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

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## ABSTRACT

Current emergency preparedness (EP) regulations do not reflect the advances in reactor designs and more recent reactor safety research, particularly with respect to small modular reactors (SMRs) and other new technologies (ONTs), such as non-light-water reactors (non-LWRs). The U.S. Nuclear Regulatory Commission (NRC) staff requested permission from the Commission to conduct rulemaking to address this issue. 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 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 is applicable only to SMRs and ONTs. The rule is intended to be consequence-oriented, performance-based, and technology-inclusive. The rule will provide for reasonable assurance of adequate protection of public health and safety.

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## ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| 10 CFR | Title 10 of the *Code of Federal Regulations* |
| CER | cumulative effects of regulation |
| DBA | design-basis accident |
| 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 |
| ETE | evacuation time estimate |
| FEMA | Federal Emergency Management Agency |
| FR | *Federal Register* |
| HTGR | high-temperature, gas-cooled reactor |
| km | kilometer or 1000 meters |
| LWR | light-water reactor |
| mSv | millisievert, 0.001 of a Sievert. |
| NEI | Nuclear Energy Institute |
| non-LWR | non-light-water reactor |
| NPV | net present value |
| NRC | U.S. Nuclear Regulatory Commission |
| NUMARC | Nuclear Utilities Management and Resources Council |
| NUREG | reports or brochures on regulatory decisions, results of research, results of incident investigations and other technical and administrative information published by the Nuclear Regulatory Commission. |
| ONT | other new technology |
| ORO | offsite response organization |
| PAG | protective action guide |
| PANS | public alert and notification system |
| 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 |
| SHINE | SHINE Medical Technologies, Inc. |
| SRM | staff requirements memorandum |
| SSC | structure, system, and component |
| Sv | Sievert, the metric system unit of dose equivalent or the biological effect of ionizing radiation |
| TEDE | total effective dose equivalent |
| TMI | Three-Mile Island used generically to refer to the 1979 Three-Mile Island accident |

# 1. INTRODUCTION

Current emergency preparedness (EP) regulations do not adequately address the advances in reactor designs, reactor safety research, and their applications to small modular reactors (SMRs) and other new technologies (ONTs). The NRC staff obtained permission from the Commission to conduct rulemaking to address EP for SMRs and ONTs applying the advances in reactor designs and reactor safety research. The purpose of this document is to inform and provide an opportunity for stakeholders to participate in the rulemaking process, consistent with the NRC's Principles of Good Regulation: Independence, Openness, Efficiency, Clarity, and Reliability. 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 reactors, describes regulatory issues that have motivated rulemaking for SMRs and ONTs, and summarizes the background documents related to these issues.

## 1.1 Scope of Document

The scope of this document encompasses EP for SMRs and ONTs only. Emergency planning, preparation, and response for large light-water reactors (LWRs), fuel cycle facilities, research and test reactors (RTRs), and other non-power, noncommercial 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.

Section 1 of this regulatory basis summarizes the background and developments leading to this rulemaking. Section 2 details the existing EP regulatory framework applicable to large LWRs, and guidance documents. Section 3 describes the major issues that have led to movement toward EP rulemaking for SMRs and ONTs. Section 4 describes the rulemaking that will 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 includes questions for stakeholders to consider while providing comments. Section 7 discusses the next steps that need to be taken toward rulemaking, as well as technical aspects that will need to be addressed in new guidance documents. References appear in Section 8.

## 1.2 Background

After the U.S. deployment of large LWRs spanning the 1950's through the 1990's, the U.S. and other countries developed and promoted many different designs, such as sodium-cooled reactors, heavy-water-moderated reactors, gas-cooled reactors, and evolutionary LWR designs with passive design features. As the industry proposed new and innovative reactor designs, the staff considered the need to modify EP requirements. The new designs typically have lower probabilities of severe accidents, and SMRs have smaller radiological source terms because they are lower in power or have special design features.

More recently, new reactor designs being developed and promoted include light-water SMRs, such as the integral pressurized-water reactor design from NuScale. Some advanced reactor designs do not use light water as a coolant or a moderator but instead are gas-cooled, liquid-metal-cooled, or molten-salt-cooled. Furthermore, some medical isotope production facilities use a fission process either within a reactor or from an accelerator target. Collectively, the designs discussed in this paragraph are considered either SMRs or ONTs. Their smaller size or innovative safety features are likely to lead to lower risk or less demanding accident

conditions, motivating reconsideration of the EP requirements that were developed to support the large LWRs in operation today.

In response to these various designs, the staff engaged the Commission on associated issues. 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," dated April 8, 1993 (NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML040210725), 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," dated January 27, 1997 (ADAMS Accession No. ML992920024), the staff stated:

> Because industry has not petitioned for changes to EP requirements for evolutionary and passive advanced LWRs [light-water reactors], 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 SRM-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," dated February 23, 2005 (ADAMS Accession No. ML050550131), 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," dated September 20, 2006 (ADAMS Accession No. ML061910707), 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 outlined several high-level concepts:

- 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
  - facility and equipment availability
  - ERO activation and reporting timelines
  - success during emergency drills

The NRC's "Policy Statement on the Regulation of Advanced Reactors" (73 FR 60612; October 14, 2008) 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.

