

## 2015 Risk-Informed Activities List

This summary highlights the 25 major Fiscal Year (FY) 2015 risk-informed and performance-based activities of the U.S. Nuclear Regulatory Commission (NRC). More details of all the Risk-Informed Activities can be found on the agency's public Web site, (<http://www.nrc.gov/about-nrc/regulatory/risk-informed/rpp.html>.)

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### **1. Medical use of Byproduct Material (10 CFR Part 35) – Medical Event Definitions, Training and Experience, and Clarifying Amendments**

#### Summary Description

In this rulemaking, the NRC addresses three ongoing rulemaking projects and several other related topics. First, this rule amends the reporting and notification requirements for a medical event for permanent implant brachytherapy. Second, the rule: (a) amends the training and experience (T&E) requirements for authorized users, medical physicists, Radiation Safety Officers, and nuclear pharmacists; (b) amends the requirements for measuring molybdenum contamination and reporting for failed technetium and rubidium generators; and (c) allows Associate Radiation Safety Officers to be named on a medical license. Third, the rule amends the T&E requirements to address a request filed in a petition for rulemaking PRM-35-20, to exempt certain board-certified individuals from certain T&E requirements (i.e., “grandfather” these individuals) so they may be identified on a license or permit for materials and uses that they performed on or before October 24, 2005, the expiration date of the prior T&E requirements. The proposed rule was published for public comment on July 21, 2014 (79 FR 42410) for 120 day public comment period. The proposed guidance was noticed on the same day. The NRC Staff is considering and responding to comments and preparing the final rule.

#### FY 2015 Status

The staff is developing the final rule. More information is on the agency's Medical Licensing Tool Kit Web site, (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>).

#### Risk Category

“Rulemaking Applications Using Risk Insights” - This rule continues the risk-informed, performance-based framework already present in Part 35. The reporting and notification requirements for medical events are being updated as part of this rulemaking and the underlying requirement differs based on the event. There is an inherent recognition of the different consequences of different types of medicals events. Furthermore, the training and experience requirements are being updated and differ based on type of use and radioisotope involved in the treatment. The administration of certain drugs represents a lower risk significance than others and this is reflected in the training and experience requirements of 10 CFR Part 35.

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## **2. NRC “Grow Your Own” PRA Capability**

### Summary Description

This NRC-wide PRA “Grow Your Own” (GYO) program was established to provide less experienced staff with high technical potential the opportunity to have a focused, hands-on experience with risk-informed regulations, licensing actions, and decision-making. At the completion of the 3-year GYO program, those staff that pass their technical boards are recognized as reliability and risk analysts at the GG-14 level or promoted if at a lower grade.

### FY 2015 Status

The initial two staff members in the program within the Office of New Reactors (NRO) and three staff members within the Office of Nuclear Reactor Regulation (NRR) completed all their required activities and passed their technical boards in the summer of 2015.

### Risk Category

“Knowledge Transfer and Enhanced Capability” - The purpose of this activity is to enhance the knowledge and capability of selected staff that have little or no specific experience in PRA or risk-informed decision-making, but demonstrate superior technical capabilities.

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## **3. Use of Risk Insights to Enhance Technical Reviews of Design Certification (DC) Applications**

### Summary Description

In support of enhancing the reviews of design certification (DC) applications, the staff develops high-level risk insights based on the DC application information and shares that information with the technical review branches to help risk-inform their decision-making for each application. These risk insights are intended to help focus staff attention on those design features and assumptions that may significantly affect plant risk, and to allow for use of alternative review approaches on less risk-significant design aspects.

### FY 2015 Status

In 2015, Korea Hydro & Nuclear Power Company (KHNP) submitted its application for the Advanced Power Reactor (APR) 1400 new reactor design. The staff developed a risk insights document to support the staff’s risk-informed review of the APR 1400 DC application. In addition, the staff developed a presentation package and conducted a series of briefings with all the technical branches involved with the APR 1400 DC review to communicate its risk insights.

### Risk Category

“Rulemaking Applications Using Risk Insights” and “Risk-informed licensing reviews” - The purpose of this activity is to integrate risk insights more fully into DC reviews and the formal certification decision-making process. This will help prioritize staff review efforts on the more risk significant aspects of the design and support final certification of the design and a new appendix to the 10 CFR Part 52 regulations.

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#### **4. Standard Review Plan, Chapter 19.0 Severe Accidents, (NUREG-0800)**

##### Summary Description

NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Chapter 19.0, "Severe Accidents," provides the staff guidance for the review of design certification and combined license application submittals related to PRA and severe accidents. This chapter will be updated to incorporate interim staff guidance, lessons learned from new reactor reviews and insights regarding small modular reactor designs.

##### FY 2015 Status

The revision to Chapter 19, which is expected to be issued in the near future, will incorporate the following:

- a. Guidance previously contained in Interim Staff Guidance DC/COL-ISG-003, "Probabilistic Risk Assessment Information to Support Design Certification and Combined License Applications," concerning the review of PRA information and severe accident assessments submitted to support the DC and COL applications,
- b. Guidance previously contained in Interim Staff Guidance DC/COL-ISG-020, "Seismic Margin Analysis for New Reactors Based on Probabilistic Risk Assessment," concerning the review of information from the PRA-based seismic margin analysis (SMA) submitted in support of the DC and COL applications,
- c. Guidance previously contained in Interim Staff Guidance DI&C/COL-ISG-003, "Interim Staff Guidance on Review of New Reactor Digital Instrumentation and Control Probabilistic Risk Assessments," concerning the review of digital instrumentation and control system PRA models,
- d. Guidance on addressing modular designs if the applicant seeks approval for multiple modules, and
- e. Additional guidance for the review of the PRA information and severe-accident assessments developed during the NRC reviews of DC and COL applications completed after Revision 2 of SRP Section 19.0 was issued.

The next revision of this SRP which is currently under development, will include, as appropriate, DC/COL-ISG-028,

##### Risk Category

"Infrastructure Development in Support of Risk-Informed Regulations" - The purpose of this activity is to improve the SRP Chapter that provides guidance to the staff in conducting the risk and severe accident reviews of DC and COL applications.

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## 5. Risk-Informing Agency Actions on Low Risk Compliance Issues

### Summary Description

The agency is developing a risk-informed approach to resolve licensee compliance issues that are determined to be of low risk/low safety significance. The goal is to provide a tool to the staff that provides a risk-informed alternative to enforcement of technical specification compliance when it can be demonstrated that the non-compliance does not pose an undue risk to public health and safety.

The staff envisions developing a risk-informed process that would ensure that the level of licensee and staff resources applied to a non-compliance issue correlate to the potential risk and safety significance of the issue. The staff envisions that this approach would focus first on evaluating the risk significance of the non-compliance. If the risk significance is determined to be low, then the staff interaction with the licensee would focus on establishing a reasonable timetable for corrective action by the licensee combined with implementing appropriate interim compensatory measures that would maintain adequate safety while the corrective action is being taken. The approach would include enforcement discretion (possibly for a long duration) to provide the licensee adequate time for implementing corrective action. This approach is envisioned to be an improvement over the current practice in that it would eliminate the need for urgent action to be taken for low risk significance compliance issues.

