JERRY W. HIATT, CHP
Certified Health Physicist
Sr. Project Manager

1201 F Street, NW, Suite 1100
Washington, DC 20004
P: 202.739.8171
jwh@nei.org
nei.org

NUCLEAR ENERGY INSTITUTE

October 1, 2015

Annette Vietti-Cook
Secretary, U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

Subject: Industry Comments on the NRC Advance Notice of Proposed Rulemaking (ANPR) for 10 CFR Part 50, Appendix I, Docket ID NRC-2014-0044

On May 4, 2015, the Nuclear Regulatory Commission (NRC) issued an advance notice of proposed rulemaking (ANPR) in the *Federal Register* to obtain input from stakeholders on the development of a regulatory basis for the NRC's regulations governing radioactive effluents from nuclear power plants.[1]

This letter provides the comments of the Nuclear Energy Institute (NEI)[2] on behalf of the nuclear power industry on the subject *Federal Register* notice. These comments were developed by an industry task force comprised of subject matter experts from utilities' operating nuclear power plants and other organizations. The task force reflects a substantial body of industry technical expertise and experience in radioactive effluents and environmental monitoring.

The NRC's stated goal in issuing the ANPR is:

> [T]o obtain input from stakeholders on the development of a regulatory basis for the NRC's regulations governing radioactive effluents from nuclear power plants. The regulatory basis would support potential changes to better align the NRC regulations governing dose assessments for radioactive effluents from nuclear power plant operations with the most recent terminology and dose related methodology published by the International Commission on Radiological Protection (ICRP) contained in ICRP Publication 103 (2007). [3]

Based on our review of the ANPR and each of the five specific issues upon which the NRC is requesting comment, the nuclear power industry's overall recommendation is that no changes be made to the existing regulations. We conclude that the changes proposed by the NRC are unnecessary from a health and

[1] 80 Fed. Reg. 25237 (May 4, 2015).

[2] The Nuclear Energy Institute (NEI) is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations and entities involved in the nuclear energy industry.

[3] 80 Fed. Reg. 25237 (May 4, 2015).

safety standpoint, are unlikely to be cost-beneficial, and will provide little to no incremental improvement in the health and safety of workers, the public or the environment.

This recommendation is consistent with recommendations contained in NEI's September 15, 2015 response[4] to the NRC's request for comments on the NRC's Common Prioritization and Re-baselining Initiatives discussed during a September 1, 2015 public meeting. NEI's response states:

> "In the Radiation Protection rulemaking, the goal is to achieve greater alignment between the NRC's radiation protection regulations and the 2007 recommendations of the International Commission on Radiological Protection. As discussed in our March 24, 2015 comment letter[5], we believe the rulemaking is unnecessary from a health and safety standpoint and will provide little to no incremental improvement in the health and safety of workers, public or environment.
>
> Similarly, the intent of the Dose Assessments for Radioactive Effluents rule is to align the NRC regulations governing dose assessments for radioactive effluents from nuclear power plant operations with the most recent terminology and dose-related methodology published by the ICRP and contained in ICRP Publication 103 (2007).
>
> In neither instance is there a safety basis for the identified changes yet the cost to implement these rules is estimated to exceed $3 million per facility. Moreover, implementation will require substantial effort by NRC and industry to revise approximately 50 regulatory guides.[6] Based on the low value to safety and high burden imposed by these proposed rules, we recommend that both rulemakings be terminated."

Overall, our recommendations are based upon the following fundamental concepts:

1. As stated by the Commission in its Staff Requirements Memorandum responding to SECY-08-0197, the current standards continue to provide adequate protection of the health and safety of workers, the public and the environment.[7] Further, the Commission has acknowledged that the recommendations contained in ICRP Publication 103 (2007) propose measures that go beyond what is needed to provide adequate protection.[8]
2. The nuclear power industry's current operating practices protect workers, the public, and the environment at a level far beyond that required by the regulatory requirements. For example:

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[4] September 15, 2015, John C. Butler (NEI) to Frederick D. Brown (NRC) "Industry Recommendations for NRC Project AIM 2020 Prioritization and Re-baselining Initiatives," p. 5.

