizona Public Service
CAP	Corrective Action Program
CAR	Corrective Action Report
CC	Concrete Cask
CFD	Computational Fluid Dynamics
CFR	Code of Federal Regulations
CIA	Compatibility Impact Assessment
CoC	Certificate of Compliance
DCR	Design Change Request
DCRM	Documentation Control Records Management
DCSS	Dry Cask Storage System
DFM	Division of Fuel Management
FR	Finding Report
FSAR	Final Safety Analysis Report
GTCC	Greater Than Class C Waste
IP	Inspection Procedure
ISFSI	Independent Spent Fuel Storage Installation
kW	Kilowatt
NCR	Nonconformance Report
NRC	Nuclear Regulatory Commission
PO	Purchase Order
PWR	Pressurized Water Reactor

QA	Quality Assurance
QAM	Quality Assurance Manual
QAP	Quality Assurance Program
QP	Quality Procedure
QVL	Qualified Vendors List
TMI	Three Mile Island
TSC	Transportable Storage Canister
VCC	Vertical Concrete Cask

1.3 Persons Contacted

The team held an entrance meeting with NAC personnel on February 24, 2020, to present the purpose and scope of the NRC inspection. On February 27, 2020, the team held a debriefing to discuss the preliminary results of the inspection. On July 22, 2020, the inspection team leader conducted a telephone exit with NAC's Vice President of Quality Assurance, Mr. Brad Greene. Table 2 documents the individuals present at these meetings.

Table 2
Entrance, Debrief, and Telephone Exit Meetings Attendees

NAME	AFFILIATION	ENTRANCE	EXIT (Debrief)	TELEPHONE EXIT
Jon Woodfield	NRC/DFM	X	X	X
Earl Love	NRC/DFM	X	X	X
Jerry Tapp	NRC/DFM	X	X	
Leira Cuadrado	NRC/DFM			X
Brad Greene	NAC	X	X	X
Douglas Jacobs	NAC	X	X	X
Eric Shewbridge	NAC	X		
Bill Barrett	NAC	X		
Heath Baldner	NAC	X		
David Jensen	NAC	X	X	
Leigh Trostel	NAC	X	X	
John Edwards	NAC	X	X	
Bianca Barner	NAC	X		
Calvin Barnett	NAC	X	X	
George Carver	NAC		X	X
Wren Fowler	NAC		X	X
Ryan Bailey	NAC		X	X
Kent Cole	NAC			X
Holger Pfeifer	NAC			X
Marc Griswald	NAC			X
Brian Hansen	APS			X
Amanda Montgomery	APS			X
Thomas Weber	APS			X

2.0 Management Controls

2.1 General

The team assessed the adequacy of management controls in the areas of NAC's QAP implementation, nonconformance controls, documentation controls, and audit program. The team reviewed NAC's practices and procedures, and their implementation, to determine the effectiveness of management controls.

2.2 Quality Assurance Policy

2.2.1 Scope

The team reviewed NAC's QAP to determine the effectiveness of instructions and procedures that implement its program. The team inspected NAC's QAP goals, objectives and practices, personnel responsibilities, QA organizational independence, management involvement, and staffing levels.

2.2.2 Observations and Findings

The team reviewed NAC's Quality Assurance Manual (QAM), Edition 2, Revision 8 and NAC's Quality Procedures (QPs) and assessed the effectiveness of the Quality Assurance (QA) program implementation at NAC. The team conducted reviews of NAC's quality program, policies, and procedures, and discussed portions of the reviewed documents with selected personnel to determine whether activities subject to 10 CFR Part 72 were adequately controlled and implemented under NAC's NRC-approved QA program. Further, the team reviewed the NAC organization charts and interviewed QA personnel to assess their organizational independence from cost, schedule, and production activities.

The team reviewed procedures and documents regarding management assessments. Specifically, the team reviewed QP 18-2, "Audits, Surveys and Corrective Actions," Revision 11. The team reviewed the management assessments performed on the status and effectiveness of the QA program from 2017 and 2018. The team determined that both reports reviewed the appropriate areas under the quality program consistent with the requirements in QP 18-2.

2.2.3 Conclusion

Overall implementation of NAC's QA program was assessed to be adequate with no concerns identified.

2.3 Nonconformance and Corrective Action Controls

2.3.1 Scope

The team reviewed NAC's nonconformance control program to assess the effectiveness of measures established for items that did not conform to requirements. The team evaluated how NAC identified and controlled any nonconforming items and any program deficiencies. The team inspected nonconformance reports (NCRs) and measures used to keep track of the status of nonconforming items. In addition, the team reviewed NAC's corrective action

program.

The team also reviewed training and implementing procedures, internal postings, supplier notifications, reporting processes, and program controls in accordance with the provisions of 10 CFR Part 21, "Reporting of Defects and Noncompliance."