This approach is consistent with the NRC's Enforcement Policy (NUREG 1600, "General Statement of Policy and Procedure for NRC Enforcement Action", Section 1.5 "Adequate Protection Standard," which states:

*Adequate protection of the public health and safety and assurance of the common defense and security and protection of the environment are the NRC's fundamental regulatory objectives. Compliance with NRC requirements plays a critical role in giving the NRC confidence that safety and security are being maintained. While adequate protection is presumptively assured by compliance with NRC requirements, circumstances may arise where new information reveals that an unforeseen hazard or security issue or security event exists or that a substantially greater potential exists for a known hazard to occur. In such situations, the NRC has the statutory authority to require action by licensees, their employees and contractors, and certificate holders above and beyond existing regulations to maintain the level of protection necessary to avoid undue risk to public health and safety, and to ensure security of materials.*

*The NRC also has the authority to exercise discretion to permit continued operations—despite the existence of a noncompliance—where the noncompliance is not significant from a risk perspective and does not, in the particular circumstances, pose an undue risk to public health and safety. When noncompliance with NRC requirements occurs, the NRC must evaluate the degree of risk posed by that noncompliance to determine whether immediate action is required. If the NRC determines that the noncompliance itself is of such safety significance that adequate protection is no longer provided, or that the noncompliance was caused by a failure of licensee controls so significant that it calls into question the licensee's ability to ensure adequate protection, the NRC may demand immediate action, up to and including a shutdown or suspension of licensed activities. Based on the NRC's evaluation of noncompliance, the appropriate action could include refraining from taking any action, taking specific enforcement action including the use of civil*

*penalties, issuing Orders, or providing input to other regulatory actions or assessments, such as increased NRC oversight of a licensee's activities. Since some requirements are more important to safety than others, the NRC endeavors to use a risk-informed approach when applying NRC resources to the oversight of licensed activities, including enforcement activities."*

#### FY 2015 Status

A working group with members from NRR, the Regions, OGC, and OE has formed, and is currently evaluating the feasibility of the proposed approach, including verifying the legality of the approach determining how the risk significance would be evaluated, and gaging the industry's interest in participating in the process once developed. The working group is also looking at the process for implementing this new approach. One implementation method under consideration is modifying the Notice of Enforcement Discretion (NOED) process for low risk compliance issues.

#### Risk Category

"Risk-Informed Oversight Activities" - The purpose of this activity is to provide the staff with a risk-informed tool for handling compliance issues that are of low risk significance.

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### **6. Risk-Informed Steering Committee (RISC)**

#### Summary Description

The NRC's RISC is an NRC senior management committee that provides strategic direction to the NRC staff to advance the use of risk-informed decision-making in licensing, oversight, rulemaking, and other regulatory areas, consistent with the Commission's PRA Policy Statement. The NRC's RISC is chaired by the Director of NRR, with membership of Deputy Office Directors from NRO, RES, NRR, NSIR, and NMSS, as well as the Region I Regional Administrator. The NRC RISC has held several public meetings with the industry's own RISC. The industry's RISC is a counterpart to the NRC RISC with its membership comprised of licensee chief nuclear officers and other senior level executives, as well as representation from the Nuclear Energy Institute (NEI). The NRC and industry each agreed to form two working groups that will focus on guidance in two selected areas related to PRA technical adequacy and dealing with uncertainties in risk-informed decision-making.

For more information, see Agency-wide Documents Access and Management System (ADAMS) Accession No. ML15244A043.

#### FY 2015 Status

The NRC RISC held multiple public meetings with the industry RISC to receive updates on the working groups' status and to discuss other risk-informed initiatives. The industry working groups developed white papers outlining gaps in current processes and the actions to close those gaps. The NRC held public meetings to discuss the review of the white papers and provided comments to the industry. The NRC working groups will each issue a memorandum to the RISC with recommended actions to close gaps identified in the white papers. The actions will be completed by the appropriate line organization in accordance with normal work practices. The staff has developed plans and continued work on the related initiatives by scheduling a

public workshop on NUREG-1855 and a public meeting to seek input on how to treat the industry developed, and NRC endorsed, Flex strategies and equipment in risk-informed decision-making. The NRC RISC will continue to hold public meetings with the industry RISC to discuss current and upcoming risk-informed initiatives of interest.

### Risk Category

“Infrastructure Development in Support of Risk-Informed Regulations” - The purpose of this activity is to provide strategic direction to the NRC staff to collaborate on and advance the use of risk-informed decision-making in licensing, oversight, rulemaking, and other regulatory areas, consistent with the Commission's PRA Policy Statement.

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## **7. Risk Prioritization Initiatives (RPI)**

### Summary Description

In February 2013, the Commission approved SRM-COMGEA-12-0001/COMWDM-12-0002 – “Proposed Initiative to Improve Nuclear Safety and Regulatory Efficiency” (ADAMS Accession No. ML13037A541), to further explore the idea of enhancing nuclear safety and regulatory efficiency by applying PRA. This initiative could encourage the use and development of high-quality, plant-specific PRA models by allowing licensees to use qualitative and quantitative risk insight to propose a schedule for implementing regulatory actions on a plant-specific basis.

In October 2013, NEI began to develop a draft process as a potential way to address RPI for operating power reactors. The NEI's draft process consists of three main elements: (1) generic prioritization by an industry generic assessment expert team, (2) plant-specific prioritization by an integrated decision-making panel of licensee experts, and (3) issue aggregation for plant-specific scheduling. The NRC staff provided comments on NEI's guidance. The guidance described the process at various stages using insights gained from tabletop exercises and discussions with stakeholders during public meetings.

Subsequently, the NRC staff informed the Commission about its observation of tabletop exercises of the NEI draft process in COMSECY-14-0014 (ADAMS Accession No. ML14069A061). Afterwards, six licensees also participated in the industry-led demonstration pilots that were conducted between May and September of 2014 to exercise the draft guidance prioritizing plant-specific issues. Lastly, a public meeting in September 2014 was held to further exercise the process in the areas of security, emergency preparedness, and radiation protection.

Other information about the NRC staff's observations can be found in “Summary of the NRC Staff Observations on the Nuclear Energy Institute Demonstration Pilots for Prioritizing and Scheduling Implementation” (ADAMS Accession No. ML14302A269). In addition, NEI provided its summary and observations of the demonstration pilots in the “Nuclear Energy Institute, Report on Prioritization and Scheduling Pilot” (ADAMS Accession No. ML14349A378). The latest version of the NEI guidance was submitted to the NRC by letter dated November 14, 2014 (ADAMS Accession No. ML14318A274).

Based on insights and feedback obtained from the public and with experience gained during tabletop exercises and demonstration pilots, the staff presented four options to the Commission in SECY-15-0050, “Cumulative Effects of Regulation Process Enhancements and Risk

Prioritization Initiative: Response to Commission Direction and Recommendations" dated April 1, 2015 (ADAMS Accession No. ML15016A075). In the SRM-SECY-15-0050 issued on August 25, 2015 (ADAMS Accession No. ML15237A142), the Commission did not approve separate RPI activities, but supported the consideration of risk insights in regulatory decision-making through existing agency processes.

For more information, see ADAMS Accession No. ML15244A046.

