

**LICENSING, INSPECTION, AND ENFORCEMENT
PROGRAMS REVIEW FOR STORAGE
AND TRANSPORTATION**

Working Group Report

**Division of Nuclear Materials Safety and Safeguards
Division of Spent Fuel Alternative Strategies**

December 13, 2011

Enclosure 2

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Acronyms Used

AFR	Away From Reactor
CAQ	Condition adverse to quality
CoC	Certificate of Compliance
DCSS	Dry Cask Storage System
HLWRS	Division of High Level Waste Repository Safety
IMC	Inspection Manual Chapter
IP	Inspection Procedure
ISFSI	Independent Spent Fuel Storage Installation
NRC	U.S. Nuclear Regulatory Commission
NRO	Office of New Reactors
NRR	Office of Nuclear Reactor Regulation
OI	Office Instruction
OIG	Office of Inspector General
QA	Quality Assurance
RAI	Request for Additional Information
ROP	Reactor Oversight Program
SER	Safety Evaluation Report
SFAS	Division of Spent Fuel Alternative Strategies
SFST	Division of Spent Fuel Storage and Transportation
WG	Working Group

Documents Referenced

Form 591, "Safety Inspection"

IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports"

IMC 0612, "Power Reactor Inspection Reports"

IMC 2690, "Inspection Program for Dry Storage of Spent Reactor Fuel at Independent Spent Fuel Storage Installations And For 10 CFR Part 71 Transportation Packagings"

IP 60851, "Design Control of ISFSI Components"

IP 60852, "ISFSI Component Fabrication by Outside Fabricators"

IP 60856, "Review of 10 CFR 72.212(b) Evaluations"

IP 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings"

NUREG-1927, "Standard Review Plan for Renewal of Spent Fuel Dry Cask Storage System Licenses and Certificates of Compliance"

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"

OI SFST – 4, "SFST Licensing Process"

OI SFST – 11, "Lessons Learned"

OI SFST – 19, "Non-Case Work Technical Issue Resolution Process"

Working Group Report

Executive Summary

On December 6, 2010, the Commission issued “Staff Requirements – COMSECY-10-0007 – Project Plan for Regulatory Program Review to Support Extended Storage and Transportation of Spent Nuclear Fuel” (ML103400287). The staff developed that project plan in response to “Staff Requirements – COMDEK-09-0001, Revisiting the Paradigm for Spent Fuel Storage and Transportation Regulatory Programs” (ML100491511). In the Staff Requirements – COMSECY-10-0007 the Commission approved, among other things, the initiative to review the licensing, inspection, and enforcement programs for storage and transportation activities conducted under the requirements of 10 CFR Parts 71 and 72 to identify improvements to increase efficiency and effectiveness.

Both U.S. Nuclear Regulatory Commission (NRC) headquarters and Regional inspectors perform storage and transportation inspections (herein referred to as Division of Spent Fuel Storage and Transportation (SFST) inspections). The charter for the Working Group (WG) assembled to review the SFST inspection program (Appendix A) identified the followings tasks that form the focus areas for this report:

- Task 1: Identify improvements to increase the efficiency and effectiveness of inspection and enforcement programs, both as documented and as implemented
- Task 2: Identify improvements through integrating technical review, licensing, and inspection activities to increase efficiency and effectiveness of the inspection process
- Task 3: Assess the inspection and enforcement oversight of aging management plans
- Task 4: Implement a communication plan that will promote participation of stakeholders in this review

Regarding Task 3, the WG determined that no changes were needed in the enforcement policy regarding SFST inspections as a result of this review. SFST inspections rarely result in enforcement findings of severity level IV or greater.

At the time of this report, Task 4 had not been addressed. Staff should address this task when decisions are made on what recommendations will be implemented.

The WG found that the SFST inspection program as implemented continues to assure the safe and secure storage and transportation of radioactive materials. However, the WG indentified a number of activities where enhancements could be made to improve the SFST inspection program efficiency and effectiveness, particularly in the areas of clarity, consistency, and predictability of inspection processes.

The focus of the WG’s recommendations is for implementation requiring minimal additional inspection resources to execute. The WG developed its recommendations with input from the project Steering Committee (identified in Appendix A) headquarters inspectors, and Regional inspectors. The WG also received input from NRC stakeholders during several public meetings. The WG’s recommendations are presented below are in the order of relative importance based on their potential impact for improving the efficiency and effectiveness of the SFST inspection program.

Recommendation 1: Revise Inspection Manual Chapter (IMC) 2690, “Inspection Program for Dry Storage of Spent Reactor Fuel at Independent Spent Fuel Storage Installations And For 10 CFR Part 71 Transportation Packagings,” to more clearly define inspection requirements and to organize inspection procedures (IPs) around key inspection areas (i.e., quality assurance, design, fabrication and construction, ISFSI operations, and aging management).

Recommendation 2: Revise IPs to more clearly define inspection criteria to provide more consistent application and verification of inspection criteria.

Recommendation 3: Integrate SFST staff possessing required technical skills into inspections to review § 72.48, “Changes, tests, and experiments,” and § 72.212, “Conditions of general license issued under § 72.210,” evaluations, as necessary, to support inspection teams.

Recommendation 4: Implement and manage the inspection process to timely resolve technical, open, unresolved, or generic issues identified during inspections (Reference Office Instruction (OI) SFST - 19, “Non-Case Work Technical Issue Resolution Process”).