2.3.2 Observations and Findings

The team reviewed selected records and interviewed personnel to verify that NAC effectively implemented nonconformance control and the corrective action program (CAP). Specifically, the team reviewed NAC's policies and the following approved implementing procedures that govern the nonconformance program and CAP for NAC to verify compliance with applicable requirements to 10 CFR Part 72:

QP 15-1, "Control of Nonconforming Items," Revision 11
QP 16-1, "Corrective Action Reports," Revision 6
QP 16-2, "Potential Significant Deficiencies and Defects and Regulatory Reporting," Revision 9

The team discussed the nonconformance and CAP controls with the NAC staff and reviewed a sample of NCRs, corrective action reports (CARs) and finding reports (FRs) for appropriate disposition. The team also determined whether NAC completed CARs and NCRs for identified deficiencies in a technically sound and timely manner as appropriate.

The team sampled five NCRs since 2017 which consisted of a variety of component types and included a mix of use-as-is and rework component dispositions. The team determined that NAC appropriately dispositioned the nonconformances reviewed and closed them in a timely manner commensurate with the safety significance, in accordance with the quality procedure.

The team sampled two CARs since 2017, which are written only for significant conditions adverse to quality. A root cause analysis was also reviewed as part of the CAR assessment. The team found that the extent of condition and corrective actions taken by NAC were timely and adequate. The team also sampled ten FRs, which are written for conditions adverse to quality or items for improvement, and included a selection of hardware, software, procedural, and vendor deficiencies. The team found that the corrective actions taken were adequate and completed in a timeframe commensurate with the safety significance of the issue, when possible.

Further, the team reviewed program controls for 10 CFR Part 21, "Reporting of Defects and Noncompliances," including QP 16-2. The team verified that NAC's procedure adequately implemented the requirements of the regulation. The team verified that NAC was meeting the 10 CFR Part 21 posting requirements of both the regulations and QP 16-2. The team found that NAC posted the 10 CFR Part 21 regulations, Section 206 of the Energy Reorganization Act of 1974, and QP 16-2 on a board in two locations at their Norcross, Georgia office where employees could readily see them. No issues were identified by the team regarding 10 CFR Part 21 program controls or implementation at NAC.

2.3.3 Conclusion

Overall, the team concluded that NAC had an adequate nonconformance control and CAP in place to identify, track and resolve quality related deficiencies and deviations. No issues of

significance were identified.

2.4 Documentation Controls

2.4.1 Scope

The team reviewed NAC's documentation control program to determine the effectiveness of the QAP in controlling quality-related documentation and records. The team reviewed instructions, procedures, and drawings for adequacy, approval signatures, document releases by authorized personnel, and document availability to personnel. The team reviewed the control of such documents as QA procedures and design drawings. The team reviewed quality records to assure that they were properly identified, retrievable, controlled, and maintained.

2.4.2 Observations and Findings

The team interviewed specific NAC personnel and reviewed selected portions of the NAC QAM as well as selected portions of NAC QPs related to document controls and records management. NACs Vice President of Quality is responsible for assuring that QA records are properly developed in conjunction with Documentation Control Records Management (DCRM) requirements and filed and dispositioned in accordance with QP 17-1 (see full title below). Upon submittal to the DCRM, record management becomes the responsibility of the Director, Licensing. NAC's designated DCRM ensures that records are maintained, reproduced properly in optical format and are properly identified and protected. The team noted, NAC procedure QP 17-1 satisfactorily depicts retention classification of quality records. The team interviewed NAC's DCRM who while using a computerized system demonstrated the effectiveness of the document control and records management system at NAC. The inspectors verified from various interviews, observation of activities, as well as the review of multiple documents associated with other aspects of this inspection, that adequate document control and records management exist at NAC. The team reviewed the following implementing procedures that govern documentation controls to verify compliance with applicable requirements to 10 CFR Part 72:

QP 6-1, "Controlled Document Distribution," Revision 9
QP 17-1, "Identification, Transmittal, Storage and Maintenance of Quality Assurance Records," Revision 14
QP 17-2, "Electronic Records Maintenance Storage," Revision 5

2.4.3 Conclusion

The team assessed that document controls and records management at NAC were adequate and effective for the dry cask storage systems for which NAC is the CoC holder.

2.5 Audit Program

2.5.1 Scope

The team reviewed NAC's audit program to determine whether audit plans, procedures, and records were developed and maintained. The team evaluated whether NAC scheduled and performed internal QA audits and vendor audits in accordance with approved procedures or checklists; whether qualified and independent personnel performed the audits; whether NAC

management reviewed audit results; and whether NAC took appropriate follow up actions in those areas found to be deficient.

2.5.2 Observations and Findings

The team reviewed the NAC internal and external audit programs to determine if they were comprehensive and NAC scheduled and performed internal audits in accordance with Section 18 of the QAM and approved implementing procedures. Specifically, the team reviewed:

QP 18-1, "Qualification and Certification of Quality Assurance Audit Personnel," Revision 5
QP 18-2, “Audits, Surveys and Corrective Actions,” Revision 11
QP 7-1, “Control of Purchased Items and Services,” Revision 11

The team reviewed a selection of internal and external audits performed from 2017 through 2019 as well as the 2018 through 2020 internal audit schedules to verify that they were conducted in accordance with the program as previously defined. The team also reviewed a selection of lead auditor training and qualification records to assess whether lead auditors were trained and qualified as required by NAC approved procedures.