In SECY-10-0034, "Potential Policy, Licensing, and Key Technical Issues for Small Modular Nuclear Reactor Designs," dated March 28, 2010 (ADAMS Accession No. ML093290268), 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," dated October 28, 2011 (ADAMS Accession No. ML112570439). 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." It also stated that 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," dated September 16, 2014 (ADAMS Accession No. ML14260A078), 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 risk and the existing framework, which was enhanced in 2011, continued to provide reasonable assurance.

In SRM-SECY-14-0038, "Staff Requirements – SECY-14-0038 – Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight," dated September 16, 2014 (ADAMS Accession No. ML14259A589), the Commission approved the staff's recommendation and specified that the staff "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," dated May 29, 2015 (ADAMS Accession No. ML15037A176), the staff proposed a consequence-oriented approach to establishing requirements commensurate with the potential consequence 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," dated August 4, 2015 (ADAMS Accession No. ML15216A492), 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," dated May 31, 2016 (ADAMS Accession No. ML16020A388), the staff proposed a plan for EP rulemaking for SMRs and ONTs such as non-LWRs and medical isotope production 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," dated June 22, 2016 (ADAMS Accession No. ML16174A166), the Commission approved the staff's proposed plan.

# 2. EXISTING REGULATORY FRAMEWORK

## 2.1 The NUREG-0396 Methodology

In 1978, a task force of NRC and U.S. Environmental Protection Agency (EPA) representatives created a technical basis for EP and published the results in NUREG-0396 (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," issued in December 1978 (ADAMS Accession No. ML051390356). The task force's report concluded that the objective of emergency response plans should be to produce dose savings for a wide spectrum of accidents that could produce offsite doses in excess of the EPA protective action guides (PAGs)[1]. 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. The task force determined that three elements needed to be considered in establishing requirements for EP. NUREG-0396 provides the following information:

(1) Distance to which planning for the initiation of predetermined protective actions is warranted

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. It identified two types of emergency planning zones (EPZs), where each has a distinct distance from the nuclear power plant and defines a zone where advanced planning is done.

1. A plume exposure pathway EPZ, where the principal exposure sources from this pathway are (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 from this pathway 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 potentially entering the food chain.

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 predetermined 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 (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 design-basis accidents (DBAs) would not exceed the EPA PAGs 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 expected 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' final safety analysis reports and accident sequence, risk, and source term data from NRC document WASH-1400 (NUREG-75/014), "Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants," issued October 1975 [2].

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 expected 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.

(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.

## 2.2 Current EP Regulations

10 CFR 50.47, "Emergency Plans" and Appendix E to 10 CFR Part 50, "Emergency Planning and Preparedness for Production and Utilization Facilities," contain the regulations governing EP for current nuclear power reactors. Other relevant regulations are in 10 CFR 50.54(q), (s), and (t). This 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 three elements discussed in Section 2.1.

NRC-approved EP programs have the capability to identify emergency conditions, assess radiological impact, communicate protective action recommendations, and mitigate the event. Offsite response organizations (OROs), maintained by local government authorities, are responsible for developing their EP programs applicable to offsite response. These programs give 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.

The NRC and its predecessor, the Atomic Energy Commission, issued 10 CFR 50.34, "Contents of Applications; Technical Information," and Appendix E to 10 CFR Part 50 in 1970 and since then, the regulations required applicants to describe EP in plans for coping with emergencies in license applications. 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 by issuing new regulations and supporting regulatory guidance in 1980. Licensees were required to submit upgraded emergency plans compliant with the new regulations and guidance.

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 with offsite response organization (ORO) participation to conduct drills and exercises to demonstrate response capability, as well as 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 shall contain, but is not necessarily limited to, in order to demonstrate compliance with EP requirements. In 10 CFR 50.54(q), the NRC gives requirements for following and maintaining the effectiveness of a licensee's emergency plan.

This EP regimen provides reasonable assurance that protective actions can and will be taken to provide adequate protection of public health and safety.

## 2.3 Guidance Documents

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 relevant guidance documents of both types.

# 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.

In 2010, in SECY-10-0034, 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 smaller size, lower power densities, lower probability of severe accidents, slower accident progression, and smaller accident offsite consequences per module that characterize 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 alert and notification requirements and the appropriateness of the protective action requirements in 10 CFR 50.47(b)(10).

## 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 and design certification or license applicants use accident source terms in dose analyses to assess site suitability and the effectiveness of the containment and plant mitigation features, and to show compliance with regulations for determining the amount of dose to workers and members of the public. However, the technical basis for EP considers a wide spectrum of potential accidents for the facility, including severe accidents. Therefore, the staff does not limit the consideration to DBAs. Reactor designers and license applicants will need to establish appropriate credible source terms for SMRs and ONTs for this spectrum of accidents. Furthermore, the staff must consider the source terms associated with the multi-module (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 fuel damage and fission product releases to the environment from more than one module.

In SECY-93-092, 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. The document provides a definition for "mechanistic source term" was given:

> 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," dated July 30, 1993 (ADAMS Accession No. ML003760774), the Commission approved the staff's recommendation. The technical basis for, and the uses of, design-specific and event-specific mechanistic source terms in licensing are critical to the resolution of this issue. 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," dated January 15, 2016 (ADAMS Accession No. ML15309A319), 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.

In summary, for SMRs and ONTs, the staff will consider an appropriate spectrum of accidents and environmental 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.

## 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). The staff will consider emergency response staffing commensurate with SMR and ONT designs and emergency response functions.

