

2017 Risk Informed Activity Entire Public Website Update

ADAMS Record of Information Released to the Public

This document continues the practice of retaining a record of information released to the public as was done last year, "2016 Risk Informed Activity Entire Public Website Update", Agencywide Documents Access and Management System (ADAMS) ML17039A668.

In Staff Requirements Memorandum (SRM), "BRIEFING ON STATUS OF RISK-INFORMED AND PERFORMANCE-BASED REACTOR REGULATION" (Agencywide Documents Access and Management System (ADAMS) ML061520304), dated June 6, 2006, the Commission directed:

"The staff should seek ways to communicate the purpose and use of PRAs in NRC's reactor regulatory program more transparently to the public and stakeholders."

The Risk-Informed Activity website accomplishes this transparency. The webpage can be accessed directly by using this URL link: <http://www.nrc.gov/about-nrc/regulatory/risk-informed/rpp.html>.

Contact Dale Yeilding at 301-415-0898 with any questions.



[Home](#) > [About NRC](#) > [How We Regulate](#) > [Risk Assessment](#) > [Current Risk-Informed Activities](#)

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
 - 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)
- Past Inactive Risk-Informed Activities

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.

[↑ TOP](#)

Page Last Reviewed/Updated Wednesday, May 09, 2018



[Home](#) > [About NRC](#) > [How We Regulate](#) > [Risk Assessment](#) > [Current Risk-Informed Activities](#) > [Operating Reactors Sub-Arena](#)

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.

[TOP](#)

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.

[TOP](#)

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.

[TOP](#)

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:

- State-of-the-Art Reactor Consequence Analyses
- Probabilistic Methodologies for Component Integrity Assessment
- Implementing Lessons Learned from Fukushima
- Accident Sequence Precursor (ASP) Program
- Design Compliance Enforcement Discretion (DCED): a Risk-Informed Approach for Addressing Low Risk, Low Safety Significance Design Compliance Issues
- Probabilistic Flood Hazard Assessment (PFHA)
- Methods, Tools and Guidance for Including Digital Systems in Nuclear Power Plant PRAs
- Risk Assessment of Operation Events (RASP Handbook)
- 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
- Consequential Steam Generator Tube Rupture Probability and Consequence Assessment
- National Fire Protection Association (NFPA) Standard 805
- Assess Debris Accumulation on Pressurized Water Reactor (PWR) Sump Performance, Generic Safety Issue (GSI)-191
- 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.

State-of-the-Art Reactor Consequence Analyses

Summary Description

The state-of-the-art reactor consequence analyses (SOARCA) project was initiated to evolve our understanding of the consequences of important severe accident scenarios at selected U.S. nuclear power plants including Peach Bottom, a BWR in Pennsylvania; Surry, a PWR with a large dry containment in Virginia; and Sequoyah, a PWR with an ice condenser containment in Tennessee. The project has focused on detailed modeling of accident progression using MELCOR and offsite consequences using MACCS (MELCOR Accident Consequence Code System). MELCOR models the severe accident processes within the plant to the point of release of fission products to the environment. MACCS models the atmospheric transport and deposition of radionuclides released to the environment as well as emergency response and long-term protective actions, exposure pathways, dosimetry, and health effects for the affected population. Staff conducted uncertainty analyses

(UA) of a subset of the scenarios to better understand the range of potential outcomes for these accidents and what drives key phenomena. Each UA included hundreds of simulations to account for uncertainty in MELCOR and MACCS input parameters and the results help corroborate the project's overall conclusions.

The staff completed deterministic and sensitivity analyses of Peach Bottom and Surry which are documented in NUREG-1935, NUREG/CR-7110, and NUREG/BR-0359. A UA was conducted for the Peach Bottom unmitigated long-term station blackout (LTSBO) scenario and was documented in NUREG/CR-7155. Subsequently the Commission approved in SRM-SECY-2012-0092 limited additional analyses to further address the SOARCA objectives and to also support agency projects such as evaluation of Fukushima Near Term Task Force recommendations and the Full-Scope Site Level 3 PRA project.

FY 2017

In FY 2017 staff completed an updated uncertainty analysis (UA) of the Sequoyah unmitigated short-term station blackout (STSBO) scenario and briefed the NRC's ACRS. This work will be published in a NUREG/CR report. In FY 2018 the staff is continuing to work on an updated UA of the Surry unmitigated STSBO leveraging insights from the Sequoyah UA.

Risk-Informed Basis

By its nature SOARCA focuses on the consequences of accidents rather than on their likelihood or on the many redundant safety systems, components, procedures, training, strategies, or the recently added backup mitigation equipment required following the Fukushima Dai-ichi nuclear power plant accident in Japan. Plant safety features and added mitigation capability drive down the likelihood of a severe accident but not necessarily the consequences. The study of the unmitigated consequences of a severe accident does not dismiss or under-value those safety features, rather it sheds light on their importance by providing insights into the possible consequences they are intended to prevent. SOARCA project's results, insights, computer code models, and modeling best practices have supported NRC rulemaking, licensing, and oversight efforts. SOARCA supported SECY-15-0137 and SECY-16-0041 which closed NRC's evaluation of post-Fukushima recommendations related to containment vents and hydrogen control and mitigation.

[TOP](#) | [RETURN TO LIST](#)

Probabilistic Methodologies for Component Integrity Assessment

Summary Description

The U.S. Nuclear Regulatory Commission (NRC) has considered insights drawn from probabilistic methodologies for component integrity assessment as part of its regulatory decision-making for several decades. The use of probabilistic methods moves the agency further towards risk-informed decision-making, which is a stated policy goal of the NRC. Furthermore, the NRC needs methodologies and procedures that enable it to perform an educated, thoughtful review of probabilistic methods proposed by the industry. The NRC currently has several active projects related to probabilistic methodologies for component integrity assessment: (1) maintenance and improved verification and validation of the Fracture Analysis of Vessels – Oak Ridge (FAVOR) code, (2) development and release of the Extremely Low Probability of Rupture (xLPR) code, and (3) development of a probabilistic fracture mechanics (PFM) Regulatory Guide.

The NRC and the U.S. nuclear industry have used probabilistic methods to inform their evaluation of postulated pressurized thermal shock (PTS) of reactor pressure vessels (RPVs) since the 1980s. In the original PTS rule (10 CFR 50.61) probabilistic evaluations provided complementary information to deterministic evaluations, and the reference temperature (RTPTS) screening criteria in 10 CFR 50.61 relate to a vessel failure frequency of $\approx 5 \times 10^{-6}$ events / reactor operating year. Several PFM codes were used in the 1980s, including VISA (Vessel Integrity Simulation Analysis) and OCA-P (Over Cooling Accident - Pressurized). In the mid-1990s these codes were combined to generate the FAVOR code, which later provided computational support for the technical basis of the alternate PTS rule, 10 CFR 50.61a. FAVOR has since found other applications (e.g., risk-informed pressure-temperature limits, evaluation of nil-ductility transition [RTNDT] uncertainties, and evaluation of quasi-laminar flaws), although these other applications have not garnered generic regulatory acceptance.

In a separate activity, NRC and the Electric Power Research Institute (EPRI) have collaboratively developed the xLPR Version 2.0 PFM code to assess the effects of active degradation mechanisms on nuclear power plant piping systems approved for leak-before-break (LBB). Specifically, beginning around the year 2000, primary water stress corrosion cracking (PWSCC) was discovered in systems that had previously been approved for LBB based on the assumed absence of active degradation mechanisms, in accordance with the General Design Criteria in 10 CFR 50. As a result of the discovery of the PWSCC active degradation mechanism, an extremely low probability of rupture could no longer be demonstrated by the deterministic methods outlined in NUREG-0800, but would instead need to be addressed probabilistically, for instance by using a PFM code such as xLPR. Technical development of the full production version of the code is now complete. Various activities were undertaken during the development phase to build confidence into the code, including a broad team of experts from diverse backgrounds, a rigorous quality assurance program, comprehensive verification and validation, and extensive documentation.

With the release of FAVOR v16.1 and xLPR v2.0, PFM use by the U.S. nuclear industry is expected to increase, as PFM may be used to develop a technical basis for relief requests, license amendments, and topical reports. Uncertainty is addressed differently in PFM when compared to deterministic fracture mechanics. In PFM, a single deterministic (usually conservative) analysis is replaced by many deterministic analyses that use randomly sampled inputs. Statistical analyses are then performed on the collection of outputs obtained to determine the probability of an event of interest. Unfortunately, it is difficult for NRC staff to reproduce or verify PFM calculations submitted by licensees, thus resulting in complex regulatory reviews. In particular, NRC staff has often perceived PFM codes as 'black boxes' with insufficient vetting of the models and the uncertainty framework. This has resulted in low confidence in the results of PFM analyses. As a result, the NRC has begun developing guidance for performing and documenting PFM analyses for regulatory applications. Specifically, NRC's Office of Nuclear Regulatory Research has been tasked with developing a PFM Regulatory Guide (RG). The process of developing the RG involves publication of a Technical Letter Report, a technical basis NUREG, and the Draft RG itself. The Technical Letter Report will be released publicly before the end of 2017.

FY 2017

A recent release of FAVOR, Version 16.1, includes updated fracture driving force solutions for surface-breaking flaws and the ability to analyze both heat-up and cool-down transients in the shell coarse region of both pressurized water reactor (PWR) and boiling water reactor designs. Planned efforts are underway to assess potential safety issues related to shallow subsurface flaws, including warm pre-stress effects, cladding residual stress modeling, and an assessment of risk-optimized pressure-temperature corridors for RPV heat-up and cooldown. NRC and EPRI are currently pursuing coordinated efforts to apply xLPR to conduct probabilistic LBB studies for the U.S. fleet of PWRs. A Technical Letter Report on important aspects to be considered for PFM has been produced and lays the foundation for the upcoming development of the PFM RG and its technical basis.

Risk-Informed Basis

PFM is typically used to determine the likelihood of a component failure, or the likelihood of a precursor to component failure. As such, PFM can answer one of the two fundamental questions in risk assessment: what is the initiating event frequency or likelihood of occurrence? The other question that PFM does not address is: what are the consequences of such an event occurring? In addition to the likelihood of an event, PFM can also be used to determine confidence bounds on the probability of an even of interest.

[TOP](#) | [RETURN TO LIST](#)

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

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.

FY 2016

The NRC staff made significant progress in developing the infrastructure to support its review of licensees' submittals of the results of their seismic probabilistic risk assessments (PRAs). The first such submittal is expected to be received in the first quarter of calendar year 2017.

FY 2017

The NRC completed the development of the infrastructure to support the review of licensees' seismic PRA submittals. The NRC received three seismic PRA submittals, on a staggered schedule over the course of the year, and began implementing the review process. The first staff assessment of a seismic PRA submittal is expected to be issued by the NRC in the first quarter of calendar year 2018. The NRC expects to receive five more seismic PRA submittals in 2018, and the remainder of the seismic PRA submittals in 2019, all on a staggered schedule. More information on this risk-informed initiative can be found on the NRC's Seismic Reevaluations Web page.