The team determined that for the internal and external audits reviewed, they were comprehensive in nature, used checklists to perform the audit, identified issues, and the audit reports were written in a timely manner. The team found that the internal audit schedules reviewed planned annual audits, at a minimum, that covered all 18 quality criteria. For the auditor training records that were reviewed, all were trained and qualified as required by the approved procedure. The team also verified that for the external audits reviewed, the suppliers were included and current on the approved Qualified Vendor List (QVL), dated February 24, 2020.

2.5.3 Conclusions

Overall, the team identified no concerns with NAC's audit program. The team verified that for the audits sampled, NAC conducted audits with qualified and certified personnel, scheduled and evaluated applicable elements of the QA program, and documented the deficiencies assessed by the audit team for resolution as required.

3.0 Design Controls

3.1 General

The team assessed the design control program described in NAC’s governing procedures to determine whether NAC implemented design controls and design changes to their dry cask storage systems in accordance with their QAP. The team reviewed selected design change packages, and interviewed NAC’s personnel involved in the design control process.

3.2 Design Development

3.2.1 Scope

The team reviewed the design control section of the NAC QAM Revision 8 and specifically reviewed the NAC quality and standard procedures associated with design control to verify that

NAC properly implemented their design control program.

3.2.2 Observations and Findings

The team reviewed the sections of the NAC QAM and NAC Quality Procedures specifically related to design development/control and modification activities. The team also had discussions with NAC engineering and quality assurance staff associated with design control. The team focused its review on NAC design activities related to the following Part 72, Certificates of Compliance (CoC):

CoC No. 72-1031: Modular Advanced Generation Nuclear All-purpose Storage - MAGNASTOR

Amendment 10 (submitted 12/9/2019)	FSAR Revision 10 (19C)
Amendment 9 (submitted 10/9/2109)	FSAR Revision 10 (19B)
Amendment 8* (submitted 9/12/2019)	FSAR Revision 9 (17A)
Amendment 7 (Effective 8/21/2017)	FSAR Revision 9

*Proposed and Direct Final Rule January 9, 2020

CoC No. 72-1015: Universal MPC System - UMS

Amendment 8 (submitted 12/18/2019)	FSAR Revision 14 (19A)
Amendment 7 (Effective 7/29/2019)	FSAR Revision 14

CoC No. 1025: Multi-Purpose Canister System - MPC

Amendment 8 (Effective March 4, 2019)	FSAR Revision 12
Renewal application dated 12/2019	

In addition, the team reviewed the following QP's associated with project planning and design control:

QP 2-4, "Order Entry and Project Planning," Revision 18
QP 3-1, "Control of Design Input," Revision 6
QP 3-2, "Preparation and Checking of Design Calculations," Revision 13
QP 3-3, "Preparation and Checking of Design and/or License Drawings, Specifications and Technical Reports/Manual," Revision 25
QP 3-4, "Design Verification," Revision 10
QP 3-7, "License Document Configuration Control," Revision 11

The team reviewed NAC's project plan dated December 17, 2019, associated with describing the integration of NAC resources to supply Exelon with MAGNASTOR (CoC No. 1031) systems to support placement of spent nuclear fuel into dry storage at the Three Mile Island (TMI) Independent Spent Fuel Storage Installation (ISFSI) facility. Specifically, the project encompasses NAC supplying and loading 46 spent fuel MAGNASTOR cask systems for storing TMI spent fuel on an ISFSI pad and one (1) GTCC system for storing waste in the spent fuel pool after placing all the spent fuel on the ISFSI pad. The team noted that NAC has filed a license amendment (Amendment No. 9) addressing regionalized fuel loading. The team noted that the NAC MAGNASTOR work scope included the design, engineering, licensing, fabrication, construction/installation, and pool-to-pad services. The team found the project plan reviewed to use the proper forms, be compliant with QP 2-4 project planning procedural requirements, initiated by the project manager and independently reviewed and approved by NAC senior management (e.g., project, engineering, licensing, and quality assurance).

The team reviewed NAC procurement Specification Nos. 71160-S-05, Revision 3, dated

January 23, 2020, “MAGNASTOR Transportable Storage Canisters, Basket Assemblies, DFCs Fuels Spacers and DFC Tools” and 790-S-05, Revision 17, dated November 21, 2014, “NAC Transportable Storage Canisters, Basket Assemblies and Fuel Cans.” The team noted that each specification contained technical and quality requirements for the procurement and fabrication for each system. The team noted that the MAGNASTOR FSAR and specification described the requirements for materials, fabrication, inspection, testing, cleaning, tagging, and preparation for shipment of the work in accordance with the American Society of Mechanical Engineers Boiler and Pressure Vessel Code (ASME) Section III, Division I, Subsection NB, 2001 Edition including 2003 Addendum, although requirements were not limited to just the code. The team noted both procurement specifications were prepared, approved, and controlled in accordance with QP 3-3. The team reviewed selected drawings and records to verify that the procurement specifications for materials, equipment, and services received by NAC met the design requirements. In addition, the team reviewed a sample of design change requests (DCR), design drawings, licensing drawings, and various revisions to the MAGNASTOR FSAR for completeness and accuracy against QP 3-3. Overall, no concerns were noted.

