Rulemaking for Emergency Preparedness for Small Modular Reactors and Other New Technologies

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ABSTRACT

Current emergency preparedness (EP) regulations do not sufficiently reflect the advances in designs and more recent safety research, particularly with respect to small modular reactors (SMRs) and other new technologies (ONTs), such as non-light-water reactors (non-LWRs) and medical isotope facilities. In 2015, the Commission approved the U.S. Nuclear Regulatory Commission (NRC) staff's recommendation to initiate a rulemaking to revise EP regulations and guidance for SMRs and ONTs. This document provides the regulatory basis for a proposed EP rule for SMRs and ONTs. It explains the current EP framework for large light-water and non-power reactors, describes regulatory issues that have motivated rulemaking for SMRs and ONTs, presents a potential alternative to rulemaking, and summarizes the background documents related to these issues. The staff is considering a proposed EP rule, which would be applicable only to SMRs and ONTs. The rule would be consequence-oriented, performance-based, and technology-inclusive and would continue to provide for reasonable assurance of adequate protection to public health and safety. The staff concludes there is sufficient justification to proceed with rulemaking.

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ABBREVIATIONS AND ACRONYMS

10 CFR	Title 10 of the *Code of Federal Regulations*
ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act
ANSI	American National Standards Institute
ANS	American Nuclear Society
COL	Combined license
CER	Cumulative effects of regulation
CP	Construction permit
DBA	Design basis accident
DG	Draft Regulatory Guide
DOE	U.S. Department of Energy
EOF	Emergency operations facility
EP	Emergency preparedness
EPZ	Emergency planning zone
EPA	U.S. Environmental Protection Agency
ERO	Emergency response organization
FEMA	Federal Emergency Management Agency
FR	*Federal Register*
FSAR	Final safety analysis report
HTGR	High-temperature gas-cooled reactor
km	Kilometer or 1,000 meters
LWR	Light-water reactor
Mo-99	Molybdenum-99
mSv	Millisievert, 0.001 of a Sievert
MWt	Megawatts thermal
NEI	Nuclear Energy Institute
non-LWR	Non-light-water reactor
NPV	Net present value
NRC	U.S. Nuclear Regulatory Commission
NUREG	U.S. Nuclear Regulatory Commission technical report designation
OL	Operating license
ONT	Other new technology
ORO	Offsite response organization
PAG	Protective action guide
PSAR	Preliminary safety analysis report
PERT	Program evaluation and review technique
PRA	Probabilistic risk assessment
rem	Roentgen equivalent man, the centimeter-gram-second system unit of equivalent dose, effective dose, and committed dose
REP	Radiological emergency preparedness
RG	Regulatory Guide
ROP	Reactor Oversight Process
SMR	Small modular reactor
RTR	Research and test reactor
SECY	Secretary of the Commission
SOARCA	State-of-the-Art Reactor Consequence Analysis
SRM	Staff Requirements Memorandum
SSCs	Structures, systems, and components

Sv	Sievert, the International System of Units (SI) unit of dose equivalent or the biological effect of ionizing radiation

1. INTRODUCTION

Current emergency preparedness (EP) regulations are primarily focused on regulating large light-water reactors (LWRs) and do not sufficiently address the advances in designs, safety research, and their applications to small modular reactors (SMRs) and other new technologies (ONTs), such as non-light-water reactors (non-LWRs) and medical isotope facilities. At this time, the U.S. Nuclear Regulatory Commission (NRC) staff is considering rulemaking for ONTs such as those utilization and production facilities to be licensed as medical isotope facilities under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and advanced reactors licensed under 10 CFR Part 50 or 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

The Commission approved the NRC staff's recommendation to conduct rulemaking to address EP for SMRs and ONTs by applying the insights from advances in designs and safety research. This document provides the regulatory basis for a proposed EP rule for SMRs and ONTs. It explains the current EP framework for large light-water and non-power reactors, describes regulatory issues that have motivated the NRC to pursue rulemaking for SMRs and ONTs, and summarizes the background documents related to these issues.

In 2016, the NRC developed a vision and strategy to assure that the NRC is ready to efficiently and effectively review potential licensing applications for non-LWR technologies. In December 2016, the NRC published its Vision and Strategy Document (Ref. 1) with a goal to further develop the NRC's non-LWR regulatory, technical, and policy infrastructure. This EP for SMRs and ONTs rulemaking represents an important facet of the NRC's overall plan to achieve non-LWR mission readiness objectives.

For the purposes of this regulatory basis, the term "SMR" refers to a nuclear reactor (or module) designed to produce heat energy or electrical energy up to a licensed thermal power rating of 1,000 megawatts (approximately 300 megawatts electric) per module, that is licensed by the Commission under the authority of Section 103 of the Atomic Energy Act of 1954, as amended (AEA), and pursuant to the provisions of 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities." The terms "SMR" and "ONT" would be defined under the proposed rulemaking in order to clarify the applicability of EP requirements for these facilities. The definition of SMR would be based, in part, on the definition of SMR in 10 CFR 170.3, "Definitions."

1.1 Scope of Document

The scope of this document is limited to EP for SMRs and ONTs, such as medical isotope facilities and non-light water reactors. Emergency planning, preparation, and response for large LWRs, fuel cycle facilities, research and test reactors (RTRs), and other non-power, non-commercial facilities are not within the scope of this regulatory basis document and subsequent rulemaking. Furthermore, the application of the proposed rule would be limited to SMR and ONT facilities. The NRC is still considering whether the proposed rule would apply to all ONTs since the NRC staff has effectively applied existing emergency preparedness regulations and guidance to the licensing reviews of current medical isotope facilities.

Section 1 of this regulatory basis summarizes the background and developments leading to this rulemaking. Section 2 details the existing EP regulatory framework and guidance documents applicable to large LWRs and non-power reactors. Section 3 describes the major issues that

have led to movement toward EP rulemaking for SMRs and ONTs. Section 4 describes the rulemaking that would reduce or eliminate the issues described in Section 3 and discusses an alternative to rulemaking. Section 5 includes the other regulatory considerations relating to the development of the new rule. Section 6 discusses stakeholder interactions and summarizes the public comments received during the 75-day public comment period on the draft regulatory basis. Section 7 discusses the next steps that need to be taken in the development of the rule and new guidance documents, as necessary. References appear in Section 8.

1.2 Background

Concurrent with large LWR deployment and design evolution, the U.S. and other countries developed and promoted many different reactor designs that are either light-water based SMRs with passive safety features or reactors that do not use light-water as a coolant or a moderator. This latter category is commonly referred to as non-LWR technology. Advanced designs using non-LWR technology include sodium-cooled reactors, gas-cooled reactors, and molten-salt-cooled reactors. A subset of these advanced designs may also be small in power size and apply modular construction concepts. In addition, proposed medical isotope facilities licensed under 10 CFR Part 50 include production and utilization facilities that are non-reactor technologies. Collectively, the designs discussed in this paragraph may be considered either SMRs or ONTs. The new designs typically have lower probabilities of severe accidents because of their smaller size or innovative safety features, which would also likely lower impacts to public health and safety from any radiological emergency. Historically, as the industry proposed new reactor designs, the staff considered the need to modify EP requirements that were developed to support the large LWRs in operation today, as set forth in the documents described below.

In SECY-93-092, “Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and Their Relationship to Current Regulatory Requirements” (Ref. 2), the staff suggested that there be no change to existing regulations governing EP for advanced reactors and stated that regulatory direction would be given at or before the start of the design certification phase in such a way that design implications for EP could be addressed.

In SECY-97-020, “Results of Evaluation of Emergency Planning for Evolutionary and Advanced Reactors” (Ref. 3), the staff stated:

> Because industry has not petitioned for changes to EP requirements for evolutionary and passive advanced LWRs, the staff did not dedicate the resources to fully evaluate these issues. The staff remains receptive to industry petitions for changes to EP requirements for evolutionary and passive advanced LWRs….

By 2004, performance-based EP became important for existing large LWR plants. In the Staff Requirements Memorandum (SRM) to SECY-04-0236, “Staff Requirements—SECY-04-0236—Southern Nuclear Operating Company’s Proposal to Establish a Common Emergency Operating Facility at its Corporate Headquarters” (Ref. 4), the Commission recognized the concept of performance-based EP:

> The staff should consider revising 10 CFR Part 50 to make the requirements for EOFs [emergency operations facilities] more performance-based to allow other multi-plant licensees to consolidate their EOFs, if those licensees can

> demonstrate their emergency response strategies will adequately cope with an emergency at any of the associated plants.

In SECY-06-0200, "Results of the Review of Emergency Preparedness Regulations and Guidance" (Ref. 5), the staff sought Commission approval to explore the feasibility of a voluntary, performance-based EP regulatory regimen. Specifically, the staff stated:

> [A]s the EP program has matured and industry performance has improved, the staff recognized the benefits of a performance-based regulatory structure. Thus, the staff is proposing a new voluntary performance-based regulatory regimen. The staff has conceptualized the basis for a voluntary performance-based EP regulatory regimen… This regimen could be adopted in lieu of the existing EP regulations contained in 10 CFR Part 50. The current regimen tends to emphasize compliance with, and control over, emergency plans and facilities. The performance-based regimen would focus licensee efforts on actual performance competencies, rather than control of emergency plans and procedures. Regulatory oversight would focus on licensee performance, instead of licensee processes and procedures. Creating a performance-based EP regulatory regimen could achieve a higher level of preparedness, as the regimen would focus on results and abilities rather than on means. The performance-based regimen would provide the NRC with enhanced oversight of the actual competencies important to protection of public health and safety while allowing licensees increased flexibility.

In SECY-06-0200, the staff also outlined several high-level concepts for large LWRs:

- The staff would develop a set of overarching performance goals to guide the design of the performance-based framework.
- The on-shift emergency response organization (ERO) would perform many competencies necessary for emergency response.
- The augmented EROs would perform the emergency response competencies specific to the emergency response facility.
- The staff would develop performance indicators that would monitor:
  - drill and exercise performance
  - ERO participation
  - alert and notification system performance
  - facility and equipment availability
  - timeliness of team response
  - demonstrated licensee success during evaluated drills and exercises

The NRC's "Policy Statement on the Regulation of Advanced Reactors" (Ref. 6) states that advanced reactor designers should consider the expectations in the policy statement to ensure that security and emergency response are considered alongside safety during the early stages of plant design.

To address the NRC's approach to SMR policy, in SECY-10-0034, "Potential Policy, Licensing, and Key Technical Issues for Small Modular Nuclear Reactor Designs" (Ref. 7), the staff identified that EP was a key technical issue for licensing SMRs.

Following public meetings with industry and stakeholders, and a review of other SMR issues, the staff issued SECY-11-0152, "Development of an Emergency Planning and Preparedness Framework for Small Modular Reactors" (Ref. 8). This paper discussed "the staff's intent to develop a technology-neutral, dose-based, consequence-oriented EP framework for SMR sites that takes into account the various designs, modularity and colocation, as well as the size of the EPZ (emergency planning zone)." It also stated, "The staff will work with stakeholders to develop general guidance on calculating the offsite dose, and is anticipating that the industry will develop and implement the detailed calculation method for review and approval by the staff."

In SECY-14-0038, "Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight" (Ref. 9), the staff stated:

> A systematic review and revision of EP requirements to employ a more performance-based oversight regimen (regulation, inspection, and enforcement) has the potential to enhance many aspects of emergency response and oversight. A performance-based oversight regimen could simplify EP regulations and focus inspection more fully on response-related performance rather than the current focus on plan maintenance and compliance.

Although the staff asserted that the performance-based framework would simplify EP regulations and focus inspections more on response-related performance, the staff recommended that the existing framework continue to be used with operating plants because changing the EP approach for those plants would require significant resources for implementing a performance-based framework and could introduce regulatory uncertainty. Additionally, the staff recognized that existing EP programs provided reasonable assurance of adequate protection of public health and safety; therefore, the staff recommended maintaining the current EP regimen.

In SRM-SECY-14-0038, "Staff Requirements – SECY-14-0038 – Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight" (Ref. 10), the Commission approved the staff's recommendation and specified that the staff, "should be vigilant in continuing to assess the NRC's emergency preparedness program and should not rule out the possibility of moving to a performance-based framework in the future. The Commission notes the potential benefit of a performance-based emergency preparedness regimen for small modular reactors, and the staff should return to the Commission if it finds that conditions warrant rulemaking."