Risk-Informed Basis

Seismic PRAs will be submitted to and reviewed by the NRC staff for about 20 sites. The risk insights from the seismic PRAs will be used by the staff to evaluate the impact of the site-specific reevaluated seismic hazard and determine whether further regulatory actions are warranted.

[TOP](#) | [RETURN TO LIST](#)

Accident Sequence Precursor (ASP) Program

Summary Description

In 1979, the U.S. Nuclear Regulatory Commission (NRC) established the Accident Sequence Precursor (ASP) Program in response to the Risk Assessment Review Group report issued in September 1978 (NUREG/CR-0400, "Risk Assessment Review Group Report to the U.S. Nuclear Regulatory Commission"). The evaluations performed for events that occurred between 1969 and 1979 were the first efforts in this type of analysis. The ASP Program systematically evaluates U.S. nuclear power plant operating experience to identify, document, and rank operational events by calculating a conditional core damage probability (CCDP) or an increase in core damage probability (Δ CDP).

The ASP Program identifies potential precursors by reviewing operational events from licensee event reports on a plant unit basis. An operational event can be one of two types: (1) the occurrence of an initiating event, such as a reactor trip or a loss of offsite power, with or without any subsequent equipment unavailability or degradation; or (2) a degraded plant condition characterized by the unavailability or degradation of equipment without the occurrence of an initiating event.

For the first type of event, the staff calculates a CCDP. This metric represents a conditional probability that a core damage state is reached given the occurrence of the observed initiating event (and any subsequent equipment failures or degradations). For the second type of event, the staff calculates a Δ CDP. This metric represents the increase in core damage probability for the time period during which a component or multiple components were deemed unavailable or degraded.

Starting in 2006, in an effort to minimize overlap and improve efficiency, Significance Determination Process (SDP) results have been used in lieu of independent ASP analyses to the extent practical and consistent with the overall objectives of both programs. More information regarding the details of this change is documented in NRC Regulatory Issue Summary 2006-24.

FY 2015

The ASP Program independently identified five precursor events in Fiscal Year (FY) 2015. In addition, four precursor events were analyzed by the SDP and accepted into the ASP Program (as described in NRC Regulatory Issue Summary 2006-24). See SECY-15-0124, "Status of the Accident Sequence Precursor Program and the Standardized Plant Analysis Risk Models," for more information on the status of the ASP Program for FY 2015.

FY 2016

In FY 2016, the ASP Program implemented a variety of administrative changes. In accordance with Project AIM, and by direction of the Commission, the status of the ASP Program will no longer be reported in the annual SECY paper "Status of the Accident Sequence Precursor Program and the Standardized Plant Analysis Risk Models." Instead, an annual summary of the ASP Program will be provided as a publicly available document. In addition, the ASP Program transitioned from a FY reporting cycle to a calendar year (CY) reporting cycle. Operational events will be organized based on the CY in which the licensee event report is submitted to the NRC. As part of this transition, the FY 2015 annual report was combined with the CY 2016 report. Annual summary reports will be made available to the public in the following CY (e.g., the CY 2016 annual report was made available to the public in CY 2017).

The NRC's Risk-Informed Steering Committee initiated an internal evaluation of the ASP Program in July 2016, performed by staff within the Office of Nuclear Reactor Regulation. A public meeting was held on October 13, 2016, to solicit feedback from external stakeholders and members of the public.

FY 2017

In FY 2017, the ASP Program published the "U.S. Nuclear Regulatory Commission Accident Sequence Precursor Program 2016 Annual Report," which summarizes the results of ASP analyses for events reported between October 2014 and December 2016. Twenty-three events were determined to be precursors. Of these 23 precursors, 15 precursors utilized SDP results in accordance with RIS 2006-24 and the remaining 8 precursors were identified via independent ASP analyses. Three of the events identified by ASP analyses had a CDDP or Δ CDP greater than or equal to 1×10^{-5} .

The NRC continues its internal evaluation of the ASP Program with a focus on identifying resource efficiencies through process changes, increasing the use of ASP results in other NRC processes, and ensuring timeliness of ASP analyses to support internal and external stakeholder needs. Recommended changes to the ASP Program will likely be communicated in early FY 2018.

Risk-Informed Basis

The ASP Program analyzes potential precursors by calculating the probability of an event leading to a core damage state. The analyses of operational events are conducted using the NRC's Standardized Plant Analysis Risk (SPAR) models and the Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE) software.

The ASP Program is one of three agency programs that assess the risk significance of issues and events. The other two programs are the Reactor Oversight Process (ROP) SDP and the event response evaluation process, as defined in Management Directive (MD) 8.3, "NRC Incident Investigation Program." In contrast to the other two programs, a comprehensive and integrated risk analysis under the ASP Program includes all anomalies observed at the time of the event or discovered after the event. These anomalies may include unavailable and degraded plant structures, systems, and components (SSCs); human errors; and/or an initiating event (e.g., reactor trip). An unavailable or degraded SSC does not have to be a performance deficiency (PD) or an analyzed condition in the plant design basis, as required in the SDP. The ASP Program analyzes concurrent, multiple PDs or degraded conditions together, unlike the SDP that analyzes PDs individually.

The ASP Program results are used to support programmatic and regulatory decisions. Specifically, RES provides recommendations for any programmatic or regulatory reviews based on results of adverse ASP trends and results of precursor analyses identifying a potentially generic issue. The ASP program provides unique and independent inputs to the Report to Congress on Abnormal Occurrences (NUREG-0090), Congressional Budget Justification (NUREG-1100), Performance and Accountability Report (NUREG-1542), Strategic Plan (NUREG-1614), and the NRC's Agency Action Review Meeting (AARM).

[TOP](#) | [RETURN TO LIST](#)

Design Compliance Enforcement Discretion (DCED): a Risk-Informed Approach for Addressing Low Risk, Low Safety Significance Design Compliance Issues

Summary Description

The agency is developing a risk-informed approach to resolve licensee design issues that render a technical specification structure, system or component inoperable and 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 design non-conformance 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 and safety significance of the non-compliance. If the issue is determined to be of low risk and low safety significance, 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

In September 2015, a working group with members from NRR, the Regions, OGC, and OE was formed, and began 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 also looked at the process for implementing this new approach. One implementation method that was considered was modifying the Notice of Enforcement Discretion (NOED) process to provide a process for addressing for low risk, low safety significance design compliance issues in a risk-informed manner.

FY 2016

Three public meetings were held to discuss this initiative. The meetings were held at NRC Headquarters on February 3, 2016, April 11, 2016, and May 23, 2016. The Commission was also briefed on the initiative during the Operating Reactor Business Line briefing on July 7, 2016. A draft outline of the proposed process was developed and circulated within NRR, the Regional Offices, OE and OGC for comment.

FY 2017

After modification of the draft outline based on internal feedback, the outline was made publicly available for feedback from external stakeholders. Based on feedback received from internal and external stakeholders from the review of the draft outline for the proposed DCED process, a draft DCED procedure was developed and circulated internally for review and a draft Commission Notation Vote paper was prepared. However, the DCED Commission Paper due date was extended to October 2018 for the following reasons:

So the staff can examine new guidance documents that are under development (e.g., backfit guidance resulting in part from Commission direction in SRM-COMSECY-16-0020 and operability guidance under development by NEI) and evaluate their potential for reducing the number of low risk and low safety significance operability issues created by non-compliances with design requirements.

If the staff concludes that the new guidance documents are unlikely to significantly reduce the number of DCED candidate issues, the staff will explore additional options consistent with feedback received from both internal and external stakeholders. The options will seek to: better balance the public's hearing rights with risk-informing the agency's response to low risk, low safety significance operability issues, align on the extent to which technical specifications can and should be risk-informed, and engage more extensively with external stakeholders.

Risk-Informed Basis

The proposed process will utilize risk insights as one of the criteria to determine if a design issue is a candidate for the licensee to request enforcement discretion under the proposed DCED process.

[TOP](#) | [RETURN TO LIST](#)

Probabilistic Flood Hazard Assessment (PFHA)

Summary Description

The PFHA research program is a wide-ranging effort to establish a sound technical basis for transitioning flood hazard assessment guidance and tools from deterministic to probabilistic approaches. The PFHA research is guided by a joint NRO-NRR 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 in 2014. RES has been implementing the research plan for approximately 3 years.

By supporting development of risk-informed licensing and oversight guidance and tools for assessing flooding hazards and consequences, this research addresses a significant gap in the probabilistic basis for external hazards since seismic and wind hazard assessments are currently conducted on a probabilistic basis. The PFHA research program is designed to support both new reactor licensing (e.g. design basis flood hazard assessments for new sites or facilities) and oversight of operating reactors (e.g. significance determination process analyses for evaluating inspection findings or event assessments involving flood hazards, flood protection, or flood mitigation at operating facilities).

FY 2015

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 Institut de Sûreté Nucléaire et de Radioprotection (IRSN).

FY 2016

Thirteen research projects have been initiated via interagency agreements with the US Army Corps of Engineers, the US Geological Survey, the Bureau of Reclamation, Idaho National Laboratory (INL), and Pacific Northwest National Laboratory (PNNL). A fourteenth project is being conducted with the University of California at Davis via a cooperative research contract with USGS under authority of the Water Resources Research Act. A fifteenth research activity has been implemented as a commercial contract. Cooperative research efforts have been initiated with the Electric Power Research Institute (EPRI) under a Flooding Research Addendum to an existing NRC-EPRI MOU. A cooperative research agreement is under development with the French Institut de Sûreté Nucléaire et de Radioprotection (IRSN).

FY 2017

Progress has continued on the existing projects initiated via interagency agreements and cooperative research contracts with other agencies and commercial contracts, as reported last year. A number of technical reports have been completed. Two new projects have been initiated via interagency agreement with Oak Ridge National Laboratory. The 2nd annual program review on the progress of PFHA research projects was held on January 23-25, 2017 at NRC headquarters. Cooperative research efforts with the Electric Power Research Institute (EPRI) have continued under the Flooding Research Addendum to an existing NRC-EPRI MOU. Two technical exchanges with EPRI were held in FY 2017. The technical aspects of a cooperative research agreement with the French Institut de Sûreté Nucléaire et de Radioprotection (IRSN) were completed and the agreement is under review by IRSN and NRC management.

Risk-Informed Basis

This activity is risk-informed because it addresses several aspects of risk: (1) probability or frequency of occurrence for various flooding scenarios; (2) fragility of flood protection features; and (3) reliability of flood protection and mitigation procedures.

[TOP](#) | [RETURN TO LIST](#)

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

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 FY 2016.
- 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 FY 2016.

More background on this approach can be found in the transcripts from an ACRS subcommittee meeting held in November 2014.

FY 2016

In collaboration with the Korea Atomic Energy Research Institute, the staff completed the development of an approach for quantifying software reliability using a Bayesian Belief Network (BBN)-based model. A NUREG/CR report describing the BBN approach was submitted for publication in FY 2016. The PRA-based statistical testing method was applied to the INL Advanced Test Reactor Loop Operating Control System. A NUREG/CR report describing the statistical testing application was submitted for publication in FY 2016.