### FY 2015 Status

In March 2015, the staff briefed ACRS with respect to a draft version of the Commission paper in which the staff presented options of RPI as a tool to reduce cumulative effects of regulation (CER). In its letter on this topic, ACRS agreed with the staff's recommendations and recommended that the staff should explicitly include risk information as an input to decisions and priorities for proposed regulatory actions regardless of the Commission's decisions about specific options or approaches in the SECY paper.

On April 1, 2015, the staff submitted SECY-15-0050, "Cumulative Effects of Regulation Process Enhancements and Risk Prioritization Initiative: Response to Commission Direction and Recommendations" (ADAMS Accession No. ML15016A075). This paper responds to the Commission's direction in SRM-COMSECY-14-0014, "Cumulative Effects of Regulation and Risk Prioritization Initiative: Update on Recent Activities and Recommendations for Path Forward," dated July 18, 2014 (ADAMS Accession No. ML14199A187). This paper provided the Commission with four options of using RPI as a tool to reduce CER for operating reactor licensees.

The first option would have maintained the status quo. Option 2 would have augmented existing regulatory processes allowing licensees to request exemptions and changes to implementation schedules for existing regulatory commitments. This option would have allowed licensees to use a risk-informed prioritization methodology as a basis for such request. Option 3 would have allowed licensees to submit a risk-informed, plant-specific implementation plan when the NRC adopts a new rule. Option 4 would have established a voluntary process that enables licensees to make plant-specific, risk-informed changes to implementation schedules for certain regulatory issues without requesting prior NRC approval.

On May 19, 2015, the staff, along with an external panel, briefed the Commission on issues related to CER and RPI. The discussions included the staff's identified lessons learned, possible approaches for implementing the RPI, as well as licensee experiences with RPI pilot projects. In the SRM-SECY-15-0050 issued on August 25, 2015 (ADAMS Accession No. ML15237A142), the Commission did not approve the RPI options. However, the Commission stated that it supports consideration of risk insights in regulatory decision-making through existing agency processes. The staff is exploring the development of additional guidance to enhance licensees' ability to use risk information in existing agency processes such as Title 10 of the *Code of Federal Regulations* (10 CFR) 50.12, "Specific Exemptions".

### Risk Category

"Infrastructure Development in Support of Risk-Informed Regulations" - Per Commission direction in SRM-SECY-15-0050, staff work on RPI is discontinued.

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## **8. Interim Staff Guidance on PRA Technical Adequacy for Advanced Light-Water Reactors**

### Summary Description

The staff is developing Interim Staff Guidance (ISG) DC/COL-ISG-028, "Assessing the Technical adequacy of the Advanced Light-Water Reactor (ALWR) Probabilistic Risk Assessment for the Design Certification Application and Combined License Application," to provide guidance to the pre-operational phase applicants and the NRC on how the NRC-endorsed ASME/ANS PRA Standard (RA-Sa-2009) can be used for assessing the technical adequacy of the PRA for these pre-operational phase applications. The ISG is needed because the existing PRA Standard was developed based on current operating reactors and did not consider the status of information and experience that will not exist for ALWRs at these pre-operational phases.

This ISG supplements Regulatory Guide (RG) 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," and SRP 19.0 to address the pre-operational phases (e.g., 10 CFR Part 52 certification and licensing) for ALWRs. It is expected to be incorporated into RG 1.200, RG 1.206, and SRP 19.0, following the issuance of the next edition of the ASME/ANS PRA Standard. The ACRS Subcommittee on Reliability and PRA was briefed on this ISG in 2014 prior to the issuance of the draft ISG for public comment.

### FY 2015 Status

The NRC received public comments on the draft interim staff guidance (DC/COL-ISG-028) from only one entity, the Nuclear Energy Institute (NEI). The NEI comments and ACRS discussions in 2014 were evaluated and the ISG was revised accordingly.

During the August 2015 ACRS Subcommittee on Reliability and PRA, various ACRS members identified issues with specific staff positions and approaches. These issues involve:

- a. Allowing a PRA-based seismic margin analysis approach at the COL stage, for which ACRS members stated that a seismic PRA should be required instead.
- b. Allowing applicants to only address Capability Category I (the lowest capability level in the ASME/ANS PRA Standard), for which ACRS members stated that Capability Category II should be required to be addressed.
- c. Designating some supporting requirements as "cannot meet" or "not applicable" (e.g., a supporting requirement that involves a walk down) while also including a clarification to perform some action, for which some ACRS members found the designations and clarifications confusing and so they suggested changing the supporting requirement designations.

The staff and senior management are currently considering the issues raised at the August 2015 ACRS Subcommittee and will determine the appropriate actions to take (e.g., revise ISG, develop SECY paper related to change in staff position, etc.) to address these issues prior to publishing the final ISG. The staff expects to publish the final ISG for use early in 2016.



### Risk Category

“Infrastructure Development in Support of Risk-Informed Regulations” and “Risk-Informed Licensing Reviews” - The purpose of this activity is to provide interim staff guidance to support the consistent consideration of the existing ASME/ANS PRA Standard for designs in the pre-operational phase. Specifically, the ISG supports use by the 10 CFR Part 52 design certification and combined license applicants and the NRC review of those applications.

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## **9. Risk Management Regulatory Framework (RMRF)**

### Summary Description

NUREG-2150, "A Proposed Risk Management Regulatory Framework" (ADAMS Accession No. ML12109A277) recommended that a RMRF applicable to all NRC program areas be adopted by the NRC. The Chairman's tasking memorandum dated June 14, 2012 (ADAMS Accession No. ML121660102) directed the staff to "...review NUREG-2150 and provide a paper to the Commission that would identify options and make recommendations, including the potential development of a Commission policy statement." The Commission's SRM dated May 19, 2014 (ADAMS Accession No. ML14139A104) on SECY-13-0132 (ML13277A413) directed that the staff's paper also include "a description of any interrelationships of ongoing risk-informed initiatives to ensure the activities are well coordinated, and effectively planned and implemented." The EDO approved an extension of the due date from November 19, 2014, until December 18, 2015.

### FY 2015 Status

The NRC staff requested public comments on draft white papers addressing RMRF issues on November 25, 2013 (78 FR 70354) and May 12, 2015 (80 FR 27191). The staff held public meetings on June 5, 2013, January 30, 2014, May 27, and July 29, 2015 (ADAMS Accession Nos. ML13197A216, ML14064A550, ML15177A209, and ML15216A649). The staff also met with the Reliability and Probabilistic Risk Assessment subcommittee of the ACRS on September 4, 2013, and February 20, and June 8, 2015. The staff will meet with the ACRS full committee in early November 2015 and the staff will update the Commission in a SECY paper in December 2015.

### Risk Category

“Infrastructure Development in Support of Risk-Informed Regulations” - The purpose of this activity is to decide whether the RMRF recommended in NUREG-2150 should be adopted by all NRC program areas.

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## **10. Probabilistic Flood Hazard Assessment (PFHA)**

### Summary Description

The Commission was briefed in January, 2014, on staff (NRR, NRO, and RES) activities and plans concerning the need for and development of a systematic program to establish a probabilistic approach for flood hazard assessment. Near term aspects of the program will

address information needs in the reactor oversight program for reviews of operating reactors while the long term program will develop a comprehensive approach for probabilistic flood assessment for new reactors. The offices agreed on a joint user need that endorsed a Research Plan developed jointly by RES, NRR, and NRO staff. A copy of the plan was provided to the Commission (ML14318A070, ML14296A442). RES has begun implementation of the research plan.