## 3.4 Co-Location of Facilities

SMRs and ONTs of the same type may be co-located 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 co-location include the need for guidance on the effect on EP of co-location, on the size of the EPZ, number of control rooms, staffing, training, and interaction with other co-located facilities.

## 3.5 Multi-module Facilities

SECY-11-0152 discusses the potential for an SMR or ONT site to employ multiple reactors (modularity as defined in 10 CFR 50.2). Probabilistic Risk Assessment (PRA) 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.

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## 3.6 Performance-Based Approach to Emergency Preparedness

The current approach for large LWRs to meet EP requirements is largely prescriptive planning standards.

In a performance-based approach to EP rulemaking, performance and results will be the primary basis for regulatory decision-making, and the licensee will have 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 or higher than that required for currently operating large LWR facilities; and
- Establishing an NRC oversight process that can ensure that a high level of EP exists and that it provides for reasonable assurance that public health and safety is protected.

Some aspects are expected to remain unchanged or 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; and
- 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 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 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 license 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. Because certain existing EP requirements could impose unnecessary regulatory burdens on SMR and ONT licensees, the potential applicants have indicated that they would request EP exemptions. This option would require site-specific analysis by the applicant and review by the NRC for each application. Option 1 would not relieve the burden imposed on both the applicant and the NRC resulting from the case-by-case exemption process addressing EPZ size and emergency plans. In addition, while the exemption process could be further enhanced through guidance development, this process would not likely result in efficiency gains. By continuing to assess EP exemptions on an individual application basis, applicants and the NRC would expend significant 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.

Boundary Determination for Emergency Planning Zones

The technical bases for establishing EPZ requirements for SMRs and ONTs are founded on the principles outlined in NUREG-0396 and the current EPA PAG Manual [4]. The bases focus on establishing the radial distance to the outer boundary of the plume exposure pathway EPZ for SMRs and ONTs, which is the critical element and affects other elements in the EP framework for these technologies. Other elements of a new EP framework are baselined with the regulatory EP framework in the *Code of Federal Regulations* for currently licensed large LWR facilities and then adapted or developed, as appropriate.

In November 2010, the staff reviewed the existing EP requirements associated with various nuclear facilities, including large and small reactors, material facilities, fuel facilities, independent spent fuel storage installations, and RTRs. This review found that all the existing types of NRC-licensed nuclear facilities use the dose-at-distance approach of NUREG-0396 to

establish the boundary of their EPZs (or other planning areas) and consider the EPA PAGs to aid in decisions to implement protective actions.

Defining the EPZs for these new facilities is central to the approach to EP regulation whether it be prescriptive or performance-based. Considering that currently proposed designs for SMRs and ONTs are designed to have a reduced potential for accident-related offsite releases, 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.

The establishment of the EPZ for the plume exposure pathway is necessary to define and scope the areas where planning for the initiation of predetermined protective actions is warranted. These prompt protective actions are directed at avoiding or reducing a projected 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.

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 co-location of these reactors, as well as the size of the EPZs. 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 co-locating the reactors near industrial facilities will also need to be addressed.

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," issued December 2013 [3], which proposed a generic methodology and criteria that could be adopted and used for establishing the technical basis for SMR-appropriate EPZs. It addressed SMRs with light-water-cooled and moderated designs only and did not specifically address other types of SMRs or other facility designs. It also focused on the plume exposure pathway EPZ. The NRC has not endorsed this White Paper.

As stated in SECY-11-0152, the staff expects that the industry will develop and implement detailed calculation methods for review and approval by the NRC. In this case, the applicant will have the burden of offering a well-justified basis for the proposed EPZs sizes consistent with the potential offsite consequence profile of the facility.

In SECY-11-0152, the staff presented examples of different plume exposure pathway EPZ boundaries that are established 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 specific reactor design being considered. The examples in SECY-11-0152 consider four discrete zone boundaries or categories: site boundary, 2 miles (3 km), 5 miles (8 km), and 10 miles (16 km):

(1) If projected accident offsite doses are less than 1 rem (10 mSv) total effective dose equivalent (TEDE) at the site boundary, then no plume exposure pathway EPZ beyond the site boundary would be required, and the offsite radiological emergency planning requirements would be limited.

(2) If the expected offsite dose is greater than 1 rem (10 mSv) TEDE offsite but less than 1 rem (10 mSv) TEDE at 2 miles (3 km), then the requirements for the plume exposure pathway EPZ would be limited to the 2-mile (3-km) zone.

(3) If the projected offsite dose is greater than 1 rem (10 mSv) TEDE at 2 miles (3 km), but less than 1 rem (10 mSv) TEDE at 5 miles (8 km), the size of the plume exposure pathway EPZ would be 5 miles (8 km).

(4) If the expected offsite dose is greater than 1 rem (10 mSv) TEDE at 5 miles (8 km), the size of the EPZ would default to the current 10-mile (16-km) plume exposure pathway EPZ.

Ingestion Exposure Pathway Emergency Planning Zone

The purpose of the ingestion exposure pathway EPZ is to prevent the ingestion of contaminated foods and water.