FY 2017

In May 2017, the NRC published NUREG/CR-7234, "Development of a Statistical Testing Approach for Quantifying Safety-Related Digital System on Demand Failure Probability." At this time, there are no plans for future work in this area as under Project AIM, support for work in this area was eliminated.

Risk-Informed Basis

This research program aims to develop methods to quantify safety related digital I&C system failure probabilities that enable the inclusion of digital I&C components into current NPP PRAs.

[TOP](#) | [RETURN TO LIST](#)

Risk Assessment of Operation Events (RASP Handbook)

Summary Description

Provide methods and guidance for the risk-informed analysis of operational events and licensee performance issues including internal and external events during both full power and low-power/shutdown operations.

Risk-Informed analyses are performed in response to needs identified in: Management Directive 8.3, "Incident Investigation Program"; Reactor Oversight Process; the Significance Determination Process (SDP); and the Accident Sequence Precursor (ASP) program. State-of-the-practice methods and guidance support risk analysts and senior reactor analysts from various NRC offices (NRR, RES, NRO, and the Regions) that use risk analysis software (SAPHIRE) and plant-specific PRA model (SPAR models).

The Risk Assessment Standardization Project (RASP) handbook and associated internal web site provides guidance and a description of the methods the NRC staff uses to achieve consistent results in the performance of risk-informed studies 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 incorporates best practices gleaned from experience on accident precursor events performed in ASP reviews and other insights gained from SDP analyses.

FY 2015

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.

FY 2016

The staff prepared for the publication of a NUREG on the application of Common Cause Failure (CCF) Analysis in Event and Condition Assessment. The intent of this report is to provide acceptable methods that the staff will accept in the area of CCF when applied to identified component and system failures which typically occur as part of SDP and ASP evaluations.

FY 2017

The staff prepared for the publication of a NUREG on the basis for the treatment of potential common-cause failure in risk-informed analysis. The intent of this report is to provide acceptable methods that the staff will perform in the area of potential CCF when applied to identified component and system failures which typically occur as part of SDP and ASP evaluations.

The staff revised the RASP handbook volume on internal events that provides additional guidance on how to credit alternate mitigating strategies (e.g., FLEX) in risk assessments. These mitigating strategies employ plant responses which utilize portable equipment to restore or maintain various safety functions during beyond design basis conditions and the loss of permanently installed plant equipment.

Risk-Informed Basis

This activity helps to put a risk perspective on operational events and inspection findings. It is not always obvious how much actual risk is associated with identified violations or component/system failures. This activity attempts to take advantage of insights gained using PRA modeling as applied to operational events discovered during normal operations, which have the potential to contribute to nuclear plant risk. As such, it provides a different and independent perspective on nuclear plant performance than would be available simply by tracking compliance with plant technical specifications and operational directives.

[TOP](#) | [RETURN TO LIST](#)

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 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), Accident Sequence Precursor (ASP) program, risk-informing 10 CFR Part 50, vulnerability assessment, advanced reactor assessment, operational experience, generic issues, and regulatory backfit.

FY 2015

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

FY 2016

The SAPHIRE development team continues to maintain the code's performance and add new features in accordance with the SAPHIRE software quality assurance program. During FY 2016 two new SAPHIRE versions were released for use by NRC staff. Improvements include enhanced seismic hazard modeling capability and development of a new quantification approach with improved accuracy for models involving high failure probabilities.

FY 2017

The SAPHIRE development team released one new version of the SAPHIRE software during FY 2017. A number of improvements were made to the reporting capabilities and user options. In addition, the number of modeled accident sequences that SAPHIRE can store was increased from 2,000,000 to 4,500,000, which was necessary as the size and complexity of models continues to grow. The new version release coincided with a significant update to all the SPAR models. The SAPHIRE team performed extensive testing with the new SAPHIRE version to identify and resolve any issues prior to releasing the updated models. The SAPHIRE development team continues to maintain the code's performance and add new features in accordance with the SAPHIRE software quality assurance program.

Risk-Informed Basis

The SAPHIRE computer code is used to develop and run PRA models (e.g., SPAR models) for a variety of risk-informed regulatory applications.

[TOP](#) | [RETURN TO LIST](#)

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. Nuclear Power Plant (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

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."

FY 2016

The staff continued to develop new SPAR model capabilities and provide technical support for SPAR model users and risk-informed programs. The staff maintains and implements a quality assurance (QA) plan for the SPAR models to ensure that the models appropriately represent the as-built, as-operated nuclear plants to support the assessment of operational events within the staff's risk-informed regulatory activities. The SPAR QA Plan provides mechanisms for model benchmarking and reviews, validation and verification, and configuration control of the SPAR models. In addition, about half of the SPAR models are updated to reflect significant plant modifications or other plant or modeling changes.

The staff also continued developing the SPAR model for the AP1000 new reactor design, adding a low power shut down model and a level 2 PRA model for the AP1000 reactor design.

FY 2017

The staff continued to maintain all SPAR models, with the implementation of the QA plan to represent the as built-as operated nuclear plants; and continued to provide technical support for SPAR model users and risk-informed programs. During FY 2017, the staff updated all SPAR models to reflect the most recent plant reliability data. For new reactor designs, the staff continued to work on expanding the AP1000 SPAR model capabilities (e.g., shutdown and Level 2 model); and initiated work on plant specific SPAR models for Vogtle (AP1000).

Risk-Informed Basis

The SPAR models are used by NRC staff in support of risk-informed activities related to the inspection program, incident investigation program, license amendment reviews, performance indicator verification, accident sequence precursor program, generic safety issues, and special studies. These models also support and provide rigorous and peer reviewed evaluations of operating experience, thereby demonstrating the agency's ability to analyze operating experience independently of licensees' risk assessments and enhancing the technical credibility of the agency.

[TOP](#) | [RETURN TO LIST](#)

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

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.

FY 2016

A substantial revision was completed for the reactor, at-power, Level 1 PRAs for internal events and internal floods, and the associated reports are nearing completion. The reactor, at-power, Level 1 PRAs for internal fires and seismic events were significantly revised to incorporate more recent licensee-supplied information, and are currently undergoing internal technical review. The dry cask storage (DCS) PRA was completed for all PRA levels and all hazards, and reviewed internally. In response to review comments, the consequence analysis for the DCS PRA is now undergoing revision. An initial reactor, low power and shutdown, Level 1 PRA for internal events is nearing completion. An approach was developed for modeling integrated site risk and a pilot application of this approach was performed based on the results of the revised Level 1 PRAs for internal events for Vogtle, Units 1 and 2. A similar pilot application is being performed based on the results of the initial Level 2 PRAs for internal events for Vogtle, Units 1 and 2.

FY 2017

A substantial revision was completed for the reactor, at-power, Level 2 PRA for internal events and internal floods, and is currently undergoing final project management review. Work is nearing completion on a substantial revision to the reactor, at-power, Level 3 PRA for internal events and internal floods. The reactor, at-power, Level 1 PRAs for internal fires and seismic events have completed their internal technical reviews, and are currently undergoing project management review. Substantial revisions were completed for the reactor, at-power, Level 1 PRA for high winds and the qualitative screening analyses for other hazards, and both are currently undergoing final project management

review. The DCS PRA for all PRA levels and all hazards was revised and is currently undergoing project management review. An initial reactor, low power and shutdown (LPSD), Level 1 PRA for internal events was completed and is currently in queue for project management review. Two-unit pilot applications of the integrated site risk approach were completed for the Level 2 PRA for internal events, the Level 1 PRA for seismic events, and the Level 1 PRA for LPSD (one unit in operation, and one unit in shutdown).

Risk-Informed Basis

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 PRA project are expected to benefit a variety of ongoing risk-informed regulatory initiatives.

[TOP](#) | [RETURN TO LIST](#)

Data Collection for Human Reliability Analysis (HRA)

Summary Description

Consistent with the Commission's policy statements on the use of probabilistic risk assessment (PRA) and for achieving an appropriate PRA quality for NRC risk-informed regulatory decision-making, the NRC has ongoing activities to improve the quality of human reliability analysis (HRA). The adequacy of data available for HRA is a concern on the credibility and consistency of human error probability estimates. To address this need, NRC's Office of Nuclear Regulatory Research (RES) has developed the Scenario Authoring, Characterization, and Debriefing Application (SACADA) system to collect operator performance information in simulator exercises. RES has collaborated with nuclear power plants and research institutes to use the SACADA system to collect their simulator training, examination, and experiment data. In addition, RES reviews literature and operations experience, and plans to collaborate with nuclear power plants to collect the human performance information of actions performed outside of the main control room. This includes actions to implement FLEX strategies to support the data needs identified by the Office of Nuclear Reactor Regulation (NRR).

FY 2015

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.

FY 2016

The following two SACADA collaborations were established in FY 2016:

- The Taiwan Power Company (TPC): To support this agreement, RES, with support of TPC, developed a Chinese version of SACADA for TPC plants to use. RES, with the support of the South Texas Project Nuclear Operating Company and the Idaho National Laboratory, provided SACADA training to the TPC instructors. TPC is piloting the SACADA system.
- The Advanced Test Reactor (ATR) of the Department of Energy: The ATR has used the SACADA system and has made data accessible to the NRC since June 2016.

FY 2017

The following are tasks accomplished in FY 2017:

- Established an agreement with the Grand Gulf Nuclear Generating Station to use the NRC's SACADA system to collect the licensed operator performance information in simulator training and to share the information with the NRC for improving HRA techniques.
- Awarded two contracts to perform independent analysis of the SACADA data for HRA. The results will be presented at a NRC-hosted HRA data workshop on March 15 and 16, 2018 at the NRC headquarters.

The following are activities are either in process or performed:

- Establishing an agreement for the Vogtle Unit 3 and Unit 4 site to use the NRC's SACADA system for operator simulator training. After the operators are licensed, the performance data will be shared with the NRC to improve HRA techniques.
- Performing literature and operations experience review to inform human performance assessment of FLEX strategy implementation.

- Plan to host a SACADA data workshop in March 2018 to discuss SACADA data analysis results and improvements.
- In negotiation with Entergy to collaborate on expanding the SACADA scope to collect operator performance in simulator training, on the job training, written tests, and actual events.
- Continue outreach to NRC licensees on using SACADA for operator simulator training.

Risk-Informed Basis

Human reliability analysis results are used in the NRC's risk-informed regulatory activities such as the reactor oversight process. The collected data would improve the reliability of NRC's HRA methods. That, in turn, improves the reliability of the NRC's risk-informed decision-making.

[TOP](#) | [RETURN TO LIST](#)

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 enhancement involves improving 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 available to evaluate human performance. The ongoing activities include:

- Developing the Integrated Human Event Analysis System (IDHEAS) for risk analyses of all nuclear-related HRA applications (SRM-M061020)
- Developing IDHEAS application for event and condition analysis (IDHEAS-ECA)

Regulatory Guide (RG) 1.200 provides an acceptable approach for determining the technical adequacy of probabilistic risk assessment (PRA) results for risk-informed regulation. HRA is a key element in the PRA. Because various HRA methods often have different assumptions and approximations that could lead to significant variability in results affecting regulatory decisions, enhancing the consistency and quality of HRA could improve regulatory decision-making.