### FY 2015 Status

The “Probabilistic Flood Hazard Assessment Research Plan” has been prepared and endorsed by NRR and NRO. Eleven new research projects have been initiated with the US Army Corps of Engineers, the US Geological Survey, the Department of Interior Bureau of Reclamation, Idaho National Laboratory (INL), Pacific Northwest National Laboratory (PNNL), and the University of California at Davis. A twelfth research activity that was issued for bid as a commercial contract has not yet been awarded. On October 13 and 14, 2015, the first annual program review on the progress for these projects will be held at NRC headquarters. Cooperative efforts are under development with Electric Power Research Institute (EPRI) and the Institute de Sûreté Nucléaire et de Radioprotection (IRSN).

### Risk Category

“Risk Tool, Maintenance & Development” – The purpose of this activity is to develop a comprehensive approach for probabilistic flood assessment for new reactors.

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## **11. Risk Informing Oversight of Emergency Preparedness (EP) and Response Plans**

### Summary Description

In coordination with the Federal Emergency Management Agency (FEMA), the staff initiated a study of performance based evaluation techniques that could be used for offsite response organization Radiological Emergency Response Plans (RERP). This effort also intends to identify how RERP program elements could be integrated with nation-wide FEMA preparedness initiatives.

State and local emergency response programs have significantly matured since the EP regulations of 1980 were implemented. FEMA has initiated several nation-wide preparedness efforts and the level of capability has greatly advanced. The effectiveness and efficiency of EP oversight may be improved by further integrating NRC radiological emergency response programs with the broader FEMA preparedness initiatives.

The staff retained a knowledgeable consultant to review FEMA evaluation techniques and NRC regulations that apply to RERP. The consultant proposed elements of evaluation that could be performance based and examined FEMA preparedness programs that may duplicate or parallel NRC EP requirements and proposed methods for integration.

The study and evaluation of a performance based regimen for offsite response organizations has been completed with the conclusion that a performance based system is feasible and could enhance the effectiveness and efficiency of EP oversight. The results are documented in NUREG/CR-7195, “Risk-Informed and Performance-Based Oversight of Radiological Emergency Response Plans,” (ADAMS Accession No. ML15134A035).

This project also informed the development of SECY-14-0038, "Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight," (ADAMS Accession No. ML13238A018) that presented the results of a staff study on the potential for a performance-based EP framework. In SRM-14-038 (ADAMS Accession No. ML14259A589), the Commission approved the staff's recommendation to continue under the current regulatory framework while remaining vigilant to the possibility of moving to a performance-based framework in the future.

#### FY 2015 Status

This study is complete; no further action is planned at this time.

#### Risk Category

"Risk-Informed Oversight Activities" - The purpose of this activity was to conduct a study of performance based evaluation techniques that could be used for offsite response organization Radiological Emergency Response Plans (RERP). The study and evaluation of a performance based regimen for offsite response organizations has been completed with the conclusion that a performance based system is feasible and could enhance the effectiveness and efficiency of EP oversight.

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## **12. Methods, Tools and Guidance for Including Digital Systems in Nuclear Power Plant PRAs**

#### Summary Description

The NRC has been investigating reliability modeling of digital systems, which encompasses both hardware and software. The objective of this research is to identify and develop methods, analytical tools, and regulatory guidance for (1) including models of digital systems in nuclear power plant probabilistic risk assessments (PRAs) and (2) incorporating digital systems in the NRC's risk-informed licensing and oversight activities.

#### FY 2015 Status

Recent accomplishments and near-term objectives include the following:

- NRC support to the development of a failure mode taxonomy for a digital instrument and control (I&C) systems performed by the OECD/NEA Working Group on Risk Assessment (WGRISK) (NEA/CSNI/R(2014)16, "Failure Modes Taxonomy for Reliability Assessment of Digital I&C Systems for PRA").
- In collaboration with the Korea Atomic Energy Research Institute, the staff developed an approach for quantifying software reliability using a Bayesian Belief Network (BBN)-based model of the software development cycle quality attributes. A report describing the BBN approach will be submitted for publication in FY2016.
- Pilot an approach for estimating the reliability of the INL Advanced Test Reactor Loop Operating Control System using PRA-based statistical testing. A report describing the statistical testing application will be submitted for publication in FY2016.

More background on this approach can be found in the transcripts from an ACRS subcommittee meeting held in November 2014 (<http://pbadupws.nrc.gov/docs/ML1434/ML14342A872.pdf>).

#### Risk Category

“Risk Tool, Maintenance & Development” – The objective of this activity is to develop methods for incorporating digital instrumentation and control (I&C) systems into nuclear plant PRAs. As the activity proceeds, additional insights on the practicality and usefulness of including digital systems in nuclear plant PRAs will be gained.

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### **13. Rule-making for Reprocessing Facilities**

#### Summary Description

In SRM-SECY-13-0093 [ML13308A403], the Commission approved development of a reprocessing-specific rule in a new 10 CFR Part 7X. In the SRM the Commission also directed that the continued development of the regulatory framework for reprocessing be limited in scope, for the time being, to the resolution of, “Safety and Risk Assessment Methodologies and Considerations for a Reprocessing Facility.”

#### FY 2015 Status

Process flow diagrams and facility descriptions were developed for a conceptual aqueous reprocessing facility, with associated event and fault trees for a hypothetical red-oil explosion. Preliminary best-estimate source term analyses were calculated and indicated a potential dose reduction of orders of magnitude, compared to the existing conservative approaches.

#### Risk Category

“Rulemaking Applications Using Risk Insights” - The purpose of this activity is to develop the foundation for the potential regulatory framework for reprocessing to enable a risk-informed licensing and oversight process by:

- Evaluating methods for hazards and risk evaluations that can be implemented for aqueous and electrochemical reprocessing facilities;
  - Identifying performance requirements for a risk-informed regulatory framework;
  - Obtaining peer review and public comments on the safety and risk assessment methodologies.
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#### **14. Assess Debris Accumulation on Pressurized Water Reactor (PWR) Sump Performance, Generic Safety Issue (GSI)-191**

##### Summary Description

This generic issue concerns the possibility that following a LOCA in a PWR, debris accumulation on the containment sump strainer(s) may inhibit flow to the Emergency Core Cooling System (ECCS) and the Containment Spray System. An additional concern is that debris may penetrate or bypass the strainer and block flow to the core.

In SECY-12-0093 dated July 9, 2012 (ADAMS Accession No. ML121310648), the staff identified several options for resolving GSI-191. These options included two risk-informed approaches. One approach, piloted by South Texas Project (STP), would address both strainer and in-vessel effects using risk. The other approach would use risk for in-vessel effects and would resolve strainer issues deterministically.

The Commission endorsed the staff's proposed options for resolving GSI-191 in SRM-SECY-12-0093, dated December 14, 2012 (ADAMS Accession No. ML12349A378). As part of the resolution process, licensees seeking additional time to pursue new testing or new approaches (including risk-informed approaches) will implement compensatory measures to mitigate the potential for debris blockage of the strainer or reactor core. Industry is also performing additional testing to support risk-informed evaluations for GSI-191.

Tentatively, 14 units propose to implement a full risk-informed resolution to GSI-191. Two units plan to risk-inform the in-vessel evaluation and use a deterministic evaluation for the ECCS strainer.

