

Memo To: File

Subject: ADAMS Record of  
2015 Risk-Informed Activity Public Website

Attached is a print out of each public webpage from the 2015 Risk-Informed Activity public website:

URL Link: <http://www.nrc.gov/about-nrc/regulatory/risk-informed/rpp.html>

Navigated from the NRC Public website by clicking:

- About NRC
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## Risk-Informed Activities

The U.S. Nuclear Regulatory Commission (NRC) undertakes a variety of activities to integrate risk information and performance measures into the agency's regulations, regulatory guidance, and oversight processes.

The current activities are organized along the agency's major arenas, subarenas, and functional distinctions, as follows:

- Reactor Safety Arena
  - Operating Reactors
  - New Light-Water Reactors
  - Advanced Reactors
  - Research and Test Reactors
- Materials Safety Arena
  - Fuel Cycle
  - Byproduct Materials
- Waste Management Arena
  - Spent Fuel Storage and Transportation
  - Low-Level Waste and Decommissioning
- Cross-Cutting Activities (span multiple subarenas)

Additionally, in early 2011, a Task Force for Assessment of Options for More Holistic Risk-Informed, Performance-Based Regulatory Approach was commissioned. The Task Force's goal was to develop a strategic vision and options for adopting a more comprehensive and holistic risk-informed, performance-based regulatory approach for reactors, materials, waste, fuel cycle, and transportation that would continue to ensure the safe and secure use of nuclear material. Findings from the task force were published in NUREG-2150.

This list of activities originates from a long history of risk plans including, the Risk-Informed and Performance-Based Plan (RPP), the Risk-Informed Regulation Implementation Plan (RIRIP) and the PRA Implementation Plan. The most recent plan, the RPP, 1) included performance-based elements, 2) organized activities along the agency's three primary regulatory arenas of reactors safety, material safety, and waste management and 3) formalized objectives, bases, and goals for each subarena to help to determine which initiatives the NRC should continue, which initiatives the agency should discontinue, and which new initiatives the agency may need to implement.

See also the [History of the NRC's Risk-Informed Regulatory Programs](#) for more information on the PRA Implementation Plan, the RIRIP, the RPP and links to the periodic status reports for each of these initiatives.



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## Operating Reactors Sub-Arena

The Nation's fleet of operating reactors comprises one of four sub-arenas that the staff of the U.S. Nuclear Regulatory Commission (NRC) identified in considering which areas of the reactor safety arena to target for greater use of risk information. This page summarizes the following aspects of the Operating Reactors Sub-Arena:

- Objective
- Basis
- Goals
- List of Risk-Informed and Performance-Based Activities

### Objective

Make continuing, incremental improvements in rulemaking, licensing, and oversight of operating reactors, while focusing on implementing existing risk-informed and performance based activities.

This objective focuses on activities that are already in progress to risk-inform the operating reactor subarena, including completed rulemaking activities, guidance documents, and implementation of some initiatives.

The NRC will revisit and update this objective (as appropriate) once the industry has implemented the currently planned activities and feedback becomes available.



### Basis

The risk-informed initiatives currently in progress were originally selected using screening criteria similar to those presented in the RPP. Consequently, the five activities (listed below) that support the goals for this subarena satisfy the following screening criteria:

- The risk-informed initiatives that are currently underway help to improve the effectiveness and efficiency of the NRC's regulatory process, including improved safety and reduction of unnecessary regulatory burden.
- Information and analytical models of operating reactors, particularly for at-power operations, exist and are fairly mature.
- The cost-beneficial nature of several of the risk-informed initiatives is evidenced by their voluntary adoption by licensees.
- No factors have been identified to date that would motivate changing the regulatory approach in the areas where risk-informed activities are already underway. Stakeholder feedback substantiates that there is no immediate need to initiate any new risk-informed initiatives, and that the NRC should focus on completing currently identified activities and allowing the industry time to implement those activities.
- Goals and activities to meet the objective for this subarena will be performance-based, to the extent that they meet the following four criteria:
  1. measurable parameters to monitor performance
  2. objective criteria to assess performance
  3. flexibility to allow licensees to determine how to meet the performance criteria
  4. no immediate safety concern as a result of failure to meet the performance criteria

Risk-informed activities for operating reactors occur in five broad categories:

- applicable regulations
- licensing process
- revised oversight process
- regulatory guidance
- risk analysis tools, methods, and data

The activities in these categories are derived from the Commission's policy statements and guidance, and include revisions to technical requirements in the regulations; risk-informed technical specifications; a new framework for inspection, assessment, and enforcement actions; guidance on other risk-informed applications (e.g., in-service inspections); and improved standardized plant analysis risk models.

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## Goals

The following goals are derived from the Commission's policy statements and guidance, which reflect the current phase of NRC and industry development, as well as the current implementation of risk-informed activities:

- Finish the development of current risk-informed regulations (e.g., 10 CFR 50.46a rulemaking) and associated regulatory/staff guidance.
- Implement existing NRC risk-informed activities [e.g., risk-informed technical specifications and pilots for 10 CFR 50.69 and the National Fire Protection Association (NFPA) Standard 805].
- Encourage the industry to implement risk-informed rules and approved/endorsed activities.
- Continue making incremental improvements to the established licensing, rulemaking, and oversight activities.
- Modify/update established activities to account for lessons learned.

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## List of Risk-Informed and Performance-Based Activities

This list shows the ongoing licensing initiatives, projects, and activities that the staff of the U.S. Nuclear Regulatory Commission (NRC) has targeted for greater use of risk information in the Operating Reactors Sub-Arena within the Reactor Safety Arena:

- Implementing Lessons Learned from Fukushima
- Risk-Informing Agency Actions on Low Risk Compliance Issues
- Probabilistic Flood Hazard Assessment (PFHA)
- Risk Informed Security Workshop
- Methods, Tools and Guidance for Including Digital Systems in Nuclear Power Plant PRAs
- Risk Assessment of Operation Events
- Maintenance and Development of the Systems Analysis Programs for Hands-on Analysis Integrated Reliability Evaluations (SAPHIRE) Code
- Standardized Plant Analysis Risk Models (SPAR)
- Full-Scope Site Level 3 PRA
- Data Collection for Human Reliability Analysis (HRA)
- Human Reliability Analysis (HRA) Methods and Practices
- Development of Human Reliability Analysis
- Develop Improved PRA Methods for Consequential Steam Generator Tube Rupture
- National Fire Protection Association (NFPA) Standard 805
- Assess Debris Accumulation on Pressurized Water Reactor (PWR) Sump Performance, Generic Safety Issue (GSI)-191
- Risk Prioritization Initiatives (RPI)
- Risk Informing Oversight of Emergency Preparedness (EP) and Response Plans
- Emergency Core-Cooling System (ECCS) Requirements: Redefinition of Loss-of-Coolant Accidents (LOCA)
- Emergency Core Cooling System (ECCS) Requirements: Loss of Coolant Accident and Loss of Offsite Power (ECCS-LOCA/LOOP)
- Develop Risk-Informed Improvements to Standard Technical Specifications (STS)
- Implement 10 CFR 50.69: Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors

*This page includes links to files in non-HTML format. See [Plugins](#), [Viewers](#), and [Other Tools](#) for more information.*

## Implementing Lessons Learned from Fukushima

### Summary Description

Following the accident at the Fukushima Dai-ichi Nuclear Plant in Japan, the NRC initiated actions to evaluate lessons learned and to implement appropriate changes in nuclear power plant designs and procedures. Initial recommendations were included in the Near Term Task Force (NTTF) report entitled "Recommendations for Enhancing Reactor Safety in the 21st Century." Several of the items (e.g., Recommendation 1 regarding improving the regulatory framework and recommendation 2.1 on re-evaluating seismic and flooding hazards) include incorporation of risk-informed, performance-based approaches into NRC activities. The status and program plans for items identified

for longer term evaluations were reported to the Commission in SECY 12-0095. Recommendation 1 was closed by the Commission without approving staff proposed improvement activities in SRM-SECY-13-0132. For NTTF recommendation 2.1—Seismic, some licensees are using a probabilistic seismic hazard approach in their responses to NRC's request for updated seismic hazard information. More information is available from the Japan Lessons Learned Web site.