Recommendation 5: Verify that Certificate of Compliance (CoC) holders and licensees capture and resolve conditions adverse to quality that are identified by NRC technical staff and inspectors during activities such as CoC and license application reviews and pre-operations inspections, in their respective corrective action programs.

Recommendation 6: Develop methods for evaluating and classifying the severity of inspection findings (including those determined to be less than Severity Level IV violations) to consistently classify findings within the context of the SFST Inspection Program.

Recommendation 7: Develop a method to track inspection findings and perform trend analysis to identify emerging negative trends to inform the inspection program process.

Recommendation 8: Write inspection reports consistent in format and content to allow findings to be assessed and trended.

Recommendation 9: Enhance the existing lessons learned process used by Regional and headquarters inspectors (Reference OI SFST - 11, “Lessons Learned”).

Recommendation 10: Assign Regional inspectors to accompany headquarters inspectors on design and fabrication inspections at CoC holders and storage cask fabrication vendors. Also assign SFST licensing staff to participate in transportation and storage inspections.

Recommendation 11: Enhance the existing licensing review process to integrate SFST inspection staff into the licensing process (Reference OI SFST - 4).

Recommendation 12: Develop an IP to address aging management inspections as detailed in NUREG-1927, “Standard Review Plan for Renewal of Spent Fuel Dry Cask Storage System Licenses and Certificates of Compliance.”

1.0 Introduction/Background

On December 6, 2010, the Commission issued “Staff Requirements – COMSECY-10-0007 – Project Plan for Regulatory Program Review to Support Extended Storage and Transportation of Spent Nuclear Fuel” (ML103400287). The staff developed that project plan in response to “Staff Requirements – COMDEK-09-0001, Revisiting the Paradigm for Spent Fuel Storage and Transportation Regulatory Programs” (ML100491511). In the Staff Requirements – COMSECY-10-0007 the Commission approved, among other things, the initiative to review the licensing, inspection, and enforcement programs for storage and transportation activities conducted under the requirements of 10 CFR Parts 71 and 72 to identify improvements to increase efficiency and effectiveness.

On April 8, 2011, the Director of the Division of Spent Fuel Alternative Strategies (SFAS), formerly the Division of High Level Waste Repository Safety, in the Office of Nuclear Materials Safety and Safeguards chartered a Working Group (WG) (Attachment A) to perform a review of the Spent Fuel Storage and Transportation (SFST) licensing, inspection, and enforcement programs. The review team members comprise a project Steering Committee, a WG, and a Consulting Group. The WG included representatives from SFAS, SFST, and contractor Center for Nuclear Waste Regulatory Analyses.

2.0 Methodology

The WG followed the guidance provided in Section 4.0, of the Charter, “Working Group Charter Task Descriptions,” (Appendix A) in conducting their activities.

Task 1: Inspection and Enforcement Programs Review

The goal of this task is to review the inspection and enforcement programs for storage and transportation conducted under the requirements of 10 CFR Parts 71 and 72 to identify efficiency and effectiveness improvements. Key activities in the Task 1 description include:

- Perform a comprehensive review of the US Nuclear Regulatory Commission (NRC) inspection manual, enforcement policy, and associated procedures and guidance documents for fabricators, certificate holders, and licensees for storage and transportation activities
- Benchmark the existing storage and transportation oversight program against other NRC inspection and enforcement programs
- Consult with NRC personnel having knowledge and experience in performing inspection and enforcement activities for fabricators, certificate holders, and licensees to obtain input on implementing inspection programs

Task 2: Licensing and Inspection Integration

The goal of this task is to identify areas where the technical review, licensing, and inspection activities can be integrated to improve efficiency and effectiveness. Key activities in the Task 2 description include:

- Perform a comprehensive assessment of procedures and guidance documents regarding technical review, licensing, and inspection activities to identify areas to integrate between the organizations
- Consult with members of the technical review, licensing, and inspection organizations to identify areas for possible integration
- Evaluate how the inspection process should be adjusted to identify technical- and quality-related issues specified in licensee's applications, technical specifications, and Certificates of Compliance (CoCs)

Task 3: Aging Management Inspection

The goal of this task is to develop recommendations for inspecting aging management programs at Independent Spent Fuel Storage Installations (ISFSIs). Key activities in the Task 3 description include:

- Review current inspection and enforcement guidance to assess applicability to the inspection and enforcement of aging management plans associated with the 40-year license renewals
- Consult with inspection staff from other NRC Offices and the Regions to determine how best to perform effective aging management inspection and enforcement

Task 4: Communication Plan

The goal of this task is to actively seek input and feedback from stakeholders during the development and implementation of any changes made to inspection and enforcement programs.

3.0 Focus Areas

3.1 Inspection and Enforcement Programs Review

Current State:

The SFST inspection program assesses 10 CFR Parts 71 and 72 CoC holders and licensees performance to determine whether activities performed regarding the storage and transportation of radioactive material are performed safely and securely and in compliance with NRC regulations. The program is defined in Inspection Manual Chapter (IMC) 2690, "Inspection Program for Dry Storage of Spent Reactor Fuel at Independent Spent Fuel Storage Installations and For 10 CFR Part 71 Transportation Packagings," and related Inspection Procedures (IPs). Inspection of ISFSIs within NRC is largely carried out by the NRC Regional Offices in their respective Divisions of Nuclear Materials Safety. Inspection of dry cask storage system (DCSS) and transportation packagings suppliers (i.e., holders of CoCs, designers, and fabricators) is largely carried out by SFST headquarters.