In 2015, the staff sought Commission approval to initiate rulemaking to revise EP regulations and guidance for SMRs and ONTs. In SECY-15-0077, "Options for Emergency Preparedness for Small Modular Reactors and Other New Technologies" (Ref. 11), the staff proposed a consequence-oriented approach to establishing requirements commensurate with the potential consequences to public health and safety and the common defense and security at SMR and ONT facilities. The staff stated that the need to establish an EP framework for SMRs and ONTs is based upon the projected offsite dose in the unlikely occurrence of a severe accident. In SRM-SECY-15-0077, "Staff Requirements – SECY-15-0077 – Options for Emergency Preparedness for Small Modular Reactors and Other New Technologies" (Ref. 12), the Commission directed the staff to proceed with rulemaking.

In SECY-16-0069, “Rulemaking Plan on Emergency Preparedness for Small Modular Reactors and Other New Technologies” (Ref. 13), the staff proposed a plan for EP rulemaking for SMRs and ONTs such as non-LWRs and medical isotope facilities. The proposed plan for rulemaking included the development of this regulatory basis document. In SRM-SECY-16-0069, “Staff Requirements – SECY-16-0069 – Rulemaking Plan on Emergency Preparedness for Small Modular Reactors and Other New Technologies” (Ref. 14), the Commission approved the staff’s proposed rulemaking plan.

A summary of the assessments and regulatory actions taken following the Fukushima accident in Japan are provided in SECY-17-0016, “Status of Implementation of Lessons Learned from Japan's March 11, 2011, Great Tohoku Earthquake and Subsequent Tsunami” (Ref. 15). The staff will, as appropriate, consider the insights from the NRC’s response to that accident during the development of the EP for SMRs and ONTs rulemaking, such as multi-unit dose assessment, communication, and staffing assessment capabilities following a beyond-design-basis event.

2. EXISTING REGULATORY FRAMEWORK

2.1 Current EP Regulations

All applicants for a construction permit (CP) or operating license (OL) for a production or utilization facility under 10 CFR Part 50 and all combined license (COL) applications submitted under 10 CFR Part 52 must provide plans for coping with emergencies as part of either a preliminary safety analysis report (PSAR) or final safety analysis report (FSAR). The specific items required to be included in emergency plans are set forth in Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities," to 10 CFR Part 50. Additionally, the regulations in 10 CFR 50.47, "Emergency Plans" provide EP requirements for nuclear power reactors. Other relevant regulations include 10 CFR 50.34, "Contents of applications; technical information," and paragraphs (q), (s), and (t) of 10 CFR 50.54, "Conditions of license." The NRC's existing EP regulations vary depending on the type of licensee. The Commission, based on its authority under the AEA, determined that these requirements are necessary for operating production and utilization facilities to provide for the public health and safety. This section describes in detail the existing regulatory frameworks applicable to large LWRs and non-power reactors.

<u>EP Regulations for Large Light-Water Power Reactors</u>

The EP regulatory framework requires each nuclear power reactor licensee to establish and maintain emergency plans and preparedness. The regulations include standards for onsite and offsite emergency response plans. These regulations and the planning basis for EP are based on the methodology presented in NRC technical report (NUREG) NUREG-0396 (U.S. Environmental Protection Agency [EPA] EPA 520/1-78-016), "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants" (Ref. 16). The following section, "The NUREG-0396 Methodology," provides additional detail.

The NRC's predecessor, the Atomic Energy Commission, issued 10 CFR 50.34 and Appendix E to 10 CFR Part 50 in 1970. After the 1979 Three Mile Island nuclear power plant accident, the NRC recognized that siting and engineered safety features provide protection, but these must be bolstered by the ability to implement protective measures during the course of an accident. Therefore, the NRC changed the scope and nature of the required emergency plans for nuclear power reactors by issuing new regulations and supporting regulatory guidance in 1980. Licensees were required to submit upgraded emergency plans compliant with the new regulations.

Through an NRC-approved EP program, a licensee has the capability to identify emergency conditions, assess radiological impact, communicate protective action recommendations, and mitigate the event. Offsite response organizations (OROs), maintained by State and local government authorities, are responsible for developing their EP programs applicable to offsite response. These programs give OROs the capability to alert and notify the public, implement protective actions as warranted, and assess radiological conditions beyond the facility to protect public health and safety.

This regulatory structure requires that site-specific emergency plans be developed and maintained in compliance with planning standards located in 10 CFR 50.47(b). Also, it requires

licensees to conduct drills and exercises to demonstrate response capabilities and to provide for critiques and corrective actions to address capability and performance weaknesses. Section IV, "Content of Emergency Plans," of Appendix E to 10 CFR Part 50, describes the information a licensee's emergency plan must contain. In 10 CFR 50.54(q), the NRC requires each licensee to follow and maintain the effectiveness of its emergency plan.

The regulations in 10 CFR 50.47 and 10 CFR 50.54 also prescribe how the NRC will make licensing decisions or take appropriate enforcement actions concerning a licensee's emergency plan. Under 10 CFR 50.47, the NRC issues OLs and COLs after making a finding "that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency." Section 50.54(s)(3) provides that the NRC will base its reasonable assurance finding on: (1) the NRC's assessment of the adequacy of the applicant's onsite emergency plan and whether there is reasonable assurance the plan can be implemented, and (2) the NRC's review of the Federal Emergency Management Agency's (FEMA)[1] findings and determinations as to whether State and local emergency plans are adequate and whether there is reasonable assurance that they can be implemented. Section 50.54(s)(2) addresses the situation when the NRC does not have reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

The NUREG-0396 Methodology

In 1978, a task force of NRC and EPA representatives established the technical basis for EP for large LWRs and published the results in NUREG-0396. The task force's report concluded that the objective of emergency response plans should be to provide dose savings for a spectrum of accidents that could produce offsite doses in excess of the EPA protective action guides (PAGs) (Ref. 18). The PAGs are reference values for radiation doses which warrant preselected protective actions for public protection, if the projected dose received by an individual in the absence of protective action exceeds the PAG. With this spectrum of accidents, the task force established the scope of the planning effort based on three key planning elements:

(1) <u>Distance to which planning for the initiation of pre-determined protective actions is warranted</u>

The task force considered that the most important guidance for planning officials is the distance from the nuclear facility, which defines the area over which planning for pre-determined actions should be carried out. NUREG-0396 introduced the EPZ concept, stating that the recommended EPZ should be "of sufficient size to provide dose savings to the population in areas where the projected dose from design basis accidents [(DBAs)] could be expected to exceed the applicable PAGs under unfavorable atmospheric conditions." It identified two types of EPZs, each of which is a distinct distance from the nuclear power plant and defined a zone where advanced planning is done.

1. A plume exposure pathway EPZ, where the principal exposure sources from this pathway are:

[1] FEMA regulations at 44 CFR Part 350, "Review and Approval of State and Local Radiological Emergency Plans and Preparedness," and a memorandum of understanding between the two agencies, first established in 1980 and last updated in 2015 (Ref. 17), set forth FEMA's role in evaluating State and local emergency plans and communicating FEMA's findings to the NRC.

a. whole body external exposure to gamma radiation from the plume and from deposited material, and

b. inhalation exposure from the passing radioactive plume.

The plume exposure pathway EPZ is the zone in which plans for prompt or urgent actions to protect the public are prepared.

2. An ingestion exposure pathway EPZ, where the principal exposure would be from ingestion of contaminated water or foods such as milk or fresh vegetables. The ingestion exposure pathway EPZ is the zone in which plans to prevent radioactive material from potentially entering the food chain are prepared.

In developing the recommendation, the task force considered several rationales for establishing the sizes of the EPZs. These rationales included the notions of risk criteria, probability limits, cost effectiveness, and a spectrum of accident consequences. The task force chose to base the rationale on a full spectrum of accidents and corresponding consequences, tempered by probability considerations. The task force stated that emergency plans for large LWRs could be based on a generic distance out to which pre-determined actions would provide dose savings for any such accidents.

Plume Exposure Pathway EPZ

The task force recommended a 10-mile (16-kilometer [km]) radius for this zone largely based on source term considerations. The EPA set the PAGs as a range from 1 to 5 rem (roentgen equivalent man) (10 millisieverts [mSv] to 50 mSv) whole body dose from external exposure and a range of 5 to 25 rem (50 mSv to 250 mSv) adult thyroid dose from radioiodine exposure. The following criteria were used to determine the generic distance (10 miles [16 km]) for the plume exposure pathway EPZ:

- The EPZ would encompass those areas in which projected dose from DBAs would not exceed the EPA PAG levels outside the zone.

- The EPZ would encompass those areas in which the doses from less severe core damage accidents (not involving large releases of radioactive material to the environment) would not exceed the EPA PAGs outside the zone.

- The EPZ would be of sufficient size to provide for substantial reduction in early severe health effects in the event of more severe core melt sequence accidents (beyond-design-basis severe events with release of substantial quantities of radioactive materials to the environment). In this case, life-threatening doses would not occur outside the zone.

- Detailed planning for protective actions within the 10-mile (16-km) EPZ should provide a basis for the expansion of response efforts beyond the plume exposure pathway EPZ, if needed.

Ingestion Exposure Pathway EPZ

The task force recommended the ingestion exposure pathway EPZ have a 50-mile (80-km) radius based on the projected distance intended for longer-term response actions and at which distance doses to the infant thyroid from ingestion of milk would not exceed the thyroid exposure PAG for milk ingestion.

The task force stated that the detailed planning within the plume exposure pathway EPZ would provide a substantial base for expanding response efforts if necessary for low-probability, high-consequence events, from which the effects could extend beyond the plume exposure pathway EPZ. The task force determined the areas in which these criteria were met by evaluating DBA data from licensees' FSARs and accident sequence, risk, and source term data from WASH-1400 (NUREG-75/014), "Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants" (Ref. 19).

Specifically, the task force calculated: (1) the release fraction from plants that exceeded EPA PAG doses beyond 10 miles (16 km) for DBAs, (2) the probability of exceeding various dose thresholds as a function of distance from the reactor, and (3) the benefit of various protective action strategies. On the basis of these analyses, the task force recommended that emergency plans should be developed for an area within a radius of about 10 miles (16 km) from the reactor for the plume exposure pathway EPZ. Using a similar rationale and considering the projected dispersal and deposition of the radioactive material and the conversion of atmospheric iodine to chemical forms that do not readily enter the ingestion pathway, the task force selected an area within a radius of about 50 miles (80 km) from the reactor for the ingestion exposure pathway EPZ.

(2) Time-Dependent Characteristics of Potential Releases and Exposures

The task force determined that, depending on the type of accident, a wide range of timing for releases is possible. The reactor safety study, WASH-1400, reported, for example, that major releases may begin in as short a time as 30 minutes to as long as 30 hours after an initiating event. The task force estimated time from the initial recognition that a serious accident is in progress to the beginning of a release of radioactive material as key information for developing emergency plans, as well as for developing the means of notifying the public of the need to take protective actions. The task force concluded that EP requirements should be based on releases that may start as early as 30 minutes following the initiation of an event.

Since the publication of NUREG-0396, the NRC has continued to evaluate the scope of EP based on time-dependent characteristics. Shortly after the operating power reactor EP regulations were established in 1980, the NRC amended its regulations to clarify EP requirements for issuing a "low power license" (Ref. 20). One of the factors considered in the basis for this regulation was that the time available for taking actions to identify and mitigate an accident is sufficient to allow adequate protective actions to be taken to protect the public near the site. In the most limiting case, the additional time available was at least 10 hours.

(3) Types of Radioactive Materials Potentially Released to the Environment

Emergency planners need information on the characteristics of potential radioactive material releases to specify the characteristics of monitoring instrumentation, develop decision aids to estimate projected doses, and identify critical exposure modes. The task force concluded that emergency plans should focus on the release of gaseous materials and volatile solids, such as noble gases and iodine, respectively, because the potential for releases to the environment decreased dramatically when progressing from gaseous materials to volatile solids to nonvolatile solids.