### FY 2015 Status

Licensees submitted updated seismic hazard information in FY 2014 and, if required, "expedited seismic evaluation process" results in FY 2015. The updated hazard information and other factors (e.g., risk insights from the Individual Plant Examination of External Events for Severe Accident Vulnerabilities) were used to determine whether certain plants need to perform a seismic risk assessment, (on the order of 20 sites screened in for performing the risk assessment.) For those sites, NRC will use that information as part of the determination of whether additional regulatory action is warranted.

### Risk Category

Risk-informed licensing reviews (NFPA 805 reviews, R-I tech specs) The seismic hazard reevaluations are in response to a 10 CFR 50.54(f) letter, which seeks information to decide whether a licensee's license should be suspended, modified, or revoked.

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## 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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**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 (cover sheet and final plan) was provided to the Commission. RES has begun implementation of the research plan.

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**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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**Risk Informed Security Workshop****Summary Description**

The staff has worked with several organizations to conduct a series of workshops on risk informed security to identify potential opportunities to better risk inform security. The initial workshop was hosted by Sandia National Laboratories in September 2010. Based on the results of the 2010 workshop a follow-on workshop was hosted by the Institute of Nuclear Materials Management (INMM) in Stone Mountain, GA in February 2014.

These workshops covered a broad range of topics in order to identify areas where further research might be conducted to improve the way that risk information is incorporated into the security regulatory process at the Nuclear Regulatory Commission. These workshops have been coordinated with the Departments of Energy and Homeland Security and the National Security Council. In addition, they have been attended by representatives of a number of foreign governments.

**FY 2015 Status**

Three workshops were conducted in FY 2015. The first workshop was hosted by the INMM and the George Washington University Elliott School of International Affairs in Washington, DC in March 2015. Risk informed security topics included cyber security, perception of risk and insider mitigation. The second workshop was hosted by the INMM and the American Nuclear Society (ANS) in conjunction with the ANS International Topical Meeting on Probabilistic Safety Assessment and Analysis in Sun Valley, ID in April 2015. This workshop brought safety and security risk professionals together to discuss how risk information is used within the two disciplines. The final workshop of the year was hosted by the INMM in Boston in September 2015, entitled the Vulnerability Assessment Tools Workshop.

### Risk Category

Risk-Informed licensing and oversight activities.

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## 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.

### 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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## Risk Assessment of Operation Events

### Summary Description

Maintain an integrated handbook and analysis methods support for staff to analyze internal, external, and low-power/shutdown operation events.

Support: The support provided is in response to requests from the program offices (NRR, NRO, and the Regions) and on-call technical assistance to senior reactor analysts (SRAs) and other practitioners of risk analysis when needed with PRA models or the risk analysis software. Specifically, staff implementing programs in the following areas are frequent recipients of this technical assistance: MD 8.3 Incident Investigation Program, Reactor Oversight Process and the Significance Determination Process, Accident Sequence Precursor Program, and the Risk Assessment Standardization Project (RASP) help desk.

Handbook: A Risk Assessment Handbook and associated Web site provides methods and guidance that NRC staff use to achieve more consistent results when performing risk assessments of operational events and licensee performance issues. It is updated periodically based on user comments and insights gained from field application. The Handbook consists of four volumes, designed to address internal events analysis, external events analysis, Standardized Plant Assessment Risk (SPAR) model reviews, and shutdown event analysis. The Handbook represents best practices based on feedback and experience from the analyses of precursors in the Accident Sequence Precursor (ASP) Program and numerous Significance Determination Process (SDP) Phase 3 analyses.

#### **FY 2015 Status**

This activity continually provides support to risk analysts and routinely updates the RASP Handbook and the associated Web site to assure accuracy and provide additional references for risk analysts' use.

#### **Risk Category**

Risk tool maintenance & development. Maintaining analysis tools and formal guidance associated with risk analysis supports risk informed decision making by the staff.

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## **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 Handson 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.

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## **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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## 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," 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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## 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; 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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## Human Reliability Analysis (HRA) Methods and Practices

### Summary Description

The purpose of the HRA method effort is to improve the methods for regulatory applications. This improvement involves increasing the consistency amongst HRA practitioners in the use of methods and developing guidance on the rigor needed for quantifying human reliability given the scarcity of empirical data to evaluate human performance. The ongoing activities include:

- Develop the IDHEAS General Methodology for risk analyses of all NPP HRA applications (SRM-M061020)
- NRC/EPRI collaborative effort to implement the General Methodology for internal at-power application
- Implement the General Methodology for Ex-Control Room actions

Risk Basis: Regulatory Guide (RG) 1.200 provides an acceptable approach for determining the technical adequacy of PRA results for risk-informed activities. HRA is a key element in the PRA; different HRA methods often have different assumptions and approximations and, therefore, may yield different results. Thus, improving HRA methods enhances the consistency and quality of HRA and PRA.

### FY 2015 Status

The report "Cognitive Basis for HRA" is finalized and will be published in 2015. The staff has been working with the ACRS Reliability and PRA Subcommittee to construct the IDHEAS General Methodology so that it can be implemented in various NPP applications. The IDHEAS internal, at-power application is currently being tested.

### Risk Category

Risk-Informed oversight activities. The purpose of the HRA method efforts is to improve the method to be used for regulatory applications and consistency among HRA practitioners in performing HRA. This will help improve HRA / PRA quality and provide a basis for risk-informed rule-making.

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## Development of Human Reliability Analysis

### Summary Description

Regulatory Guide (RG) 1.200 provides an acceptable approach for determining the technical adequacy of PRA results for risk-informed activities. However, RG 1.200 (including the PRA standards reflected and endorsed by RG 1.200) is a high-level regulatory guide, addressing what to do but not the how to do it. Consequently, there may be several approaches for addressing certain analytical elements, which may meet the RG 1.200 and associated standards, but may do so by making different assumptions and approximations and, therefore, may yield different results. This is particularly true for human reliability analyses (HRA) for which many methods are available to model mitigative actions in PRAs. The staff is addressing this issue by developing lower level guidance documents to support the implementation of RG 1.200.

This work supports the NRC's action plan for stabilizing PRA quality expectations and requirements (described in SECY-04-0118 and SECY-00-0007). It also is responsive to the November 8, 2006, staff requirements memorandum (SRM) (SRM-M061020) in which the Commission, based on ACRS concerns, directed the staff to evaluate different human reliability models in an effort to propose a single model for the agency to use or guidance on which model(s) should be used in specific circumstances." The following activities are addressing HRA improvement needs:

#### (1) HRA Method Benchmarking:

Participate in the International HRA Empirical Study in an effort to benchmark HRA methods by comparing HRA predictions to crew performance on a nuclear power plant simulator.