The team reviewed two MAGNASTOR calculation packages. The first was Calculation No. 30076-3005, “Transfer Cask Steady State Thermal Evaluation,” Revision 1, dated August 30, 2019. This calculation evaluated the thermal performance of the TMI NAC MAGNASTOR system containing a loaded PWR canister. It determined the maximum temperatures and temperature distributions of the MAGNASTOR transfer cask with a TSC containing a PWR fuel basket with greater than 35.5kW heat load for three different heat load patterns and under various operational conditions at steady state. A quarter 3D symmetrical computational fluid dynamics (CFD) model was used for the calculation. The team noted the computational fluid dynamics program FLUENT, Version 16.2, was used to perform the CFD analyses. The second calculation reviewed was Calculation No. 71160-5016, Revision 1, dated August 12, 2019 “MAGNASTOR PWR Additional Hardware Shielding Analysis.” It evaluated the shielding effects of loading additional non-fuel hardware (e.g., sources and reconstituted fuel assemblies) in the PWR MAGNASTOR System. The Monte Carlo N-particle (MCNP5) radiation transport code, version 1.3, was used to perform dose rate calculations.

The team noted both calculations were performed in accordance with NAC QP 3-2, “Preparation and Checking of Design Calculations,” and that each calculation package contained independent design verification check sheets, summaries, assumptions, design inputs, detailed analysis records, results, and applicable references. In addition, the team noted that both the FLUENT and MCNP5 programs were acquired and maintained by NAC and were verified prior to use. The team noted that both packages were subjected to NAC’s independent reviews and were approved. Further, each package contained updated summaries of computer outputs depicting project name, number, input file number, calculation number, title of analysis, program, operating system, computer identification and computer verification report number. Overall, Applicable technical characteristics were determined to be satisfactory and complied with NAC design control procedures.

The team reviewed NAC’s verification of FLUENT, version 16.2 and MCNP5, version 1.3 computer programs (report numbers: EA913-1030-016 dated May 20, 2020, and EA913-1060-003, dated July 15, 2015, respectively). Overall, the team noted that both computer programs were adequately controlled and validated prior to use and that each of the verification packages were compliant to the requirements of QP 3-5, “Computer Program Verification.”

The team reviewed Calculation No. 71160-3040, Revision 9, dated July 20, 2016, “Thermal

Evaluation for MAGNASTOR Concrete Cask with Additional Shielding Containing TSC with PWR Fuel." The Purpose of the calculation was to evaluate the thermal performance of the NAC MAGNASTOR vertical concrete cask (VCC) with a loaded PWR canister with a heat load of 35.5kW. The team noted that the CC5 configuration is similar to the CC3 configuration and the bounding component temperatures from the thermal analysis results using models for CC1/2 and CC3 are applicable to CC4. As a result, NAC concluded that no additional model was needed for the CC5 configuration. The team noted that models used for the thermal evaluation are explained as a basis in detail within 72-1031, FSAR Revision 8 and that calculation No. 71160-3040 includes a Thermal Evaluation for the MAGNASTOR Configuration CC4 that bounds CC5. The team noted that CC4, was evaluated in 2012 using QA controlled software, FLUENT, version 6.3.26.

3.2.3 Conclusions

The team determined that administrative controls and procedures were adequately established to control NAC storage cask system and component design consistent with the requirements of the QAM and 10 CFR 72.146, Design control. Engineering design control program procedures and processes were clearly defined and contained adequate controls for design input, analysis, and design verification. Design verification methods (design review, alternate calculations, qualification testing) were described in procedure QP 3-4, Design Verification, with clear instructions for verifying final design adequacy.

3.3 Design Changes/Modifications

3.3.1 Scope

The team reviewed selected records and interviewed personnel to assess NAC's design change process associated with modifications. The team focused its review in the following areas: 1) adequacy of Design Change Requests and 2) adequacy of 10 CFR 72.48 screenings and evaluations. The team reviewed NAC procedures related to the implementation instructions for 10 CFR 72.48 evaluations and control of modification activities. Specifically, the team reviewed NAC's procedure QP 3-8, "10 CFR 72.48 Determinations for Changes to NAC Dry Storage Cask Systems," Revision 7.