EP Regulations for Research and Test Reactors

While non-power production or utilization facilities must meet the emergency planning requirements of 10 CFR 50.34(a)(10), 50.34(b)(6)(v), 50.54(q), and Appendix E to 10 CFR Part 50, the requirements of 10 CFR 50.47 do not apply to these facilities. Additionally, in section I.3 of Appendix E to 10 CFR Part 50, the NRC differentiates between emergency planning requirements for nuclear power reactors and non-power facilities, stating:

> The potential radiological hazards to the public associated with the operation of research and test reactors and fuel facilities licensed under 10 CFR parts 50 and 70 [“Domestic Licensing of Special Nuclear Material”] involve considerations different than those associated with nuclear power reactors. Consequently, the size of Emergency Planning Zones (EPZs) for facilities other than power reactors and the degree to which compliance with the requirements of this section and sections II, III, IV, and V of this appendix as necessary will be determined on a case-by-case basis.

Furthermore, Footnote 2 of Appendix E allows the use of Regulatory Guide (RG) 2.6, “Emergency Planning for Research and Test Reactors” (Ref. 21) for the development and evaluation of emergency response plans at non-power reactors.

2.2 Guidance Documents

Similar to EP regulations, EP-related implementation guidance varies depending on the type of licensee. This section discusses the guidance documents that apply both to large LWRs and to non-power reactors.

EP Guidance for Large Light-Water Reactors

The NRC published, or the industry generated and NRC endorsed, many EP guidance documents. The NRC Web site at http://www.nrc.gov/about-nrc/emerg-preparedness/regs-guidance-comm.html lists many relevant guidance documents of both types.

EP Guidance for Research and Test Reactors

Consistent with the radiological risks associated with operating power levels between 5 watts thermal and 20 megawatts thermal (MWt) for currently licensed RTRs, RG 2.6 (Ref. 21) endorses the use of the source term and power-level based emergency planning guidance

contained in American National Standards Institute (ANSI)/American Nuclear Society (ANS) standard ANSI/ANS-15.16-1982, “Emergency Planning for Research Reactors” (Ref. 22).

ANSI/ANS-15.16, originally developed in 1982, and updated in 2008 and 2015, provides specific criteria and guidance for RTRs to comply with the applicable requirements set forth in 10 CFR 50.34, 10 CFR 50.54, and Appendix E to 10 CFR Part 50. These criteria provide a basis for RTR licensees and applicants to develop acceptable emergency response plans and improve EP at their facilities.

The NRC staff issued NUREG-0849, “Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors” (Ref. 23) in 1983 as a standard review plan for evaluating emergency plans submitted by RTR licensees. Consistent with ANSI/ANS-15.16, NUREG 0849 provides areas of review, planning standards, and evaluation items for NRC staff to evaluate a licensee’s or applicant’s compliance with the applicable emergency planning requirements, described above. Both NUREG-0849 and ANSI/ANS-15.16 were incorporated by reference into Section 12.7, “Emergency Planning,” of the RTR standard review plan, NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content” (Ref. 24) and NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria” (Ref. 25), as well as the Interim Staff Guidance augmenting NUREG-1537, “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors” (Ref. 26) and “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors” (Ref. 27). This guidance forms the basis for all CP and OL application reviews of RTRs and other non-power production or utilization facilities. Relevant non-reactor emergency planning guidance contained in the Interim Staff Guidance augmenting NUREG-1537 is based on NUREG-1520, Revision 1, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility” (Ref. 28).

The guidance contained in both ANSI/ANS-15.16 and NUREG-0849 addresses EPZs for RTRs ranging from the operations boundary to 800 meters for facilities up to 50 MWt. Facilities operating above 50 MWt are to be considered on a case-by-case basis.

The postulated radioactive releases from credible accidents associated with the operation of RTRs will not result in offsite radiological doses to the general public exceeding the EPA PAGs of 1 rem (10 mSv) whole body or 5 rem (50 mSv) thyroid. Therefore, these facilities would not include the General Emergency class of accidents requiring Federal assistance as part of their emergency response plans.

3. REGULATORY ISSUES

This section describes the regulatory issues stemming from the fact that SMRs and ONTs could differ substantially from the existing fleet of large LWRs. Differences may include the size of the EPZs, source terms, offsite dose consequences, siting requirements, operator staffing levels, collocation of facilities, and multi-module designs.

In 2010, in SECY-10-0034 (Ref. 7), the staff identified potential policy and licensing issues for SMRs based on the preliminary design information supplied in pre-application interactions and discussions with SMR designers and the U.S. Department of Energy (DOE). In general, these issues result from the key differences between the new designs and the current-generation large LWRs, such as size, moderator, coolant, fuel design, and operational parameters. Also, the issues result from industry-proposed review approaches and industry-proposed modifications to current policies and practices. The sections below discuss licensing issues identified in SECY-10-0034 that directly affect EP.

3.1 Size of the EPZ and Other Offsite EP Requirements

The potential for smaller reactor core sizes, lower power densities, lower probability of severe accidents, slower accident progression, and smaller accident offsite consequences per module that characterize some SMR and non-LWR designs have led DOE, SMR designers, and potential operators to revisit the determination of the appropriate size of the EPZs, the extent of onsite and offsite emergency planning, and the number of response staff needed. Other topics raised by the industry involve the potential to revise public alert and notification requirements and the appropriateness of the protective action requirements in 10 CFR 50.47(b)(10).

In carrying out its responsibility under the AEA, the Commission establishes regulatory standards for offsite radiological emergency planning when there is a need to determine that reasonable assurance exists regarding the adequacy of the offsite plans. (In this context, “adequate” means that the plans meet the NRC’s standards for such plans.) In the case of EP regulations for RTRs, fuel cycle facilities, and independent spent fuel storage facilities, there are no regulatory requirements for dedicated offsite radiological emergency plans as part of the NRC license. Accordingly, NRC guidance for such facilities states that FEMA findings and determinations are not needed to support NRC licensing decisions. Similarly, for SMRs and ONTs within the scope of this rulemaking, if the NRC determines that assurance of offsite radiological EP (REP) is not required for specific facilities where the EPZs do not extend beyond the site boundary, then FEMA findings and determinations regarding reasonable assurance under 10 CFR 50.54(s)(3) would likely not be needed. In such cases, even in the absence of NRC requirements for offsite radiological emergency planning, the responsible OROs would continue to take actions to protect the health and safety of the public by using the community’s general emergency response capabilities, which are not unique to radiological emergency response.

3.2 Source Term, Dose Calculations, and Siting

The staff evaluates the radiological consequences of the hypothetical DBAs for determining the appropriate siting and the level of safety of the plant design. The staff uses accident source terms in dose analyses to assess site suitability and the effectiveness of the containment or confinement and plant mitigation features, and to show compliance with regulations for determining the amount of dose to workers and members of the public. The technical basis for

EP for large LWRs established in NUREG-0396 (Ref. 16) considers a wide spectrum of potential accidents for the facility, including severe accidents. NUREG-0396 states that while it is not appropriate to develop specific plans for the most severe and most improbable events, consideration should be given to the characteristics of these events, "in judging whether emergency plans based primarily on smaller accidents can be expanded to cope with larger events." This approach provides reasonable assurance that capabilities exist to minimize the impacts of even the most severe events. Consistent with this guidance from NUREG-0396, the staff does not limit its consideration to DBAs. Furthermore, the staff must consider the source terms associated with the multi-module (for example, multi-reactor) designs of some SMRs and ONTs, where those modules share structures, systems, and components (SSCs) to such an extent that there is a potential for fission product releases to the environment from more than one module. Facility designers and license applicants will need to establish appropriate credible source terms for SMRs and ONTs for this spectrum of accidents.

In SECY-93-092 (Ref. 2), the staff proposed that accident source terms for high-temperature gas-cooled reactors (HTGRs) and sodium fast reactors should be based on a bounding mechanistic analysis that meets certain performance and modeling criteria supported by research and test data. That SECY paper provides the following definition for "mechanistic source term":

> A mechanistic source term is the result of an analysis of fission product release based on the amount of cladding damage, fuel damage, and core damage resulting from the specific accident sequences being evaluated. It is developed using best-estimate phenomenological models of the transport of the fission products from the fuel through the reactor coolant system, through all holdup volumes and barriers, taking into account mitigation features, and finally, into the environs.

The conditions under which the use of design-specific and event-specific mechanistic source terms can be justified and used in licensing non-LWRs would have to be supported by experimental data to confirm the bounding parameters of the source term. In SRM-SECY-93-092, "Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and Their Relationship to Current Regulatory Requirements," (Ref. 29), the Commission approved the staff's recommendation. The technical basis for, and the uses of, design-specific and event-specific mechanistic source terms methods in licensing are critical to the resolution of whether mechanistic source terms could be used for SMRs and ONTs. Also, the staff will ensure that uncertainties are appropriately taken into account. The staff expects non-LWR designs of other types to follow this recommendation also. In SECY-16-0012, "Accident Source Terms and Siting for Small Modular Reactors and Non-Light Water Reactors" (Ref. 30), the staff noted that SMR and non-LWR applicants can employ modern analysis tools to demonstrate quantitatively the safety features of those designs. Hence, applicants may use mechanistic source term analysis methods to demonstrate the ability of the enhanced safety features of plant designs to mitigate accident releases.

The existing regulations and planning basis for EP for large LWRs are based upon an anticipated prompt response to a wide spectrum of events. Similarly, for SMRs and ONTs, the staff will consider an appropriate spectrum of accidents and consequences to provide a basis for judging the adequacy of features such as functional containment design and offsite emergency planning. The staff intends to consider accident scenarios during power ascension, full-power operation, power decrease, shutdown, and low-power operations. All sources of potential accidental radiological releases from the facility will be considered. For potential

licensing of non-LWRs, the staff is working with stakeholders to modernize the framework for selection of licensing basis events for safety analysis using a risk-informed approach. As activities progress, the NRC will maintain alignment between this rulemaking and the implementation of other non-LWR activities as intended in the Vision and Strategy Document (Ref. 1).

3.3 Operator Staffing

Some SMR and ONT designs may use multiple modules at one site with a single, centralized control room. Designers have indicated that they are considering designs that can operate with a staffing complement that is less than what is currently required of large LWRs by 10 CFR 50.54(m), which sets forth the minimum licensed operator staffing requirements. The staff will consider emergency response staffing commensurate with SMR and ONT designs and emergency response functions.

3.4 Collocation of Facilities

SMRs and ONTs of the same type may be collocated together on the same site or with large reactors, at industrial facilities, with different reactor types, or any combination of the above. The policy issues associated with collocation include the need for guidance on the effect on EP of collocation, including the size of the EPZ, number of control rooms, staffing, training, and interaction with other collocated facilities.

3.5 Multi-Module Facilities

SECY-11-0152 discusses the potential for an SMR or ONT site to accommodate multiple facilities (Ref. 8). The staff acknowledges the need to address a range of complex considerations, including shift staffing changes if a licensee increases the number of modules and the impact on modules that have common or shared systems.

Probabilistic risk assessment (PRA) or bounding analysis techniques can be used to obtain accident sequences, source terms, fission product releases, and dose assessments to define EP requirements that consider the maximum number of reactor modules licensed for the site and the sharing of SSCs.

3.6 Performance-Based Approach to Emergency Preparedness

The current approach for large LWRs to meet EP requirements is largely prescriptive planning standards. As discussed in Section 1 of this document, the NRC staff has previously considered the appropriateness of a performance-based framework for EP for SMRs and ONTs. The NRC has a long history of successful implementation of performance-based EP requirements (for example, performance-based requirements for emergency facilities and staffing, Reactor Oversight Process (ROP), and use of performance indicators). In a performance-based approach to EP rulemaking, performance and results are the primary basis for regulatory decisionmaking, and the licensee has the flexibility to determine how to meet the established performance criteria for an effective EP program.

The preliminary criteria for defining the performance-based regulation include:

- identifying suitable performance-based requirements that will consider the 16 planning standards of 10 CFR 50.47(b) and the requirements of 10 CFR 50.54(q) and Appendix E to 10 CFR Part 50

- implementing procedures, facilities, organization, training, activation processes, duty roster qualifications, shift staffing, response organizations, communication systems, facility location, and emergency requirements that are part of the licensee's responsibility to be demonstrated by setting up appropriate performance indicators

- defining an appropriate corrective action process for identified weaknesses and their correction consistent with the significance of the weaknesses

- demonstrating EP performance in terms of protecting public health and safety at a level comparable to that required for currently operating large LWR facilities

- establishing an NRC oversight process that can ensure that an appropriate level of EP exists and that it provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency

Some aspects are expected to remain unchanged or be revised appropriately from the current approach. Examples of these aspects include:

- initial licensing review and issuance of safety evaluations for licensing submittals

- notification requirements to Federal, State, and local authorities

- drills and exercises demonstrating EP performance

- appropriate public alert and notification methods

- maintenance of a complete Emergency Response Data System that can be used to appropriately investigate the emergency condition that occurred

- changes to the emergency plan being subject to 10 CFR 50.54(q)

4. REGULATORY APPROACHES

This section considers two options to enhance the effectiveness and efficiency of the regulatory framework for applicants and future licensees of SMRs and ONTs and the NRC while providing assurance of public health and safety.