The International HRA Empirical study was a multinational multi-team effort supported by the Organization for Economic Co-Operation and Development (OECD) Halden Reactor Project. The Halden Reactor Project provided facilities, crews, and expertise to collect and analyze simulator crew performance data and HRA analyst teams from multiple organizations used their preferred HRA methods to analyze and predict

the performance of these crews. The objective of the study was to develop an empirically-based understanding of the performance, strengths, and weaknesses of the various HRA methods used to model human response to accident sequences in probabilistic risk assessments (PRAs). This study was the first of its kind; no previous HRA benchmarking studies have been performed using crew simulator data. Its pilot phase has been documented in NUREG/IA-0216, Vol.1, "International HRA Empirical Study – Phase 1 Report, Description of Overall Approach and First Pilot Results from Comparing HRA Methods to Simulator Data," November 2009 (Halden report HWR-844). Its second phase consisted of the analysis and comparison of HRA predictions for nine steam generator tube rupture (SGTR) human actions and is documented in NUREG/IA, Vol. 2, "International HRA Empirical Study – Phase 2 Report, Results from Comparing HRA Method Predictions to Simulator Data from SGTR Scenarios," (Halden report: HWR-915), August 2011. Phase 3 consisted of the comparison of four loss-of-feedwater (LOFW) human actions and will be documented in NUREG/IA Vol.3, "The International Empirical Study – Phase 3 Report – Results from Comparing HRA Method Predictions to Simulator Data from LOFW Scenarios," (Halden report HWR-951), published in 2014.

The overall findings of the study were documented in NUREG-2127 (HWR-373), entitled "The International HRA Empirical Study – Final Report – Lessons Learned from Comparing HRA Methods Predictions to HAMMLAB Simulator Data," published in August 2014. The results of the Empirical Study will provide a technical basis for improving individual methods, improving existing guidance documents for performing and reviewing HRAs (e.g., NUREG-1792, HRA Good Practices), and developing additional guidance and training materials for implementing individual methods.

The study has also produced many conference papers, presented at the annual Institute of Electrical and Electronics Engineers Conference on Human Factors, August 2007, at the American Nuclear Society International Probabilistic Safety Conference 2008 (PSA8), September 2008, and at the International Conference on Probabilistic Safety Assessment and Management (PSAM) conferences: PSAM9, May 2008, PSAM10, May 2010, and PSAM 11, June 2012.

## (2) HRA Method Improvement Using US Simulator Runs:

As noted above, RES participates in and supports the International HRA Empirical Study to benchmark HRA models by comparing HRA results to empirical data generated through crew simulator runs. The International HRA Empirical Study has clearly identified important strengths and weaknesses of the various methods and identified areas for improvement in HRA methods and practices. In particular, an important conclusion from the study was that improving the qualitative analysis aspects of HRA methods could increase their robustness and reduce some of the sources in the variability of results that are seen in applications of different methods. However, since there was only one case in the International study where the same HRA method was applied by different teams, it was difficult to clearly separate method specific effects from differences created by the analysts' application of a given method. Thus, in addition to examining differences across methods, a major objective of the US simulator study (performed on a US nuclear power plant simulator) is to test the consistency and accuracy of HRA predictions among different analyst teams using the same methods. A particular area of interest in these comparisons is examination of the qualitative analysis performed by different methods and teams to identify shortcomings that contribute to inconsistencies in results and to determine the extent to which the shortcomings are due to analyst differences or due to inherent shortcomings in the methods.

Two other potential limitations of the International study are also addressed in the US study:

First, in the International study, the HRA teams were unable to visit the Halden simulator and collect HRA related information through interviews with plant operators and trainers and through observations of actual operating crews in the simulator, as is typically done in performing an HRA for a nuclear power plant PRA. This type of information was provided to the HRA teams to the extent possible by the study team in the International study and the HRA teams were allowed to submit written questions that were answered by the study team and plant personnel as needed. Some of the HRA teams in the International study felt this significantly limited their ability to perform an adequate HRA. In the US study, the HRA teams were able to visit the reference plant and collect information relevant to performing their HRA as it would normally be done in a PRA.

Second, there was some concern that because the international study was based on the results of simulator runs using European crews at the Halden Reactor Project, the results might not be directly generalizable to what would occur with US nuclear power plant crews. Some of the HRA teams in the international study thought that their expertise was more geared to understanding what US crews would do and that their US bias may have influenced their decision-making in applying their HRA method. Thus, the US study would serve as a check against the effects of such bias on the results.

In SRM-M090204B, dated February 18, 2009, the Commission directed the staff "to continue to pursue possibly working with EPRI, INPO, and/or international partners to test U.S. nuclear plant operating crews' performance in a variety of situations and keep the Commission informed on the progress in developing a human reliability analysis (HRA) database and benchmarking projects." Thus, the US Empirical Study is directly responsive to this SRM.

To perform the US Empirical Study, RES established an MOU with a US utility volunteering to participate in this study by offering simulator facilities, crews and expertise to support the design and execution of the experimental runs. Further, RES initiated work with the objective to evaluate HRA methods currently used in regulatory applications through a comparison of HRA predictions to crew performance in simulator experiments performed at the US nuclear power plant. The Halden Reactor Project, Idaho National Laboratory, Sandia National Laboratories, Paul Scherrer Institute (Switzerland) and EPRI are also participating and supporting the study.

To accomplish the goals of the study, 4 crews from the plant performed 3 different scenarios: 1) a Loss of Feedwater followed (after recovery of feedwater) by a Steam Generator Tube Rupture, 2) a Loss of Component Cooling Water and Reactor Coolant Pump seal water, and 3) a basic Steam Generator Tube Rupture. Crew performance on several human failure events that would normally be modeled in a PRA was evaluated and compared with the predictions from 9 human reliability analysis teams using 4 different methods (ATHEANA, SPAR-H, EPRI Calculator, and ASEP/THERP). Both qualitative and quantitative predictions are being evaluated.

A workshop was hosted by the NRC in June, 2011 to discuss the preliminary results from the study with the study participants. Based on the input from the workshop participants, the data analysis is continuing. Plans are to complete a NUREG documenting the experimental design, results, and conclusions of the US study and another NUREG discussing the overall conclusions and lessons learned from both the International and US studies in 2015.

The results will be used to:

- Assess the impact of potential limitations in the data collected in the International Empirical Study as described above.
- Provide an improved basis for determining how to best improve HRA methodology and use this information as an input to the HRA Model Differences Project (Item 3 below).

### (3) Address HRA Model Differences:

Many models are available for HRA. There is evidence that the results associated with a particular human failure event analysis could vary depending on the HRA model/method used and/or the analyst applying the method. Because HRA results and insights are frequently used to support risk-informed regulatory decision making, the NRC continues to improve the robustness of PRA/HRA through targeted activities (e.g., supporting and endorsing PRA standards developed by professional societies). Recognizing that HRA model differences contribute to the variability of PRA/HRA results, the Commission directed the Advisory Committee on Reactor Safeguards (ACRS) (SRM-M061020) to work with the staff and external stakeholders to evaluate the different human reliability models and either propose a single model for the agency to use or guidance about which model(s) should be used for the different regulatory applications.