IMC 2690, "Inspection Program For Dry Storage Of Spent Reactor Fuel At Independent Spent Fuel Storage Installations And For 10 CFR Part 71 Transportation Packagings," initially released in 2001, describes an arrangement of IPs roughly falling into several ISFSI life cycle phases:

- Design
- Fabrication and construction
- Preoperational testing and dry runs
- Spent fuel loading and unloading operations
- Monitoring after loading

IMC 2690 initially addressed an inspection program solely applicable to ISFSI-related items and activities, i.e., DCSS components. Subsequently, the scope of IMC 2690 was expanded to include 10 CFR Part 71 transportation packagings and IP 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings."

IMC 2690 is supported by nine IPs:

- One IP applicable to transportation packagings entities
- Three IPs applicable to DCSS entities
- Four IPs applicable to ISFSI licensees
- One IP applicable to DCSS entities and ISFSI licensees

Other NRC Inspection Activities

In its assignment to benchmark the existing storage and transportation oversight program against other NRC inspection and enforcement programs, the WG determined that the NRC Offices of Nuclear Reactor Regulation (NRR) and New Reactors (NRO) have implemented, or are in the process of implementing, inspection oversight programs that offer significant enhancements over basic inspection programs, such as that employed by SFST. The key characteristics of the oversight programs include actions to:

- Assess key performance areas containing "cornerstones" of safety to reflect the essential aspects of safe plant operation
- Use inspection findings developed from selective examinations and performance indicator data, where available, to assess plant performance within the framework of the safety cornerstones
- Apply a risk-informed baseline inspection program that establishes the minimum regulatory interaction for all licensees
- Employ a significance determination process to evaluate the safety significance of inspection findings
- Use minimum thresholds for licensee safety performance, below which increased NRC interaction (including enforcement) would be warranted
- Take a graded approach to oversight, increasing the level of regulatory attention to plants where safety is declining

- Assess overall plant performance and communicate the results to the public

Discussion

The WG used the following methods in evaluating the SFST inspection program, making observations, and developing recommendations:

- Review of existing SFST inspection program documents and other NRC Offices' inspection and oversight program documents
- Discussions with SFST and Region inspection staff, stakeholder outreach, group discussion
- Professional judgment

The WG identified opportunities for increasing efficiency and effectiveness in IMC 2690 and associated IPs as follows:

- The framework of IPs described in IMC 2690 does not clearly establish that all of the essential elements requiring inspection (i.e., quality assurance (QA), design, fabrication and construction, and operations) would be addressed.
 - DCSS and transportation packagings design- and fabrication-related activities are not directly associated with the life cycle of an ISFSI as described in IMC 2690. DCSS and transportation packagings inspections follow a CoC, design, and fabrication life cycle.
 - The life cycle model of IMC 2690 is not appropriate for the range of inspectable entities needing to be covered by IMC 2690. Specifically, CoC holders and DCSS designers and fabricators are not addressed.
 - Inspection of QA programs (an essential inspection element) is not described in IMC 2690.
- IMC 2690 has no provisions for reporting findings or for requiring licensee actions for conditions less than Enforcement Program Severity Level IV violations.
- IMC 2690 does not provide for an inspection program that is risk-informed. Useful safety information is available in NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety," which could be applied to inspection requirements, inspection criteria, sample selection guidance, sample size guidance, and inspection finding severity determination.
- The various reporting options in IMC 2690 do not encourage consistent report format and content. Inspection findings corrected during inspections may not be captured.
- CoC holders and licensees are required by their QA programs to implement effective corrective action programs to identify and resolve conditions adverse to quality (CAQs). Not all CAQs identified by technical staff and inspectors during activities such as application reviews and pre-operations inspections are captured by applicants, CoC

holders, or licensees in their respective corrective action programs. As a result, the CAQs may not be properly addressed or resolved.

- IMC 2690 does not define inspector training and qualification requirements.
- IMC 2690 and IPs do not distinguish between initial inspections (that should be mainly compliance based) and periodic inspections (that should be more performance-based).
- Specific license ISFSI design inspection is not addressed in an IP. IP 60856, "Review of 10 CFR 72.212(b) Evaluations," covers general license ISFSI design inspection and IP 60851, "Design Control of ISFSI Components," only covers ISFSI components (e.g., the DCSS).
- In general, guidance is not provided for the use of information referenced in the IMC and IPs as inspection requirements, guidance, or acceptance criteria.
- The specific guidance provided in many IPs is limited and requires significant interpretation by the inspector. Inspectors gather inspection criteria and guidance from various referenced and unreferenced sources in order to adequately inspect entities.
- In practice, inspectors rely on NUREG/CR-6314, "Quality Assurance Inspections for Shipping and Storage Containers," for detailed guidance for design, fabrication, and QA inspections of DCSS and transportation packaging entities. IP 60851 and IP 60852, "ISFSI Component Fabrication by Outside Fabricators," provide limited guidance that is more oriented to periodic follow-up inspections and do not adequately address initial inspections. Also, IP 86001 is largely redundant with NUREG/CR-6314.
- Inspections related to 10 CFR 72.48 and 10 CFR 72.212(b) evaluations require technical expertise that may be beyond that of the inspectors usually assigned to these inspections and the process for obtaining technical assistance is vaguely defined.

In the "Audit of NRC's Oversight of Independent Spent Fuel Storage Installations Safety," OIG-11-A-12 May 19, 2011, the Office of Inspector General (OIG) indicated that opportunities exist to improve ISFSI safety inspector training, particularly in regard to consistency among the Regions. Because SFST is taking action to address the OIG recommendation, the WG will not duplicate this recommendation.