FY 2015

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.

FY 2016

The following are tasks accomplished in FY 2016:

- Published NUREG-2199, Vol.1, "An Integrated Human Event Analysis System (IDHEAS) for Nuclear Power Plant Internal Events At-Power Application".
- Completed the testing of IDHEAS for internal at-power applications.
- Published NUREG-2156, "The U.S. HRA Empirical Study – Assessment of HRA Method Performances against Operating Crew Performance on a U.S. Nuclear Power Plant Simulator".
- Published NUREG-2180, "Determining the Effectiveness, Limitations, and Operator Response for Very Early Warning Fire Detector Systems in Nuclear Facilities (DELORES-VEWFIRE)".

FY 2017

The following are tasks accomplished in FY 2017:

- Published NUREG-2170, "A Risk-informed Approach to Understanding Human Error in Radiation Therapy"
The following are activities are in process:
 - Completing the IDHEAS framework for risk analyses of all nuclear-related HRA applications.
 - Developing the IDHEAS application for event and condition analysis to support the NRC's inspection, licensing, and enforcement activities.
 - Working with the Electric Power Research Institute to develop an approach to perform HRA related to main control room abandonment in fire events:

- In publication: NUREG-1921, Supplement 1, "EPRI/NRC-RES Fire Human Reliability Analysis Guidelines: Qualitative Analysis for Main Control Room Abandonment Scenarios"
- Completing development of NUREG-1921, Supplement 2, "EPRI/NRC-RES Fire Human Reliability Analysis Guidelines: HRA Quantification for Main Control Room Abandonment Scenarios"

Risk-Informed Basis

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

[TOP](#) | [RETURN TO LIST](#)

Consequential Steam Generator Tube Rupture Probability and Consequence Assessment

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

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.

FY 2016

The "Consequential SGTR Analysis for Westinghouse and Combustion Engineering Plants with Thermally Treated Alloy 600 and 690 Steam Generator Tubes – Draft Report for Comment (NUREG-2195)," was issued for public comments. Public comments were received and were addressed. A final NUREG is expected to be issued late in 2017.

FY 2017

The final NUREG-2195 is in the publication process and will be available by early calendar year 2018.

Risk-Informed Basis

This project provides a method to assess the conditional SGTR probability given SG tube challenge (temperature-induced) during severe accidents or as an initiating event (pressure-induced). This probability can be used to assess the potential plant risk.

[TOP](#) | [RETURN TO LIST](#)

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 SRM-SECY-11-0033, "Proposed NRC Staff Approach to Address Resource Challenges Associated with Review of a Large Number of NFPA 805 License Amendment Requests," dated April 20, 2011, 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 28 applications to date and expects another application by April of 2018.

FY 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. Additional FY 2015 information is available.

FY 2016

The NRC staff issued seven non-pilot NFPA 805 license amendments. Five license amendment requests (LARs) are currently under review. Additional FY 2016 information is available.

FY 2017

The NRC staff issued five non-pilot NFPA 805 license amendments. Two LARs are currently under review. Additional FY 2017 information is available.

Risk-Informed Basis

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.

[TOP](#) | [RETURN TO LIST](#)

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 Loss of Coolant Accident (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 sump strainer(s) 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-SECY-12-0093, dated December 14, 2012. Since the Commission's endorsement, 11 licensees (18 units) have proposed to implement a risk-informed approach to address GSI-191 concerns. In consideration of the additional time required to implement risk informed approaches and/or complete further testing, subject licensees have implemented mitigative measures to address the potential for debris blockage of the strainer or reactor core.

SRM-SECY-12-0093, Title 10 of the Code of Federal Regulations (CFR) Section 50.46c, addresses ECCS performance during a LOCA. SECY-12-0034, dated January 7, 2013, directed that a provision allowing NRC licensees, on a case-by-case basis, to use risk informed alternatives should be included as part of proposed revisions to 10 CFR 50.46c. The proposed rule containing this provision was published in the Federal Register on March 24, 2014 (79 FR 16106).

In accordance with SRM-COMSECY-13-006, dated May 9, 2013, draft guidance related to implementation of the GSI-191 risk informed alternative was developed in parallel with its review of the STP pilot submittal, and published it in the Federal Register for public comment on April 20, 2015 (75 FR 21658).

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.

FY 2016

Preparations were made to ensure that final regulatory guidance (RG 1.229, "Risk-Informed Approach for Addressing the Effects of Debris on Post-Accident") could be issued concurrent with the revised 10 CFR 50.46c rule. Proposed 50.46c rule changes were still pending Commission approval at the end of FY16. Several pre-submittal public meetings were conducted in preparation for forthcoming GSI-191 risk-informed closure submittals.

FY 2017

The staff completed its review of the STP pilot and issued a safety evaluation and license amendment approving the risk informed closure of GSI-191 for STP. Currently, eight additional units are expected to request similar risk-informed closures.

Risk-Informed Basis

Site-specific closeout of GSI-191 according to the risk-informed approach involves the use of a systematic processes to evaluate the risk from debris in terms of core damage frequency (CDF) and large early release frequency (LERF). The systematic risk assessment would rely on, at minimum, a plant-specific at-power, internal events probabilistic risk assessment (PRA) and take into consideration all hazards, initiating events, and plant operating modes. The risk attributable to debris would be compared to the risk calculated assuming debris is not present yielding values for the change in CDF and LERF (Δ CDF and Δ LERF, respectively).

Licensees pursuing risk-informed approaches to address GSI-191 concerns, will be submitting license amendment requests subject to RG 1.174, Revision 2, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decision on Plant-Specific Changes to the Licensing Basis."

[TOP](#) | [RETURN TO LIST](#)

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 ADAMS Accession Nos. ML093570241 and ML103360003.

Initiative 4b, "Risk-Informed Completion Times," modifies technical specification completion times to reflect a configuration risk-management approach that is more consistent with the approach described in the Maintenance Rule, as specified in 10 CFR 50.65(a)(4). As reported previously in SECY-07-0191, "Implementation and Update of the Risk-Informed and Performance-Based Plan," dated October 31, 2007, 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. Five additional applications to implement TSTF-505 have been received and are currently being reviewed by the technical staff. The five additional applications were received on November 25, 2013; December 5, 2014; December 23, 2014; July 31, 2015 and February 25, 2016. The five 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, 2014, and October 6, 2014, after the NRC requested additional information and the participating licensees decided not to pursue these initiatives.

FY 2015

The NRC staff continued review of STS initiatives as they were received. Additional FY 2015 information is available.

FY 2016

The NRC staff performed reviews of STS initiatives based license amendment applications as they were received. Additional FY 2016 information is available.

FY 2017

In late 2016 TSTF-505 was suspended pending updates required to address technical issues not previously identified. These issues are still being addressed. Although work is nearing completion, TSTF-505 remains suspended.

Risk-Informed Basis

The activity uses risk insights and results to identify appropriate improvements to the current STS and to determine appropriate compensatory risk management actions associated with plant equipment that is deemed inoperable per STS. Decisions concerning changes to STS are reached in an integrated fashion, considering traditional engineering and risk information, and may be based on qualitative factors as well as quantitative analyses and information.

[TOP](#) | [RETURN TO LIST](#)

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).

FY 2015

Completed the pilot application for the Vogtle Electric Generating Plant (VEGP) in December 2014. Additional FY 2015 information is available.

FY 2016

Although no new submittals seeking to implement 10 CFR 50.69 were received by the NRC in FY 2016, the industry has expressed interest in its widespread implementation. The NRC staff met with industry representatives in August 2016 to discuss future 50.69 LAR submittals and their content. Additional FY 2016 information is available.

FY 2017

NRC has received seven submittals to implement 10 CFR 50.69 in FY 2017. Additionally NRC met with industry representatives in several public meetings to discuss 50.69 topics of interest, such as content of License Amendment Requests, and industry proposed deviations from RG 1.201 guidance for addressing seismic and fire risk (ADAMS Accession Numbers ML17027A251, ML17177A063, ML17265A020). Additional licensee submittals to implement 10 CFR 50.69 are anticipated in FY 2018. The NRC staff met with industry representatives in October 2017 to discuss industry proposed approach to implementing 10 CFR 50.69 for licensees that do not have seismic probabilistic risk assessment or a seismic margins analysis (ADAMS Accession Number ML17305A242). Public meetings will continue in FY 2018.

Risk-Informed Basis

10 CFR 50.69 and its implementation relies heavily on risk insight and metrics, such as importance measures, to categorize the safety significance of systems, structures, and components (SSCs). The rule revises requirements with respect to 'special treatment,' that is, those requirements that provide increased assurance (beyond normal industrial practices) that SSCs perform their design basis functions. This rule permits licensees (and applicants for licenses) to remove SSCs of low safety significance, as determined based on the risk metrics, from the scope of certain identified special treatment requirements and to revise requirements for SSCs of greater safety significance. The plant-specific Probabilistic Risk Analysis (PRA) model is utilized to generate the risk metrics used for the categorization resulting in a quantifiable method of determining the risk significance of the components on the safe operation of the nuclear plant.

[TOP](#) | [RETURN TO LIST](#)

Page Last Reviewed/Updated Thursday, May 10, 2018



[Home](#) > [About NRC](#) > [How We Regulate](#) > [Risk Assessment](#) > [Current Risk-Informed Activities](#) > [Light-Water Reactors Sub-Arena](#)

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

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

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.

[TOP](#)

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

[TOP](#)

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).

[TOP](#)

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:

- Evaluate and Develop Risk-Informed Regulatory Guidance for New Reactors
- Interim Staff Guidance on PRA Technical Adequacy for Advanced Light-Water Reactors

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

The staff continued to work on the Commission's directions from the SRM on SECY-13-0137. The staff worked 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 was held in September 2015 to discuss updates on the staff's activities and to obtain stakeholder feedback.

FY 2016

The staff continued to hold meetings internally and with stakeholders to develop documents related to the ROP program for new reactors. A draft white paper was issued on September 7, 2016.

FY 2017

The staff continued to hold meetings internally and with stakeholders. The staff drafted a response to the commission direction in SRM-SECY-13-0137 which has been reviewed by internal and external stakeholders including the ACRS. The draft SECY is planned to be submitted to the Commission by December 2017.

Risk-Informed Basis

This activity supports risk-informing the ROP for new reactors.

[TOP](#) | [RETURN TO LIST](#)

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.

FY 2015

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 involved:

- 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.

FY 2016

The staff addressed the comments from ACRS on the designations used for the supporting requirements with a plan to publish the final ISG for use in FY2017.

FY 2017

The staff issued the final ISG (DC/COL-ISG-028) for use in November 2016.

Risk-Informed Basis

This document is being developed in support of risk-informed regulations and risk-informed licensing reviews.