The Office of Nuclear Regulatory Research (RES) has taken the lead in addressing SRM-M061020. The ACRS has kept abreast of developments and provides input through periodic meetings. This work is performed collaboratively with the Electric Power Research Institute (EPRI) under a RES/EPRI Memorandum of Understanding and its update. *ML07274014, ML100490657*

The main tasks of this work include: (1) Identification of current and emerging regulatory applications in which HRA results could have an impact on the decision; (2) identification and evaluation of currently available methods for their suitability and adequacy to treat human performance issues associated with the various regulatory applications and domains of interest (e.g., event analysis for shutdown operations); (3) development a cognitive foundation for HRA through synthesizing literature on why human makes errors (4) development of a generic HRA methodology based on the cognitive foundation for all NPP HRA applications; and 5) development of a HRA method for internal, procedural HRA analysis that integrates the strengths of the existing HRA models into a unified HRA structure and have new components to address the key limitations in current models. The new method is referred to as "Integrated Human Event Analysis System (IDHEAS)."

The development of the new HRA method needs to go through all stages of new model development: (1) developing a technical basis to understand human performance under accident situations from cognitive sciences and operational experience; (2) constructing a method for analyzing human performance and estimating human error probabilities supported by the technical basis; (3) developing tools for using the model; (4) reviewing and testing the work; (5) documenting the results and the development process; and (6) producing training materials and user guides. The staff is currently engaged in the development of the method, sought to be ready for pilot testing and revision in the end of 2015. The staff expects to complete the material development by December 2015.

The staff believes that these efforts will result in producing a HRA method that is well understood and appropriately characterized for its suitability and usefulness in different regulatory applications.

Primary Priority: High

Secondary Priority: Medium

Project Considerations: The HRA guidance addresses many issues associated with the use of HRA in decision-making, including the suitability of an individual method to a regulatory application, consistency among HRA practitioners in implementing HRA methods, and the absence of guidance on the rigor needed for quantification of human reliability.

### FY 2015 Status

Ongoing

### Risk Category

Risk tools maintenance and development.

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## 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 draft version of the report was provided to the ACRS.

#### 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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## 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. 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. 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 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 SRMSECY-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, 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 and approved in SRM-SECY-11-0061, dated June 10, 2011. 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. Additional information is available.

#### 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, dated June 2015, is available.

#### 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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## 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, 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-SECY12-0093, dated December 14, 2012. 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 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. Additional information is available.

### FY 2015 Status

ML14295A220

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 DG1322.

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## 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", 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. 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". In addition, NEI provided its summary and observations of the demonstration pilots in the "Nuclear Energy Institute, Report on Prioritization and Scheduling Pilot." The latest version of the NEI guidance was submitted to the NRC by letter dated November 14, 2014.

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. In the SRM-SECY-15-0050 issued on August 25, 2015, the Commission did not approve separate RPI activities, but supported the consideration of risk insights in regulatory decision-making through existing agency processes. Additional information is available.

#### FY 2015 Status

ML15244A046

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." 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. 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, 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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## **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." This project also informed the development of SECY-14-0038, "Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight," that presented the results of a staff study on the potential for a performance based EP framework. In SRM-14-038, 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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## **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, 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)." 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. 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," 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. Additional information is available.

ML 15245A603

#### 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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## Emergency Core Cooling System (ECCS) Requirements: Loss of Coolant Accident and Loss of Offsite Power (ECCS-LOCA/LOOP)

### Summary Description

The proposed rule would amend the Commission's regulations to eliminate, based upon appropriate risk considerations, the assumption of a coincident LOOP for postulated LBLOCAs (low frequency) in General Design Criterion (GDC) 35. The proposed rule would provide a voluntary alternative to existing requirements in situations where specified acceptance criteria are satisfied, and also would address a petition for rulemaking submitted by Bob Christie (Performance Technology) (PRM-50-77). The staff's approach was to develop the technical basis for a LOOP-LOCA rule by reviewing the Boiling Water Reactor Owners Group (BWROG) topical report (TR), NEDO-33148, "Separation of Loss of Offsite Power from Large Break LOCA," dated April 27, 2004. In the March 31, 2003, SRM directing the staff to go forward with a risk-informed rule decoupling LOOP from LOCA, the Commission stated that the rule should consider the risk impacts of a "delayed LOOP and possible double-sequencing of safety functions." During the review of the BWROG TR, the potential safety impact of a LOCA followed by a delayed LOOP became a major issue. Existing nuclear plants are designed to handle only the simultaneous LOCA and LOOP. The capability of many plants to successfully mitigate upsets causing a delayed LOOP has not been determined. In December 2007, in COMSECY-07-0041, "Status of Staff Activities on Proposed Rule for Risk-Informed Decoupling of Assumed Loss-of-Offsite Power From Loss-of-Coolant Accident Analyses," the staff indicated its plans to reassess the need for a LOOP-LOCA rule after making final decisions on the BWROG TR and on the 10 CFR 50.46a risk-informed ECCS rule. In an SRM related to SECY-07-0082 dated August 10, 2007, the Commission agreed with the staff's recommendation that completing the rulemaking should be assigned a medium priority. Prior to completing its review of the TR, the staff concluded that the approach could not be approved without evaluating an individual plant's capability to successfully cope with a delayed LOOP. By letter dated June 12, 2008, the BWROG withdrew the TR from further NRC review after concluding that continued development of the report was no longer cost effective, and if ultimately approved in the form desired by NRC staff, adoption by licensees would most likely be prohibitively expensive. In September 2009, SECY-09-0140, "Rulemaking Related to Decoupling an Assumed Loss of Offsite Power from a Loss of Coolant Accident, 10 CFR part 50, Appendix A, General Design Criterion 35," provided options for completing the rulemaking and recommended the option to discontinue the rulemaking effort. The staff's recommendation was based on the lack of a fully developed regulatory basis and expenditures of staff time to develop one would not be expected to result in a quantifiable safety improvement. In the SRM related to SECY-09-0140 dated July 12, 2010, the Commission directed the staff to defer the decision on the rulemaking effort until the 10 CFR 50.46a rule is implemented. In response to the SRM on SECY-13-0132, "Nuclear Regulatory Commission Staff Recommendation for the Disposition of Recommendation 1 of the Near-Term Task Force Report", the staff requested extension to this and other initiatives, across all 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. Additional information is available.

#### FY 2015 Status

ML 15243A463

No action in 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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**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 at 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, 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; December 5, 2014; December 23, 2014; and July 31, 2015. 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. 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. 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 after the NRC requested additional information and the participating licensees decided not to pursue these initiatives. Additional information is available.

**FY 2015 Status**

ML15243A474

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.

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**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, Revision 1, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," in May 2006.

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, 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. Additional information is available.

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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## New Light-Water Reactors Sub-Arena

New light-water reactors (LWRs) comprise one of four sub-arenas that the staff of the U.S. Nuclear Regulatory Commission (NRC) identified in considering which areas of the reactor safety arena to target for greater use of risk information. This page summarizes the following aspects of this sub-arena:

- Objective
- Basis
- Goals
- List of Risk-Informed and Performance-Based Activities

### Objective

Implement risk-informed and performance-based activities to address the PRA elements of Title 10, Part 52, of the Code of Federal Regulations (10 CFR Part 52), and to increase the effectiveness and efficiency of the design certification, licensing, and oversight activities that the NRC staff conducts for new LWRs.