The ingestion exposure pathway EPZ for large LWRs is established at about 50 miles (80 km), as reflected in regulations in 10 CFR Part 50. The duration of any exposure could range from hours to months and represents a longer-term response need. Additionally, the source terms for SMRs and for many ONTs are small and may, following the above described process, have a small plume exposure pathway EPZ or none required, if the offsite projected dose would not exceed the EPA PAGs at the site exclusion area boundary. Because the source terms are small for these technologies and related ingestion represents a longer-term response, a scaled approach where the size ranges from the site boundary to a fixed-distance beyond the site boundary may be appropriate for the ingestion exposure pathway EPZ. That is, if the plume exposure pathway EPZ is the site and bounded by the site boundary, no ingestion exposure pathway EPZ may be necessary. Reinforcing this premise, the United States has had considerable experience with the expedient large-scale quarantining of foods in response to contamination outbreaks of E. coli, salmonella, bovine spongiform encephalopathy (mad cow disease), and others. 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.

Technology-Inclusive Approach

The EP measures established for the current NRC-licensees have proven effective regardless of the technology. A similar technology-inclusive approach can be applied to SMR and ONT facilities while taking into account the various designs, systems, and purposes of the facilities.

*Small Modular Reactors*

The staff considered the use of multiple reactors and the potential for SMRs to be co-located near or adjacent to industrial sites during the development of this document. Co-location 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. Also, the staff considered the need for preparedness from hazards from events which may occur at co-located facilities.

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. Burying part or all of the reactor and structures 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 drainage times and correspondingly longer accident progression times. Passive safety features that do not depend on electric power also lead to longer accident progression time. 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. As discussed previously, 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, in February 2016, the NRC approved a construction permit for a new and innovative medical isotope production facility submitted by SHINE. The safety evaluation report [5] related to the construction permit for the SHINE facility states, "The size of the EPZ should be established so that the dose to individuals beyond the EPZ is not projected to exceed the [EPA] PAGs," NUREG-2189, "Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility."

Assessment of Option 2

The staff has discussed the benefits of EP rulemaking for SMRs and ONTs in SECY-15-0077. A 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: In the performance-based approach, the applicants will demonstrate how their proposed facilities will achieve EPA PAG dose limits at specified EPZ distances for their site, which may include the site boundary. This framework is intended to be established generically without site- or design-specific information about source terms, fission products, or projected offsite dose. Other EP planning standards and requirements will be commensurate with those determinations. This approach will give clear guidance to the applicants such that the applicants 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 performance-based framework intended for the rule, such advances are inherently recognized. Facilities with reduced potential offsite consequences will have reduced EP requirements and vice versa. A performance-based approach is an effective way to make regulatory requirements consistent with design features and associated potential accident consequences.

- Credit small reactor core size and associated differences in accidents: SMRs and many ONTs involve smaller sized reactor cores, and the accident profiles are significantly different from large LWRs. These designs are associated with a low likelihood of severe accidents, slower transient response times, and relatively small and slow release of

fission products. Current EP rules and requirements were developed for large LWRs. A new 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. Different aspects of the EP regulations and requirements will be defined consistent with the characteristics of the accident scenarios.

- Eliminate the current regulatory need to request exemptions from EP requirements: Licensing SMRs and ONTs within the current regulations, developed for large LWRs, requires approval of exemption requests. This approach is known to lead to inconsistencies and undue burden for both the applicant and the regulatory authority. A 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 Conclusions

Option 1 would not relieve the burden imposed on both the applicant and the NRC resulting from the case-by-case exemption process. In addition, while the exemption process could be further enhanced, this process would not likely result in the efficiency gains possible through Option 2. By continuing to assess EP exemptions on an individual application basis, applicants and the NRC would 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 provides for regulatory stability and predictability.

Considering the above options, the staff concludes that 1) the principle of using a dose-at-distance 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 for SMRs and ONTs.

The staff notes that EP regulations currently, and will in the future, rely on accident analyses to determine potential radiological consequences, given as dose-at-distance. 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.

# 5. OTHER REGULATORY CONSIDERATIONS

## 5.1 Cost and Impact Considerations

### 5.1.1 Introduction

The potential benefits and costs justification must be considered for (1) SMR and ONT licensees, (2) offsite government organizations (i.e., State, local, and Tribal), 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 would be carried out during the regulatory analysis that would be part of the next step toward rulemaking (see Section 7.1).

The staff considered the exemption and guidance alternative to a rulemaking action, is discussed in Section 4.1 of this document. The NRC is pursuing rulemaking action because it offers a comprehensive regulatory framework that would result in enhanced regulatory stability, predictability, clarity in the licensing process, 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 and SRM-SECY-16-0069.

The analyses in this chapter 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; 10 CFR 50.90, "Application for Amendment of License, Construction Permit, or Early Site Permit"; and Appendix E to 10 CFR Part 50. 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

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 comments on the preliminary rule language and proposed rule language as these products are developed.

### 5.1.2 Potential Effect on Licensees

This rulemaking will create a set of EP regulations specifically for reactor 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, using the assumption that four applicable nuclear power plants will be built in the near future, and that 1,483 hours of labor are needed for every plant, and that the weighted hourly labor rate is $117 per hour.

**Table 5-1 Industry Operation: Emergency Planning Exemption Requests**

| Year | Activity | Total Averted Cost | | |
|---|---|---|---|---|
| | | Undiscounted | 7% NPV | 3% NPV |
| 2019 | Two exemption requests for SMRs/ONTs | $348,000 | $304,000 | $328,000 |
| 2020 | Two exemption requests for SMRs/ONTs | $348,000 | $284,000 | $318,000 |
| | **Total:** | **$696,000** | **$588,000** | **$646,000** |

Note: NPV = net present value.