The team reviewed selected DCRs and associated 72.48 screenings and evaluations performed since the last inspection in January 2017. In addition, the team specifically selected a representative sample of NAC 72.48 determinations based on judgement of risk significance from NAC 10 CFR 72.48(d)(2) reports, "Biennial Summaries of Changes, Tests, and Experiments," relating to NAC-UMS, NAC-MPC, and MAGNASTOR Dry Cask Storage Systems covering back to 2015.

3.3.2 Observations and Findings

At the time of the inspection, based on input from NRC Region IV's ongoing inspection at Palo Verde Nuclear Generating Station, the team reviewed DCR 71160-FSAR-7Q. In this DCR, NAC performed a design change to the concrete cask (overpack) for the MAGNASTOR System and called the modified concrete cask CC5 (a reinforced concrete structure with a structural steel inner liner and base).

The team specifically reviewed the following Design Changes and 72.48 Documents associated with the CC5 cask configuration:

72.48 Evaluation: NAC-16-MAG-018, dated 12/30/2016

DCR(L) No.: 71160-FSAR-7Q, dated 11/22/2016, “MAGNASTOR FSAR” Description of change: Revise Chapters 1, 3, 4 and 5 as detailed in the attachment which provides description and bounding evaluation results for adding the CC5 concrete cask configuration.

DCR(L) No.: 71160-561-8B, dated 10/12/2016, “STRUCTURE, WELDMENT, CONCRETE CASK, MAGNASTOR”

DCR(L) No.: 71160-562-8B, dated 10/12/2016, “REINFORCING BAR AND CONCRETE PLACEMENT, CONCRETE CASK, MAGNASTOR”

DCR(L) No.: 71160-590-7A, dated 10/12/2016, “LOADED CONCRETE CASK, MAGNASTOR”

NAC Calculation No. 71160-2014, Revision 6, dated 12/01/2017, “Structural Evaluation for all MAGNASTOR Concrete Cask Configurations”

NAC MEMORANDUM, dated 11/07/2019, “Justification of Current MAGNASTOR VCC Tip-Over Evaluations for Palo Verde Spent Fuel Storage Project”

As part of qualifying the CC5 design change, NAC had to qualify CC5 loaded with a TSC for tip-over. The MAGNASTOR FSAR Section 3.7.3.7, “Concrete Cask Tip-Over,” states, in part, that the concrete cask tip-over analyses are performed using LS-DYNA. LS-DYNA is an explicit finite element program used for the nonlinear dynamic analysis of structures in three dimensions. FSAR Section 3.10.4.4, “Concrete Cask Finite Element Model for Tip-Over Evaluation,” states, in part, that two half-symmetry finite element models of the concrete cask, concrete pad, and soil subgrade are constructed of solid brick elements using the LS-DYNA program for the cask tip-over evaluation. LS-DYNA had been used to qualify for tip-over the original concrete cask design CC1.

Instead of using LS-DYNA, NAC used linear scaling (ratios) to account for changes in the design. The MAGNASTOR concrete cask overpack design was changed from a “standard” concrete cask model 1, called a CC1, to a CC5. There were several differences between the CC1 and CC5 concrete cask overpack designs, including: cask height, cask steel liner thickness, cask lid thickness, the addition of 3-inch steel bars in ventilation inlets, and rebar spacing. The concrete cask may be supplied in five different configurations designated CC1 through CC5. CC1 and CC5 are standard 225.27 inch and 225.9 inch high cylinders, respectively. CC2 is also 225.27 inches high but is a segmented design. The CC3 and CC4 configurations are shorter variants at 218.3 inches high. CC1, CC2 and CC4 are equipped with a 1.75-in thick carbon steel liner, while CC3 and CC5 have a 3 inch thick carbon steel liner. CC1, CC2 and CC4 are equipped with standard concrete lids, having a constant thickness, while CC3 and CC5 lids have a thicker center section for enhanced shielding. The CC3, CC4 and CC5 cask configurations are equipped with additional shielding at the air inlets.

The team noted that Sections 3.7.3.7 and 3.10.4.4 of the MAGNASTOR FSAR, stated that LS-DYNA (a software modeling program) was the method of evaluation for cask tip-over accidents applied to the original design. Instead of using LS-DYNA, NAC used linear scaling (ratios) to account for changes to the casks. NAC’s usage of the scaling method resulted in NAC’s determination that the angular velocity of the two casks were the same. As a result, NAC concluded the CC5 tip-over results were the same as for a CC1 tip-over.

The team consulted the NRC Materials and Structural Branch in the Division of Fuel Management of the Office of Nuclear Material Safety and Safeguards and independently assessed the two cask designs and determined that the angular momentums were not the same due to the differences in the casks' masses. The inspectors determined that NAC's usage of a scaling method resulted in the errant determination that each cask had a uniform density cylinder. Despite the CC1 and CC5 casks having differences (e.g., cask height, cask center of gravity, cask steel liner thickness, cask lid thickness, the addition of 3-inch steel bars in ventilation inlets to CC5, and rebar spacing) NAC failed to analyze the CC5 cask with LS-DYNA as applied to the original design. It was determined that the linear scaling method utilized was non-conservative and that it was not the FSAR-described method (LS-DYNA).