- Option 1 would use the existing regulatory framework supplemented by guidance on applying for exemptions to the rules.
- Option 2 would provide new regulations through rulemaking to define the level of EP appropriate for an SMR or an ONT facility.

4.1 Option 1: Exemptions and Guidance

This option would maintain the current EP regulations in effect. Relief from regulatory requirements would continue to be granted on a case-by-case basis through the exemption process. Guidance on applying for such exemptions would be developed.

Assessment of Option 1

This option would retain the current EP provisions in 10 CFR Part 50. Certain existing EP requirements could impose regulatory burdens on SMR and ONT applicants and licensees that are not necessary to protect the public health and safety. While potential SMR and ONT applicants and licensees would likely request EP exemptions, this option would require site-specific analysis by the applicant or licensee and review by the NRC for each exemption request. For example, Tennessee Valley Authority requested exemptions from EP-related regulations as part of its Early Site Permit Application. This process would not likely result in efficiency gains or predictable regulatory outcomes because of the expected variations in SMR and ONT designs and a potentially significant number of applicants. However, Option 1 could be a cost-effective approach and be efficiently implemented if a limited number of applicants submit license applications. In addition, the exemption process for EP could be further enhanced through guidance development. Option 1 would not relieve the burden imposed on applicants, licensees, and the NRC resulting from the case-by-case exemption process addressing EPZ size and emergency plans. By continuing to assess EP exemptions on an individual basis, which is an acceptable regulatory process, applicants, licensees, and the NRC would continue to expend resources on preparing and processing exemption requests.

4.2 Option 2: Conduct Rulemaking

This option would provide EP regulations and guidance developed specifically for SMR and ONT facilities. In particular, this option would establish an alternative regulatory framework for determining the size of plume exposure pathway and ingestion exposure pathway EPZs for SMRs and ONTs. Emergency preparedness planning standards and requirements would be established commensurate with EPZ size determinations.

Technology-Inclusive Approach

The EP measures established for the current NRC licensees have proven effective regardless of the technology. Under Option 2, a similar technology-inclusive approach would be applied to

SMR and ONT facilities that take into account the various designs, systems, and purposes of the facilities.

Small Modular Reactors

As discussed in Section 3, SMRs may consist of multiple reactors and could be collocated near or adjacent to industrial sites. Collocation offers the potential for SMRs of the same type to be located together or with large reactors, at industrial facilities, with different SMR types, or any combination of the above. Potential licensees for SMRs may need to be prepared for events associated with other collocated facilities' proximate hazards.

Some SMR designs are employing inherent passive safety characteristics, below-grade or in-ground construction, natural circulation decay heat removal, interconnected systems, and advanced fuel types. Locating part or all of the reactor and structures below ground level will affect the height of a release, which would be at or near ground level. A ground-level release would affect the dispersion of the plume. Buried reactor structures and pools may have longer coolant loss times and correspondingly longer accident progression times. Passive safety features that do not depend on electric power also could lead to longer accident progression times. These design aspects will determine the accident frequency, progression, and potential consequences.

Other New Technologies

The NRC has not issued a license for a commercial non-LWR facility for construction or operation since Fort St. Vrain in 1973. The NRC has licensed LWRs with relatively low power (Big Rock Point and La Crosse) and an HTGR (Fort St. Vrain), each with a plume exposure pathway EPZ size that was smaller than those for large LWRs. The plume exposure pathway EPZs for Fort St. Vrain, Big Rock Point, and La Crosse were each established at 5 miles (8 km). Additionally, the NRC has reviewed a variety of conceptual non-LWR designs, at varying levels of detail, between 1978 and 2010. A brief history of non-LWR safety reviews is available in the NRC's Vision and Strategy Document (Ref. 1). As described in the previous section on SMRs, non-LWRs may also be collocated and require event preparedness reflective of proximate hazards.

The NRC is reviewing the emergency plans for non-power production or utilization facilities intending to produce medical radioisotopes, such as molybdenum-99 (Mo-99), using the guidance published in ANSI/ANS-15.16 (Ref. 22), NUREG-0849 (Ref. 23), and the Interim Staff Guidance augmenting NUREG-1537 (Ref. 26 and Ref. 27).
Use of the Interim Staff Guidance augmenting NUREG-1537 (Ref. 26 and Ref. 27) accounts for the unique emergency planning considerations associated with the production facilities that would be used to chemically process low enriched uranium targets to separate Mo-99 from other fission products.

Additionally, based on discussions with potential advanced reactor applicants, the NRC staff anticipates that some applicants for molten salt reactors may submit applications for production facilities to conduct onsite fuel cleanup activities. Due to the nature of these chemical processes, these production facilities may share similar safety and emergency planning considerations with existing fuel cycle facilities and proposed medical isotope facilities. As such, the NRC staff may consider guidance in either the Interim Staff

Guidance Augmenting NUREG-1537 (Ref. 26 and Ref. 27) or NUREG-1520 (Ref. 28), as appropriate, in its reviews of emergency plans for these production facilities.

Background on Establishing Emergency Planning Zones

The technical bases for establishing EPZ requirements are outlined in current power reactor and non-power reactor guidance, such as NUREG-0396 (Ref. 16), ANSI/ANS-15.16 (Ref. 22), and the current EPA PAG Manual (Ref. 31). NUREG-0396 established fixed EPZ requirements for large LWRs at 10 miles (16 km) (plume exposure pathway EPZ) and 50 miles (80 km) (ingestion exposure pathway EPZ). Existing EP requirements associated with various nuclear facilities use a dose-at-distance, consequence-oriented approach to establish the boundary of their EPZs (or other planning areas) and consider the EPA PAGs to aid in decisions to implement protective actions.

The establishment of the EPZ for the plume exposure pathway is necessary to define the areas where planning for the initiation of predetermined prompt protective actions is warranted. These prompt protective actions are directed at avoiding or reducing dose to the members of the public. The ingestion exposure pathway EPZ provides an area of consideration for major exposure pathways associated with the ingestion of contaminated food and water. The duration of any exposure to contaminated food or water could range from hours to months and represents a longer-term response need.

SECY-11-0152 discusses the staff's intent to develop a technology-neutral (or technology-inclusive), dose-based, consequence-oriented EP framework for SMR sites that takes into account the various designs, modularity, and collocation of these reactors, as well as the size of the EPZs (Ref. 8). The staff's approach is based on the concept that EP requirements could be scaled to be commensurate with the accident source term, fission product release, and associated dose characteristics of the SMR design. Issues relating to the modularity of the designs and potential for collocating the reactors near industrial facilities will also need to be addressed.

In SECY-11-0152, the staff presented example calculations for establishing different plume exposure pathway EPZ boundaries based on the 1-rem (10-mSv) EPA PAG reference value. It used an example assessment of dose-at-distance for the plume exposure pathway EPZ boundary to obtain a range of EPZs based on the projected source term, which is a function of the specific reactor design being considered. SECY-11-0152 included example calculations for four boundaries: site boundary, 2 miles (3 km), 5 miles (8 km), and 10 miles (16 km). The staff will consider these examples, as well as different approaches, when determining different EPZ boundaries.

In response to SECY-11-0152, the Nuclear Energy Institute (NEI) prepared "White Paper: Proposed Methodology and Criteria Establishing the Technical Basis for Small Modular Reactor Emergency Planning Zone" (Ref. 32), which proposed a generic methodology and criteria that could be adopted and used for establishing the technical basis for SMR-appropriate EPZs. It addressed only SMRs with light-water-cooled and moderated designs and the plume exposure pathway EPZ. It did not address other designs or the ingestion exposure pathway EPZ. The NRC has not endorsed this White Paper.

Boundary Determination for EPZs for SMRs and ONTs

Defining the EPZs for SMRs and ONTs is central to the approach to EP regulation, whether it be prescriptive or performance-based. Considering that proposed SMRs and ONTs are designed to have a reduced potential for offsite releases from radiological emergencies, the staff expects that consequences from an accident involving these technologies may have a limited impact on public health and safety, thereby forming a basis for smaller EPZs.

Option 2 would provide a general framework for establishing the size of EPZs for SMRs and ONTs. The general framework, like the current regulatory framework, would rely on accident analyses to determine potential radiological consequences, given as dose-at-a-distance, and would be established without site- or design-specific information about source terms, fission products, or projected offsite doses. The general framework could guide pre-application discussions between the applicant and the NRC.

Specific information regarding source term, isotopic mix, release pathways, accident types and consequence assessment for SMRs and ONTs will be provided as required, and as part of the application process under 10 CFR Parts 50 and 52. Applicants proposing site-specific EPZs would be required to demonstrate that projected dose from a range of accidents, including DBAs and severe accidents, would not exceed the EPA PAGs levels outside the zone, which may be limited to the site boundary or include areas immediately adjacent to the site boundary. Applicants proposing site-specific EPZs would also be required to show a substantial reduction in risk to public health and safety at the chosen plume exposure pathway EPZ outer boundary for very severe accidents, similar to the evaluation in NUREG-0396 (Ref. 16). After receiving site- and design-specific information from an SMR or ONT applicant, the NRC staff would then assess the need to provide site-specific guidance concerning the accident scenarios being considered.

Because of the range of potential source terms and designs for SMRs and ONTs, the NRC is considering a scalable method for determining EPZ size for these facilities rather than the fixed 10-mile [16-km] and 50-mile [80-km] EPZs established for large LWRs. The staff will leverage the substantial improvements over the last several years in the understanding and modeling of severe accident phenomena, including the insights learned from the State-of-the-Art Reactor Consequence Analysis (SOARCA), while developing the rule and guidance. An appropriate method for analyzing plume exposure pathway EPZ size may involve: (1) using PRA insights to calculate the probability of exceeding PAGs as a function of distance from the site boundary for a spectrum of accidents, (2) establishing criteria for determining the point at which the probability of exceeding the PAGs is acceptably low, and/or (3) concluding that the proposed EPZ size is supported by an acceptable spectrum of consequences. Although this is a more rigorous site- and design-specific approach, it will be analogous to the methodology discussed in NUREG-0396. While the staff will work with stakeholders to develop general guidance on calculating offsite dose and criteria, it is anticipated that the industry will develop and implement detailed calculation methodologies for review and approval by the staff. The applicant would have the burden of offering a well-justified basis for the proposed EPZs consistent with the potential offsite consequences resulting from a spectrum of accidents and the application of any insights from SOARCA.

The source terms for SMRs and many ONTs are expected to be small, and relative to the ingestion pathway may have a longer-term response component and a scaled approach to address protective actions. For these technologies, the ingestion exposure pathway EPZ size ranges may be appropriately sized from the site boundary to a fixed-distance beyond the site boundary. In case the plume exposure pathway EPZ is bounded by the site boundary, no ingestion exposure pathway EPZ would be necessary. Even in the absence of an offsite

ingestion exposure pathway EPZ, the successful quarantine and removal from public access of contaminated food and water products in response to biological contamination suggest that a response to prevent ingestion of contaminated foods and water could be performed in an expeditious manner, without pre-planned actions. Three notable incidents documented by the Center for Disease Control and Prevention that demonstrate the capability to conduct large-scale quarantines are the multi-state outbreaks of E. Coli O157:H7 infections from spinach (September-October 2006), the multi-state outbreak of human *salmonella enteritis* infections associated with shell eggs (July-December 2010), and the multi-state outbreak of fungal meningitis and other infections (October 2012).

The successful quarantine and removal from public access of contaminated food and water products in response to biological contamination suggest that for SMRs and ONTs, the response to prevent ingestion of contaminated foods and water, were it deemed necessary, could be performed in a similar manner. The NRC staff is considering an approach for establishing ingestion exposure pathway EPZ size based on varying plume exposure pathway EPZ sizes and conducting sampling of agricultural and food products during any accident release to determine the need for quarantine. The staff will provide additional clarification on this topic as part of the proposed rule.