SRM-SECY-12-0034, "Proposed Rulemaking – 10 CFR 50.46c: Emergency Core Cooling System Performance During Loss-of-Coolant Accidents RIN 3150-AH42," dated January 7, 2013 (ADAMS Accession No. ML13007A478), directed that the "the 50.46c proposed rule should contain a provision allowing NRC licensees, on a case-by-case basis, to use risk-informed alternatives without an exemption request." The proposed rule containing this provision was published on March 24, 2014.

Per SRM-COMSECY-13-006, "10 CFR 50.46c Rulemaking: Request to Defer Draft Guidance and Extension Request for Final Rule and Final Guidance," dated May 9, 2013, the draft guidance related to the GSI-191 risk-informed alternative was not published concurrent with the proposed rule. Rather, that draft guidance (DG-1322, "Alternative Risk-Informed Approach for Addressing the Effects of Debris on Post Accident Long-Term Core Cooling") was developed in parallel with the staff's review of the STP pilot and was issued for public comment on April 20, 2015. The public comment period closed on July 6, 2015. The final regulatory guide (RG 1.229 (DG-1322), "Risk-Informed Approach for Addressing the Effects of Debris") will be issued with the final 10 CFR 50.46c rule.

For more information, see ADAMS Accession No. ML15244A042.

##### FY 2015 Status

In FY 2015, the staff has continued to review the STP pilot and has published draft guidance (DG-1322) for licensees choosing to implement the optional, risk-informed provision in 10 CFR 50.46c. The draft guide (which will ultimately be published as RG 1.229) was issued for public

comment on April 20, 2015. The public comment period closed on July 6, 2015, and the staff has since resolved all public comments and updated the DG accordingly. RG 1.229 is scheduled to be issued with the new 10 CFR 50.46c rule in the second quarter of FY 2016.

### Risk Category

“Rulemaking Applications Using Risk Insights” - The purpose of this activity consistent with Commission direction is to provide a provision in 10 CFR 50.46c that would allow a risk-informed treatment of debris when assessing long-term core cooling.

“Risk-Informed Licensing Reviews” - The purpose of this activity is to perform a risk-informed review of the STP pilot License Amendment Request (LAR) using the guidance in RG 1.174 and SRP Chapter 19. The STP pilot has informed the development of 10 CFR 50.46c and DG-1322.

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## **15. Emergency Core-Cooling System (ECCS) Requirements: Redefinition of Loss-of-Coolant Accidents (LOCA)**

### Summary Description

The staff prepared a proposed rule containing ECCS evaluation requirements that could be used as an alternative to the current requirements in 10 CFR 50.46, “Acceptance Criteria for Emergency Core Cooling Systems (ECCS) for Light-Water Nuclear Power Reactors.” That proposed rulemaking is designed to redefine the large-break LOCA (LBLOCA) requirements to provide a risk-informed alternative maximum break size. In October 2006, the staff produced a draft final rule and briefed the Advisory Committee on Reactor Safeguards (ACRS).

In response, ACRS recommended that the Commission should not issue the rule in its present form. As a result, the staff prepared SECY-07-0082, “Rulemaking To Make Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements: 10 CFR 50.46a, ‘Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors,’” dated May 16, 2007 (ADAMS Accession No. ML070180466), to provide a plan (including resource and schedule estimates) for responding to the ACRS recommendation and related comments.

On April 1, 2008, the Executive Director for Operations provided the staff’s schedule for completing the final rule to the Commission. Following Commission approval, the NRC published a supplemental proposed rule, “Performance-Based Emergency Core Cooling System Acceptance Criteria” (74 FR 40765, August 13, 2009), for public comment. The public comment period ended in January 2010.

After reviewing public comments and making changes to address these comments (and ACRS comments), the staff submitted a final rulemaking package to the Commission for approval on December 10, 2010, in SECY-10-0161, “Final Rule: Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements (10 CFR 50.46a) (RIN 3150-AH29)” (ADAMS Accession No. ML102210460). On April 20, 2012, the staff requested withdrawal of the 10 CFR 50.46a final rule from Commission consideration so that the staff could review the rule and ensure its compatibility with the ongoing regulatory framework activities under Recommendation 1 of the Fukushima Near-Term Task Force (NTTF) report. The Commission approved the staff’s request in SRM-SECY-10-0161, dated April 26, 2012 (ADAMS Accession No. ML12117A121).

The staff does not plan to publish a notice in the *Federal Register* withdrawing the 10 CFR 50.46a final rule. The staff intends to resubmit the draft final rule for Commission consideration after receiving Commission direction in conjunction with NTTF Recommendation 1. In response to the Staff Requirements Memorandum (SRM) on SECY-13-0132, "Nuclear Regulatory Commission Staff Recommendation for the Disposition of Recommendation 1 of the Near-Term Task Force Report," (ADAMS Accession No. ML13277A413), the staff requested an extension to this and other initiatives, across other NRC program areas, to evaluate the Risk Management Regulatory Framework (RMRF) approach recommended in NUREG-2150 as well as alternative approaches for achieving a risk-informed regulatory framework. The staff will submit a Commission paper on RMRF by December 18, 2015 and it will provide an update on the staff's path forward on this activity.

For more information, see ADAMS Accession No. ML15245A603.

#### FY 2015 Status

No action in fiscal year (FY) 2015, as this item is on hold.

#### Risk Category

"Rulemaking Applications Using Risk Insights" - The purpose of this activity is to incorporate risk insights into the *Code of Federal Regulations*.

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### **16. Standardized Plant Analysis Risk Models (SPAR)**

#### Summary Description

The SPAR models provide agency risk analysts with an independent risk assessment tool to support a variety of risk-informed agency programs, including the Reactor Oversight Program (ROP) and the Accident Sequence Precursor (ASP) program. SPAR models are built with a standard modeling approach, using consistent modeling conventions, that enables staff to easily use the models across a variety of U.S. NPP designs. Unlike industry PRA models, SPAR models are run on a single software platform, the Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE) computer code. The staff currently maintains and updates the 75 SPAR models representing 99 commercial NPPs. The scope of every SPAR model includes logic modeling covering internal initiating events at power through core damage (i.e., Level-1 PRA model). A portion of the SPAR models also include external hazard (e.g., seismic and high wind), internal fire, and shutdown models. The staff develops and maintains SPAR models for both operating reactors and new reactor designs (e.g., AP1000).

#### FY 2015 Status

An updated status of the SPAR model program can be found in SECY 15-0124, "Status of the Accident Sequence Precursor Program and the Standardized Plant Analysis Risk Models".

#### Risk Category

"Risk Tool, Maintenance & Development" - The purpose of this activity is to develop standardized risk analysis models and tools for staff analysts to support various regulatory

activities, including the Accident Sequence Precursor (ASP) Program and Phase 3 of the Significance Determination Process (SDP as described in Inspection Manual Chapter 0609

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## **17. Develop Improved PRA Methods for Consequential Steam Generator Tube Rupture**

### Summary Description

Consequential steam generator tube ruptures (C-SGTRs) are potentially risk-significant events because thermally-induced steam generator tube failures caused by hot gases from a damaged reactor core can result in a containment bypass event and a large release of fission products to the environment. The main accident scenarios of interest are those that lead to core damage with high reactor pressure, a dry-steam generator, and low steam generator pressure (high-dry-low) conditions. A typical example of such an accident scenario is a station blackout with loss of auxiliary feedwater. The objective of this program is to develop a simplified methodology for the quantitative assessment C-SGTR probability and large early-release frequency (LERF) for pressurized-water reactors (PWRs). A draft report was updated using the latest thermal hydraulic MELCOR results for Combustion Engineering (CE) plants.