[⏮ TOP](#) | [⏮ RETURN TO LIST](#)

Page Last Reviewed/Updated Wednesday, May 09, 2018



[Home](#) > [About NRC](#) > [How We Regulate](#) > [Risk Assessment](#) > [Current Risk-Informed Activities](#) > [Advanced Reactors Sub-Arena](#)

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

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

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.

[TOP](#)

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.

[7. TOP](#)

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

[8. TOP](#)

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:

- Risk-Informed Review of Small Modular Reactor (SMR) Designs
- Non-Light Water Reactor Licensing Modernization
- Staff Review of NuScale Emergency Planning Zone Licensing Topical Review

Risk-Informed Review of 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 (SSCs) 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. One aspect of this review plan is the Design Specific Review Standards (DSRSs).

FY 2015 Status

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 continued to evaluate the comments received.

FY2016

The final version of the NuScale DSRS was published on August 5, 2016. A working group was organized to develop tools for conducting the safety review of the NuScale DCA. The staff developed a SSC review tool to assist the technical reviewers in their review. The staff briefed the ACRS on the technical review process on August 16, 2016.

FY2017

The staff applied the SSC review tool concepts including risk insights to enhance the safety focus of the NuScale DCA. The staff developed graded review approaches for each technical review areas. Senior managers presented these review approaches to their peers for feedback and to achieve a common management understanding of the proposed scope and depth of review in the various technical disciplines. The staff also briefed the ACRS on the staff's review approaches on May 3, 2017. The staff continues to monitor the implementation of the graded review for the NuScale DCA.

Risk-Informed Basis

This activity uses risk insights to prioritize staff review efforts on the more safety significant aspects of the NuScale design for a more effective and efficient review.

[TOP](#) | [RETURN TO LIST](#)

Non-Light Water Reactor Licensing Modernization

Summary Description

The NRC is supporting risk-informed activities related to the Licensing Modernization Project (LMP) being led by Southern Company, coordinated by NEI, and cost-shared by DOE. The LMP's objective is to assist the NRC to develop technology-inclusive, risk-informed, and performance based regulatory guidance for licensing non-LWRs.

FY 2017 Status

The staff completed its review of two LMP white papers, "Modernization of Technical Requirements for Licensing of Advanced Non-Light Water Reactors - Selection of Licensing Basis Events (Draft Report)," and "Modernization of Technical Requirements for Licensing of Advanced Non-Light Water Reactors - Probabilistic Risk Assessment Approach (Draft Report)." The staff provided written comments to the LMP and the staff discussed the issues in public stakeholder meetings. The staff is currently reviewing one LMP white paper, "Modernization of Technical Requirements for Licensing of Advanced Non-Light Water Reactors - Safety System Classification." An additional LMP white paper on defense-in-depth is expected to be submitted in calendar year 2017. The staff is discussing the LMP project with industry and other interested stakeholders during a series of public meetings on non-light water reactor licensing issues.

Risk-Informed Basis

This activity supports risk-informing the licensing process for non-light water reactors.

[TOP](#) | [RETURN TO LIST](#)

Staff Review of NuScale Emergency Planning Zone Licensing Topical Review

Summary Description

The purpose of this licensing topical report (LTR) is to provide a methodology to establish the technical basis for plume exposure emergency planning zone (EPZ) sizing, for the NuScale small modular reactor (SMR) plant design. Nuclear power plant emergency planning regulatory requirements are codified under 10 CFR and in coordination with FEMA. The current regulatory plume exposure EPZ for power reactors is ten miles but there is a provision for a different EPZ size for reactors with a thermal power of 250 MWt or less on a case-by-case basis. As the NuScale small modular reactor is a passive, 160 MWt (50 MWe) per module reactor, NuScale submitted a methodology to establish the technical basis for EPZ sizing with calculated results to illustrate its usability.

FY 2017 Status

The staff initiated the review of this LTR in December 2016.

Risk-Informed Basis

This activity will determine the acceptability of the risk-informed methodology to establish the EPZ sizing for the NuScale plant.

[TOP](#) | [RETURN TO LIST](#)

Page Last Reviewed/Updated Wednesday, May 09, 2018



[Home](#) > [About NRC](#) > [How We Regulate](#) > [Risk Assessment](#) > [Current Risk-Informed Activities](#) > [Research and Test Reactors Sub-Arena](#)

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.

[⌂ TOP](#)

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.

[⌂ TOP](#)

Page Last Reviewed/Updated Wednesday, May 09, 2018



[Home](#) > [About NRC](#) > [How We Regulate](#) > [Risk Assessment](#) > [Current Risk-Informed Activities](#) > [Fuel Cycle Sub-Arena](#)

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

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

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.

[TOP](#)

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.

[TOP](#)

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.

[TOP](#)

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 Materials Safety Arena:

- Implementation of Lessons Learned from Uranium Accumulation Event
- Rulemaking for Reprocessing Facilities

Implementation of Lessons Learned from Uranium Accumulation Event

Summary Description

In 2016 a fuel fabrication facility discovered a significant amount of uranium had accumulated within a process ventilation system that exceeded the system's criticality safety evaluation limits. Although a criticality did not occur, the event was considered significant. In addition to the expected regulatory response to the event (including an augmented inspection, confirmatory action letter, information notice, etc.), the staff initiated an effort to capture lessons from the event that could be used to improve the regulatory processes so that similar events are avoided or identified earlier.

FY 2017

In January 2017, the lessons-learned team issued a report that identified potential improvements in five regulatory process areas: license application review, inspection program, operating experience program, roles and responsibilities, and knowledge management. An action plan was developed to prioritize and further evaluate the potential improvements identified in the lessons-learned report. The activity is in the implementation phase for the recommended high-priority items.

Risk-Informed Basis

Many of the areas identified for potential improvement within the lessons-learned report relate to the consideration of, and technical bases for, the risk insights and significance derived from the licensee's analyses. The use of these insights can have a direct effect on the license review process and inspection program. There are also related potential improvements to the operating experience program (including reporting guidance), roles and responsibilities, and knowledge management.

[TOP](#) | [RETURN TO LIST](#)

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

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.

FY 2016

Mindful of limiting the scope of work as directed in SRM-SECY-13-0093, event and fault trees were developed for a hypothetical loss of cooling (LOC) accident to a concentrated high level waste storage tank. Preliminary quantification of the accident sequence was carried out using generic failure and probability data. Items Relied On For Safety (IROFS) were identified for both the hypothetical red-oil explosion and LOC accident sequences.

FY 2017

Work on the fuel reprocessing regulatory framework related to assessing the application of quantitative risk analysis (identified as Gap 5 in SECY-13-0093) was delayed during FY 2017 because of other higher priority activities.

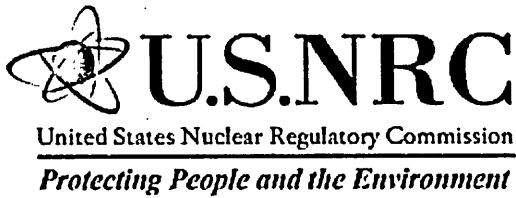
Risk-Informed Basis

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; and
- Obtaining peer review and public comments on the safety and risk assessment methodologies.

[TOP](#) | [RETURN TO LIST](#)

Page Last Reviewed/Updated Wednesday, May 09, 2018



[Home](#) > [About NRC](#) > [How We Regulate](#) > [Risk Assessment](#) > [Current Risk-Informed Activities](#) > [Byproduct Materials Sub-Arena](#)

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

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

Objective

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

[⤴ TOP](#)

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.

[⤴ TOP](#)

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.

[⤴ TOP](#)

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 Materials Safety Arena:

- Inspection Manual Chapter 2800, "Materials Inspection Program"
- Medical use of Byproduct Material (10 CFR Part 35) – Medical Event Definitions, Training and Experience, and Clarifying Amendments

Inspection Manual Chapter 2800, "Materials Inspection Program"

Summary Description

The revision of IMC 2800 allowed the addition of more flexible and logical extensions to the time between inspections, i.e., inspection intervals for material licensees. The revision included: (1) increasing the current 25 percent buffer to 50 percent for inspection timeliness; (2) extending the initial inspection period if licensees are not in possession of material; and (3) allowing extensions of inspection intervals based on good performance on a case-by-case basis. The flexibility and logical extensions to the inspection intervals of material licenses is not expected to have an adverse impact on the health and safety of the public, and the NRC's ability to plan and conduct inspection activities will continue to be consistent with the NRC's mission, values, and the principles of good regulation including a risk-informed and performance-based oversight process.

FY 2016

The staff started efforts to review and update IMC 2800 per Commission direction in SRM-SECY-16-009.

FY 2017

On September 19, 2017, the revised IMC 2800 was issued.

Risk-Informed Basis

Materials inspections continue to be risk-informed. IMC 2800 was revised to continue and enhance risk-informed, relative priorities for routine inspections of all licensees and a program of special inspection activities.

[TOP](#) | [RETURN TO LIST](#)

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 several ongoing rulemaking projects related to NRC regulations of medical use of byproduct material. First, this rule amends the medical event definition for reporting and notification requirements for permanent implant brachytherapy. This rule also amends the training and experience (T&E) requirements to (1) remove the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized and (2) address a petition request filed to exempt certain board-certified individuals from certain T&E requirements (i.e., "grandfather" these individuals). Additionally, this rule amends the requirements for measuring molybdenum contamination; adds a new requirement for the reporting of failed technetium and rubidium generators; and allows licensees to name associate radiation safety officers (ARSOs) on a medical license. The proposed rule was published on July 21, 2014 (79 FR 42410) for 120-day public comment period. The proposed guidance was noticed on the same day.

FY 2015

The NRC staff considered public comments as they developed the proposed final rule.

FY 2016

The staff sent the proposed final rule to the Commission for their approval in SECY-16-0080.

FY 2017

The Commission approved the final rule on August 17, 2017, in Staff Requirements Memorandum M170817: Affirmation Session - SECY-16-0080 – Final Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-AI63: NRC-2008-0175). The NRC staff is finalizing the rule and estimates publication no later than early March 2018.

Risk-Informed Basis

This rule continues the risk-informed, performance-based framework already present in 10 CFR 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. The medical event criteria are being revised to more accurately reflect the different risks of different uses of byproduct material in medical applications. This will result in the NRC receiving notification of medical events that are clinically significant. 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.

[TOP](#) | [RETURN TO LIST](#)

Page Last Reviewed/Updated Thursday, May 10, 2018



[Home](#) > [About NRC](#) > [How We Regulate](#) > [Risk Assessment](#) > [Current Risk-Informed Activities](#) > [Spent Fuel Storage and Transportation Sub-Arena](#)

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

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

Objective

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

[⌂ TOP](#)

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.

[⌂ TOP](#)

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."

[⌂ TOP](#)

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 Waste Management Arena:

- Regulatory Framework for Spent Fuel Storage and Transportation

Regulatory Framework for Spent Fuel Storage and Transportation

Summary Description

The goal of this effort was 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. 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.

FY 2015

After meetings with internal and external stakeholders and consideration of the relatively low risk of dry cask storage based on previously conducted industry and NRC probabilistic risk assessments, the NRC decided to develop a graded approach primarily based on safety functions and defense-in-depth considerations.