Other Topics under Consideration

In addition to providing a general framework for establishing EPZ size, the NRC staff is considering the following topics for incorporation in the proposed rule under Option 2:

- definitions for specific terms used for this rule
- collocation, including collocation with existing NRC licensees, industrial facilities, and other SMRs or ONTs
- multi-module facilities
- offsite REP, including the applicability of 10 CFR 50.54(s) when a plume exposure pathway EPZ does not extend beyond the site boundary
- emergency response staffing
- periodic drills and exercises

Assessment of Option 2

The staff has discussed the benefits of EP rulemaking for SMRs and ONTs in SECY-15-0077 (Ref. 11). A consequence-oriented, technology-inclusive, and performance-based approach to EP regulation, as discussed in this regulatory basis, is being considered at this time as the appropriate means to achieve objectives, such as:

- Promote regulatory stability, predictability, and clarity: Under Option 2, the applicants will demonstrate how their proposed facilities will achieve EPA PAG dose limits for their proposed site-specific EPZs, which may be limited to the site boundary or extend some distance beyond the site boundary. While applicants would need to provide site- and design-specific information to justify their proposed EPZs, the overall regulatory framework established under Option 2 would be technology-inclusive. This approach

will give clear guidance to the applicants so they can structure their applications to support predictable regulatory decisions.

- Recognize technological advancements embedded in design features: SMRs and ONTs are expected to encompass many advances in technology in their varied designs. In the generic framework intended for the rule, such advances are inherently recognized. Facilities with reduced potential offsite consequences will have reduced EP requirements.

- Credit small reactor core size and associated differences in accidents: SMRs and many ONTs involve smaller sized reactor cores, and the accident profiles may be significantly different from large LWRs. These designs are associated with a potential low likelihood of severe accidents, slower transient response times, and relatively small and slow release of fission products. Current EP requirements were developed for large LWRs. A new consequence-oriented, technology-inclusive, risk-informed, and performance-based EP rule for SMRs and ONTs will assess and take into account the small size reactor core and source terms for these designs, which potentially could provide for lower risk to the public as compared to large LWRs. Different aspects of the EP regulations and requirements will be defined consistent with the characteristics of the accident scenarios.

- Eliminate the potential regulatory need to request exemptions from EP requirements: Licensing SMRs and ONTs within the current regulations, developed for large LWRs, may require approval of exemption requests. This approach may lead to inconsistencies and undue burden for applicants, licensees, and the NRC staff. A consequence-oriented, technology-inclusive, and performance-based approach to EP regulation that is generically established without site- or design-specific information about source terms, fission products, or projected offsite dose has the potential to eliminate any need to consider exemptions for SMRs and ONTs.

4.3 Staff Recommendations

Option 1 could be a cost-effective approach if a limited number of applicants submit license applications. The exemption process could be further enhanced through the development of guidance. However, this process would not likely result in the efficiency gains possible through Option 2 or predictable regulatory outcomes because of the expected variations in SMR and ONT designs and a potentially significant number of applicants. By continuing to assess EP exemptions on an individual basis, applicants, licensees, and the NRC would continue to expend resources on preparing and processing exemption requests.

Option 2 would provide a clear set of rules and guidance for EP for SMRs and ONTs and reduce the need for EP exemptions as applicants request permits and licenses. It would provide additional benefits for SMR and ONT licensees because this rulemaking would establish greater regulatory stability, predictability, and clarity in the licensing process. Option 2 would incur costs to develop rulemaking but would cost less in implementation.

The staff will also ensure that the implementation of Option 2 does not conflict with existing regulatory requirements and emergency planning guidance for facilities outside of the scope of this option, such as large LWRs and RTRs. The staff has already received an exemption request from an applicant planning to construct an SMR and could receive additional requests

before final EP for SMRs and ONTs rule is implemented. The staff will work to ensure consistency between the review of exemption requests submitted by SMR or ONT facilities and the development of requirements for the proposed rule. The NRC will state in the final rule that any compliance dates established in licensing actions approved before the effective date of the final rule would continue to apply once the final rule is in effect.

Considering the above options, the staff concludes that: (1) the principle of using a scalable dose-at-distance and consequence-oriented approach to determine an EPZ size can be applied to SMRs and ONTs, and (2) the rulemaking for SMRs and ONTs is the most effective and desirable path for both the NRC and applicants and licensees for SMRs and ONTs while still providing reasonable assurance that adequate protective measures will be taken in the event of a radiological emergency at such a facility.

The staff recommends pursuing rulemaking (Option 2) and using a scalable dose-at-distance and consequence-oriented approach to determine EPZ size for SMRs and ONTs.

5. OTHER REGULATORY CONSIDERATIONS

5.1 Cost and Impact Considerations

5.1.1 Introduction

The potential benefits and costs of the options must be considered for: (1) SMR and ONT licensees, (2) State, local, and Tribal government organizations, and (3) the NRC. The analyses in this section are based on the staff's assessment and input from stakeholders. Impacts to the general public are not included at this stage of the process. A more detailed evaluation of benefits and costs will be provided during the regulatory analysis that will be included in the proposed rule (see Section 7.1 of this document).

The staff considered the exemption and guidance alternative to a rulemaking action, as discussed in Section 4.1 of this document. The NRC is pursuing a rulemaking because it would establish a comprehensive regulatory framework that would result in enhanced regulatory stability, predictability, clarity in the licensing process, and opportunity for stakeholder input on the regulatory framework. This is also in keeping with the implementation of the Commission's direction in SRM-SECY-15-0077 (Ref. 12) and SRM-SECY-16-0069 (Ref. 14).

The analyses in this section present the incremental benefits and costs that would be incurred by the licensees, NRC, and offsite governmental organizations from the rulemaking action. Incremental benefits and costs are calculated values and impacts that are above the baseline condition. The baseline condition for this rulemaking action includes the benefits and costs to comply with current EP regulations in 10 CFR 50.34; 10 CFR 50.47(b); 10 CFR 50.54; and Appendix E to 10 CFR Part 50, as well as 10 CFR 50.12, "Specific Exemptions," as applicable. Based on the staff's assessment, the incremental benefits and costs for this rulemaking action may include the following:

- incremental averted costs to eliminate the current regulatory need for certain applicants to request exemptions from current EP regulations
- incremental averted costs to adopt an appropriate scalable EPZ size that differs from current EPZ sizes
- incremental costs to the NRC for rulemaking and the development of associated guidance documents

This cost estimate compares Option 1 (exemption requests) to Option 2 (rulemaking). It is important to note that both options have considerable averted costs when compared to complying with the current EP regulations. This is because both options provide for a regulatory action to reduce or possibly eliminate the siren stations, the siren station maintenance, and various EP activities that affect protective actions outside the site boundary. The staff recognizes that the benefits and costs described in this draft analysis are order of magnitude estimates subject to further refinement and input from stakeholders. However, these estimates are useful to eliminate unviable solutions, to establish feasibility, and to identify potential trade-offs early in the process. The staff expects that the proposed rule and related guidance development associated with the proposed rule would clarify the scope and would allow for further refinement of these analyses. The staff will offer additional opportunities for comment on

the proposed rule language, as well as on the updated benefits and costs, as these products are developed.

5.1.2 Potential Effect on Licensees

This rulemaking will create a set of EP regulations specifically for designs that fall within the definition of SMRs and ONTs. Therefore, those licensees will not have to incur the incremental costs normally associated with the exemption process that would have been otherwise required for the current EP regulations. This includes the costs of preparing the exemption requests and responding to the NRC's requests for additional information via multifaceted interactions, such as correspondence, teleconferences, and meetings. Table 5-1 shows these averted costs, based on the NRC assumption that two applicants of SMRs or ONTs will submit license applications in the near future (2020), with possibly six more applications submitted after 2025. The NRC estimates that each applicant would need 1,483 person-hours to prepare and submit an exemption request, and the NRC estimates that the weighted hourly labor rate for personnel preparing these documents is $117 per hour. The data on future license applications is based on the staff's current knowledge of the affected entities plans and the expected timing of their license applications. A detailed table showing all the input costs that were used for this analysis is included in Appendix A of this final regulatory basis.

Table 5-1 Industry Operation: Emergency Planning Exemption Requests

Year	Activity	Total Averted Cost		
		Undiscounted	7% NPV	3% NPV
2020	Two exemption requests	$348,000	$284,000	$318,000
2025	Six exemption requests	$1,044,000	$608,000	$824,000
	Total:	**$1,392,000**	**$892,000**	**$1,142,000**

Note: NPV = net present value.

Under current regulations for large LWR designs, the plume exposure pathway EPZ size is about 10 miles (16 km). However, for SMRs and ONTs with comparatively smaller source terms as well as with passive design features, and with the proposed adoption of a scalable plume exposure pathway EPZ size approach, the potential exists for the plume exposure pathway EPZ to be at the site boundary. The staff believes that this aspect of the rule would represent significant incremental averted costs to licensees. For example, licensees would only need to establish an onsite emergency plan with demonstrable performance indicators for the NRC to find reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. Averted costs (compared to the regulatory baseline) in this scenario would result from the removal of the requirements for: (1) evacuation time estimates and corresponding annual and decennial updates, (2) public alert and notification system installation and annual maintenance, (3) FEMA annual user fees, (4) annual drills and exercises, and (5) State agreement and licensing annual fees. Both Option 1 and Option 2 avert these EP-related costs from each future SMR licensee throughout its license term. The staff is using the assumption of eight applicants based on proprietary, non-publicly available information provided to the NRC. It is important to note that Option 2 would avert exemption request costs from any future SMR and ONT applicants and licensees beyond the eight discussed in this regulatory basis, providing additional averted costs under the rulemaking alternative.

When the plume exposure pathway EPZ is determined to be outside of the licensee's site boundary and less than about 10 miles (16 km), the licensee would be required to include offsite response coordination in its emergency plans, in accordance with 10 CFR 50.54(q), 10 CFR 50.47(b), and Appendix E to 10 CFR Part 50. This is because the costs for establishing, for example, a 2-mile plume exposure pathway EPZ offsite emergency plan would be different from the costs of establishing the current 10-mile plume exposure pathway EPZ offsite emergency plan. This averted cost would depend on factors such as the complexity of emergency planning due to the geographical areas associated with governmental organizations and OROs and the magnitude of the public alert and notification system required. This aspect of the rule would result in an incremental averted cost to licensees when compared to the regulatory baseline, but both Option 1 and Option 2 in this regulatory basis would result in approximately the same averted cost. This regulatory basis does not provide a cost estimate for this averted cost, as compared to the regulatory baseline, since it is not a significant incremental averted cost difference between Option 1 and Option 2.

Lastly, additional benefits for SMR and ONT licensees will be realized under Option 2 because this rulemaking will give greater regulatory stability, predictability, and clarity to the licensing process. This is mostly because the licensee would no longer need to use the exemption process to establish EP criteria commensurate with site- and design-specific considerations. Based on the cost estimate with an EPZ inside the site boundary, the rulemaking alternative (Option 2) results in estimated averted costs to the industry that range from $892,000 using a 7 percent NPV to $1.14 million using a 3 percent NPV, when compared to Option 1, as shown in Table 5-2.

Table 5-2 Total Industry Averted Costs

Attribute	Undiscounted	7% NPV	3% NPV
Total Industry Implementation Cost:	$0	$0	$0
Total Industry Operation Cost:	$1,392,000	$892,000	$1,142,000
Total Industry Cost:	**$1,392,000**	**$892,000**	**$1,142,000**

Note: NPV = net present value.

5.1.3 Potential Effect on Offsite Governmental Organizations

Because SMRs and ONTs are being designed with smaller source terms, and with the adoption of the scalable plume exposure pathway EPZ size, the potential exists for the plume exposure pathway EPZ to be at the licensee's site boundary. However, when the plume exposure pathway EPZ is determined to be outside of the licensee's site boundary and less than about 10 miles (16 km), offsite governmental organizations may need to establish formal offsite radiological emergency plans. The staff believes that this potential requirement would represent an incremental averted cost, when compared to the regulatory baseline, to offsite governmental organizations in the plume exposure pathway EPZ because the cost for establishing, for example, a REP program for a 2-mile plume exposure pathway EPZ would most likely be different from the cost to establish a REP program for the current 10-mile plume exposure pathway EPZ. This averted cost would depend on factors such as the complexity of the offsite radiological emergency response programs due to the geographical areas associated with offsite governmental organizations. These averted costs are not expected to significantly differ between Option 1 and Option 2.