### FY 2015 Status

A draft report is being finalized to document the research results from this study. It is expected that the report will be issued for public review and comment in late calendar year 2015 and finalized in 2016. This work was presented to the ACRS Metallurgy and Reactor Fuels Subcommittee on April 7, 2015 (a meeting transcript is available at <http://pbadupws.nrc.gov/docs/ML1513/ML15133A412.pdf> ). A draft version of the report was provided to the ACRS and is publicly available (<http://pbadupws.nrc.gov/docs/ML1502/ML15028A283.pdf> ).

### Risk Category

“Risk Tool Maintenance & Development” - This work is intended to develop an enhanced risk-assessment tool for assessing C-SGTR. A key focus of the work is closing technical gaps associated with thermal-hydraulic and structural analyses, assessment of SG flaw distributions, and PRA modeling. The risk insights obtained and process and tools developed can be used to support operating reactor and new reactor risk assessment.

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## **18. Develop Risk-Informed Improvements to Standard Technical Specifications (STS)**

### Summary Description

The staff continues to work on the risk-informed technical specifications (RITS) initiatives to add a risk-informed component to the STS. The following summaries highlight these activities:

Initiative 1, “Modified End States,” would allow licensees to repair equipment during hot shutdown rather than cold shutdown. The Topical Reports (TRs) supporting this initiative for boiling water reactor (BWR), Combustion Engineering (CE), Babcock & Wilcox (B&W), and Westinghouse Electric Company (Westinghouse) plants have been approved, and revisions to



the BWR, CE, B&W, and Westinghouse STS are available (ADAMS Accession Nos. ML093570241 and ML103360003).

Initiative 4b, "Risk-Informed Completion Times," modifies technical specification completion times to reflect a configuration risk-management approach that is more consistent with the approach described in the Maintenance Rule, as specified in 10 CFR 50.65(a)(4). As reported previously in SECY-07-0191, "Implementation and Update of the Risk-Informed and Performance-Based Plan," dated October 31, 2007 (ADAMS Accession No. ML072690619), the staff issued the license amendment for the first pilot plant, South Texas Project (STP), in July 2007.

In July 2010, Southern Nuclear Company (SNC) submitted a letter of intent for Vogtle Electric Generating Plant (VEGP) (Units 1 and 2) to implement RITS Initiative 4b. The NRC granted an associated fee waiver request and received a pilot application in September 2012. The NRC staff is nearing completion of its review of the application, and is actively working to resolve the remaining technical issues. The associated Technical Specification Task Force guidance (TSTF-505) to revise the STS was published in March 2012. Four additional applications to implement TSTF-505 have been received and are currently being reviewed by the technical staff. The four additional applications were received on November 25, 2013 (ADAMS Accession No. ML13330A557); December 5, 2014, (ADAMS Accession No. ML14353A016); December 23, 2014, (ADAMS Accession No. ML15029A297); and July 31, 2015, (ADAMS Accession No. ML15218A300). The four additional applications are not classified as "pilot applications."

Initiative 6, "Add Actions to Preclude Entry into LCO 3.0.3," modifies technical specification action statements for conditions that result in a loss of safety function related to a system or component included within the scope of the plant technical specifications. The staff approved the industry's TR for CE nuclear power plants (Revision 2 to WCAP-16125-NP-A, "Justification for Risk-Informed Modifications to Selected Technical Specifications for Conditions Leading to Exigent Plant Shutdown") in August 2010 (ADAMS Accession No. ML110070500). The associated Technical Specification Task Force (TSTF) guidance (Revision 5 of TSTF-426) to revise the CE STS was submitted for NRC review by letter dated November 2011 (ADAMS Accession No. ML113260461). Based on the approved CE TR, the industry has also submitted requests to revise the B&W STS (Revision 0 of TSTF-538) and the STS for BWRs (Revision 0 of TSTF-540) in March 2012 and May 2012, respectively. However, these TSTFs were withdrawn per letters dated January 6 and October 6, 2014 (ADAMS Accession Nos. ML14006A045 and ML14279A584, respectively) after the NRC requested additional information and the participating licensees decided not to pursue these initiatives.

For more information, see ADAMS Accession No. ML15243A474.

#### FY 2015 Status

The NRC staff continued review of STS initiatives as they were received.

#### Risk Category

"Risk-Informed Licensing Reviews" - Consistent with the Commission's policy statement on technical specifications and the use of probabilistic risk assessment (PRA), the NRC and the industry continue to develop more fundamental risk-informed improvements to the current system of technical specifications. Initiatives for fundamental improvements to the STS are being developed by the industry and discussed with the NRC staff in public meetings.

## **19. National Fire Protection Association (NFPA) Standard 805**

### Summary Description

In 2004, the Commission approved a voluntary risk-informed and performance-based fire protection rule for existing nuclear power plants. The rule endorsed NFPA consensus standard NFPA 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants." In addition, the NEI developed NEI 04-02, "Guidance for Implementing a Risk-Informed, Performance-Based Fire Protection Program Under 10 CFR 50.48(c)," dated September 2005 (ADAMS Accession No. ML052590476). The staff endorsed NEI 04-02 in RG 1.205, "Risk-Informed, Performance-Based Fire Protection for Existing Light-Water Nuclear Power Plants," issued in May 2006 (ADAMS Accession No. ML061100174). To date, nearly half of the nuclear power units operating in the United States, including those that participated in the pilot program, have committed to transition to NFPA 805 as their licensing basis. The Oconee Nuclear Station (Oconee) and Shearon Harrison Nuclear Power Plant (Shearon Harris) were the pilot plants for 10 CFR 50.48(c). In June 2010, a safety evaluation approved the Shearon Harris NFPA 805 pilot application. A safety evaluation in December 2010 approved the Oconee NFPA 805 pilot application. NEI 04-02 was revised (Revision 2) in April 2008 and the staff revised RG 1.205 (Revision 1) in December 2009 (ADAMS Accession No. ML092730314) to reflect lessons learned from the pilot reviews. The staff developed NUREG-800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Chapter 9, "Auxiliary Systems," Section 9.5.1.2, "Risk-Informed, Performance-Based Fire Protection Program Review Responsibilities," issued December 2009, to provide staff guidance for the review of licensee applications to transition to NFPA 805. In addition, the NRC developed a Frequently Asked Question process to review and establish a preliminary staff position on NFPA 805 application, review, and implementation issues.