This objective has two main parts:

- First, this objective involves using the plant-specific PRA to implement risk-informed and performance-based programs. For example, the maintenance rule (10 CFR 50.65) will utilize the PRA to a great extent. Other examples include initiatives that a new reactor licensee may voluntarily pursue, such as risk-informed technical specification completion time, risk-informed in-service inspection, or special treatment under 10 CFR 50.69.
- Second, this objective involves using risk insights and PRA results to improve the NRC's effectiveness and efficiency in the licensing and oversight processes. For example, the staff will use risk insights, in conjunction with other considerations, to focus its review of a new reactor license application on those aspects that are important to risk. Other examples include developing risk-informed acceptance criteria for applications and adopting a risk-informed approach to sampling the inspection, testing, analysis, and acceptance criteria (ITAAC) to confirm the acceptability of the as-built plant.

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### Basis

The risk-informed and performance-based activities (listed below) for this sub-arena satisfy the following screening criteria:

- The stated objective will help to improve the effectiveness and efficiency of the NRC's regulatory process, while increasing nuclear plant safety and reducing unnecessary regulatory burden.
- The bases for developing a risk-informed and performance-based regulatory structure for licensing and oversight of new LWRs are articulated in several Commission documents, policy statements, and processes (including the 10 CFR Part 52 rulemaking).
- Goals and activities to meet the objective for this sub-arena will be performance-based, to the extent that they meet the following four criteria:
  1. measurable parameters to monitor performance
  2. objective criteria to assess performance
  3. flexibility to allow licensees to determine how to meet the performance criteria
  4. no immediate safety concern as a result of failure to meet the performance criteria

An applicant for a combined license (COL) for a new LWR is required to perform a PRA. The NRC staff expects such PRAs to be used for the following purposes:

- Identify risk-informed safety insights.

- Demonstrate how risk compares to the Commission's goals.
- Assess the balance between accident prevention and mitigation.
- Identify and address vulnerabilities, reduce risk contributors, and select among design alternatives during the design phase.
- Demonstrate that the plant design represents a reduction in risk (compared to existing operating plants).
- Demonstrate that the design addresses the requirements in 10 CFR 50.34(f), as they relate to Three Mile Island (TMI).

PRA results and insights are used to support the following programs (among others):

- Regulatory Treatment of Non-Safety Systems (RTNSS)
- Inspection, test, analysis, and acceptance criteria (ITAAC)
- Reliability Assurance Program (RAP)
- Future aspects of regulatory oversight, technical specifications, the maintenance rule (10 CFR 50.65), and others

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## Goals

The following goals are derived from the Commission's policy statements and guidance, which reflect the current phase of NRC and industry development, as well as the current implementation of risk-informed activities:

- Ensure (during the design certification phase) that the applicant used risk-informed safety insights to select among alternative features, operational strategies, and design options to reduce or eliminate the significant risk contributors of existing operating plants.
- Ensure that the risk associated with the design compares favorably with the Commission's goals of less than 1E-04/year for core damage frequency (CDF) and less than 1E-06/year for large release frequency (LRF).
- Using the results and insights from the PRA, ensure that the COL applicant supported the RTNSS process, including the identification of structures, systems, and components (SSCs).
- Using the results and insights from the PRA, ensure that the COL holder supported regulatory oversight processes, as well as programs associated with plant operations (such as technical specifications, reliability assurance, human factors, and maintenance rule implementation).
- Using the results and insights from the PRA, ensure that the applicant identified and supported the development of specifications and performance objectives for plant design, construction, inspection, and operation (such as the ITAAC, RAP, technical specifications, and COL action items and interface requirements).

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## List of Risk-Informed and Performance-Based Activities

This list shows the ongoing licensing initiatives, projects, and activities that the staff of the U.S. Nuclear Regulatory Commission (NRC) has targeted for greater use of risk information in the Light-Water Reactors Sub-Arena within the Reactor Safety Arena:

- Standard Review Plan, Chapter 19.0 Severe Accidents (NUREG-0800)
- Evaluate and Develop Risk-Informed Regulatory Guidance for New Reactors

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## 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:

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,

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,

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,

Guidance on addressing modular designs if the applicant seeks approval for multiple modules, and

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, "Assessing the Technical Adequacy of the Advanced Light-Water Reactor Probabilistic Risk Assessment for the Design Certification Application and Combined License Application."

### **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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## **Evaluate and Develop Risk-Informed Regulatory Guidance for New Reactors**

### **Summary Description**

In response to the staff requirements memorandum (SRM) on SECY-12-0081, "Risk-informed Regulatory Framework for New Reactors," the staff submitted SECY-13-0137, "Recommendations for Risk-Informing the Reactor Oversight Process (ROP) for New Reactors." In that SECY paper the staff recommended the development of an integrated risk-informed approach for evaluating the safety significance of inspection findings for new reactor designs.

In its SRM on SECY-13-0137, the Commission approved the staff's recommendation to develop appropriate performance indicators (PIs) and thresholds for new reactors. The Commission requested that the staff develop, with appropriate stakeholder input, the necessary updates to the PIs, including any new PIs or changes to thresholds, and submit them to the Commission for approval before power operation for the first new reactor units.

The Commission disapproved the staff's recommendation to develop an integrated risk-informed approach for evaluating the safety significance of inspection findings for new reactor designs. The Commission directed the staff to enhance the Significance Determination Process (SDP) by developing a structured qualitative assessment for events or conditions that are not evaluated in the supporting plant risk models, such as those conditions that might arise with passive safety systems, digital instrumentation and control (I&C), and human performance issues. The Commission requested that the staff submit a paper to the Commission with its proposed approach for any revisions to the SDP for new reactors at least 1 year before the scheduled implementation of any changes to the Reactor Oversight Program (ROP).

### **FY 2015 Status**

The staff continues to work on the Commission's directions from the SRM on SECY-13-0137. The staff is working with stakeholders and the public to develop appropriate PIs and enhance the SDP. In May 2015, the staff discussed its approach and plans for responding to the SRM on SECY-13-0137 with stakeholders during a ROP working group public meeting. Another public meeting with stakeholders will be held in September 2015 to discuss updates on the staff's activities and to obtain stakeholder feedback. The staff plans to submit its proposed approach to the Commission one year before the scheduled implementation of any changes to the ROP.

### **Risk Category**

Risk-Informed oversight activities. The purpose of this activity is related to risk-informing the ROP for new reactors.

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## Advanced Reactors Sub-Arena

Advanced reactors comprise one of four sub-arenas that the staff of the U.S. Nuclear Regulatory Commission (NRC) identified in considering which areas of the reactor safety arena to target for greater use of risk information. This page summarizes the following aspects of this sub-arena:

- Objective
- Basis
- Goals
- List of Risk-Informed and Performance-Based Activities

### Objective

Develop a coherent risk-informed and performance-based regulatory structure for design certification, licensing, and oversight of advanced reactors.

A coherent risk-informed and performance-based regulatory structure would offer significant improvements in effectiveness and efficiency (compared to the structure that has evolved for current-generation LWRs). For example, such coherence would ensure that the safety reviews conducted by the NRC consider design and operational aspects in an integrated manner. The bases for developing such a regulatory structure for licensing and oversight of advanced reactors are articulated in numerous Commission documents and policy statements. However, this guidance occurs largely in the context of existing and new LWRs and, consequently, needs to be adapted for advanced reactors.