Under current regulations for large LWR designs, the plume exposure pathway EPZ size is about 10 miles. However, for SMRs and ONTs with comparatively smaller reactor cores and power levels (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 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 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 (PANS) installation and annual maintenance, (3) Federal Emergency Management Agency (FEMA) annual user fees, (4) annual drills and exercises, and (5) State agreement and licensing annual fees.

For the purposes of this regulatory basis, the staff assumed that the four plants used in this analysis will each have a plume exposure pathway EPZ inside the licensee's site boundary. Table 5-2 and Table 5-3 show the total averted costs to these plants as a result of this proposed rulemaking. The (averted) total costs shown in Table 5-2 and Table 5-3 are the totals for the four future plants discussed in this analysis that the staff has assumed will be affected by this rulemaking.

**Table 5-2 Industry Implementation: Averted Costs with the Plume Exposure Pathway EPZ Inside the Site Boundary**

| Year | Activity | Total Averted Cost | | |
|---|---|---|---|---|
| | | Undiscounted | 7% NPV | 3% NPV |
| 2019 | Evacuation time estimate averted costs | $750,000 | $655,000 | $707,000 |
| 2020 | Evacuation time estimate averted costs | $750,000 | $612,000 | $686,000 |
| 2019 | Initial plan development with ORO | $9,384 | $8,197 | $8,846 |
| 2020 | Initial plan development with ORO | $9,384 | $7,660 | $8,588 |
| 2019 | Siren stations (ANS) setup averted costs | $7,670,000 | $6,700,000 | $7,230,000 |
| 2020 | Siren stations (ANS) setup averted costs | $7,670,000 | $6,260,000 | $7,020,000 |
| | **Total:** | **$16,900,000** | **$14,200,000** | **$15,700,000** |

Note: NPV = net present value.

**Table 5-3 Industry Operation: Recurring Averted Costs with the Plume Exposure Pathway EPZ Inside the Site Boundary**

| Year | Activity for All Four Plants | Total Cost | | |
|---|---|---|---|---|
| | | Undiscounted | 7% NPV | 3% NPV |
| 2020–2077 | Evacuation time estimate (ETE) annual updates | $1,650,000 | $350,000 | $740,000 |
| 2020–2077 | FEMA annual user fee averted costs | $146,700,000 | $31,430,000 | $65,850,000 |
| 2020–2077 | ANS annual maintenance fee | $278,700,000 | $59,710,000 | $125,100,000 |
| 2020–2077 | Drills/exercises averted costs | $24,650,000 | $5,280,000 | $11,070,000 |
| 2020–2077 | State agreement/licensing fees | $802,700,000 | $172,000,000 | $360,400,000 |
| 2020–2077 | Letters of Agreement | $1,080,000 | $230,000 | $480,000 |
| 2020–2077 | Offsite Coordinator | $27,470,000 | $5,890,000 | $12,330,000 |
| 2030 | ETE decennial update | $350,000 | $140,000 | $240,000 |
| 2040 | ETE decennial update | $350,000 | $73,000 | $180,000 |
| 2050 | ETE decennial update | $350,000 | $37,000 | $130,000 |
| 2060 | ETE decennial update | $350,000 | $19,000 | $97,000 |
| 2070 | ETE decennial update | $350,000 | $10,000 | $72,000 |
| 2030 | PAR Development post decennial update | $290,000 | $120,000 | $200,000 |
| 2040 | PAR Development post decennial update | $290,000 | $62,000 | $150,000 |
| 2050 | PAR Development post decennial update | $290,000 | $31,000 | $110,000 |
| 2060 | PAR Development post decennial update | $290,000 | $16,000 | $82,000 |
| 2070 | PAR Development post decennial update | $290,000 | $8,000 | $61,000 |
| | **Total:** | **$1,286,000,000** | **$275,400,000** | **$577,300,000** |

Note: NPV = net present value.

When the plume exposure pathway EPZ is determined to be outside of the licensee's site boundary and less than about 10 miles, 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. However, the staff believes that this aspect of the rule would result in an incremental averted cost to licensees. This is because the cost for establishing, for example, a 2-mile plume exposure pathway EPZ offsite emergency plan would most likely 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.

Table 5-4 shows the revised estimate of averted costs to industry for scenarios where the plume exposure pathway EPZ is outside the site boundary but with a radius of less than 10 miles. In these scenarios, to be conservative, the costs listed in Table 5-3 are no longer considered averted costs. Additionally, the evacuation time estimates and initial plan development costs are no longer considered as averted costs. The remaining averted cost in this regulatory basis is from the less extensive ANS required due to the smaller plume exposure pathway EPZ relative to the 10 mile radius plume exposure pathway EPZ currently in regulations. Table 5-4 scales the averted industry implementation costs from Table 5-2, based on the area of the plume exposure pathway EPZ in square miles, relative to the area of a plume exposure pathway EPZ with a 10 mile radius. Finally, this analysis assumes that licensees would still submit exemption requests, as the rulemaking would not be able to consider all possible plume exposure pathway EPZ size scenarios. Therefore, these exemption requests are also not considered as an averted cost if the plume exposure pathway EPZ is outside the site boundary.