The WG did not identify any changes needed in the enforcement policy regarding SFST inspections as a result of this review. SFST inspections rarely result in enforcement findings of severity level IV or greater. Therefore, the focus of the WG recommendations is on potential findings of less than level IV severity.

The WG found that the SFST inspection program as implemented continues to assure the safe and secure storage and transportation of radioactive materials. However, the WG identified a number of activities where enhancements could be made to improve the SFST inspection program efficiency and effectiveness, particularly in the areas of clarity, consistency, and predictability of inspection processes.

The focus of the WG's recommendations is for near term implementation requiring minimal additional inspection resources to execute. The WG developed its recommendations with input

from the project Steering Committee (identified in Appendix A) headquarters inspectors, and Regional inspectors. The WG also received input from NRC stakeholders during several public meetings.

Following are the WG's recommendations presented in the order of relative importance based on their potential impact for improving the efficiency and effectiveness of the SFST inspection program.

Recommendation 1: Revise Inspection Manual Chapter (IMC) 2690, "Inspection Program for Dry Storage of Spent Reactor Fuel at Independent Spent Fuel Storage Installations And For 10 CFR Part 71 Transportation Packagings," to more clearly define inspection requirements and to organize inspection procedures (IPs) around key inspection areas (i.e., quality assurance, design, fabrication and construction, ISFSI operations, and aging management).

Recommendation 2: Revise IPs to more clearly define inspection criteria to provide more consistent application and verification of inspection criteria.

Recommendation 3: Integrate SFST staff possessing required technical skills into inspections to review § 72.48, "Changes, tests, and experiments," and § 72.212, "Conditions of general license issued under § 72.210," evaluations, as necessary, to support inspection teams.

Recommendation 4: Implement and manage the inspection process to timely resolve technical, open, unresolved, or generic issues identified during inspections (Reference Office Instruction (OI) SFST - 19, "Non-Case Work Technical Issue Resolution Process"). Define staff roles and responsibilities and assign resolution of issues to specific individuals responsible for driving the issues to closure.

Recommendation 5: Verify that CoC holders and licensees capture and resolve conditions adverse to quality that are identified by NRC technical staff and inspectors during activities such as CoC and license application reviews and pre-operations inspections, in their respective corrective action programs. (Refer to Appendix B for an approach to track and follow up on corrective actions).

Recommendation 6: Develop methods for evaluating and classifying the severity of inspection findings (including those determined to be less than Severity Level IV violations) to consistently classify findings within the context of the SFST Inspection Program. Develop methods to verify the determination of inspection findings severity levels to assure application consistency (Refer to Appendix C for a proposed methodology to use for determining the severity of inspection findings). It is not recommended that inspection findings severity level determinations be made available to entities, but use the information internally to trend and analyze performance to improve overall safety of storage and transportation activities.

Because very limited risk information is available to quantitatively evaluate SFST inspection findings, this process would necessarily be qualitative. An SFST finding severity determination process would therefore not be comparable in any way to the Significance Determination Process used in the NRC Office of Nuclear Reactor Regulation Reactor Oversight Process which relies heavily on quantitative risk determinations.

Recommendation 7: Develop a method to track inspection findings and perform trend analysis to identify emerging negative trends to inform the inspection program process.

Recommendation 8: Write inspection reports consistent in format and content to allow findings to be assessed and trended.

Recommendation 9: Enhance the existing lessons learned process used by Regional and headquarters inspectors (Reference OI SFST - 11, "Lessons Learned"). This will facilitate increased communication among inspectors; improve the efficiency and effectiveness of inspections, and provide for continuous improvement of the SFST inspection program.

Recommendation 10: Assign Regional inspectors to accompany headquarters inspectors on design and fabrication inspections at Certificate of Compliance (CoC) holders and storage cask fabrication vendors. Also assign SFST licensing staff to participate in transportation and storage inspections. This will improve the efficiency and effectiveness of the licensing and inspection processes by increasing and integrating the knowledge base of inspectors.

The WG also identified an opportunity for long-term improvement of the SFST inspection program that would require greater levels of time and resources to develop and implement. SFST should consider developing an oversight program such as implemented by the Office of Nuclear Reactor Regulation in their Reactor Oversight Program and the Office of New Reactor Operations in their construction Reactor Oversight Program (ROP). Because an oversight program requires extensive risk information not available for storage and transportation activities, developing such a program is not appropriate at this time. However, the WG provides its observations regarding a potential ISFSI inspection oversight program in Appendix D of this report.

3.2 Licensing and Inspection Integration

Current State:

OI SFST - 4, "SFST Licensing Process," provides guidance to SFST staff on establishing a consistent methodology and expectations for reviewing 10 CFR Parts 71 and 72 applications. This includes performing acceptance reviews and technical reviews, and preparing requests for additional information (RAIs), Safety Evaluation Reports (SERs), and QA program approvals. There are no provisions in OI SFST - 4 to include SFST inspection staff in the technical review activities for applications or supporting documentation. Inspection staff is assigned the responsibility for reviewing only QA programs.

Discussion:

The ultimate goal of the SFST team review process is to ensure that safety is assured in the licensing process in the most efficient and effective manner. Based on recurring problems being identified in applications, inspection staff review would provide necessary expertise to resolve problems and prevent recurrence over time through effective corrective actions. To increase efficiency and effectiveness in the application approval process, it is necessary to request inspection staff to provide technical review support from a QA perspective. The assigned Project Manager, with input from the Rules, Inspections and Operations Branch Chief, should decide on the level of participation by inspection staff based on the nature and complexity of the specific application and the historical performance of the applicant.