FY 2016

The staff continued to work with internal and external stakeholders on developing a graded approach.

FY 2017

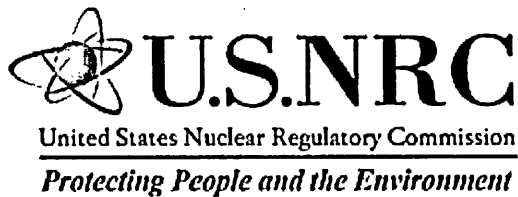
As a continuation of the efforts to improve efficiency, the staff and industry developed a set of graded-approach criteria to evaluate licensing requirements in the technical specifications and Certificate of Compliance to determine what information can be relocated to the final safety analysis report (FSAR) or removed. Licensing information appropriate for the FSAR can be evaluated for change by the more efficient 10 CFR 72.48 change process. TN Americas, LLC, submitted a pilot amendment application to test this improvement process.

Risk-Informed Basis

As shown in existing probabilistic risk assessment studies, the risk associated with dry cask storage is very low. The NRC's graded approach to improve the dry cask storage regulatory process takes into consideration quantitative and qualitative risk insights, as well as, qualitative evaluations that rely on safety functions, defense-in-depth, and engineering judgement, while also maintaining safety and security and ensuring that the associated regulatory requirements are met.

[TOP](#) | [RETURN TO LIST](#)

Page Last Reviewed/Updated Wednesday, May 09, 2018



[Home](#) > [About NRC](#) > [How We Regulate](#) > [Risk Assessment](#) > [Current Risk-Informed Activities](#) > [Low-Level Waste and Decommissioning Sub-Arena](#)

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

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

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.

[TOP](#)

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.

[TOP](#)

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.

[TOP](#)

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 Waste Management Arena:

- SECY-16-0106: Final Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61)

SECY-16-0106: Final Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61)

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.

FY 2015

Developed SECY for final rule.

FY 2016

The 10 CFR Part 61 Rule was provided to the Commission for consideration in September 2016.

FY 2017

On September 8, 2017, the staff received direction from the Commission on the path forward in Staff Requirements – SECY-16-0106 – Final Rule: Low-Level Radioactive Waste Disposal (10 CFR PART 61) (RIN 3150-AI92). The Commission directed the staff to make substantive revisions to the draft final rule and subsequently republish it as a supplemental proposed rule for a 90-day public comment period. The associated guidance documents must also be revised and be made publicly available, concurrent with the comment period on the supplemental proposed rule.

Risk-Informed Basis

This rulemaking uses risk insights of disposal of significant quantities of depleted uranium, other long-lived wastes, and other wastes not fully analyzed during the initial 10 CFR Part 61 rulemaking process.

[TOP](#) | [RETURN TO LIST](#)

Page Last Reviewed/Updated Wednesday, May 09, 2018



[Home](#) > [About NRC](#) > [How We Regulate](#) > [Risk Assessment](#) > [Current Risk-Informed Activities](#) > [Cross-Cutting Activities](#)

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:

- Update RG 1.200, An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities
- PRA Standards Development
- Industry Peer Review Guidance Development
- Risk-Informed Steering Committee (RISC)
- 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 NUREG 1855, Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decisionmaking

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

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

Summary Description

Regulatory Guide (RG) 1.200 provides the staff position regarding what constitutes an 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 definition for what constitutes a PRA and a staff position on PRA acceptability addressing the (1) scope of a PRA, (2) technical elements of a PRA, (3) level of detail of a PRA, and (4) plant representation in the PRA model. RG 1.200 also provides a staff position on consensus PRA standards and industry peer review PRA programs, demonstration of the acceptability of a PRA, and documentation to support a regulatory submittal. RG 1.200 also provides the NRC endorsement of the published ASME/ANS PRA standards and the NEI peer review guidance documents.

Associated Risk-Informed Activities below:

- PRA Standards Development
- Industry Peer Review Guidance Development

FY 2015

Staff and industry continue to use RG 1.200 in support of risk-informed activities.

FY 2016

Staff and industry continue to use RG 1.200 in support of risk-informed activities. Staff developed a draft position for a process for closure of peer review findings. This staff position has not yet been incorporated into RG 1.200.

FY 2017

Staff and industry continue to use RG 1.200 in support of risk-informed activities. Staff initiated efforts for Revision 3 of RG 1.200.

Risk-Informed Basis

Under this activity the infrastructure is developed to support risk-informed decision-making. The purpose of this activity is to provide the agency position on an acceptable base PRA such that the results from the PRA can be used in risk-informed decision-making.

[TOP](#) | [RETURN TO LIST](#)

PRA Standards Development

Summary Description

Staff participates with the ASME and ANS efforts to develop PRA Standards. ASME and ANS work together under the Joint Committee for Nuclear Risk Management (JCNRM). JCNRM is developing a suite of standards which (1) address operating LWRs, advanced LWRs in the design certification stage, and non-LWRs, (2) address all operating modes (at-power and low power and shutdown), (3) address both internal hazards (i.e., internal events, internal floods and internal fires) and external hazards (seismic, high winds, external floods and others), and (4) address all risk metrics (CDF, LERF/LRF, radiological release frequency, and consequences). These standards include:

- Level 1 (CDF)/LERF PRA standard for at-power conditions, both internal (i.e., internal events, floods and fires) and external (i.e., fires, seismic, high winds, floods and others) hazards for operating LWRs. This standard was published as an ANSI standard in 2008, Addendum A in 2009 and Addendum B in 2013.
- Level 2 (radiological release frequency) PRA standard for all operating modes and for both internal and external hazards for LWRs. This standard was published as an ASME/ANS Trial Use standard in 2015.
- Level 3 (consequences) PRA standard for nuclear facilities and for all operating modes and both internal and external hazards. This standard has not been published.
- LPSD PRA standard for Level 1/LERF for LWRs. This standard was published as an ASME/ANS Trial Use standard in 2015.
- Advanced LWR PRA standard for new LWRs in the design certification phase addressing Level 1/LERF. This standard has not been published.
- Non-LWR PRA standard for all three PRA Levels and all operating modes for both internal and external hazards and addressing multi-units at a single site. This standard was published as an ASME/ANS Trial Use standard in 2009.

To date, the staff has endorsed the Level 1/LERF PRA standard, specifically the 2009 addendum (i.e., ASME/ANS RA-Sb-2009).

FY 2015

Staff continues to support JCNRM efforts on the various standard activities:

- working on the new edition to the published Level 1 (CDF)/LERF PRA standard
- published trial use Level 2 PRA standard
- developing the Level 3 PRA standard for trial use
- piloting the published trial use LPSD PRA standard
- developing the Advanced LWR PRA standard for trial use
- piloting the published trial use non-LWR PRA standard

FY 2016

Staff continues to support JCNRM efforts on the various standard activities:

- working on the new edition to the published Level 1 (CDF)/LERF PRA standard
- piloting the published trial use Level 2 PRA standard
- developing the Level 3 PRA standard for trial use
- piloting the published trial use LPSD PRA standard
- developing the Advanced LWR PRA standard for trial use
- piloting the published trial use non-LWR PRA standard

FY 2017

Staff continues to support JCNRM efforts on the various standard activities:

- working on the new edition to the published Level 1 (CDF)/LERF PRA standard
 - JCNRM published a Code Case which provides an alternate approach to Part 5 of the standard addressing seismic PRA

- NRC developed draft comments on the Code Case (for approval) and planned to request external stakeholder feedback
- piloting the published trial use Level 2 PRA standard
- developing the Level 3 PRA standard for trial use
- piloting the published trial use LPSD PRA standard
- developing the Advanced LWR PRA standard for trial use
- piloting the published trial use non-LWR PRA standard

Risk-Informed Basis

Under this activity the infrastructure is developed to support risk-informed decision-making. The purpose of this activity is to provide the agency position on an acceptable base PRA such that the results from the PRA can be used in risk-informed decision-making.

[TOP](#) | [RETURN TO LIST](#)

Industry Peer Review Guidance Development

Summary Description

Staff reviews and endorses the PRA peer review guidance issued by NEI in RG 1.200 for how to demonstrate conformance with the ASME/ANS PRA standards. RG 1.200 provides the staff position for what constitutes an acceptable peer review program. The NEI guidance documents include:

- NEI 00-02 (published in 2000) provides the initial peer review guidance for internal events and internal floods Level 1 PRA. It also include a self-assessment to address the gap between the review criteria in NEI 00-02 and the ASME/ANS PRA standard. It is endorsed in RG 1.200.
- NEI 05-04 (published in 2005) provides the updated guidance to NEI 00-02 to be commensurate the ASME/ANS PRA standard and addresses internal events and internal floods Level 1/LERF PRA. It is endorsed in RG 1.200.
- NEI 07-12 (published in 2007) provides the peer review guidance for internal fire Level 1/LERF PRA. It is endorsed in RG 1.200.
- NEI 12-13 (published in 2012) provides the peer review guidance for external hazards Level 1/LERF PRA. NRC issued a letter providing comments on the guidance, it has not been endorsed in RG 1.200.

FY 2015

NEI 00-02 – continues to be endorsed in RG 1.200

- NEI 05-04 – continues to be endorsed in RG 1.200
- NEI 07-12 – continues to be endorsed in RG 1.200
- NEI 12-13 – has not been endorsed in RG 1.200

FY 2016

NEI 00-02 – continues to be endorsed in RG 1.200

- NEI 05-04 – continues to be endorsed in RG 1.200
- NEI 07-12 – continues to be endorsed in RG 1.200
- NEI 12-13 – has not been endorsed in RG 1.200

FY 2017

NEI 00-02 – continues to be endorsed in RG 1.200

- NEI 05-04 – continues to be endorsed in RG 1.200
- NEI 07-12 – continues to be endorsed in RG 1.200
- NEI 12-13 – has not been endorsed in RG 1.200
 - NRC developed draft comments on NEI 12-13 (for staff approval) and planned to request external stakeholder feedback
- Appendix "x" – The staff continued to observe uses of the appendix. The staff issued a letter providing interim approval of the process given certain staff comments were addressed. This appendix has not yet been endorsed in RG 1.200.

- NEI informed the staff of their intention to develop guidance, "Performance of PRA Peer Reviews Using the ASME/ANS PRA Standard." This guidance document is meant to replace the previous individual guidance documents.

Risk-Informed Basis

Under this activity the infrastructure is developed to support risk-informed decision-making. The purpose of this activity is to provide the agency position on an acceptable base PRA such that the results from the PRA can be used in risk-informed decision-making.

[TOP](#) | [RETURN TO LIST](#)

Risk-Informed Steering Committee (RISC)

Summary Description

The NRC's RISC was established in 2014 to provide strategic direction to the NRC staff to advance the use of risk-informed decision making (RIDM) in various NRC activities, consistent with the Commission's Probabilistic Risk Assessment (PRA) Policy Statement. The NRC's RISC comprises of a senior management committee representing the NRC program offices (NRR, NRO, RES, NMSS, and NSIR as well as a senior executive from a regional office). The RISC is chaired by the NRR Office Director.