**Table 5-4 Industry Implementation: Scaling Averted Costs for a Plume Exposure Pathway EPZ Outside the Site Boundary**

| Radius (miles) | Total Cost | | |
|---|---|---|---|
| | Undiscounted | 7% NPV | 3% NPV |
| 1 | $12,420,000 | $10,490,000 | $11,710,000 |
| 2 | $9,810,000 | $8,290,000 | $9,250,000 |
| 3 | $7,510,000 | $6,350,000 | $7,080,000 |
| 4 | $5,520,000 | $4,660,000 | $5,200,000 |
| 5 | $3,830,000 | $3,240,000 | $3,610,000 |
| 6 | $2,450,000 | $2,070,000 | $2,310,000 |
| 7 | $1,380,000 | $1,170,000 | $1,300,000 |
| 8 | $610,000 | $520,000 | $580,000 |
| 9 | $150,000 | $130,000 | $140,000 |
| 10 | $0 | $0 | $0 |

Note: NPV = net present value.

As can be seen by comparing Table 5-4 to the NRC rulemaking costs given in Table 5-5 below, if the plume exposure pathway EPZ has a radius of 4 miles or less from the site boundary, this regulatory basis shows that the costs of the rulemaking are estimated to be less than the averted costs shown above, indicating this rulemaking will be quantitatively cost effective.

Lastly, additional benefits for SMR and ONT licensees will be realized 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 the reactor design.

### 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, offsite governmental organizations may need to establish a formal radiological emergency preparedness (REP) program. The staff believes that this potential requirement would represent an incremental averted cost 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 REP program due to the geographical areas associated with offsite governmental organizations. These averted costs are reimbursed to the offsite governmental organizations through FEMA fees and State agreements, shown in Table 5-3 above.

### 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 regulatory basis document, 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 (e.g., a draft regulatory analysis, draft environmental analysis, and draft Office of Management and Budget Paperwork Reduction Act supporting statement), a *Federal Register* 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. These estimated costs are shown in Table 5-5, where costs are for the single action in each row at a labor rate of $128 per hour.

**Table 5-5 NRC Implementation: Rulemaking Costs**

| Year | Activity | Hours | Total Cost | | |
|---|---|---|---|---|---|
| | | | Undiscounted | 7% NPV | 3% NPV |
| 2016-2017 | Develop regulatory basis | 4,025 | ($515,000) | ($515,000) | ($515,000) |
| 2017 | Develop regulatory guide (RG) for proposed rule | 1,610 | ($206,000) | ($206,000) | ($206,000) |
| 2017 | Develop proposed rule | 4,025 | ($515,000) | ($515,000) | ($515,000) |
| 2017 | Revise RG after public comments | 1,610 | ($206,000) | ($206,000) | ($206,000) |
| 2018 | Develop/issue RG for final rule | 1,610 | ($206,000) | ($193,000) | ($200,000) |
| 2018 | Develop/issue final rule | 4,025 | ($515,000) | ($481,000) | ($500,000) |
| 2019 | Develop/issue RG for final rule | 1,610 | ($206,000) | ($180,000) | ($194,000) |
| 2019 | Develop/issue final rule | 4,025 | ($515,000) | ($450,000) | ($486,000) |
| | | **Total:** | **($2,885,000)** | **($2,747,000)** | **($2,823,000)** |

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," issued August 2014) 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 an averted cost (benefit) from the expected four exemption requests that will not be submitted by industry and, therefore, will not be reviewed by the staff. Table 5-6 shows these averted costs, assuming 713 hours of effort for each request and a labor rate of $128 per hour.

**Table 5-6 NRC Operation: Averted Exemption Request Reviews**

| Year | Activity | Total Averted Cost | | |
|---|---|---|---|---|
| | | Undiscounted | 7% NPV | 3% NPV |
| 2020 | Review two exemption requests | $183,000 | $149,000 | $167,000 |
| 2021 | Review two exemption requests | $183,000 | $139,000 | $162,000 |
| | **Total:** | **$365,000** | **$288,000** | **$329,000** |

Note: NPV = net present value.

5.1.5 Cost Justification

Relative to the no-action baselines of the EP regulations for SMRs and ONTs, the staff concludes that the benefits of improved regulatory efficiency and certainty to the licensees and the NRC, and the averted incremental costs to the licensees and offsite governmental organizations, especially the flexibility for licensees to adopt an appropriate scalable plume exposure pathway EPZ, justify the incremental costs for this rulemaking action by the NRC. Furthermore, the rulemaking would also benefit the NRC because no future resources would be expended for evaluating routine exemptions requests to current EP regulations by SMR and ONT applicants. Table 5-7 shows a significant net benefit (averted cost) for the quantitative factors discussed above. This cost estimate reflects the assumption that the plume exposure pathway EPZ will be inside the site boundary, which the staff considers to be a likelihood based on discussions with industry. 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 5-7 Total Costs with the Plume Exposure Pathway EPZ Inside the Site Boundary**

| Attribute | Total Averted Costs | | |
|---|---|---|---|
| | **Undiscounted** | **7% NPV** | **3% NPV** |
| Industry implementation | $16,850,000 | $14,240,000 | $15,650,000 |
| Industry operation | $1,286,740,000 | $276,000,000 | $577,900,000 |
| *Total industry cost* | *$1,303,600,000* | *$290,200,000* | *$593,600,000* |
| NRC implementation | ($2,890,000) | ($2,750,000) | ($2,820,000) |
| NRC operation | $370,000 | $290,000 | $330,000 |
| *Total NRC cost* | *($2,520,000)* | *($2,460,000)* | *($2,490,000)* |
| **Net** | ***$1,301,070,000*** | ***$287,800,000*** | ***$591,100,000*** |

Note: NPV = net present value.