5.1.4 Potential Effect on the NRC

The NRC's development and implementation of EP regulations for SMRs and ONTs through a rulemaking would result in incremental costs to the NRC. These costs include the preparation of the rule language, and accompanying draft guidance documents. The costs would include both staff and contractor time to prepare proposed rule language, draft guidance, supporting analyses (for example, a draft regulatory analysis, draft environmental analysis, and draft Office of Management and Budget Paperwork Reduction Act supporting statement), a FR notice, and public outreach during the proposed rule and draft guidance development phase. After publishing the proposed rule, the NRC would incur costs associated with public comment resolution and preparation of the final rule, final guidance, and supporting documentations for the rulemaking. The NRC has committed a significant number of technical staff to develop the rulemaking and related guidance over a 4-year period. The cost estimate below takes into account the fact that under Option 1 (exemption requests), the staff would also generate guidance documents to instruct applicants and licensees regarding what would need to be addressed in an exemption. Therefore, the costs for RG development below represent the incremental cost of the rulemaking RGs relative to the guidance documents for the exemption requests. These estimated costs are shown in Table 5-, where costs for each action are estimated at a labor rate of $129 per hour.

Table 5-3 NRC Implementation: Rulemaking Costs

Year	Activity	Hours	Total Cost		
			Undiscounted	7% NPV	3% NPV
2017	Develop RG for proposed rule	805	($104,000)	($104,000)	($104,000)
2017	Develop proposed rule	2,013	($260,000)	($260,000)	($260,000)
2018	Revise RG after public comments	805	($104,000)	($97,000)	($101,000)
2018	Develop proposed rule	2,013	($260,000)	($243,000)	($252,000)
2018	Develop/issue final rule	2,013	($260,000)	($243,000)	($252,000)
2019	Develop/issue RG for final rule	805	($104,000)	($91,000)	($98,000)
2019	Develop/issue final rule	2,013	($260,000)	($227,000)	($245,000)
		Total:	**($1,350,000)**	**($1,270,000)**	**($1,310,000)**

Note: NPV = net present value.

The benefits to the NRC include meeting the goals of the NRC's 2014–2018 Strategic Plan (NUREG-1614, Volume 6, "Strategic Plan: Fiscal Years 2014–2018" (Ref. 33) in relation to the strategic goal of safety, and the cross-cutting strategies of regulatory efficiency and openness, as discussed in Section 5.5 of this document. Additionally, the NRC will receive averted costs (benefit) from the expected eight exemption requests that will not be submitted by industry (under Option 2 when compared to Option 1) and, therefore, will not be reviewed by the staff. Table 5- shows these averted costs, assuming 713 hours of effort for each request and a labor rate of $129 per hour.

Table 5-4 NRC Operation: Averted Exemption Request Reviews

Year	Activity	Total Averted Cost		
		Undiscounted	7% NPV	3% NPV
2020	Review two exemption requests	$184,000	$150,000	$168,000
2025	Review six exemption requests	$552,000	$321,000	$436,000
	Total:	**$736,000**	**$471,000**	**$604,000**

Note: NPV = net present value.

Combined, these costs and averted costs show an estimated cost to the NRC as a result of this rulemaking, ranging from ($800,000) using a 7 percent NPV to ($710,000) using a 3 percent NPV, as shown in Table 5-5. It is important to note that Option 2 would avert exemption request costs from any future SMR and ONT applicants beyond the eight discussed in this regulatory basis, providing additional averted costs under the rulemaking alternative.

Table 5-5 Total NRC Costs

Attribute	NRC Costs		
	Undiscounted	**7% NPV**	**3% NPV**
Total NRC Implementation Cost:	($1,350,000)	($1,270,000)	($1,310,000)
Total NRC Operation Cost:	$740,000	$470,000	$600,000
Total NRC Cost:	($610,000)	($800,000)	($710,000)

Note: NPV = net present value.

5.1.5 Cost Justification

Relative to Option 1 of using the exemption request process to the EP regulations for SMRs and ONTs, the staff concludes that the averted incremental costs to the licensees and offsite governmental organizations, and the benefits of improved regulatory efficiency and certainty to the licensees and the NRC justify the incremental costs for this rulemaking action (Option 2) by the NRC. Furthermore, the rulemaking would also benefit the NRC because no future resources would be expended for evaluating routine exemption requests to current EP regulations by SMR and ONT applicants and licensees. Table 5- shows a marginal net benefit (averted cost) for the quantitative factors discussed above. The qualitative factors are also primarily averted costs and benefits and are expected to be of a lesser order of magnitude than the costs quantified in this regulatory basis.

Table 5-6 Total Costs with the Plume Exposure Pathway EPZ Inside the Site Boundary

Attribute	Total Averted Costs		
	Undiscounted	**7% NPV**	**3% NPV**
Industry implementation	$0	$0	$0
Industry operation	$1,392,000	$892,000	$1,142,000
Total industry cost	$1,392,000	$892,000	$1,142,000
NRC implementation	($1,350,000)	($1,270,000)	($1,310,000)
NRC operation	$740,000	$470,000	$600,000
Total NRC cost	($610,000)	($800,000)	($710,000)
Net	**$782,000**	**$92,000**	**$432,000**

Note: NPV = net present value. There may be small differences between tables due to rounding.

The incremental cost estimate between Option 1 and Option 2 is the difference between the rulemaking costs of Table 5- and the exemption request costs of Table 5-1 and Table 5-. These costs are approximately the same so that there is no quantitative cost justification for choosing Option 1 versus Option 2. However, the rulemaking alternative (Option 2) would avert exemption request costs for any future SMR and ONT applicants and licensees beyond the eight included in this analysis, making Option 2 incrementally more cost beneficial than Option 1

in the long term. The averted costs to the industry and NRC of exemption requests if the rulemaking option is pursued, as seen by summing up the averted costs in Table 5-1 and Table 5-, range from $1.36 million (7 percent NPV) to $1.75 million (3 percent NPV), and the costs for the NRC rulemaking actions under the rulemaking option range from $1.27 million (7 percent NPV) to $1.31 million (3 percent NPV), as shown in Table 5-. Therefore, the rulemaking option is marginally cost justified (less than $100,000) because the averted costs exceed the costs of the rulemaking process.

As noted in Section 4.2, "Assessment of Option 2," of this regulatory basis, the rulemaking option would provide additional benefits for SMR and ONT licensees because it would: 1) promote regulatory stability, predictability, and clarity; 2) recognize technological advancements; 3) credit small reactor core size and associated differences in accidents; and 4) eliminate the potential regulatory need to request exemptions from EP requirements.

5.1.6 Uncertainty Analysis

The staff completed a Monte Carlo sensitivity analysis for this regulatory basis using the specialty software @Risk®.[2] The Monte Carlo approach answers the question, "What distribution of net benefits results from multiple draws of the probability distribution assigned to key variables?"

As this regulatory basis utilizes estimates of values that are sensitive to plant-specific cost drivers and plant dissimilarities, the NRC staff provides the following analysis of the variables that have the greatest amount of uncertainty.

Monte Carlo simulations involve introducing uncertainty into the analysis by replacing the point estimates of the variables used to estimate base case costs and benefits with probability distributions. By defining input variables as probability distributions instead of point estimates, the influence of uncertainty on the results of the analysis (in other words, the net benefits) can be effectively modeled.

The probability distributions chosen to represent the different variables in the analysis were bounded by the range-referenced input and the NRC staff's professional judgment. When defining the probability distributions for use in a Monte Carlo simulation, summary statistics are needed to characterize the distributions. These summary statistics include the minimum, most likely, and maximum values of a program evaluation and review technique (PERT) distribution,[3] the minimum and maximum values of a uniform distribution, and the specified integer values of a discrete population. The staff used the PERT distribution to reflect the relative spread and skewness of the distribution defined by the three estimates.

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[2] Information about this software is available at http://www.palisade.com.

[3] A PERT distribution is a special form of the beta distribution with specified minimum and maximum values. The shape parameter is calculated from the defined *most likely* value. The PERT distribution is similar to a triangular distribution in that it has the same set of three parameters. Technically, it is a special case of a scaled beta (or beta general) distribution. The PERT distribution is generally considered superior to the triangular distribution when the parameters result in a skewed distribution, as the smooth shape of the curve places less emphasis in the direction of skew. Similar to the triangular distribution, the PERT distribution is bounded on both sides and therefore may not be adequate for some modeling purposes if it is desired to capture tail or extreme events.

The NRC performed the Monte Carlo simulation by repeatedly recalculating the results, 10,000 times. For each iteration, the values were chosen randomly from the probability distributions that define the input variables. The values of the output variables were recorded for each iteration, and these resulting output variable values were used to define the resultant probability distribution. Figure 1, Figure 2, and Figure 3 display the histograms of the incremental benefits and costs of the rulemaking option (Option 2) compared to the exemption request option (Option 1). The analysis shows that both the industry and the NRC would benefit if the rulemaking alternative is pursued, given the staff's assumption, for the purposes of this analysis, that the plume exposure pathway EPZ will be inside the site boundary for these SMRs.