Lessons learned from the pilot applications indicated that the staff and the industry underestimated the complexity and resources necessary to complete the reviews. In SRM-SECY-11-0033, "Proposed NRC Staff Approach to Address Resource Challenges Associated with Review of a Large Number of NFPA 805 License Amendment Requests," dated April 20, 2011 (ADAMS Accession No. ML111101452), the Commission approved the staff's recommendation to increase resources to review NFPA 805 applications, develop a staggered review process, and modify the current enforcement policy. The NRC sent the revised enforcement policy to the Commission in SECY-11-0061, "A Request to Revise the Interim Enforcement Policy for Fire Protection Issues on 10 CFR 50.48(c) to Allow Licensees to Submit License Amendment Requests in a Staggered Approach," dated April 29, 2011 (ADAMS Accession No. ML11117A264) and approved in SRM-SECY-11-0061, dated June 10, 2011 (ADAMS Accession No. ML111610616). To enhance the efficiency and effectiveness of the NFPA 805 application reviews, the industry developed an application template and the staff developed a safety evaluation template. The staff has received 26 applications to date and expects another two by the end of calendar year 2016.

For more information, see ADAMS Accession No. ML15245A621.

### FY 2015 Status

In 2015, the NRC staff issued six non-pilot NFPA 805 license amendments with three more expected to be completed by the end of the year. Thirteen LARs are currently under review.

The current status and update of work can be found in ADAMS Accession No. ML15155B105 dated June 2015.

### Risk Category

"Risk-Informed Licensing Reviews" - NFPA 805 is a performance-based standard, endorsed via 10 CFR 50.48(c) that critically depends on risk information in the form of Fire PRA to enable licensees to transition from existing "deterministic" fire protection programs to ones that are "risk-informed, performance-based." Fire PRA is an integral part of the new licensing basis, and includes both quantitative evaluations of base risk and changes to base risk in accordance with RG 1.174 guidelines as well as supporting qualitative considerations, such as traditional defense in depth and safety margin, also as per RG 1.174.

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## **20. Revise the Fuel Cycle Oversight Program (RFCOP)**

### Summary Description

As directed by the Commission, staff is developing and evaluating approaches to use risk information to determine the significance of inspection findings at fuel cycle facilities.

For more information, see ADAMS Accession No. ML14295A233.

### FY 2015 Status

On June 8, 2015, the staff completed and issued the cornerstone development document for public comment (ADAMS Accession No. ML15140A630). The cornerstones and associated key safety and security attributes will help ensure that the core inspection program is supporting the NRC's mission.

### Risk Category

"Risk-Informed Oversight Activity" – The purpose of this activity is to develop approaches for using risk to improve oversight of fuel cycle facilities.

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## **21. Full-Scope Site Level 3 PRA**

### Summary Description

As directed in SRM-SECY-11-0089, "Options for Proceeding with Future Level 3 Probabilistic Risk Assessment (PRA) Activities" (ADAMS Accession No. ML112640419), the staff is conducting a full-scope multi-unit site Level 3 PRA that addresses all internal and external hazards; all plant operating modes; and all reactor units, spent fuel pools, and dry cask storage.

The full-scope site Level 3 PRA project includes the following objectives:

- Develop a Level 3 PRA, generally based on current state-of-practice methods, tools, and data, that (1) reflects technical advances since completion of the NUREG-1150 studies, and

(2) addresses scope considerations that were not previously considered (e.g., low power and shutdown, multi-unit risk, and spent fuel storage).

- Extract new risk insights to enhance regulatory decision making and help focus limited agency resources on issues most directly related to the agency's mission to protect public health and safety and the environment.
- Enhance PRA staff capability and expertise and improve documentation practices to make PRA information more accessible, retrievable, and understandable.
- Obtain insight into the technical feasibility and cost of developing new Level 3 PRAs.

Consistent with the objectives of this project, the Level 3 PRA study is based on current state-of-practice methods, tools, and data. However, there are several gaps in current PRA technology and other challenges that require advancement in the PRA state-of-practice. The general approach to addressing these challenges for the Level 3 PRA study is to primarily rely on existing research and the collective expertise of the NRC's senior technical advisors and contractors, and to perform limited new research only for a few specific technical areas (e.g., multi-unit risk).

Based on a set of site selection criteria and with the support of the NEI, Southern Nuclear Operating Company's Vogtle Electric Generating Plant, Units 1 and 2, was selected as the volunteer site for the Level 3 PRA study. The Level 3 PRA project team is leveraging the existing and available information on Vogtle and its licensee PRAs, in addition to related research efforts (e.g., SOARCA), to enhance efficiency in performing the study.

The Level 3 PRA project team is using the following NRC tools and models for performing the Level 3 PRA study:

- SAPHIRE, Version 8.
- MELCOR Severe Accident Analysis Code.
- MELCOR Accident Consequence Code System, Version 2 (MACCS).

In addition, the Level 3 PRA study is being developed consistent with many of the modeling conventions used for NRC's SPAR models.

#### FY 2015 Status

A PWR Owners Group (PWROG)-led ASME/ANS PRA Standard-based peer review of the reactor, at-power, high wind, Level 1 PRA and a screening evaluation of reactor, at-power "other" hazards (i.e., hazards other than internal events, internal floods, internal fires, high winds, and seismic events) was performed in November 2014. A PWROG-led ASME/ANS PRA Standard-based peer review of the reactor, at-power, internal event and internal flood Level 2 PRA was performed in December 2014. A PWROG-led workshop was held in January 2015 to identify peer review criteria for dry cask storage PRA. An expert elicitation was completed in June 2015 to address the frequency of interfacing systems LOCAs. The reactor, at-power, internal event and internal flood Level 3 PRA was completed in August 2015 and its peer review will be completed in October 2015. Initial versions of reactor, at-power, Level 1 PRA models for

internal fires and seismic events were completed in FY 2015, but they are in the process of being significantly revised to incorporate more recent licensee-supplied information.

### Risk Category

“Infrastructure Development in Support of Risk-Informed Regulations” - The Commission-directed Level 3 PRA Project is not supporting a specific risk-informed regulatory application. However, as described in SECY 12-0123, “Update on Staff Plans to Apply the Full-Scope Site Level 3 PRA Project Results to the NRC’s Regulatory Framework,” the results and insights of the Level 3 Project are expected to benefit a variety of ongoing regulatory initiatives.

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## **22. Implement 10 CFR 50.69: Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors**

### Summary Description

In 1998, the Commission decided to consider issuing new regulations that would provide an alternative risk-informed approach for special treatment requirements in the current regulations for power reactors. The NRC published the final rule (10 CFR 50.69, “Risk-Informed Categorization and Treatment of Structures, Systems and Components [SSCs] for Nuclear Power Reactors”) in the *Federal Register* on November 22, 2004 (69 FR 68008). The NRC staff issued Regulatory Guide (RG) 1.201, “Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance,” Revision 1, in May 2006 (ADAMS Accession No. ML061090627).

By letter dated December 6, 2010, the Southern Nuclear Company (SNC) informed the NRC of its intent to submit a license amendment request for implementation of 10 CFR 50.69 for Vogtle Electric Generating Plant (VEGP) Units 1 and 2, and requested pilot plant status and a waiver of review fees. By letter dated June 17, 2011, the staff informed SNC that the NRC granted the fee waiver request for the proposed licensing action in accordance with 10 CFR 170.11(b). SNC submitted a pilot plant application to implement 10 CFR 50.69 on August 31, 2012. By letter dated December 17, 2014, (ADAMS Accession No. ML14237A034) the NRC staff issued a License amendment to SNC revising the licensing basis for the VEGP by adding license conditions that allow for the voluntary implementation of 10 CFR 50.69. Lessons learned from the application review will be used to revise the associated industry guidance and RG 1.201.