If the plume exposure pathway EPZ is outside the site boundary, but less than 10 miles in radius, then the total cost estimate for the rulemaking is variable depending on the plume exposure pathway plume exposure pathway EPZ radius. A cost estimate for a 4 mile plume exposure pathway EPZ is shown below in Table 5-8, demonstrating that a plume exposure pathway EPZ of 4 miles in radius or less will result in averted costs exceeding the costs of NRC rulemaking. Based on information provided by industry, the NRC does not expect that future SMRs and ONTs would have a plume exposure pathway EPZ greater than 4 miles outside the site boundary. Therefore, the rulemaking would be cost justified because the averted costs would exceed the costs of the rulemaking process.

**Table 5-8 Total Costs with the Plume Exposure Pathway EPZ 4 Miles Outside the Site Boundary**

| Attribute | Total Averted Costs (Costs) | | |
|---|---|---|---|
| | **Undiscounted** | **7% NPV** | **3% NPV** |
| Industry implementation* | $5,520,000 | $4,660,000 | $5,200,000 |
| Industry operation | $0 | $0 | $0 |
| *Total industry cost* | *$5,520,000* | *$4,660,000* | *$5,200,000* |
| NRC implementation | $0 | $0 | $0 |
| NRC operation | ($2,890,000) | ($2,750,000) | ($2,820,000) |
| *Total NRC cost* | *($2,890,000)* | *($2,750,000)* | *($2,820,000)* |
| **Net** | ***$2,630,000*** | ***$1,920,000*** | ***$2,380,000*** |

*Industry implementation averted costs depend on the size of the plume exposure pathway EPZ outside the site boundary.
Note: NPV = net present value.

## 5.2 Backfitting and Issue Finality

Backfitting and issue finality regulations do not apply to this action. The proposed revisions to performance-based EP requirements would not constitute backfitting because they would contain new requirements to ensure adequate emergency response for new facilities. There are

no current SMR or ONT license holders who would be affected by the proposed rule.[1] The intended rule defining the new performance-based EP regulations and guidance for SMRs and ONTs would be in place before any licenses are granted for new SMRs or ONTs. The backfitting and issue finality regulations do not protect current or future applicants. Therefore, the NRC will not prepare a backfit analysis for the proposed rule.

## 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 is specifically requesting comment on the cumulative effects that may result from the proposed amendment to 10 CFR Part 50 and any other NRC actions that may affect the same entities. These requests are part of the questions for public comment in Section 6.2.

## 5.4 Environmental Analysis

This rulemaking would develop performance-based EP requirements for these technologies that would be commensurate with the potential consequences to public health and safety 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. An environmental assessment developed along with the rulemaking would likely conclude that there would not 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 planned rulemaking supports the NRC's 2014–2018 Strategic Plan (NUREG-1614) in relation to the strategic goal of safety and the cross-cutting strategies of regulatory efficiency and openness.

For the safety goal, the planned 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 these technologies that would be commensurate with the potential 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 other new technologies.

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1 One medical isotope facility (SHINE) currently holds a construction permit; however, the review only included a preliminary emergency plan. This facility may apply for an operating license in the future, at which time EP will be considered.

Of the cross-cutting strategies, the planned 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," dated December 16, 2004, 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 recent DOE-NRC Workshops on Advanced Non-Light Water Reactors in September 2015 [6] and June 2016 [7] addressed many of these issues. An April 2016 report from the Nuclear Innovation Alliance, "Enabling Nuclear Innovation: Strategies for Advanced Reactor Licensing" [8], also addressed many of these issues.

As the discussion of rulemaking for EP has evolved (see Section 1.2.3), some of the interactions with stakeholders have specifically dealt with EP. Of notable interest is the December 2013 NEI white paper [3] 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, is important to note [9]:

> 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-light-water reactor (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 Program (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.

## 6.2 Questions for Public Comment

The NRC welcomes comments on any aspect of this draft regulatory basis but is particularly interested in obtaining additional information related to the following questions in these categories (please be as specific as possible in your responses):

Scope of the Draft Regulatory Basis

(1) Is the NRC considering an appropriate approach for each objective described in the draft regulatory basis?

(2) Section 3 of the draft regulatory basis discusses the regulatory concerns the NRC expects to address through rulemaking. Section 4 presents the intended regulatory changes to address those regulatory concerns and discusses alternatives to rulemaking considered by the staff. Are there other regulatory concerns within or related to the scope of the rulemaking efforts (see Section 4) that the NRC should consider? Are there other approaches or alternatives the NRC should consider to resolve those regulatory concerns?

(3) Are there any other alternatives EP for SMR and ONT for beyond those discussed in the draft regulatory basis that the NRC should consider?

(4) Are there other EP related issues that the staff should consider in further developing this regulatory basis?

(5) Is the scope of facilities to be included under the ONT umbrella (see Section 1.1) appropriate or can you suggest additions or deletions and the associated basis or rationale?