Recommendation 11: Enhance the existing licensing review process to integrate SFST inspection staff into the licensing process (Reference OI SFST - 4). Inspection staff's technical review activities, from a QA perspective, should include, but not be limited to:

- Meeting with applicants to discuss QA program matters
- Application acceptance review (availability of acceptable design and fabrication drawings and other QA related documents)
- Application Technical review (verification of required design, fabrication, and QA requirements)
- Interface with technical reviewers to establish appropriate technical criteria, verifiable during inspections, for inclusion into SERs and identify the need for technical reviewer assistance to perform verification activities during inspections
- RAI production, concurrence, and response acceptance
- SER and technical specifications development and concurrence
- Corrective actions taken by applicants to improve application quality based on a combination of significance, repetitiveness, and quantity of identified issued (refer to Appendix B for a proposed corrective action process)

3.3 Aging Management Inspection

Current State:

Spent fuel cask CoCs are initially issued for a term of 20 years, and ISFSI licenses are initially issued for 40 years. CoC holders and ISFSI licensees may apply for license renewals for up to 40 additional years following the approach defined in NUREG-1927, "Standard Review Plan for Renewal of spent Fuel Dry Cask Storage System Licenses and Certificates of Compliance." Granting the license renewal is dependent upon the CoC holder or licensee establishing aging management plans and programs. Aging management inspections for CoC holders and ISFSI licensees are not addressed in any IMC or IP.

Discussion:

Inspection of the implementation of CoC holder and licensee aging management programs is necessary to verify that the additional monitoring, inspections, and maintenance are adequately integrated or added to existing facility programs.

Recommendation 12: Develop an IP to address aging management inspections as detailed in NUREG-1927.

3.4 Communication Plan

The WG did not perform activities relating to the communication plan during the period covered by this report. Staff should address this task during the first quarter of Fiscal Year 2012 when SFST makes decisions on what recommendations will be implemented.

4.0 Plans for Continued Development

The goal of this review was to provide recommendations for enhancing the SFST inspection program to improve efficiency and effectiveness. In accomplishing this goal, the WG identified initiatives that are needed to supplement the recommendations discussed above. These initiatives will require additional resources to fully develop and implement the recommended inspection program enhancements. SFST should consider establishing additional teams to perform reviews in areas to include, but not be limited to, the following:

- Regarding Recommendation 4, develop and implement a predictable process for consistent and timely identification and resolution of unresolved issues, open items, and generic issues.
- Regarding Recommendation 5, develop a process to verify that CoC holders and licensees capture CAQs identified by technical staff and inspectors during activities such as application reviews and pre-operations inspections in their respective corrective action programs. SFST and Regional management should hold the CoC holders and licensees accountable for timely and effective resolution of the identified problems and any underlying causes to prevent recurrence.
- Regarding Recommendation 6, form a standing committee chaired by SFST and comprising inspection representatives from headquarters and the Regions to validate the preliminary level of findings severity determined by inspectors.
- Also regarding Recommendation 6, review risk categorization to determine completeness, correctness, and adequacy. Feedback from Regional inspectors indicates that the existing guidance provided in NUREG/CR-6407 leaves room for interpretation.
- Regarding Recommendation 7, develop the process for capturing, tracking, and trending findings documented in inspection attributes lists and reports.
- Regarding Recommendation 8, develop a single format for documenting inspection reports to increase efficiency, effectiveness, consistency, and clarity of inspection results. SFST and Regional inspectors complete inspection reports using IMC 0610, IMC 0612, "Power Reactor Inspection Reports," and Form 591, "Safety Inspection."
- Regarding Recommendation 9, further develop the inspector periodic teleconference meetings to formally address lessons learned from recent inspections to promote continuous improvement in the SFST inspection program. Utilize information gained from inspection findings tracking and trending and the findings evaluation process to supplement the discussions of good practices and areas for improvement.
- Regarding inspection resource estimates, determine the correct level and allocation of resources to perform the inspections based on the revised IMC and IPs. Ascertain that a significant portion of inspector time is attributed to planning and preparation to increase inspection effectiveness and efficiency.

- Regarding integrating ISFSI and NRR's ROP inspection findings, revisit how ISFSI inspection results can be combined with ROP information. Consider integrating cross-cutting insights and attributes. (Refer to Appendix D)

5.0 Implementation of Recommendations

The WG has completed its review of the SFST inspection program and has identified recommendations to increase efficiency and effectiveness of the SFST inspection program. The WG now turns the inspection program review project over to SFST for final development and implementation. The WG recommends that SFST take the following steps to implement the recommendations:

- Make the final determination regarding which recommendations will be implemented and develop a plan and schedule for completion. Conduct additional outreach with stakeholders throughout Fiscal Year 2012.
- Establish SFST teams to complete review of inspection processes for the recommendations that are scheduled to be implemented.
- Communicate with affected staff regarding development and revision of inspection processes to coordinate activities and gain alignment.
- Train SFST headquarters staff and Regional inspectors on the revised inspection processes. Test the revised inspection processes in the field using both SFST inspectors and Regional inspectors to verify effectiveness and make adjustments, as necessary.
- Implement the revised SFST inspection processes and monitor performance.