Title 10 CFR 72.146(c), "Design control," requires, in part, that a certificate holder shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval.

Contrary to the above, prior to December 30, 2016, the certificate holder (NAC) implemented a design change for the MAGNASTOR spent fuel cask without ensuring that design control measures were commensurate with those applied to the original design as described in the MAGNASTOR FSAR for the tip-over accident analysis. Specifically, NAC failed to use the nonlinear LS-DYNA computer model (identified in the MAGANASTOR FSAR Sections 3.7.3.7 and 3.10.4.4 as the method of evaluation for concrete cask tip-over analysis applied to the original design) for cask tip-over accidents for the assessment of acceleration values for a design basis tip-over accident of the MAGNASTOR CC5 spent fuel cask. Instead, NAC implemented a design change to particular MAGNASTOR CC designs using a linear scaling method to compare hand calculated acceleration results to the previous non-linear LS-DYNA acceleration results. The original design basis used the nonlinear LS-DYNA computer model to obtain acceleration values to establish and maintain the safety function of the concrete cask following a design basis tip-over accident.

The team characterized this as an Apparent Violation (in accordance with NRC Enforcement Policy) for which the NRC staff has not made a final enforcement determination.

<u>10 CFR 72.48 Screenings and Evaluations</u>

The team assessed an initial sample of eighteen 10 CFR 72.48 determinations (evaluations and/or screenings) to verify that NAC appropriately concluded that changes did not require prior NRC approval or a full evaluation following a screening in accordance with NRC requirements and NAC procedures. The team reviewed selected procedures to verify that NAC effectively implemented its 72.48 program. Specifically, the team reviewed the following implementing procedures that govern the 72.48 program for NAC to verify compliance with applicable requirements of 10 CFR Part 72:

QP 3-7, "License Document Configuration Control," Revision 11
QP 3-8, "10 CFR 72.48 Determinations for Changes to NAC Dry Storage Cask Systems," Revision 7

The team assessed the QP 3-8 procedure to be thorough and to provide adequate guidance on the 72.48 process for performing 72.48 screenings and evaluations. Section 6.1 of QP 3-8 states that in accordance with 10 CFR 72.48(d)(6)(iii) the CoC holder (NAC) will provide a copy of the record for any changes to a spent fuel storage cask design to any general or site-specific

cask system user within 60 days of implementing the change. As standard practice NAC will issue the record of changes at approximately 60-day intervals to all applicable cask system users. The record of changes will include the applicable NAC generated 72.48's. The team reviewed a sample of the transmittal documents showing that NAC was complying with 10 CFR 72.48(d)(6)(iii) and sending licensees copies of their DCSS 72.48's and changes within 60-days.

In QP 3-7, section 7.1, "Compatibility Impact Assessment Procedure (CIA)," NAC has developed a CIA procedure to identify, evaluate, and track 10 CFR 72.48 changes that may affect other storage and transport cask systems. A CIA review form is completed for each 10 CFR 72.48 determination that is initiated for any NAC storage system. The purpose of the CIA review form is to ascertain if a cask design change made to a specific storage system affects other storage system designs. CIA review meetings are held bi-monthly to review all NAC generated 72.48 determinations completed since the last CIA meeting. Meeting attendees include the following: Vice President or Director of engineering, Licensing and the Licensing Engineer, and the Technical Editor. The team reviewed a sampling of the CIA review forms for process compliance and assessed that the process itself was being followed and the meetings held on time.

The team reviewed a sampling of 72.48 training records for NAC staff that performed the initial eighteen 72.48 determinations that were reviewed by the team and assessed that all the training records reviewed were complete and adequate.

The team reviewed eighteen 72.48 determinations pre-selected prior to the inspection based on the information provided in NAC biennial 72.48 update letters to the NRC. The eighteen selected were based on judgement of risk significance from the short description of the change provided in the NAC letters. The team assessed that all the eighteen 72.48's reviewed were adequately performed and NRC prior approval was not required before making the change to the DCSS design or FSAR.

However, at the time of the inspection, based on input from NRC Region IV's ongoing inspection at Palo Verde Nuclear Generating Station the team reviewed a nineteenth 72.48 Determination, NAC-16-MAG-018. This 72.48 determination was part of the selection pool from which the initial eighteen were selected but based on the NAC biennial letter description it was not selected since the description stated there was no change in method of evaluation. NAC-16-MAG-018 was written for DCR 71160-FSAR-7Q.

In this DCR, as discussed above, NAC performed a design change to the concrete cask (overpack) for the MAGNASTOR System and called the modified concrete cask CC5. As part of qualifying the CC5 design change, NAC had to qualify CC5 loaded with a TSC for tip-over. The MAGNASTOR FSAR Section 3.7.3.7, "Concrete Cask Tip-Over," states, in part, that the concrete cask tip-over analyses are performed using LS-DYNA. LS-DYNA is an explicit finite element program used for the nonlinear dynamic analysis of structures in three dimensions. FSAR Section 3.10.4.4, "Concrete Cask Finite Element Model for Tip-Over Evaluation," states, in part, that two half-symmetry finite element models of the concrete cask, concrete pad, and soil subgrade are constructed of solid brick elements using the LS-DYNA program for the cask tip-over evaluation. LS-DYNA had been used to qualify for tip-over the original concrete cask design CC1.