Performance-Based Approach

(1) What are the benefits and drawbacks of a performance-based EP approach, other than those described in this draft regulatory basis document?

(2) Should NRC continue research to establish performance-based criteria in the EP area? Examples of such research are in SECY-14-0038.

(3) Is it appropriate to establish combined risk-informed and performance-based criteria, and can you suggest EP areas or methods where they could successfully be implemented?

Regulatory Impacts

(1) Section 5 of the draft regulatory basis presents the staff's initial consideration of costs and other effects for several key aspects of the potential regulatory changes. This initial assessment is limited; therefore, the staff is seeking data and input relative to expected or unintentional effects from the desired regulatory changes. What would be the potential effects on stakeholders, such as applicants, licensees, and the public, from implementing any of the desired regulatory changes described in this draft regulatory basis? The staff is also seeking comments on reasonable cost estimates for implementation of the EP regulations for SMRs and ONTs, including one-time startup cost and annual cost.

(2) What would the cost be for licensees under 10 CFR Part 52, "Licenses, Certifications and Approvals for Nuclear Power Plants," to be licensed under the proposed performance-based EP approach? What would be the cost difference between this new EP approach and the current EP approach in 10 CFR Part 50?

(3) What effects, other than cost, would result from the rulemaking action under consideration?

Cumulative Effects of Regulation

(1) In light of any current or projected CER challenges, what should be a reasonable effective date, compliance date, or submittal date from the time the final rule is published to the actual implementation of any new proposed requirements, including changes to programs, procedures, or the facility?

(2) If current or projected CER challenges exist, what should be done to address this situation? For example, if more time is required to implement the new requirements, how much time would be sufficient, and why is such a timeframe necessary?

(3) Do other regulatory actions (e.g., orders, generic communications, license amendment requests, inspection findings of a generic nature) by the NRC or other agencies influence the implementation of the potential proposed requirements?

(4) Are there unintended consequences? Does the potential proposed action create conditions that would be contrary to the potential proposed action's purpose and objectives? If so, what are the consequences and how should they be addressed?

# 7. NEXT STEPS

## 7.1 Steps toward Rulemaking

After this draft regulatory basis is published in the *Federal Register*, it will be available during a 75-day period for comment from stakeholders, including industry (vendors and utilities), governmental and nongovernmental organizations, and individuals. The public is encouraged to include responses to the questions in Section 6.2.

No significant policy or legal issues were identified during the development of this draft regulatory basis that would need to be resolved before commencing a rulemaking. The Advisory Committee on Reactor Safeguards will review the proposed rule, and the final rule.

The process for rulemaking is given in NRC Directive Handbook 6.3 [10], 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 handbook, the regulatory analysis "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 decision making by NRC managers and the Commission."

NRC Directive Handbook 6.3 also describes the responsibilities and makeup of a working group for rulemaking that might be considered. It describes the responsibilities and makeup of a steering committee for rulemakings "that are unusually controversial or complex and those for which the implementation responsibilities cut across several divisions or offices." The handbook also describes how public participation will take place.

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 developing 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 new guidance documents. A new RG would be developed to describe an acceptable approach for SMR and ONT licensees to implement the EP requirements in the proposed rule. The RG would be developed as a standalone guidance document using concepts drawn from the existing guidance documents. The RG would describe one acceptable way for these facilities to implement an EP program to assure that adequate protective measures can and will be taken in the event of a radiological emergency. The draft RG will be made available for public comment when the proposed rule is issued. Existing guidance documents will remain applicable to large LWRs.

# 8. REFERENCES


1. U.S. Environmental Protection Agency, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," EPA-520/1-75-001, September 1975.

2. U.S. Nuclear Regulatory Commission, "Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants," WASH-1400 (NUREG 75/014), October 1975.

3. Nuclear Energy Institute, "White Paper: Proposed Methodology and Criteria Establishing the Technical Basis for Small Modular Reactor Emergency Planning Zone," December 2013.

4. U.S. Environmental Protection Agency, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," EPA-400/R-16/001, November 2016

5. U.S. Nuclear Regulatory Commission, "Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility," NUREG 2189, August 2016.

6. Mazza, Jan, U.S. Nuclear Regulatory Commission, memorandum to Michael E. Mayfield, U.S. Nuclear Regulatory Commission, "Summary of September 12, 2015, Nuclear Regulatory Commission and Department of Energy Co-Hosted Workshop on Advanced Non-Light Water Reactors," October 1, 2015.

7. Tartal, George M., U.S. Nuclear Regulatory Commission, memorandum to Michael E. Mayfield, U.S. Nuclear Regulatory Commission, "Summary of June 7–8, 2016, Department of Energy and Nuclear Regulatory Commission Co-Hosted Workshop on Advanced Non-Light Water Reactors," July 7, 2016.

8. Nuclear Innovation Alliance, "Enabling Nuclear Innovation: Strategies for Advanced Reactor Licensing," June 7, 2016.

9. Rosales-Cooper, Cindy, U.S. Nuclear Regulatory Commission, memorandum to Marissa Bailey, U.S. Nuclear Regulatory Commission, "Summary of August 22, 2016, Public Meeting To Discuss a Performance-Based Approach to Emergency Preparedness for Small Modular Reactors and Other New Technologies," September 15, 2016.

10. U.S. Nuclear Regulatory Commission Directive Handbook 6.3, "The Rulemaking Process," DT-13-14, July 22, 2013.