6.0 Conclusions

In conclusion, the WG found that the SFST inspection program as implemented continues to assure the safe and secure storage and transportation of radioactive materials. However, the WG identified a number of activities where enhancements could be made to improve the SFST inspection program efficiency and effectiveness, particularly in the areas of clarity, consistency, and predictability of inspection processes. The WG also suggested long-term enhancements for consideration which will require significant levels of time and resources to develop and implement.

Appendix A

DIVISION OF HIGH-LEVEL WASTE REPOSITORY SAFETY LICENSING, INSPECTION, AND ENFORCEMENT PROGRAMS REVIEW FOR STORAGE AND TRANSPORTATION CHARTER

March 17, 2011

1.0 Background

On December 6, 2010, the Commission issued “Staff Requirements – COMSECY-10-0007 – Project Plan for Regulatory Program Review to Support Extended Storage and Transportation of Spent Nuclear Fuel.” The staff developed that project plan in response to staff requirements memorandum (SRM) COMDEK-09-0001, “Revisiting the Paradigm for Spent Fuel Storage and Transportation Regulatory Programs.” In the Staff Requirements – COMSECY-10-0007 the Commission approved several initiatives regarding storage and transportation.

2.0 Scope

The staff will review the licensing, inspection, and enforcement programs for storage and transportation activities conducted under the requirements of 10 CFR Parts 71 and 72. The purpose of this review is to identify improvements to increase efficiency and effectiveness of the licensing, inspection, and enforcement programs. The review team members comprise a Steering Committee (SC), staff Working Group (WG), and staff Consulting Group (CG) as identified in Section 6.0. The review will be completed by September 30, 2011, and the level of effort for CG members is no more than 20 hours. Additional time will be required of WG members to perform the detailed review. After the WG and CG members are designated the Project Manager will provide task assignments and charge numbers to team members. This Charter will be revised, as appropriate, to keep the information current, maintain proper focus, and ensure that meaningful outcomes are achieved.

3.0 Tasks

The tasks of the Licensing, Inspection, and Enforcement Programs Review are:

- Task 1: Identify improvements to increase the efficiency and effectiveness of inspection and enforcement programs, both as documented and as implemented
- Task 2: Identify improvements through integrating technical review, licensing, and inspection activities to increase efficiency and effectiveness of the inspection process
- Task 3: Assess the inspection and enforcement oversight of aging management plans
- Task 4: Implement a communication plan that will promote participation of stakeholders in this review

4.0 Task Descriptions

4.1 Task 1: Inspection and Enforcement Programs Review

The goal of this task is to review the inspection and enforcement programs for storage and transportation conducted under the requirements of 10 CFR Parts 71 and 72 to identify efficiency and effectiveness improvements. There are two phases to completing this task. In Phase 1 the staff will review the inspection and enforcement programs as they are documented. Staff will:

- Perform a comprehensive review of the NRC inspection manual, enforcement policy, and associated procedures and guidance documents for fabricators, certificate holders, and licensees for storage and transportation activities
- Benchmark the existing storage and transportation oversight program against other NRC inspection and enforcement programs
- Identify inconsistencies, missing information, or other issues in the inspection and enforcement documents and recommend actions that are risk-informed and performance-based, as appropriate
- Assess and recommend how inspection findings, information from site loading campaigns, emergent technical issues, and operating experience are combined, managed, and addressed using the licensing, inspection, enforcement, and reactor oversight programs
- Identify good practices and assure that they are carried forward
- Recommend immediate implementation of any significant changes that can be made in advance of completing the full program review

In Phase 2 the staff will review the inspection and enforcement programs as they are implemented. Staff will:

- Consult with NRC personnel having knowledge and experience in performing inspection and enforcement activities for fabricators, certificate holders, and licensees to obtain input on implementing inspection programs
- Identify inconsistencies, errors, or other issues in performing inspection and enforcement activities and identify actions that are risk-informed and performance-based, as appropriate
- Assess resource utilization by determining the estimated and actual level of effort necessary to conduct inspection activities
- Identify good practices and assure that they are carried forward
- Recommend immediate implementation of any significant changes that can be made in advance of completing the full program review

4.2 Task 2: Licensing and Inspection Integration

The goal of this task is to identify areas where the technical review, licensing, and inspection activities can be integrated to improve efficiency and effectiveness. To accomplish this task the staff will:

- Perform a comprehensive assessment of procedures and guidance documents regarding technical review, licensing, and inspection activities to identify areas to integrate between the organizations
- Consult with members of the technical review, licensing, and inspection organizations to identify areas for possible integration
- Evaluate how the inspection process should be adjusted to identify technical- and quality-related issues specified in licensee's applications, technical specifications, and Certificates of Compliance
- Assure that appropriate technical- and quality-related issues identified in the licensing process are addressed by qualified staff during the inspection process
- Evaluate whether adjustments should be made to the licensing process in response to licensee performance findings identified during inspections
- Identify good practices and assure that they are carried forward
- Assess if changes are necessary to key regulatory and licensing documents such as the inspection manual and the enforcement policy
- Examine how NRC inspects and enforces licensee change authority and QA
- Recommend immediate implementation of any significant changes that can be made in advance of completing the full program review
- Identify integration changes to improve the effectiveness of licensing and inspection activities that are risk-informed and performance-based, as appropriate

4.3 Task 3: Aging Management Inspection

The goal of this task is to develop recommendations for inspecting aging management programs at Independent Spent Fuel Storage Installations. The staff will:

- Review current inspection and enforcement guidance to assess applicability to the inspection and enforcement of aging management plans associated with the 40-year license renewals
- Consult with inspection staff from other NRC Offices and the Regions to determine how best to perform effective aging management inspection and enforcement
- Identify actions for effective inspection and enforcement of aging management activities that are risk-informed and performance-based, as appropriate

4.4 Task 4: Communication Plan

The goal of this task is to actively seek input and feedback from stakeholders during the development and implementation of any changes made to inspection and enforcement programs. To facilitate effective communication with stakeholders, NRC staff will:

- Develop and align key messages for the inspection and enforcement programs
- Identify key target audiences for input/feedback
- Develop appropriate communication tools to coordinate the timely and effective dissemination of information with stakeholders and the public
- Provide opportunities that encourage stakeholders to provide input/feedback on evolving issues

NRC staff's outreach efforts will also seek to maintain and leverage existing external networks that have been developed for spent fuel transportation and storage.