The objectives of the RISC include engaging the industry relative to the use of PRA to support regulatory decision-making, discussion of NRC driven initiatives that incentivize industry to continue to develop PRAs thereby providing a framework to make decisions in light of inherent uncertainty in PRA models, and discussion of industry actions necessary to achieve the vision of future use of PRA to support regulatory decisions. Recently, in response to comments from the Advisory Committee on Reactor Safety (ACRS) on SECY-15-0168, the NRC staff agreed with the ACRS's view that continued enhancements to the usage of risk-informed regulatory approaches should be pursued in future regulatory activities and stated that NRC activities in this and related areas will be overseen by NRC's RISC committee.

The NRC RISC regularly interfaces with its industry counterpart which comprises of licensee chief nuclear officers, senior level executives, and representation from the Nuclear Energy Institute (NEI). At the time NRC's RISC was formed in 2014, technical adequacy and uncertainties in risk-informed decision making were areas of focus. Technical adequacy was viewed as a solution to some of the PRA quality issues that arose in NPPA-805 reviews and the second issue stemmed from the aggregation of core damage frequency contributions from multiple initiators. Consequently, the NRC and industry each agreed to form two working groups; one focused on technical adequacy of PRAs and the other focused on treatment of uncertainty in RIDM. The NRC RISC, to address its objectives, has undertaken several activities in recent years under the auspices of these two working groups. Additional information is available.

FY 2015

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.

FY 2016

The NRC RISC held multiple public meetings with the industry RISC to receive updates on the working group's status and to discuss other risk informed initiatives. The NRC RISC working group held a public workshop to discuss draft guidance documents from the industry on the topic of a proposed approach to close out the comments generated by a peer-review of the licensee's PRA model. The NRC staff also observed an industry pilot project to implement the proposed approach and derive lessons learned for future discussions on the topic. NRC staff held a public meeting to discuss the new approach, termed the vetting panel process, proposed by the RISC's technical adequacy working group to determine the technical adequacy of a new PRA methods. The staff is currently developing internal guidance for the implementation of the proposed approach. These initiatives are expected to improve the staff's efficiency in the review of future risk-informed licensing actions. The NRC RISC engaged the industry in activities related to crediting FLEX/mitigating strategies (MS) equipment in RIDM. The industry developed white papers and held a workshop with good participation from both industry and the NRC. The white papers were found to address a large number of issues that are important to the NRC staff in RIDM. The industry revised the white papers based on NRC staff comments.

The staff plans to update internal guidance for considering credited FLEX/MS equipment during the review of risk-informed licensing applications.

In addition, NRC has held public meetings to seek stakeholder input on the update on NUREG-1855, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making". As a result of the interaction at the public meetings, NRC is currently developing training related to the treatment of uncertainties in RIDM.

The NRC RISC directed the evaluation of the use of licensee PRA models in regulatory applications where SPAR models are currently being utilized. This evaluation was intended to evaluate the potential benefits, pitfalls, and cost of shifting to this approach. Ultimately, it was revealed that while there may have been some incremental cost savings after a full implementation period, the risk to the Agency of pursuing this initiative was too great to justify continued evaluation at this time. The NRC RISC will continue to hold public meetings with the industry RISC to discuss current and upcoming risk-informed initiatives of interest.

FY 2017

The NRC and industry RISCs held multiple public meetings to discuss a number of activities important to NRC's RISC or industry's RISC. The key issues discussed at the FY 2017 meetings were Technical Specification (TS) Initiative 4B, the peer review Facts and Observations (F&O) closure process, risk-informed categorization and treatment of SSCs for nuclear power reactors (10 CFR 50.69), diverse and flexible coping strategies (FLEX) in risk-informed decision making (RIDM), Fire PRA realism, PRA methods vetting process, realism in the reactor oversight process (ROP), and Risk Aggregation. Some highlights of these risk informed initiatives are provided below:

- TS Initiative 4B: The NRC staff issued its amendment to implement TS Initiative 4B for the pilot plant in August 2017. The NRC is developing a revised version of TSTF-505 which the licensee will use in support of Tech Spec 4B. The revised TSTF-505 is less complex but more restrictive than the approved pilot's TS Initiative 4B program.
- Facts and Observations (F&O) closure process: The NRC staff provided a letter dated May 3, 2017, accepting industry's guidance on the F&O independent assessment process (ADAMS Accession No. ML1707A427). The staff plans to incorporate its expectations for closure of F&Os as a staff regulatory position in the next update to RG 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities." The staff regulatory position will be used as the basis for endorsement of NEI's guidance for the F&O independent assessment process.
- 10 CFR 50.69: The NRC informed industry that it has resources to review 10 license amendment applications per year. The staff believes that the facts and observations (F&O) closure process will result in more efficient licensing reviews. The NRC completed the pilot license amendment request (LAR) for this initiative.
- FLEX in RIDM: FLEX is currently being credited in multiple-risk applications. The NRC staff has developed several guidance documents to promote consistency and efficiency in applications in these areas. The staff is continuing to monitor the licensees' use of FLEX and is evaluating the need for additional guidance changes.
- Fire PRA Realism: The NRC's Office of Nuclear Regulatory Research (RES) is working closely with EPRI to address a number of areas to improve the level of realism in fire PRA. This effort encompasses topics such as main control room abandonment, heat release rates, fire ignition frequencies, fire growth rate assumptions, and the potential influence of aluminum in high-energy arcing faults. Industry and the NRC are discussing the most effective means to update the NUREG/CR-6850 methodology.
- PRA Methods Vetting process: In April 2017, the staff approved a fee waiver to industry to permit the piloting of three new PRA methods through the vetting panel process. In June 2017, the staff and industry discussed and agreed on changes to draft NEI 16-04 that would guide the pilot actions for the vetting panel process.
- Realism in the ROP: On March 21, 2017 NRC transmitted their plan to address industry concerns for the treatment of Common Cause Failures (CCF), the treatment of dependency between human errors in accident sequences, and the methods used to model various performance deficiencies. Several public meetings have been held to move forward on these topics. The industry has proposed that pursuing the CCF issue is the highest priority.
- Risk Aggregation: The staff has prepared training material for NUREG 1855, Revision 1 that will discuss uncertainty and decision-making in risk-informed applications. The upcoming revision to RG 1.174 in March 2018 will expand the explanations and definitions of deterministic consideration, which will help when making risk-informed licensing decisions. EPRI has published a report that provides its approach for addressing risk aggregation (EPRI Report 3002003116). At this time, the Pressurized-Water Reactor Owners Group is in the process of piloting this framework.

The RISC will be continuing to meet and discuss the current and upcoming risk-informed initiatives to provide the strategic direction to advance the risk-informed decision making in NRC activities.

Risk-Informed Basis

The RISC engages the industry and addresses concerns relative to the use of PRA to support regulatory decision-making. The RISC provides strategic direction to the NRC staff by using a holistic, risk-informed, approach to decision making.

[TOP](#) | [RETURN TO LIST](#)

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.

FY 2016 Status

The NRC continues to provide staff training on various aspects of PRA including use of the agency risk models/software and their application to analyze events and Licensee applications. The agency graduated 1 employees this year and currently has 8 program participants projected to graduate soon.

FY 2017 Status

Six additional staff members in the program within the Office of Nuclear Reactor Regulation (NRR) have completed their required activities and qualified by passing their technical boards in April and May 2017. Two additional staff members are projected to graduate in the third quarter of FY 2018 from within the Office of Nuclear Reactor Regulation (NRR).

Risk-Informed Basis

Enhancing the PRA knowledge and capability of NRC staff supports the application of risk-informed decision-making.

[TOP](#) | [RETURN TO LIST](#)

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

As directed by the Commission in SRM SECY 11 0014, Regulatory Guide (RG) 1.174 is being revised to assure consistent interpretation and implementation of the defense-in-depth philosophy. RG 1.174 provides guidance on the use of PRA findings and risk insights to support licensee requests for changes to a plant's licensing basis, as in requests for license amendments and technical specification changes under Title 10 of the Code of Federal Regulations (10 CFR) Sections 50.90, "Application for Amendment of License, Construction Permit, or Early Site Permit," and 50.92, "Issuance of Amendment."

FY 2015 Status

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

FY 2016 Status

During this fiscal year, the staff continued to meet with internal and external stakeholders to solicit their input into the update of RG 1.174. The focus of this activity is a review and update of RG 1.174 and other related guidance documents (e.g., RGs 1.175, 1.177, and 1.178) to clarify the staff position on how the defense-in-depth principles of the integrated risk-informed decision-making process are addressed in the review of a licensee's request to change its licensing basis.

FY 2017 Status

During this fiscal year, the staff continued revising the defense-in-depth guidance and soliciting input from internal and external stakeholders, including feedback from the Advisory Committee on Reactor Safeguards (ACRS) Subcommittee on Reliability and PRA. The staff published for public review and comment an update of the draft regulatory guide for Revision 3 of RG 1.174 (i.e., DG 1285). The staff resolved all internal and external stakeholder comments on DG-1285 and prepared to meet with and receive feedback from the ACRS Full Committee on the final draft of the revised RG.

Risk-Informed Basis

RG 1.174 describes an acceptable approach for assessing the nature and impact of proposed licensing basis changes by considering engineering issues and applying risk insights. The intent of the assessment is to demonstrate the proposed licensing basis changes will only result in small increases in risk and only when it is also reasonably assured that, among other things, consistency with the defense-in-depth philosophy and sufficient safety margins are maintained.

[TOP](#) | [RETURN TO LIST](#)

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

Revision to the document is under review.

FY 2016

A public workshop was held to "pilot" the Revision 1 draft and finalize for publication.

FY 2017

The staff published Revision 1 to the NUREG. The revision provided additional text to further clarify the guidance and the relationship to the associated EPRI documents. In addition, the staff developed a Web-based training course for both internal and external stakeholders. The course is designed for both staff and management. It teaches the concepts used in the guidance for treating PRA uncertainties in risk-informed decisionmaking. The course has options that allows the user to take a shorter version of the course or go into more detail.

Risk-Informed Basis

NUREG-1855 helps the decision maker understand to what extent the risk results are impacted by the uncertainties, understand whether there are risk results that may challenge the risk acceptance guidelines, and to determine if the driver for the large uncertainties can be identified and remediated.

[TOP](#) | [RETURN TO LIST](#)

Page Last Reviewed/Updated Wednesday, May 09, 2018

**Risk Informed Activities
Completed or Not Active
(FY2017 Update)**

The following risk-informed activities were removed from the public website because they are no longer active:

Risk Prioritization Initiatives (RPI)

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)

Risk-Informed In-service Inspection (ISI)

Standard Review Plan, Chapter 19.0 Severe Accidents (NUREG-0800)

Staff Review of NuScale Licensing Topical Report on Risk Significance Determination

Use of Risk Insights to Enhance Technical Reviews of Design Certification (DC) Applications

Revise the Fuel Cycle Oversight Program (RFCOP)

Enhance Regulatory Framework for Extended Storage and Transportation

Risk Management Regulatory Framework (RMRF)

Reactor Safety Arena

Operating Reactors

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.