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### Basis

The bases for a coherent risk-informed and performance-based regulatory structure arise from the potential to realize benefits that are captured in the screening criteria that the NRC staff considers in undertaking regulatory improvement initiatives:

- **Effectiveness:** One hallmark of effectiveness is the ability to model the tradeoffs that are involved in a complex safety review. Sometimes, such tradeoffs are represented as the ability to achieve desired outcomes in the licensing process. A risk-informed and performance-based regulatory structure is inherently better able to do this, especially if it is applied in the early phases of developing a new regulatory structure for advanced reactors.
- **Effective Communication:** The explicit modeling of decision-making promotes transparency. Sometimes, the traditional prescriptive regulatory structure lacks transparency because it tends to emphasize compliance with a prescribed quantity, rather than focusing on the safety function.
- **Research:** The NRC staff has conducted significant research into the models and methodologies for the risk-informed and performance-based regulatory structure and the products and expertise from this work are available for implementation. Particularly notable examples include NUREG-1860, NUREG/BR-0303, and SECY-05-0138. Specific details will need to be determined and guidance developed based on the particular technology and design aspects of the application.
- **Costs:** The implementation of a coherent risk-informed and performance-based regulatory structure for advanced reactors will entail a combination of short- and long-term costs. The new regulatory approaches are likely to result in short-term costs. However, when considered in the context of implementing the Commission's strategic objectives, there are sound reasons to expect a significant reduction in the total cost to society.
- **Obstacles:** There are no apparent factors (e.g., state-of-the-art, adverse stakeholder perception) that would preclude implementing a risk-informed and performance-based approach to the design certification, licensing, and oversight of advanced reactors once sufficient operating experience is available to provide input to the activities.

The NRC developed its strategic planning process as a result of considerable effort (beginning in the late-1990s) to improve the agency's regulatory structure in a forward-looking way, while preserving the gains that the agency had achieved in operating reactor safety. Using the

most recent version of the Strategic Plan, development of a coherent risk-informed and performance-based regulatory structure for advanced reactors will involve implementing the strategies that the Commission articulated in the goal of "Safety". Under "Safety" strategies, the Commission directed the staff to "Use sound science and state-of-the-art methods to establish, where appropriate, risk-informed and performance-based regulations." This element continues to be part of the Strategic Plan for the Fiscal Year (FY) 2008–2013.

The basic infrastructure for the implementation of a risk-informed and performance-based approach exists at a high-level in Commission documents, such as the "White Paper on Risk-Informed and Performance-Based Regulation." The staff has also developed some specific guidance, including the risk-informed process for implementing the single-failure criterion (SECY-05-0138), but more may need to be developed. In many instances, the high-level documents superficially apply only to existing LWRs; however, more thorough study reveals considerable applicability to all reactor technologies. For example, the Reactor Oversight Process (SECY-99-007 and SECY-99-007A, as well as related staff requirements memorandum) provides a risk-informed and performance-based structure, although it is overlaid on top of existing LWR requirements.

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## Goals

The staff's risk-informed and performance-based goals for advanced reactors relate to the following activities:

- Ensure advanced reactor applicants use risk-informed safety insights to select among alternative features, operational strategies, and design options to reduce or eliminate the significant risk contributors of existing operating plants.
- Ensure that the risk associated with advanced reactor designs compare favorably with the Commission's goals of less than 1E-04/year for core damage frequency and less than 1E-06/year for large release frequency

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## List of Risk-Informed and Performance-Based Activities

This list shows the ongoing licensing initiatives, projects, and activities that the staff of the U.S. Nuclear Regulatory Commission (NRC) has targeted for greater use of risk information in the Advanced Reactors Sub-Arena within the Reactor Safety Arena:

- Use of Risk Insights to Enhance Technical Reviews of Design Certification (DC) Applications
- Interim Staff Guidance on PRA Technical Adequacy for Advanced Light-Water Reactors
- Pre-Application Review for Small Modular Reactor (SMR) Designs

*This page includes links to files in non-HTML format. See [Plugins](#), [Viewers](#), and [Other Tools](#) for more information.*

## 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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## 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 preoperational 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:

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.

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.

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 preoperational 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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## Pre-Application Review for Small Modular Reactor (SMR) Designs

### Summary Description

In the Staff Requirements Memorandum (SRM) COMGBJ-10-0004/COMGEA-10-0001, "Use of Risk Insights to Enhance the Safety Focus of Small Modular Reactor Reviews," dated August 31, 2010, the Commission provided direction to the NRC staff on the preparation for, and review of, small modular reactor (SMR) applications, with a near-term focus on integral pressurized-water reactor designs. The Commission directed the NRC staff to more fully integrate the use of risk insights into pre-application activities and the review of applications and, consistent with regulatory requirements and Commission policy statements, to align the review focus and resources to risk-significant structures, systems, and components and other aspects of the design that contribute most to safety in order to enhance the effectiveness and efficiency of the review process. The Commission directed the NRC staff to develop a design-specific, risk-informed review plan for each

SMR design to address pre-application and application review activities. An important part of this review plan is the Design Specific Review Standards (DSRSs). The staff has developed a DSRS for the mPower™ design and prepared another DSRS for the NuScale design.

#### **FY 2015 Status**

Pre-application reviews are currently in progress for the NuScale design. The DSRS for the NuScale design has been drafted to provide guidance to the NRC technical staff for review of the NuScale Design Certification Application (DCA). In the Federal Register Notice of June 30, 2015, the NRC solicited public comment on the DSRS and Safety Review Matrix for the NuScale design. The comment period ended on August 31, 2015 and the staff is currently evaluating the comments received.

#### **Risk Category**

Infrastructure development in support of risk-informed regulations and Risk-Informed licensing reviews. The purpose of this activity is to integrate risk insights more fully into design certification reviews and the formal licensing decision-making process. Specifically, the activity involves developing review guidance for specific new reactor design certification applications. This helps prioritize and focus staff review efforts towards the more risk significant aspects of the design.

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## Research and Test Reactors Sub-Arena

Research and test reactors comprise one of four sub-arenas that the staff of the U.S. Nuclear Regulatory Commission (NRC) identified in considering which areas of the reactor safety arena to target for greater use of risk information.

The staff will be conducting a review of NUREG-2150, "A Proposed Risk Management Framework," that will consider how modifications to the regulatory framework could be incorporated into important agency policy documents. As part of this review, the staff will seek stakeholder input on proposed options and recommendations. The proposed options and recommendations will be included in a paper to the Commission that will identify options and make recommendations. Those options and recommendations may or may not be applicable to research and test reactors. Estimated completion of this review, including the Commission Paper, is August of 2013.

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### List of Risk-Informed and Performance-Based Activities

There are no current Risk-Informed and Performance-Based Activities in the Research and Test Reactors Sub-Arena.

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## Fuel Cycle Sub-Arena

The Nation's fuel cycle facilities comprise one of two sub-arenas that the staff of the U.S. Nuclear Regulatory Commission (NRC) identified in considering which areas of the materials safety arena to target for greater use of risk information. This page summarizes the following aspects of this sub-arena:

- Objective
- Basis
- Goals
- List of Risk-Informed and Performance-Based Activities

### Objective

For fuel cycle facilities, make continuous improvement in licensing and oversight, and risk inform new regulations as needed, while performing existing risk-informed functions.