5.0 Performance Measures

The staff will establish performance measures to ensure the achievement of the desired outcomes as described in this Charter. The staff will:

- Consult with inspection personnel from NRC headquarters to capture baseline inspection performance information for reference
- Assure that future activities performed in licensing, inspection, and enforcement programs are tracked to measure effectiveness and efficiency improvements resulting from changes made to associated procedures
- Refine the performance measures during execution of the tasks described in this Charter, as appropriate

6.0 Team Members

Steering Committee

Aby Mohseni, Deputy Director, Licensing and Inspection Directorate (LID), Division of High Level Waste Repository Safety (HLWRS), Office of Nuclear Material Safety and Safeguards (NMSS)

Doug Weaver, Deputy Director, LID, Division of Spent Fuel Storage and Transportation, NMSS

Patrick Loudon, Deputy Director, Division of Nuclear Material Safety, Region III

Working Group

Thomas Matula, Project Manager, HLWRS, NMSS
Jack Parrott, HLWRS, NMSS
Earl Love, SFST, NMSS
Robert Brient, Center for Nuclear Waste Regulatory Analyses
George Adams, Center for Nuclear Waste Regulatory Analyses
Steve Ruffin, HLWRS, NMSS (Outreach)

Consulting Group

Rob Temps, SFST inspector
Jim Pearson, SFST inspector
Clyde Morrell, SFST inspector
TBD, RI inspector
TBD, RII inspector
TBD, RIII inspector
TBD, RIV inspector
TBD, NRR inspector
TBD, FCSS inspector
TBD, NRO inspector
TBD, Licensing Branch, SFST
TBD, Structural Mechanics, and Materials Branch, SFST
TBD, Criticality, Shielding, and Dose Assessment Branch, SFST
TBD, Thermal and Containment Branch, SFST
TBD, OE
TBD, OGC

Other staff members will be asked to serve on the CG, as necessary.

7.0 Team Responsibilities

The SC monitors the overall implementation and effectiveness of the review and provides advice and guidance to the WG. The responsibilities of the SC are:

- Interact with internal and external stakeholders regarding the Review
- Oversee and resolve crosscutting issues
- Ensure effective interdivision and interoffice coordination and integration on emerging issues
- Identify and assign necessary resources to complete tasks
- Assign and delete activities, and adjust schedules based on available resources and changes in priorities

The WG comprises a Project Manager and technical representatives to serve as the primary staff responsible for completing review tasks. The responsibilities of the WG are:

- Prepare adequately for each meeting for maximum contribution
- Provide quality and timely documentation as required
- Complete tasks as assigned by the PM
- Monitor task progress and inform the PM of any deviations
- Update the SC and PM on the progress of the review
- Identify updates to the review and revise the review plan as directed by the PM

The CG comprises personnel from other NRC Offices and the Regions who are experienced and knowledgeable in spent fuel storage and transportation or other oversight programs. Members of the CG will be called upon, as needed, for specific activities in completing certain tasks. Therefore, the time requirement for CG members will be significantly less than that required of the WG members. The primary responsibilities of the CG are:

- Prepare adequately for each meeting for maximum contribution
- Provide quality and timely documentation as required
- Provide input and perspective to the team based on their knowledge and experience
- Complete review assignments as assigned by the PM
- Update the PM on the progress of the review

Meetings with the SC, WG, and CG will be scheduled and coordinated by the PM or his designated representative. Meetings will be held by teleconference for those not located at NRC Headquarters to reduce travel time and expenses. The overall plan for the Review is available through the PM.

Vonna Ordaz, Director
 Division of Spent Fuel
 Transportation and Storage
 Office of Nuclear Material Safety
 And Safeguards

Lawrence Kokajko, Director
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Appendix B

Corrective Action Verification Process

When SFST staff or Regional inspectors identify conditions adverse to quality (CAQs) during activities such as application reviews and inspections, applicants, CoC holders, and licensees (entities) are required by their quality assurance programs to capture the identified CAQs in their respective corrective action programs.

The level of corrective actions taken by entities to track, trend, and resolve CAQs should be based on severity (a combination of significance, repetitiveness, and quantity). Increasing levels of action required by SFST may include:

- Level 1 – Entities should document all CAQs in their respective corrective action programs and make their corrective action logs available to inspectors for verification and follow up action
- Level 2 – Entities should provide their corrective action plans to resolve the CAQs to SFST for verification and follow up action
- Level 3 – Entities should provide their corrective action documentation, including root cause analysis and actions to preclude recurrence of the CAQs, for verification and follow up action

Inspectors will verify corrective actions taken by entities during inspections. Inadequate corrective actions may result in possible rejection of future applications, reactive inspections, or additional NRC actions, as appropriate.