FY 2015

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." Additional FY2015 information is available.

FY 2016

No activity since 2015 based on Commission directive in SRM-SECY-15-0050. Additional FY2016 information is available.

Risk-Informed Basis

This initiative, discontinued since August 2015, intended to 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.

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

Summary Description

As part of the staff's program to risk-inform the technical requirements of 10 CFR Part 50 (discussed under Option 3 from SECY-98-300), the staff identified 10 CFR 50.46, "Acceptance Criteria for Emergency Core Cooling Systems (ECCS) for Light-Water Nuclear Power Reactors", Appendix K to 10 CFR Part 50, "ECCS Evaluation Models," and General Design

Criteria (GDC) 35, "Emergency Core Cooling," of Appendix A to 10 CFR Part 50, as regulations that warranted revision.

The staff prepared a proposed rule (SECY-10-0161; ML102210460) containing ECCS evaluation requirements that could be used as an alternative to the current requirements in 10 CFR 50.46. The proposed rulemaking was designed to redefine the large-break LOCA (LBLOCA) requirements to provide a risk-informed alternative maximum break size. In 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.

In SECY-16-0009, the NRC staff requested Commission approval to discontinue work on the 10 CFR 50.46a rulemaking. The reasons for the staff's request were that the licensees indicated that the rule, as proposed, would not provide them the benefits that were originally expected, and that the NRC has higher priority work. In SRM-SECY-16-0009, the Commission approved discontinuing the 50.46a ECCS rulemaking. In addition, per Commission directive in SRM-SECY-16-0009, the NRC staff published a Federal Register notice (81 FR 69446) to inform the public that the rule is being discontinued. As a result of these actions, the 50.46a rule has not been issued and work on this effort has been discontinued.

FY 2015

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

FY 2016

No activities were performed and the effort has been discontinued per Commission directive in SRM-SECY-16-0009. Federal Register notice (81 FR 69446) published to inform the public that the rule is being discontinued.

Risk-Informed Basis

The proposed rule would have utilized risk insights, such as frequency of occurrence, to redefine the large-break LOCA (LBLOCA) requirements. The proposed rule relied heavily on risk insights to provide a risk-informed transition break size for analysis.

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, a Staff Requirements Memorandum (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 2012 the staff requested withdrawal of the 10 CFR 50.46a final rule from Commission consideration. The Commission approved the staff's request in SRM-SECY-10-0161. In response to the SRM-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. The Commission, via SRM-SECY-15-0168, directed the staff to: 1) maintain the existing regulatory framework for the nuclear power reactor safety program area, and 2) refrain from developing an overarching, agency-wide risk management policy statement. The proposed 50.46a rule was not subsequently issued and work on this effort has been discontinued. As a result, the staff has started engaging with the industry to determine the need for and interest in the rulemaking decoupling LOOP assumption from LBLOCA analysis.

FY 2015

No action in FY 2015, as this item is on hold. Additional FY2015 information is available.

FY 2016

In July 2016, the NRC held a public meeting to provide an opportunity for external stakeholders and the NRC staff to exchange information on the need for a rulemaking action to risk-inform decoupling of assumed LOOP from the LOCA analysis. NRC staff will consider the comments provided during the public meeting and plans to hold additional meetings solicit stakeholder feedback on interest in the rulemaking. Additional FY2016 information is available.

Risk-Informed Basis

Risk insights, such as relative likelihood occurrence, are used to determine the categorize break sizes and to decouple the assumption of a coincident LOOP from the analysis of postulated large break sized LOCA (low likelihood of occurrence events). Such breaks must also be mitigated but they may be analyzed with more realistic analytical methods and initial conditions without postulating the loss of offsite power or the worst case single failure.

Risk-Informed In-service Inspection (ISI)

Summary Description

Risk-informed ISI has been utilized by operating reactors. Risk-informed ISI programs focus resources on the most safety-significant systems and components. RG 1.178, "An Approach For Plant-Specific Risk-Informed Decision-making – In-service Inspection of Piping," describes methods acceptable to the NRC staff for integrating insights from probabilistic risk assessment (PRA) techniques with traditional engineering analyses into ISI programs for piping, and addresses risk-informed approaches that are consistent with the basic elements identified in RG 1.174. EPRI published a topical report on risk-informed ISI procedures that the NRC found acceptable for referencing in licensing applications.

FY 2016

The staff received the first new reactor risk-informed ISI submittal from VC Summer, Units 2 and 3 on August 12, 2016. A pre-submittal meeting was held on May 26, 2015. Documents were submitted for this meeting on May 17, 2016.

Risk-Informed Basis

Risk-informed ISI programs use risk-significant information to improve the effectiveness of inspection of pipe segments by focusing on the most safety-significant segments.

New Light-Water Reactors

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

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

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

The next revision of this SRP which is currently under development, will include, as appropriate, DC/COL-ISG-028, "Assessing the Technical Adequacy of the Advanced Light-Water Reactor Probabilistic Risk Assessment for the Design Certification Application and Combined License Application."

FY 2016

This activity is complete and the final Rev. 3 document was published in 12/2015.

Risk-Informed Basis

This document provides guidance to the staff in conducting the risk and severe accident reviews of DC and COL applications.

Advanced Reactors

Staff Review of NuScale Licensing Topical Report on Risk Significance Determination

Summary Description

In a July 30, 2015, letter, NuScale Power, LLC, submitted licensing topical report (LTR) TR 0515 13952 NP, Revision 0, "Risk-Significance Determination" to the U.S. Nuclear Regulatory Commission (NRC) staff for review and approval. The staff initiated a review of the LTR in October 2015. The LTR describes the methods NuScale has elected to identify candidate risk-significant structures, systems, and components (SSCs) using probabilistic risk assessment (PRA). This method involves using alternative metrics than those contained in Regulatory Guide (RG) 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk Informed Activities," for defining the term "significant." In the report, NuScale notes that the metrics for determining risk significance given in RG 1.200 are relative in nature and the specific values were established based on the collective results of PRAs performed for operating reactors in the 1990s and later (i.e., estimates of CDF and large early release frequency (LERF)). Based on design and analysis work performed to date, NuScale believes that, because of the simplicity and extensive use of passive design features in the NuScale design, its PRA will yield risk estimates that are several orders of magnitude lower than those of operating plants. Using the traditional metrics specified in RG 1.200 with a PRA that produces risk estimates several orders of magnitude lower than those of operating plants would likely result in identification of many components as risk significant that are not truly risk significant (i.e., components whose assumed failure would not increase CDF nor LRF significantly.) Such a result is counter to NRC policy (60 FR 42622) on use of PRA to help focus resources on the most truly safety significant issues. Therefore, to reflect reduced risk in its determination of risk significance, NuScale developed and proposed a method for determining risk significance based *absolute* risk metrics.

FY 2016

The staff completed its review of the LTR in 2016. On March 1, 2016, the staff discussed the findings from their review with the Advisory Committee on Reactor Safeguards (ACRS) subcommittee on Future Plant Designs. On April 21, 2016, the staff issued a draft safety evaluation of the LTR. The staff discussed its draft safety evaluation report with the full ACRS during the 634th meeting of the ACRS held on May 5-6, 2016. On May 18, 2016, the ACRS issued a letter to the NRC Executive Director for Operations regarding its review of the LTR and the staff's draft Safety evaluation. The ACRS stated in their letter that: "The approach proposed by NuScale is reasonable provided that the CDF and LRF after completion of a comprehensive probabilistic risk assessment remain consistent with current estimates. However, if the CDF and LRF are found to be significantly higher than currently estimated and used in the topical report,

NuScale and the staff do not have a logical and consistent framework to adjust the quantitative risk significance criteria." The ACRS also included several recommendations pertaining to the general subject of methods for determining risk significance. The staff responded to the ACRS recommendations in a letter dated July 11, 2016. By letter dated July 13, 2016, the NRC issued a final safety evaluation report documenting the NRC staff conclusion that the LTR is acceptable for referencing in licensing applications for the NuScale small modular reactor design.

Risk-Informed Basis

The purpose of this activity is to assure that NuScale uses a technically acceptable criteria for determining the structures, systems and components in the NuScale design that are risk significant.

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

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.

FY 2016

The staff continued to use the risk insights document developed in FY2015 to support their ongoing review.

Risk-Informed Basis

The purpose of this activity is to integrate risk insights more fully into DC reviews and the formal certification decision-making process.

Materials Safety Arena

Fuel Cycle

Revise the Fuel Cycle Oversight Program (RFCOP)

Summary Description

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

FY 2015

The staff published its Cornerstone Document for public comment on July 11, 2015 (80 FR 33303). The staff addressed the comments received on the Cornerstone Document in August 2015.

FY 2016

This activity has been discontinued per Commission direction in SRM-SECY-16-0005, its response to the staff's Cornerstone SECY.

Waste Management Arena

Spent Fuel Storage and Transportation

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

The NRC staff identified and addressed potential technical and/or regulatory issues associated with the EST of spent nuclear fuel (SNF). The staff completed its evaluation of the Priority 1 and 2 technical issues identified in its report, "Identification and Prioritization of the Technical Information Needs (TIN) Affecting Potential Regulation of Extended Storage and Transportation of Spent Nuclear Fuel," hereinafter called the TIN Report.

FY 2016

As described in SECY-16-0067, this activity has been completed. The staff determined that aging issues will be addressed through the dry cask storage license renewal framework and the EST program can be closed with no adverse impact on safety, security, or environmental protection.

Risk-Informed Basis

Infrastructure development in support of risk-informed regulations.

Cross-Cutting Activities

Risk Management Regulatory Framework (RMRF)

Summary Description

NUREG-2150, "A Proposed Risk Management Regulatory Framework," (RMRF) recommended that a risk management regulatory framework applicable to all NRC program areas be adopted by the NRC. The Chairman's tasking memorandum dated June 12, 2012, directed the staff to "Review NUREG-2150 and 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 providing recommendations with respect to NUREG-2150 also include "a description of any interrelationships of ongoing risk-informed initiatives to ensure the activities are well coordinated, and effectively planned and implemented."

FY 2015

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.

FY 2016

The staff submitted SECY-15-0168 in December 2015 to seek Commission direction on RMRF related issues. In response to the SECY, the Commission, via a SRM-SECY-15-0168, approved the staff's recommendations to: 1) maintain the existing regulatory framework for the nuclear power reactor safety program area, and 2) refrain from developing an overarching, agency-wide risk management policy statement. Additionally, the Commission also agreed with the staff's conclusions that a formal design-basis extension category of requirements should not be established, and a formal agency-wide definition and criteria for determining the adequacy of

defense in depth should not be developed. Based on the Commission's directive in the SRM no further work is expected to be performed on the RMRF.

Risk-Informed Basis

The Task Force was chartered "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." The resulting framework included the following objective: "Manage the risks from the use of byproduct, source and special nuclear material through appropriate performance-based regulatory controls and oversight" and a corresponding "Risk Management Goal."