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### Basis

SECY-99-100 and SECY-04-0182, as well as the related staff requirements memorandum (SRM), provide the conceptual framework for risk-informing the NRC's fuel cycle activities. Guidance on how to apply this framework is provided in "Risk-Informed Decision-Making for Material and Waste Applications, Rev. 1," which is available in the NRC's Agencywide Documents Access and Management System (ADAMS), under Accession No.ML080720238. In particular, individual risk-informed applications must meet the established screening criteria.

The screening criteria applied to the goals (below) of implementing the NRC's revised regulatory requirements, as specified in Title 10, Part 70, of the Code of Federal Regulations (10 CFR Part 70), would indicate that the given activity was undertaken to increase confidence in the margin of safety of fuel cycle facilities by requiring the use of a risk-informed approach to identify and manage items that are relied on for safety. Cost/benefit was not a consideration, and technical feasibility was known because two licensees had already implemented such systems. The revision of 10 CFR Part 70 is expected to reduce staff effort, while improving regulatory effectiveness, by providing more frequent updates of licensee design information and related risk information.

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### Goals

The staff has established the following goals for risk-informed and performance-based activities in this sub-arena:

- Revise the existing licensing guidance to reflect lessons learned from implementation of 10 CFR 70 Subpart H.
- Complete revision of inspection guidance to make use of the resulting risk information to focus inspections.
- Revise the Fuel Cycle Oversight Program to make it more risk-informed and performance-based consistent with Commission direction.

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### List of Risk-Informed and Performance-Based Activities

This list shows the ongoing licensing initiatives, projects, and activities that the staff of the U.S. Nuclear Regulatory Commission (NRC) has targeted for greater use of risk information in the Fuel Cycle Facilities Sub-Arena within the Reactor Safety Arena:

- Rulemaking for Reprocessing Facilities

- Revise the Fuel Cycle Oversight Program (RFCOP)

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## Rulemaking for Reprocessing Facilities

### Summary Description

In SRM-SECY-13-0093, 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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## 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 Revised Fuel Cycle Oversight Process (RFCOP).

### FY 2015 Status

On June 8, 2015, the staff completed and issued the cornerstone development document for public comment. 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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## Byproduct Materials Sub-Arena

Byproduct materials comprise one of two sub-arenas that the staff of the U.S. Nuclear Regulatory Commission (NRC) identified in considering which areas of the materials safety arena to target for greater use of risk information. This page summarizes the following aspects of this sub-arena:

- Objective
- Basis
- Goals
- List of Risk-Informed and Performance-Based Activities

### Objective

Utilize risk information on a case-by-case basis for byproduct material regulation, licensing, and oversight.

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### Basis

NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems," documents an assessment of risks for various byproduct material systems. (This report is not publicly available.) The assessment was used to support NRC staff activities, as described in SECY-00-0048.

In June 2001, the NRC published NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Material," which documents the staff's assessment of doses associated with byproduct and source material exemptions. NUREG-1717 also includes dose assessments for certain devices that are currently used under general or specific licenses that have been identified as candidates for use under exemptions. In addition, staff activities identified in SECY-07-0147, "Response to U.S. Government Accountability Office Recommendations and Other Recommendations to Address Security Issues in the U.S. Nuclear Regulatory Commission Materials Program," will address possible revisions to the agency's regulatory framework.

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### Goals

The staff has established the following goals for risk-informed and performance-based activities in this sub-arena:

- Continue making incremental improvement (as practicable) to enhance the risk-informed and performance-based nature of rulemaking and guidance development, licensing, and oversight activities for byproduct materials.
- Encourage the industry and NRC licensees to use a risk-informed and performance-based approach in demonstrating compliance with the NRC's risk/dose criteria.

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### List of Risk-Informed and Performance-Based Activities

This list shows the ongoing licensing initiatives, projects, and activities that the staff of the U.S. Nuclear Regulatory Commission (NRC) has targeted for greater use of risk information in the Byproduct Materials Sub-Arena within the Reactor Safety Arena:

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

*This page includes links to files in non-HTML format. See [Plugins](#), [Viewers](#), and [Other Tools](#) for more information.*

## **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**

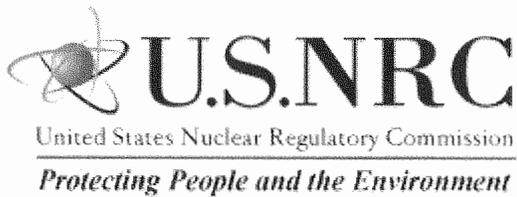
The staff is developing the final rule. More information is on the agency's [Medical Licensing Tool Kit Web site](#).

### **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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## Spent Fuel Storage and Transportation Sub-Arena

Spent fuel storage and transportation comprises one of three sub-arenas that the staff of the U.S. Nuclear Regulatory Commission (NRC) identified in considering which areas of the waste management arena to target for greater use of risk information. This page summarizes the following aspects of this sub-arena:

- Objective
- Basis
- Goals
- List of Risk-Informed and Performance-Based Activities

### Objective

Utilize risk information on a case-by-case basis to prioritize and address regulatory initiatives in spent fuel storage and radioactive materials transportation.

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### Basis

SECY-99-100 and SECY-04-0182, as well as the related staff requirements memorandum (SRM), provide the conceptual framework for risk-informing the NRC's waste activities. Guidance on how to apply this framework is provided in "Risk-Informed Decision-Making for Material and Waste Applications". In particular, individual risk-informed applications must meet the established screening criteria.

In this subarena, the NRC staff is limited in its ability to risk-inform the agency's regulatory activities because it is not cost-beneficial to perform risk-assessment of each of the numerous storage or transport designs. As a result, the agency has conducted (or sponsored) risk assessments for a few selected designs. In addition, the staff may apply risk assessments to specific activities on a case-by-case basis, provided that the screening criteria are met. For example, the staff has completed and documented a pilot study PRA of a dry cask storage facility, and determined that the risk from that facility was negligibly small.

The goal described below meets the screening criterion for cost/benefit by assessing risk impacts by judgment.

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### Goals

The staff has established the following goal for risk-informed and performance-based activities in this subarena:

- Produce updated versions of NUREG-1536, "Standard Review Plan for Dry Cask Storage Systems," and NUREG-1567, "Standard Review Plan for Spent Fuel Dry Storage Facilities."

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### List of Risk-Informed and Performance-Based Activities

This list shows the ongoing licensing initiatives, projects, and activities that the staff of the U.S. Nuclear Regulatory Commission (NRC) has targeted for greater use of risk information in the Spent Fuel Storage and Transportation Sub-Arena within the Reactor Safety Arena:

- Enhance Regulatory Framework for Extended Storage and Transportation
- Regulatory Framework for Spent Fuel Storage and Transportation

*This page includes links to files in non-HTML format. See [Plugins](#), [Viewers](#), and [Other Tools](#) for more information.*

## Enhance Regulatory Framework for Extended Storage and Transportation

### Summary Description

Extended Storage and Transportation (EST) Regulatory Program Review responds to the Commission's direction in SRM-COMSECY-10-0007 to conduct a thorough review of the regulatory programs for spent nuclear fuel (SNF) storage and transportation, and to evaluate their adequacy for ensuring safe and secure storage of SNF for extended periods of time.

### FY 2015 Status

Over the past year, the staff has continued its focus on technical areas where additional information is needed to inform program decisions as documented on 2015 Annual Status Report (SECY-15-0076). During this period, the staff has also begun developing the necessary means to translate this technical information into potential changes in the existing regulatory framework for the Commission's consideration. As has been the case since 2014 Annual Status Report (SECY-14-0057), the staff anticipates that EST efforts are more likely to lead to changes in staff guidance and inspection procedures, rather than changes in regulations.