The corrective action verification process should be incorporated in the appropriate inspection procedures to assure consistent application and effectiveness.

Appendix C

Evaluation of Inspection Findings

Following is a proposed methodology to use for determining the severity of inspection findings:

- a. Review completed inspection attributes lists for identified issues.
- b. Inspection items with one or more samples not meeting all acceptance criteria (i.e., noncompliant) shall be evaluated. Evaluations should be initially performed by the inspector and reviewed by a standing committee chaired by SFST consisting of representatives from SFST and Regional management, inspectors, and technical and licensing staff to ensure consistency.
- c. Noncompliances that are potentially generic issues (i.e., issues that may apply to several entities) should be identified and promptly communicated to all potentially affected entities.
- d. The Finding Evaluation should be conducted as follows:

STEP 1: Determine the importance to safety of the system, structure, or component associated with the noncompliance or potentially affected by the noncompliance. NUREG/CR-6407 (McConnell, et al., 1996) should be used to identify the importance to safety of the noncompliance. NUREG/CR-6407 (McConnell, et al., 1996) includes lists of systems, structures, and components in the three categories:

Category A: Critical to Safe Operation—Category A items include structures, components, and systems whose failure could directly result in a condition adversely affecting public health and safety. The failure of a single item could lead to release of radioactive material, loss of shielding, or unsafe geometry compromising criticality control.

Category B: Major Impact on Safety —Category B items include structures, components, and systems whose failure or malfunction could indirectly result in a condition adversely affecting public health and safety. The failure of a Category B item, in conjunction with the failure of an additional item, could result in an unsafe condition.

Category C: Minor Impact on Safety —Category C items include structures, components, and systems whose failure or malfunction would not significantly reduce its effectiveness and would not be likely to create a situation adversely affecting public health and safety.

Findings related to ISFSI operations may potentially impact several structures, components, and systems that have different importance to safety categories. In such cases, the category assigned to the finding should be that of the highest importance to safety structures, components, and systems potentially affected by the noncompliance.

STEP 2: Determine the degree of noncompliance, as follows:

High: Finding involves the following deficiencies: recurring significant conditions adverse to quality; multiple repairs or replacements needed to meet acceptance criteria; extensive reanalysis involving reduction of margin to design limits needed; and failure on retest or re-inspect.

Medium: Finding involves the following deficiencies: reanalysis involving reduction of margin to design limits needed; a recurring condition adverse to quality.

Low: Finding involves the following deficiencies: limited rework is necessary to meet the acceptance criteria; the untimely development of corrective actions to address a previously identified condition adverse to quality, simple repair or replacement or reanalysis needed to meet acceptance criteria.

Minimal: No repair, replacement or reanalysis needed to meet acceptance criteria, or, program or process corrective actions are sufficient.

As in Step 1, findings related to ISFSI operations may potentially impact structures, components, and systems to varying degrees. In such cases, the degree of noncompliance assigned to the finding should be that of the highest degree potentially affected by the noncompliance.

STEP 3: Determine the severity of the finding using Table 2690.06-2 based on the determinations performed in Steps 1 and 2.

Table 2690.06-2. Finding Evaluation Matrix				
Finding Severity Level		Safety Significance		
		Category C: Minor Impact on Safety	Category B: Major Impact on Safety	Category A: Critical to Safe Operation
Degree of Noncompliance	High	2	3	4
	Medium	1	2	3
	Low	1	1	2
	Minimal	1	1	1

- e. Findings severity levels should be recorded in the Findings Column of the inspection attributes list. Additional remarks regarding the specific nature of findings should be recorded in the comments column for the inspection attribute item.
- f. Inspection attributes lists include an additional area for recording the overall comments related to the inspection element. This area should be used to summarize the overall conclusions related to the element considering the cumulative significance of all findings.
- g. Inspection attributes lists will be used by the inspectors as an information source for generating the inspection reports. The inspection attributes lists are not intended to be given to the entities inspected.

Appendix D

Comments Regarding an SFST Oversight Program

SFST should consider long range development of an oversight program modeled after the existing NRR and NRO programs. An important consideration is that oversight programs rely heavily on risk information, which is not available for DCSS, transportation packagings, or ISFSIs. The necessary risk information would need to be developed in order to successfully implement all the elements of a true oversight program.

In order to be meaningful to the ROP, ISFSI inspection findings should be evaluated using a risk-based Significance Determination Process. While NUREG/CR-6407 classifies transportation packaging and dry cask storage system components based on importance to safety, NUREG/CR-6407 provides no information regarding the risk basis for the classifications. Significant effort, analysis, and operating experience would be necessary to develop risk information sufficient to support an SFST Significance Determination Process.

The ROP risk basis relates to reactor core damage frequency. ISFSI operations are very highly unlikely to have any potential influence on reactor core damage frequency and the basis for an SFST Significance Determination Process would necessarily be something other than reactor core damage frequency. Therefore, even if a risk-informed ISFSI Significance Determination Process was developed, the ROP and ISFSI significance determinations would not be equivalent and should not be mixed.

An additional factor that may influence a decision regarding an SFST oversight program is that current NRC oversight programs are focused on single licensee types, such as operating reactors (the Reactor Oversight Program), new reactor construction (the Construction Reactor Oversight Program), and Fuel Cycle facilities (Fuel Cycle Safety and Safeguards Oversight Program), where SFST has several different types of inspected entities; DCSS and transportation packagings CoC holders (and their suppliers) and general and specific licensed ISFSI facilities. Such a variety of inspected entities may require individual significance determination processes and action matrices for each type.