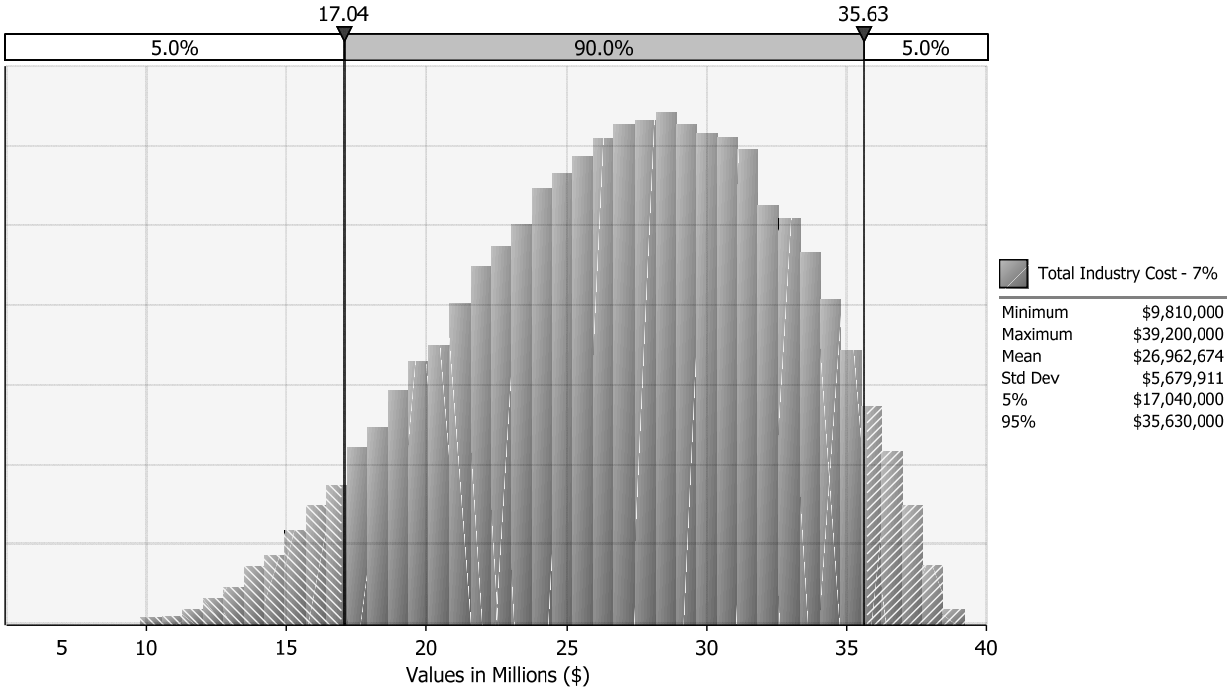

Figure 1 Industry Total Averted Cost – 7 Percent NPV

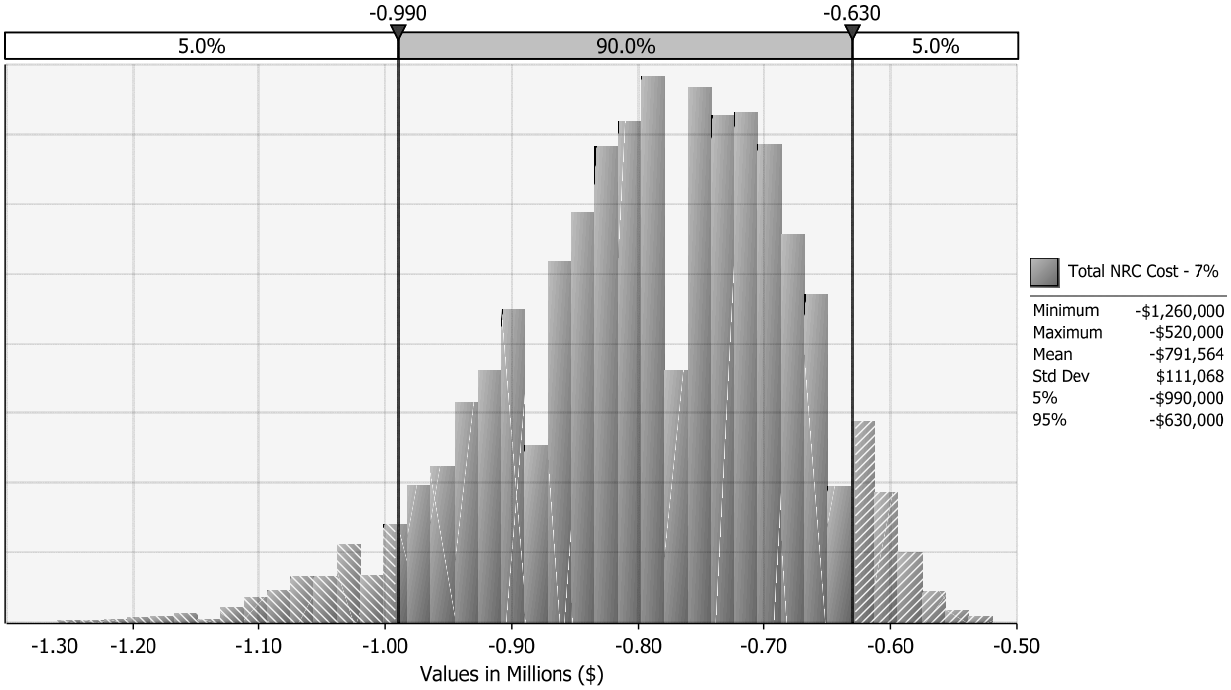

Figure 2 NRC Total Costs – 7 Percent NPV

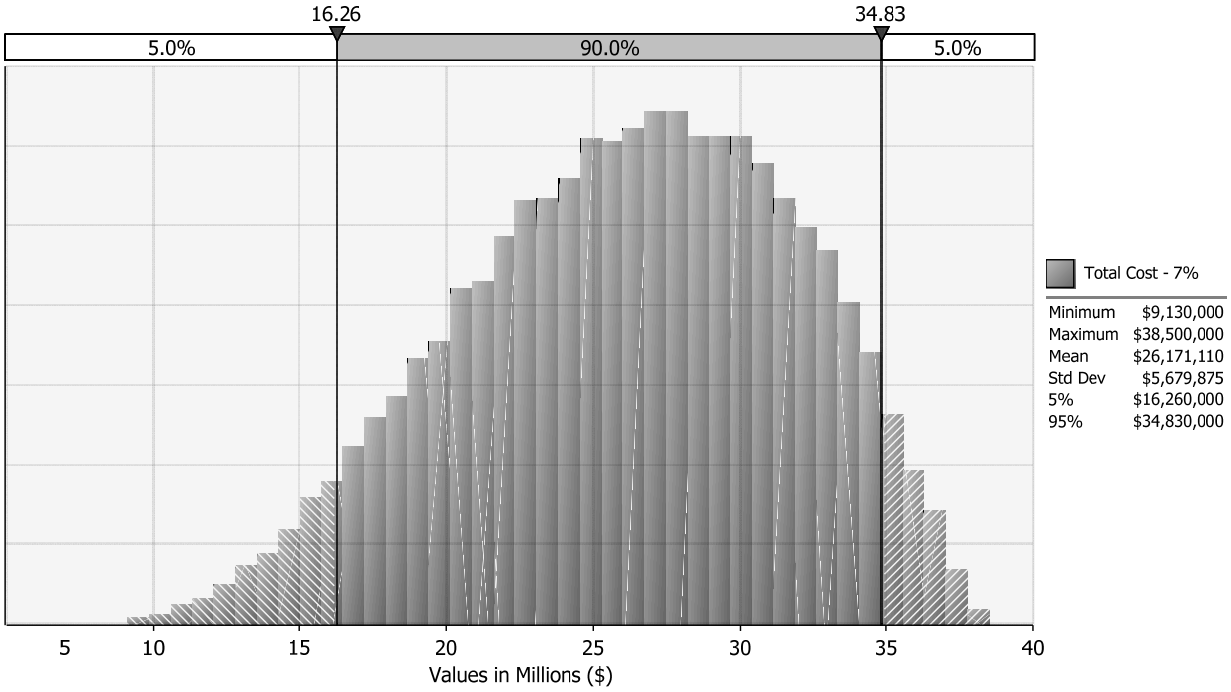

Figure 3 Total Averted Cost – 7 Percent NPV

Table 5- presents descriptive statistics on the uncertainty analysis. The 5 percent and 95 percent values (in other words, the bands marked 5.0% on either side of the 90.0% confidence interval) that appear as numerical values on the top of the vertical lines in Figure 1, Figure 2, and Figure 3 are reflected in Table 5- (rounded) as the 0.05 and 0.95 values, respectively.

Table 5-7 Uncertainty Results Descriptive Statistics – 7 Percent NPV

Uncertainty Result	Incremental Cost-Benefit (2017 million dollars)					
	Min	Mean	St. Dev.	Max	0.05	0.95
Total Industry Cost	$0.64	$0.89	$0.08	$1.15	$0.76	$1.02
Total NRC Cost	($1.29)	($0.79)	$0.11	($0.51)	($0.99)	($0.63)
Total Cost	($0.52)	$0.10	$0.14	$0.55	($0.13)	$0.32

Note: There may be small differences between tables due to rounding.

Examining the range of the resulting output distribution provided in Table 5-, it is possible to more confidently discuss the potential incremental costs and benefits of the regulatory basis. This table displays the key statistical results, including the 90-percent confidence interval in which the net benefits would fall between the 5-percent and 95-percent percentile values.

Figure 4 shows a tornado diagram that identifies the key variables whose uncertainty drives the largest impact on total costs (and averted costs) for this regulatory basis. This figure ranks the variables based on their contribution to cost uncertainty. Three variables—the hours to develop the proposed rule, the hours to develop the final rule, and the industry weighted hourly rate—drive the most uncertainty in the costs. The remaining key variables show diminishing variation.

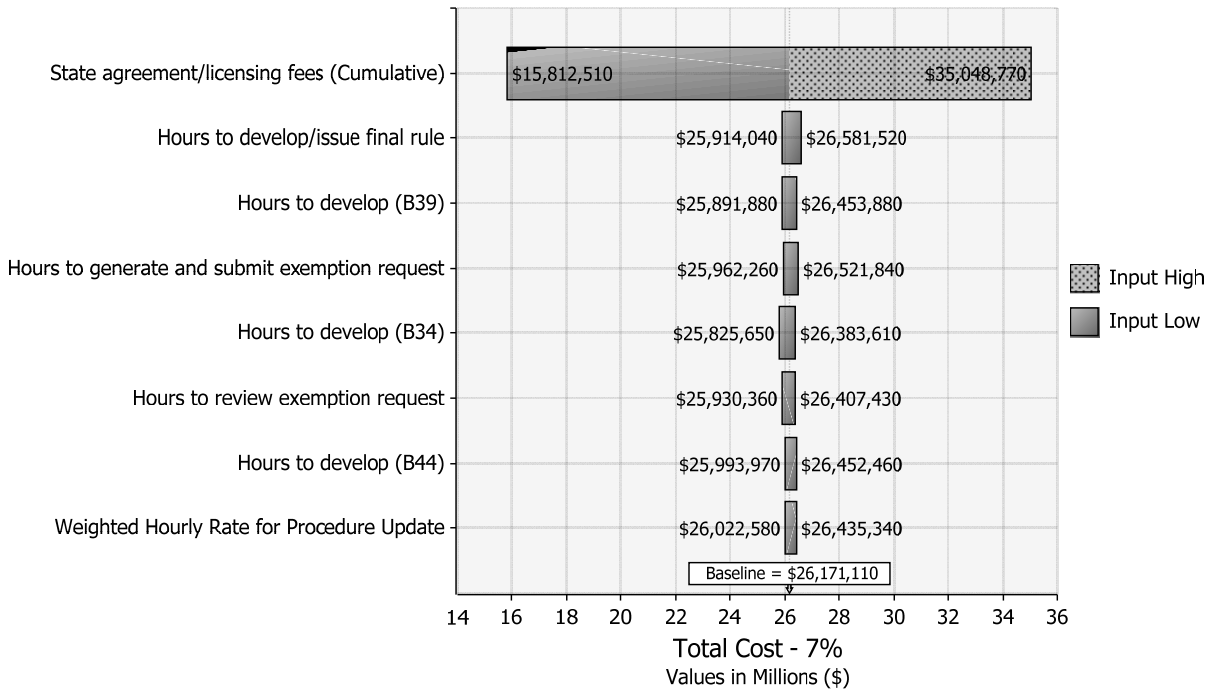

Figure 4 Tornado Diagram – Total Averted Costs – 7 Percent NPV

As can be seen in Table 5-, the averted costs for the industry and the NRC for this regulatory basis have a mean value of $100,000 at a 7 percent discount rate with EPZs inside the site boundary. The uncertainty analysis shows a 76.5 percent chance that the rulemaking would be cost effective. This is the primary reason for concluding that the benefits of this rulemaking marginally outweigh the costs.

5.2 Backfitting and Issue Finality

Neither of the two options presented by the NRC staff in this regulatory basis is subject to the NRC's backfitting regulation at 10 CFR 50.109, "Backfitting," and issue finality regulations in 10 CFR Part 52. Option 1 is the current regulatory baseline, thereby imposing no change in requirements or NRC staff positions. Option 2, the proposed revisions to EP requirements, would not constitute backfitting because the revisions would contain new requirements for new facilities, with the possible exception of some ONT licenses for non-power production or utilization facilities. The intended rule defining the new EP regulations for SMRs and ONTs would be in place before any other licenses are expected to be granted for new SMRs or ONTs. Because the backfitting and issue finality regulations do not protect current or future applicants from changes to applicable requirements, the NRC would not prepare a generic backfit analysis under 10 CFR 50.109 or further address the issue finality criteria in 10 CFR Part 52 in the proposed rule. For the non-power production or utilization facility ONTs that may obtain a license before the effective date of the new rule, the NRC would not prepare a facility-specific backfit analysis because 10 CFR 50.109 and the issue finality regulations in 10 CFR Part 52 do not apply to non-power production or utilization facility licensees.

5.3 Cumulative Effects of Regulation

The NRC has implemented a program to address the possible cumulative effects of regulation (CER) in the development of regulatory bases for rulemakings. The CER is an organizational effectiveness challenge that results from a licensee or other affected entity implementing several complex positions, programs, or requirements within a prescribed implementation period and with limited available resources, including the ability to access technical expertise to address a specific issue. The NRC requested feedback from the public at the draft regulatory basis stage on the cumulative effects that may result from an amendment to the EP requirements in 10 CFR Part 50 and any other NRC actions that may affect SMRs and ONTs. The NRC did not receive any comments during the 75-day public comment period indicating unintended consequences of the proposed rule (Option 2). The NRC will continue to engage and request feedback from the public, at the proposed rule stage, on the cumulative effects that may result from the new EP requirements. During the development of the final rule, the NRC also plans to conduct a public meeting to better understand and clarify the cumulative effects of the new EP requirements.

5.4 Environmental Analysis

This rulemaking would develop performance-based EP requirements for SMRs and ONTs that would be commensurate with the potential consequences to public health and safety from radiological emergencies and would not be a major Federal action significantly affecting the quality of the human environment; therefore, an environmental impact statement would not be required. Based on the staff's preliminary analysis, the staff would not expect there to be a significant impact to the public from this action because safety and dose criteria would be chosen to ensure that public health and safety will be protected. The environmental impacts associated with licensing SMRs or ONTs will be considered in the process for individual license applications.