Instead of using LS-DYNA, NAC used linear scaling (ratios) to account for changes in the design. The MAGNASTOR concrete cask overpack design was changed from a "standard" concrete cask model 1, called a CC1, to a CC5. There were several differences between the CC1 and CC5 concrete cask overpack designs, including: cask height, cask steel liner thickness, cask lid thickness, the addition of 3-inch steel bars in ventilation inlets, and rebar spacing. NAC's usage of the scaling method resulted in NAC's determination that the angular velocity of the two casks were the same. As a result, NAC concluded the CC5 tip-over results were the same as for a CC1 tip-over.

As discussed previously above, it was determined that the linear scaling method utilized was non-conservative and that it was not the FSAR-described method (LS-DYNA). The inspection team determined that this was a new or different method of evaluation used to make this design change than previously described in the MAGNASTOR FSAR.

The inspection team determined that to qualify CC5 for a design basis tip-over accident, NAC must use LS-DYNA to establish and maintain design basis shielding, geometry control of contents, and content confinement performance requirements. Further, the staff assessed that this new or different method of linear scaling or ratioing would likely not be approved by the technical staff because so many variables such as the concrete and soil material properties, pad and soil configurations (e.g., compressive strength) can change simultaneously and there is an inter-dependence between those input parameters. Non-linear dynamic computer codes, like LS-DYNA, are exclusively used for tip-over analyses because these type of analyses are difficult to solve using linear analysis methods. To summarize, NAC changed the method of evaluation described in the MAGNASTOR FSAR by using a linear scaling method instead of LS-DYNA to qualify the concrete cask design for the tip-over accident analysis.

NAC prepared the 72.48 determination, "NAC-16-MAG-018," dated December 30, 2016, which contained a screening and 72.48 evaluation associated with the design change to the CC5 as one of six qualified variations of the MAGNASTOR System. Question eight in this evaluation states: Does the change result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses? NAC answered "No" in the response to the question. In the explain box, NAC stated: *The CC5 configuration is structurally evaluated using the same methodology as used for the previous casks and is shown to meet the applicable design requirements. Therefore, the change does not involve revising or replacing an evaluation methodology described in the cask licensing documents.*

The inspection team assessed that based on the review of the 72.48 regulatory requirements and guidance document, NAC required prior NRC review and approval for the design change to CC5 in using linear scaling of prior CC1 LS-DYNA results to qualify the CC5 design instead of analyzing CC5 using a cask specific LS-DYNA model. Specifically, NAC changed from a method of evaluation described in the FSAR to another method that was not approved by the NRC for tip-over accident analyses.

10 CFR 72.48(c)(2)(viii), "Changes, tests, and experiments" requires, in part, that a certificate holder shall obtain a CoC amendment pursuant to 10 CFR 72.244, prior to implementing a proposed change that would result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.

Contrary to the above, on December 30, 2016, the certificate holder (NAC) failed to obtain a

CoC amendment from the NRC pursuant to 10 CFR 72.244 prior to implementing a design change for the MAGNASTOR CC5 spent fuel cask that resulted in a departure from a method of evaluation described in the MAGNASTOR FSAR (as updated). Specifically, NAC failed to utilize LS-DYNA, a non-linear analysis methodology described in Section 3.7.3.7, "Concrete Cask Tip-Over," when implementing a design change for the MAGNASTOR CC5 spent fuel storage cask.

The team characterized this as an Apparent Violation (in accordance with NRC Enforcement Policy) for which the NRC staff has not made a final enforcement determination.

3.3.3 Conclusions

The inspectors performed a review of NAC's design change/modification and 72.48 procedures, actual design changes (DCRs), and 72.48 determinations that had been performed since the previous inspection.

The inspectors identified two apparent violations related to NAC's MAGNASTOR tip-over analysis. NAC failed to subject design changes (CC5) to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval in accordance with 10 CFR 72.146(c).

Additionally, the inspectors identified NAC's tip-over evaluation departed from a method of evaluation described in the MAGNASTOR FSAR to another method that was not approved by the NRC for the intended application and did not obtain a license amendment prior to implementing the proposed change in accordance with 10 CFR 72.48(c)(2)(viii).

4.0 Fabrication Controls

4.1 General

This was a NAC corporate office inspection that did not involve any actual fabrication. However, NAC's Corporate office often does have involvement in the direct procurement of some materials used in fabrication by its fabrication vendors. Therefore, the team assessed the adequacy of fabrication controls in only the area of NAC's corporate office limited involvement in direct material procurement. The team also reviewed NAC's process of procuring fabrication services for its dry cask storage systems.