### Risk Category

Infrastructure development in support of risk-informed regulations

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## 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 develop 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.

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## Low-Level Waste and Decommissioning Sub-Arena

Low-level waste and decommissioning comprise one of three sub-arenas that the staff of the U.S. Nuclear Regulatory Commission (NRC) identified in considering which areas of the waste management arena to target for greater use of risk information. This page summarizes the following aspects of this sub-arena:

- Objective
- Basis
- Goals
- List of Risk-Informed and Performance-Based Activities

### Objective

Facilitate the application of risk-informed and performance-based approaches in implementing the NRC's rulemaking, licensing, and oversight functions for low-level waste, including waste incidental to reprocessing, and decommissioning on a case-by-case basis.

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### Basis

The NRC staff engages with the agency's licensees and stakeholders (including the public) in making significant decommissioning decisions and implementing significant actions focusing on risk-significance and potential environmental impacts. The NRC's Office of Nuclear Material Safety and Safeguards (NMSS), in coordination with the Office of Nuclear Regulatory Research (RES) and the Center for Nuclear Waste Regulatory Analysis (CNWRA), is continuing development, maintenance, and evaluation of probabilistic environmental models and codes for risk/dose analysis. Use of probabilistic distributions as inputs to uncertain physical and behavior parameters is common in independent staff reviews in determining risk-significance and request for additional information development. The NRC also uses probabilistic tools with uncertainty analysis to review and assess dose impacts to demonstrate compliance with the dose criteria set forth in Subpart E of 10 CFR Part 20.

In review of waste determinations to be made by the U.S. Department of Energy that waste is incidental to reprocessing, the staff utilizes risk-informed performance-based approaches including uncertainty/sensitivity analyses and alternate conceptual models. The risk insights gained during the review are utilized to establish the monitoring areas for a site.

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### Goals

The staff has established the following goals for risk-informed and performance-based activities in this subarena:

- Continue to evaluate current dose modeling approaches for low-level waste and decommissioning, and provide recommendations for a path-forward to enhance the use of risk-informed and performance-based approaches in licensing reviews and regulatory implementation.
- Continue making incremental improvement (as practicable) in rulemaking and guidance development, licensing, and oversight, to enhance the use of risk-informed and performance-based approaches.
- Encourage the industry and NRC licensees to use a risk-informed and performance-based approach in demonstrating compliance with the NRC's risk/dose criteria.

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## List of Risk-Informed and Performance-Based Activities

This list shows the ongoing licensing initiatives, projects, and activities that the staff of the U.S. Nuclear Regulatory Commission (NRC) has targeted for greater use of risk information in the Low-Level Waste and Decommissioning Sub-Arena within the Reactor Safety Arena:

- Part 61 Revisions: Require Site-Specific Analysis for Disposal of Unique Waste Streams

*This page includes links to files in non-HTML format. See [Plugins](#), [Viewers](#), and [Other Tools](#) for more information.*

## Part 61 Revisions: Require Site-Specific Analysis for Disposal of Unique Waste Streams

### Summary Description

Conduct rulemaking to require site-specific analysis for licensed low-level waste disposal facilities. This rule improves on the risk-informed, performance-based framework already present in Part 61 to ensure that the safety analyses performed to evaluate long-term isolation are comprehensive and consistent. The proposed rule (80 FR 16082) and related guidance (80 FR 15930) were published in the Federal Register for public comment on March 26, 2015. The comment period originally ended on July 24, 2015. It was reopened (80 FR 51964) on August 27, 2015 and closed on September 21, 2015.

### FY 2015 Status

Developing SECY for final rule

### Risk Category

Rulemaking applications using risk insights

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## Cross-Cutting Activities

This list shows the ongoing licensing initiatives, projects, and activities that the staff of the U.S. Nuclear Regulatory Commission (NRC) has targeted for greater use of risk information that substantially crosscut multiple subarenas within the Reactor Safety Arena:

- Risk-Informed Steering Committee (RISC)
- Risk Management Regulatory Framework (RMRF)
- NRC "Grow Your Own" PRA Capability
- Update Regulatory Guide 1.174, An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant Specific Changes to the Licensing Basis
- Update RG 1.200, An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities
- Update NUREG 1855, Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decisionmaking

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### 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. Additional information is available.

#### FY 2015 Status

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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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### Risk Management Regulatory Framework (RMRF)

**Summary Description**

NUREG-2150, "A Proposed Risk Management Regulatory Framework" recommended that a RMRF applicable to all NRC program areas be adopted by the NRC. The Chairman's tasking memorandum dated June 14, 2012 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 on SECY-13-0132 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, 2015, and July 29, 2015. 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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**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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**Update Regulatory Guide 1.174, An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant Specific Changes to the Licensing Basis****Summary Description**

This activity is a review and update of Regulatory Guide (RG) 1.174 and other related guidance documents (e.g., RGs 1.175, 1.177, and 1.178) to incorporate revised and new guidance and insights resulting from other related work on risk-informed activities.

**FY 2015 Status**

The current status of this activity remains unchanged from the previous risk-informed activities update. Additional information is available.

**Risk Category**

ML14295A220

Infrastructure development in support of risk-informed regulations. The purpose of the review and update is to incorporate revised and new guidance and insights related to the development of PRA consensus standards; insights gained from the Risk Management Regulatory Framework activities; and consideration of information related to NRC's efforts to better integrate the concepts of defense-in-depth and risk-informed regulation, which is intended to help assure that the NRC's defense-in-depth philosophy is interpreted and implemented consistently within a risk-informed regulatory framework.

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## **Update RG 1.200, An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities**

### **Summary Description**

To support risk-informed regulatory activities, the expectations for PRA technical acceptability need to be provided. These expectations are in Regulatory Guide (RG 1.200) which provides the staff position regarding what constitutes a technically acceptable PRA and how the PRA standards and peer review guidance are used to demonstrate conformance with the staff position. In this regard, RG 1.200 provides a staff position (i.e., endorsement) of the published ASME/ANS PRA standards and the NEI peer review guidance documents.

### **FY 2015 Status**

Staff continues to work with standard developing organization (SDO) and industry to develop necessary PRA standards and related peer review guidance for defining PRA technical acceptability in support of risk-informed activities.

### **Risk Category**

Infrastructure development in support of risk-informed regulations. The purpose is to ensure the agency position on any changes to the PRA standard is documented.

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## **Update NUREG 1855, Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decisionmaking**

### **Summary Description**

This document provides guidance on how to treat uncertainties associated with PRA in risk-informed decision-making with regard to: 1) Identifying and characterizing the uncertainties associated with PRA in support of the PRA standard, 2) Performing uncertainty analyses to understand the impact of the uncertainties on the results of the PRA, and 3) Factoring the results of the uncertainty analyses into decision-making. This NUREG also provides guidance on how to meet the ASME/ANS PRA standard requirements for addressing uncertainties in the PRA model. NRC recognized that the Electric Power Research Institute (EPRI) also was performing work in this area with similar objectives. Both NRC and EPRI believed a collaborative effort to have technical agreement and to minimize duplication of effort would be more effective and efficient.

### **FY 2015 Status**

Revision to the document is under review.

### **Risk Category**

Infrastructure development in support of risk-informed regulations.

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