5.5 NRC Strategic Plan

The proposed rulemaking (Option 2) would support the NRC's 2014–2018 Strategic Plan (NUREG-1614) (Ref. 33) in relation to the strategic goal of safety and the cross-cutting strategies of regulatory efficiency and openness.

For the safety goal, the proposed rulemaking would support NRC Safety Strategy 2, "Enhance the risk-informed and performance-based regulatory framework in response to advances in science and technology, policy decisions, and other factors," because it would develop performance-based EP requirements for SMRs and ONTs that would be commensurate with the potential accident-related consequences to public health and safety. In addition, the planned rulemaking would support NRC Safety Strategy 3, "Ensure the effectiveness and efficiency of licensing and certification activities to maintain both quality and timeliness of licensing and certification reviews," by developing a performance-based regulatory framework that would significantly support an NRC licensing initiative with a future regulatory benefit, considering Commission and congressional interest in SMRs and ONTs.

Of the cross-cutting strategies, the proposed rulemaking would support Regulatory Effectiveness Strategy 2, "Regulate in a manner that effectively and efficiently manages known risks and threats, clearly communicates requirements, and ensures that regulations are consistently applied, are practical, and accommodate technology changes in a timely manner,"

because the rulemaking would allow the reduction of plume exposure pathway EPZ sizes that could be smaller than what is currently required by 10 CFR 50.47(c)(2) but still reflect offsite consequences and radiation risks to public health and safety. In addition, soliciting input from the public on this regulatory basis during the development of the rulemaking supports Openness Strategy 1, “Transparency: Make clear information about the NRC’s responsibilities and activities accessible to stakeholders.”

5.6 Regulatory Flexibility Act

The Regulatory Flexibility Act, enacted in September 1980, requires agencies to consider the effect of their regulatory proposals on small entities, analyze alternatives that minimize effects on small entities, and make their analyses available for public comment.

None of the applicable licensees fall within the definition of “small entities” set forth in the size standards established by the NRC in 10 CFR 2.810, “NRC Size Standards.” Therefore, a proposed rulemaking would not have a significant economic effect on a substantial number of small entities.

5.7 Peer Review of Regulatory Basis

The Office of Management and Budget’s “Final Information Quality Bulletin for Peer Review” (Ref. 34), requires each Federal agency to subject “influential scientific information” to peer review before dissemination. The Office defines “influential scientific information” as “scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.” This regulatory basis document does not contain “influential scientific information.” Therefore, there is no need for a peer review of the regulatory basis.

6. STAKEHOLDER INTERACTIONS

6.1 Past Interactions

Many public meetings and other interactions have taken place between the NRC and stakeholders on licensing issues related to SMRs and ONTs. The well-attended DOE-NRC Workshops on Advanced Non-Light Water Reactors in September 2015 (Ref. 35) and June 2016 (Ref. 36) addressed many of these issues. An April 2016 report from the Nuclear Innovation Alliance entitled, "Enabling Nuclear Innovation: Strategies for Advanced Reactor Licensing" (Ref. 37), also addressed many of these issues.

As the discussion of rulemaking for EP has evolved, some of the interactions with stakeholders have specifically dealt with EP. Of notable interest is the December 2013 NEI white paper (Ref. 32) which focused on the plume exposure EPZ for light-water SMRs. The stated objective of the paper was as follows:

> to propose a generic methodology and criteria that can be adopted and used for establishing the technical basis for SMR-appropriate EPZs. To that end, [the] paper is intended to serve as a vehicle to support the continuing dialogue with the staff that should result in a mutually agreeable methodology and criteria, and thus provide the SMR developers and applicants sufficient guidance as they proceed to develop their design-specific and site-specific technical basis.

The approach in the NEI white paper:

> is rooted in: (1) the expectation of enhanced safety inherent in the design of SMRs (e.g., increased safety margin, reduced risk, smaller and slower fission product accident release, and reduced potential for dose consequences to population in the vicinity of the plant); (2) the applicable SECY-11-0152 concepts including utilization of existing emergency preparedness regulatory framework and dose savings criteria of NUREG-0396; and (3) the significant body of risk information available to inform the technical basis for SMR-appropriate EPZ, including severe accident information developed since NUREG-0396 was published in 1978, and information from the design-specific and plant-specific probabilistic risk assessments (PRAs) which will support SMR design and licensing.

A recent example of the continuing dialogue referred to in the NEI white paper is the NRC Category 3 public meeting in August 2016 to discuss a performance-based approach to EP for SMRs and ONTs. The participant feedback, as summarized in a September 2016 NRC memo (Ref. 38), is important to note:

> Overall, the feedback from participants was in support of the staff proceeding with a performance-based approach for EP, indicating that it will be more effective because it will focus on achieving desired outcomes. Participants also favored the approach as one that allows for innovation, noting that it should have enough flexibility to accommodate and account for a broad range of sequence of events of various SMR and non-LWR designs. Additionally, attendees expressed gratefulness for the NRC's initiative in considering a performance-based approach at this time.

Other important aspects of this meeting were summarized as follows:

> Specific feedback highlighted the need for NRC to ensure that a performance-based approach would assess: capabilities of the licensees to maintain their emergency plans; adequacy of communications with off-site responders and other interested stakeholders; staff proficiency; and, the availability of facilities and equipment. It was acknowledged that this should be done through inspection and oversight of drills and exercises at a pre-determined frequency. It was also suggested that the validity of the performance indicators be inspected on a periodic basis similar to the current EP Reactor Oversight Process (ROP) Performance Indicator inspection methodology. With respect to inspection and enforcement, feedback supported the use of a program similar to the ROP. Performance indicators submitted could be inspected on a periodic basis similar to approaches used now and could include a review of data collection and verification of recording. However, it was noted that an appropriate approach to enforcement would be necessary to ensure accountability for inadequate performance.
>
> Participants also pointed out the need for determining an appropriate process for changes to EP plans, similar to the current 10 CFR 50.54(q) process. The staff responded that this would be addressed as the rule language and guidance documents would be developed. The potential need for an entire new suite of guidance documents, including the change process, was the only disadvantage identified by participants as it would require additional up-front work to reflect the new approach. Participants responded favorably to the need for this additional work.

In addition, the NRC hosted a public meeting on the draft regulatory basis on May 10, 2017.

6.2 Public Comments on Draft Regulatory Basis

The NRC made available a draft regulatory basis in the FR on April 13, 2017 for a 75-day public comment period (82 FR 17768). In the draft regulatory basis, the NRC requested feedback from the public on questions related to the scope of the draft regulatory basis, performance-based approach, regulatory impacts, and CER.

The NRC received 57 written comment submittals from governmental and non-governmental organizations and individuals, which are available at https://www.regulations.gov under Docket ID NRC-2015-0225. These commenters included approximately 45 individuals, 4 environmental groups, 3 industry groups, 1 Native American Tribal organization, 3 State organizations, and 1 Federal agency. The NRC staff reviewed all comments submitted on the draft regulatory basis, grouped the comments into categories by comment topic, and developed a resolution for each topic. The most notable comments that were received include topics such as: consequence-based approach, collocation, dose assessment, EPZ and offsite EP, general approach, siting of multi-module facilities, performance-based approach, regulatory analysis, scope of the draft regulatory basis, safety, and technology-inclusive approach.

The staff revised the regulatory basis as appropriate based on public comments. Many commenters, including members of the public, Federal and State government agencies, SMR

designers, non-governmental organizations, and industry, addressed the NRC's proposed approach for determining the size of an EPZ. In response to some comments requesting additional detail on this process, the staff revised and restructured Section 4 to provide additional information on the general framework for establishing the size of EPZs for SMRs and ONTs. In addition, in response to questions about the applicability of the proposed rulemaking, the staff clarified in Section 1 the terms "SMR" and "ONT" and stated that definitions for "SMR" and "ONT" will be defined under the proposed rulemaking. In response to comments from FEMA, the industry, and other commenters, the staff clarified its discussion of the ingestion exposure pathway EPZ in Section 4.2. To address industry comments, the staff added discussion into Section 3.2 about the use of a risk-informed approach for this rulemaking and also provided additional detail in Appendix A about the inputs and assumptions used to estimate the cost and benefits of the rulemaking option (Option 2).

7. NEXT STEPS

7.1 Development of Proposed Rule

The NRC staff will proceed with developing a proposed rule, as previously outlined in Option 2, to resolve the regulatory issues identified in Section 3. The Advisory Committee on Reactor Safeguards will review the proposed rule and the final rule.

The process for rulemaking is presented in NRC Management Directive 6.3 (Ref. 39), which should be referenced for more information on next steps. In addition to the regulatory basis, a regulatory analysis is required. As noted in the MD 6.3 (Ref. 39), the regulatory analysis process "systematically provides complete disclosure of relevant information supporting a regulatory decision. The conclusions and recommendations included in a regulatory basis document are neither final nor binding, but are intended to enhance the soundness of decisionmaking by NRC managers and the Commission."

This rulemaking is considered to be of medium priority and is being tracked by the Commission. As such, this rulemaking is included in the NRC budget process. Budgeted activities include development of the proposed and final rule packages, stakeholder interaction, guidance development, and development of inspection procedures.

7.2 Future Guidance Documents

Rulemaking would require consideration of developing new guidance documents and revising existing guidance documents, as appropriate. For this rulemaking, it is anticipated that new draft RGs (DGs) would be developed to describe an acceptable approach for SMR and ONT licensees to implement the EP requirements in the proposed rule. The new guidance documents would be all inclusive, using concepts drawn from the existing guidance documents. Draft guidance documents will be made available for public comment when the proposed rule is issued. Existing guidance documents will remain applicable to large LWRs, fuel cycle facilities, RTRs, and other non-power production or utilization facilities and may be revised as a result of this proposed rulemaking. For example, RG 1.219, "Guidance on Making Changes to Emergency Plans for Nuclear Power Reactors" (Ref. 40) may be revised to include SMRs and ONTs rather than develop a new RG. The DGs and revised guidance documents would be issued as final guidance documents upon issuance of the final rule.

8. REFERENCES

1. U.S. Nuclear Regulatory Commission, “NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness,” December 2016, ADAMS Accession No. ML16356A670.

2. U.S. Nuclear Regulatory Commission, “Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and Their Relationship to Current Regulatory Requirements,” SECY-93-092, April 8, 1993, ADAMS Accession No. ML040210725.

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APPENDIX A: COST ESTIMATE INPUTS

Activity	Mean Estimate	Low Estimate	Best Estimate	High Estimate
EP Exemption Requests for SMRs				
Weighted hourly rate	$117	$94	$118	$139
Hours to generate and submit exemption request	1483	1250	1500	1650
NRC Review EP Exemption Requests				
Hourly rate for NRC	$129	$129	$129	$129
Hours to review	713	620	710	820
NRC Develop Regulatory Guide				
Hours to develop	805	630	700	1400
NRC Develop Proposed Rule				
Hours to develop	4025	3150	3500	7000
NRC Revise Regulatory Guide				
Hours to develop	805	630	700	1400
NRC Finalize/Issue Regulatory Guide				
Hours to develop	805	630	700	1400
NRC Develop/Issue Final Rule				
Hours to develop	4025	3150	3500	7000

SUBJECT: FINAL REGULATORY BASIS FOR THE EMERGENCY PREPAREDNESS FOR SMALL MODULAR REACTORS AND OTHER NEW TECHNOLOGIES RULEMAKING DATED XX-XXXX

ADAMS Accession No: ML17206A265 ***via email**

OFFICE	NRO/DNRL/LB3	NSIR/DPR/POB	NRO/DSRA/ARPB	NSIR/DPR/POB	NRR/DPR/PRLB
NAME	ACarrera*	KThomas*	ACosta*	RKahler*	AAdams*
DATE	07/25/2017	07/25/2017	7/27/17	08/02/2017	08/02/2017
OFFICE	NRO/DSRA/LB3	NRO/DSRA/ARPB	NRR/DPR/PRMB	NRO/DSEA	NRO/DSEA
NAME	JColaccino*	JSegala*	MKhanna*	LBurkhart*	ACampbell*
DATE	08/09/2017	08/08/2017	08/08/2017	08/02/2017	08/11/2017
OFFICE	NSIR/DPR	NRR/DPR	NRO/DSRA	NRO/DNRL	OGC
NAME	SCoffin*	LLund*	MFranovich*	ABradford	HBenowitz*
DATE	08/11/2017	08/10/2017	08/11/2017	08/11/2017	09/15/2017
OFFICE					
NAME					
DATE					

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