In addition, the NRC staff issued draft Inspection Procedure 37060, “10 CFR 50.69 Risk-Informed Categorization and Treatment of Structures, Systems, and Components Inspection,” on February 16, 2011. The Nuclear Energy Institute (NEI) and one licensee provided comments on the procedure. The NRC staff addressed the comments and issued the revised inspection procedure in 2011. The NRC will focus its inspection efforts on the most risk-significant aspects related to implementation of 10 CFR 50.69 (i.e., proper categorization of SSCs and treatment of Risk-Informed Safety Class (RISC)-1 and RISC-2 SSCs).

As part of the Regulatory Guide Periodic Review, the NRC reviewed RG 1.201 to determine whether changes were necessary to incorporate lessons learned from the VEGP pilot application. The review concluded that the RG could be updated, but identified no safety concerns if the guide is not updated. The NRC staff did not recommend an update because no additional LARs have been submitted.

For more information, see ADAMS Accession No. ML15245A618.

#### FY 2015 Status

Completed the pilot application for the Vogtle Electric Generating Plant (VEGP) in December 2014.

#### Risk Category

“Risk-Informed Licensing Reviews” - The purpose of this activity was to review a pilot application of 10 CFR 50.69, grant the amendment as appropriate, and apply any lessons to future reviews and update RG 1.201, if necessary.

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### **23. Data Collection for Human Reliability Analysis (HRA)**

#### Summary Description

Consistent with the Commission's policy statements on the use of PRA and for achieving an appropriate PRA technical adequacy for NRC risk-informed regulatory decision-making, the NRC has ongoing activities to improve the technical basis for HRA. The adequacy of data available for HRA is an issue for the adequacy and consistency of human error probability estimates. To address this need, the staff has signed an agreement with the STP Nuclear Operating Company (STPNOC) to collect the STPNOC's licensed operator simulator training data for HRA (ADAMS Accession No. ML110730582; an amendment to this agreement was signed on September 2013 to extend the agreement until June 2018). The staff has developed the Scenario Authoring, Characterization, and Debriefing Application (SACADA) database application to support the agreement. The SACADA system was developed to collect licensed operator simulator data to inform HRA and to improve operator training programs. Since a data collection pilot study in May 2012, the STPNOC has used the SACADA system for its operator training program to collect licensed operator simulator training data and has shared the data with the NRC.

A database is useful only if it has sufficient data and the data are informative. The staff has worked to achieve the following two objectives: increasing the number of data providers and evaluating the data effectiveness in informing HRA. In the past year the following international organizations have collaborated with the NRC on the use of and the evaluation of the SACADA system:

- The NRC signed an agreement in September, 2013 with the Korea Atomic Power Research Institute (KAERI) on HRA data research. KAERI researchers use the SACADA system to collect and analyze Korean nuclear power plants' operator simulator exercise data to evaluate the SACADA system.
- The Halden Reactor Project (HRP) has used the SACADA system to collect the operator simulator experiment data generated at the HRP's Halden Human Machine Laboratory (HAMMLAB) since June 2014.

- A bilateral agreement between the NRC and the nuclear research institute, ÚJV Řež, a. s., of the Czech Republic, was signed in February 2015 to promote collaboration on HRA data collection.
- A work item on HRA data collection was added as a working item of the TECRO-AIT (Taiwan Economic and Culture Representative Office – American Institute in Taiwan) Joint Standing Committee on Civil Nuclear Cooperation (JSCCNC) in November, 2014. As such, an agreement between TECRO and AIT (designated to Taiwan Power Company (TPC) and the NRC) is in process to collect TPC’s operator simulator training data using the SACADA system.
- The staff held an HRA data workshop in April 2015 with domestic and international participants to discuss the experience in using the SACADA system and the use of SACADA data for HRA. In this workshop, participants demonstrated several methods of using SACADA data to inform HRA, using the roughly 8,000 data points collected in the SACADA database from three sources (plant operator simulator training and two simulator experiments). The results showed positive indications on using SACADA data for HRA method improvement.
- The staff presented the acquisition of SACADA data for HRA method improvement to the Advisory Committee on Reactor Safety Subcommittee on Reliability and Probabilistic Risk Assessment. The subcommittee members provided positive feedback about the SACADA system and recommended that the staff continue its data analysis program to further enhance the use of simulator data for HRA method improvement.
- The NRC continues its outreach to domestic nuclear power stations and nuclear industry human performance stakeholders for HRA data collection.

#### FY 2015 Status

The key near term SACADA research activities include:

- Analyzing the collected data to inform human reliability and human performance. This includes demonstrating the use of the data to inform human error probability (HEP) calculations in HRA.
- Collaborating with more data providers to increase the size of the data pool.

#### Risk Category

“Risk Tool, Maintenance and Development” – Improvement of HRA methods and data collection will improve the quality of analyses.

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## **24. Maintenance and Development of the Systems Analysis Programs for Hands-on Analysis Integrated Reliability Evaluations (SAPHIRE) Code**

### Summary Description

The NRC has developed and maintains the SAPHIRE (Systems Analysis Programs for Hands-on Integrated Reliability Evaluation) computer code for performing probabilistic risk analyses (PRAs). SAPHIRE offers state-of-the-art capability for assessing the risk associated with core

damage frequency (Level 1 PRA) and the risk from containment performance and radioactive releases (Level 2 PRA). SAPHIRE supports the agency's risk-informed activities, which include the Standardized Plant Analysis Risk (SPAR) model development plan, the risk assessment standardization project, the Significance Determination Process (SDP), risk-informing 10 CFR Part 50, vulnerability assessment, advanced reactors, operational experience, generic issues, and regulatory backfit.

#### FY 2015 Status

An updated status of SAPHIRE computer code activities can be found in SECY 15-0124, "Status of the Accident Sequence Precursor Program and the Standardized Plant Analysis Risk Models".

#### Risk Category

"Risk Tool, Maintenance & Development" – The SPAHIRE computer code is used to develop and run PRA models (e.g., SPAR models) for a variety of regulatory applications.

### **25. Develop Regulatory Framework for Spent Fuel Storage and Transportation**

#### Summary Description

The goal of this effort is to develop a framework for spent fuel storage to enable the staff to perform a more risk-informed regulatory review, improve guidance, streamline casework activities, help assess 10 CFR 72.48 changes, and evaluate requests for exemptions to the regulation while maintaining appropriate margins of safety and security. During the past year, NMSS/DSFM developed a scoping and implementation plan for risk-informing storage regulatory activities. Several tasks in this plan have been completed. These include identifying applicable risk information and defining the application of defense-in-depth for dry cask storage. The effort is currently focused on developing a decision metric that incorporates a surrogate risk measurement that does not require a detailed consequence calculation. NMSS/DSFM will be engaging stakeholders to solicit input in the near future. The remaining tasks in the implementation plan include defining and applying the risk-informed approach to a pilot; finalize the risk-informing approach; and developing staff training.

#### FY 2015 Status

At present, this effort is focused on developing a decision metrics that would simplify the implementation of risk. This current effort includes engaging stakeholders to solicit input.

#### Risk Category

"Infrastructure development in support of risk-informed regulations" -- ,” the completion of tasks in the scoping and implementation plan for risk-informing storage regulatory activities are expected to benefit a variety of regulatory initiatives.