4.2 Material Procurement

4.2.1 Scope

The team reviewed a sample size of six NAC purchase orders (PO) to vendors on its Qualified Vendors List. These vendors provide materials to be used in the fabrication of NAC's dry cask storage systems or provide actual fabrication services to NAC. The team assessed the PO's for compliance with NAC's procurement procedures.

4.2.2 Observations and Findings

The team reviewed selected procedures to verify that NAC effectively implemented its procurement program for materials and services. Specifically, the team reviewed the following

implementing procedures that govern NAC's corporate procurement program in accordance with its QAP:

QP 7-1, "Control of Purchased Items and Services," Revision 11
QP 7-2, "Acceptance of Documentation for Subcontracted Items & Services," Revision 15
QP 7-3, "Graded Quality Categories," Revision 8
QP 7-4, "Dedication of Commercial Items and Services," Revision 8
QP 7-5, "QA Evaluation of Nuclear Industry Assessment Corporation (NIAC) Assessment Reports," Revision 8

The team assessed the procedures associated with the procurement of materials and services to be thorough and to provide adequate guidance on the NAC corporate program.

The team assessed a sample of six purchase orders to four vendors which provide materials for fabrication or actual fabrication services. All four vendors were on NAC's Qualified Vendors List. The team determined that all the purchase orders were well detailed in the requirements of the material or services to be purchased or provided and in compliance with all applicable procedures.

4.2.3 Conclusion

Overall implementation of NAC's corporate office material procurement in support of its fabrication vendors was assessed to be adequate with no concerns identified. The team also reviewed NAC's procurement of fabrication services for its dry cask storage systems and determined them to be adequate.

5.0 Exit Meeting

On February 27, 2020, the NRC inspection team presented the inspection results and observations during an on-site debriefing exit meeting. On July 22, 2020, the NRC inspection team leader conducted a final telephone conference exit with Mr. Brad Greene of NAC. Table 2 of this report shows the attendance for the entrance, debriefing and exit meetings.

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at NAC International (hereafter referred to as NAC), on February 24 through February 27, 2020, with exiting on July 22, 2020, a team of inspectors identified two apparent violations of NRC requirements. In accordance with the NRC Enforcement Policy, the violations are listed below:

APPARENT VIOLATIONS BEING CONSIDERED FOR ESCALATED ENFORCEMENT

Apparent Violation A:

10 CFR 72.146(c), "Design control," requires, in part, that a certificate holder shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval.

Contrary to the above, prior to December 30, 2016, the certificate holder (NAC) implemented a design change for the MAGNASTOR spent fuel cask without ensuring that design control measures were commensurate with those applied to the original design. Specifically, NAC failed to use the nonlinear LS-DYNA computer model (identified in the MAGANASTOR FSAR Sections 3.7.3.7 and 3.10.4.4 as the method of evaluation for concrete cask tip-over analysis applied to the original design) for the assessment of acceleration values for a design basis tip-over accident of the MAGNASTOR CC5 spent fuel cask.

Apparent Violation B:

10 CFR 72.48(c)(2)(viii), "Changes, tests, and experiments," requires, in part, that a certificate holder shall obtain a CoC amendment pursuant to § 72.244 prior to implementing a proposed change that would result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.

MAGNASTOR FSAR Section 3.7.3.7, "Concrete Cask Tip-Over," states, in part, that the concrete cask tip-over analyses are performed using LS-DYNA.

Contrary to the above, on December 30, 2016, the certificate holder (NAC) failed to obtain a CoC amendment from the NRC pursuant to 10 CFR 72.244 prior to implementing a design change for the MAGNASTOR CC5 spent fuel cask that resulted in a departure from a method of evaluation described in the MAGNASTOR FSAR. Specifically, NAC failed to utilize LS-DYNA, a non-linear analysis methodology that was described in the MAGASTOR FSAR Section 3.7.3.7, when implementing a design change for the MAGNASTOR CC5 spent fuel storage cask.

NRC INFORMATION NOTICE 96-28

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action or written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VI.A of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence.

In some cases, such violations are documented on Form 591 (for materials licensees) which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional enforcement conference may be held to discuss those actions.

The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation. Typically, such reviews include:

    Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.

    Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the current requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide a record that can be audited and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

   Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns and prevent recurrence of the violation.

4. It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, immediate corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?

2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?

3. Have precursor events been considered and factored into the corrective actions?

4. In the event of loss of radioactive material, should security of radioactive material be enhanced?

5. Has your staff been adequately trained on the applicable requirements?

6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?

7. Has your staff been notified of the violation and of the applicable corrective action?

8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?

10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?

11. Is a system in place for keeping abreast of new or modified NRC requirements?

12. Does your staff appreciate the need to consider safety in approaching daily assignments?

13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?

14. Have work hours affected the employees' ability to safely perform the job?

15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?

16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?

19. Has management communicated its expectations for safety and compliance?

20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?