[5] March 24, 2015, Ellen Anderson (NEI) to Annette Vietti-Cook (NRC), "Industry Comments on the NRC ANPR for 10 CFR Part 20, Radiation Protection" (ML15083A063)

[6] http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise/divison-reg-guide.html

[7] "The Commission agrees with the staff and the Advisory Committee on Reactor Safeguards (ACRS) that the current NRC regulatory framework continues to provide adequate protection of the health and safety of workers, the public, and the environment." Staff Requirements – SECY-08-0197 – Options to Revise Radiation Protection Regulations and Guidance with Respect to the 2007 Recommendations of the International Commission on Radiological Protection (SRM-SECY-08-0197).

[8] "From a safety regulation perspective, ICRP Publication 103 proposes measures that go beyond what is needed to provide for adequate protection." (SRM-SECY-08-0197)

a. Based on data from NUREG/CR-2907, Vol. 15,[9] the thirty year trend for the commercial nuclear power plant (NPP) industry has shown a factor of 100 decrease per reactor in the curies released to liquid effluents and a factor of 1000 decrease per reactor in the curies released in gaseous noble gas effluents. These decreases resulted from improvements in fuel design, chemistry controls and plant management and have been achieved consistently across the industry. This decrease in liquid and air effluents also demonstrates that operators of commercial plants are good stewards of the environment.

b. "Doses to the public due to effluents from NPPs are less than 0.1% (one-tenth of one percent) of what the average person receives each year from all sources of radiation." [10] Further "the staff has concluded that offsite doses to individual members of the public as a result of these routine releases are ALARA and a small fraction of the dose limits specified in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection Against Radiation," specifically 10 CFR 20.1301(a) and (e)."[11]

3. The cumulative effect of regulation (CER) resulting from the changes described in the ANPR for 10 CFR Part 50, Appendix I will place substantial resource burdens on nuclear power licensees, while yielding little or no additional protection of occupational workers, the public, or the environment. The industry estimates the actions necessary for revising procedures, policies, training and equipment/instrumentation to achieve compliance with changes to 10CFR50, Appendix I could result in a cost of $400,000 per operating site or roughly $25 million to the industry as a whole.

   Changes to 10 CFR Part 50, Appendix I will, at a minimum, require:

   - Development of a comprehensive industry change management plan and individual facility-specific change management plans;
   - Re-evaluation of previous licensing commitments;
   - Revision of compliance documents (e.g. technical specifications, etc.) and associated implementing procedures;
   - Development and implementation of revised training programs for impacted personnel (e.g. radiation protection, chemistry, radwaste, etc.);
   - Modification or purchase of new computer software;
   - Potential modification or purchase of new effluent monitoring instrumentation; and

[9] NUREG/CR 2907, "Radioactive Effluents from Nuclear Power Plants," Vol. 15, August 2013.

[10] Ibid p. 2-6.

[11] SECY-15-0104, Policy Issue Information Letter from Mark A. Satorius to The Commissioners, Subject: "Analysis of Cancer Risks in Populations Near Nuclear Facilities Study," August 21, 2015.

- Reassessment of effluent-related resources and staffing levels to address industry participation in the review and comment on the development or revision of associated regulatory guides and documents.

This regulatory burden on the industry will be further compounded should the potential changes to 40 CFR Part 190[12] proposed by the U.S. Environmental Protection Agency in its February 2, 2014, ANPR and the changes proposed in the ANPR for 10 CFR Part 20, "Standards for Protection Against Radiation" [13]be imposed on licensees.

Our comments are summarized below, and each issue is addressed in detail in the attachment to this letter:

Issue No. 1 - *Closer Alignment of 10 CFR Part 20 and 10 CFR Part 50, Appendix I, With the Terminology and Methodology Recommendations of ICRP Publication 103.*

The nuclear power industry recommends that the Nuclear Regulatory Commission (NRC) not revise 10 CFR Part 50, *Domestic Licensing of Production and Utilization Facilities*, Appendix I, *Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion "As Low as is Reasonably Achievable" for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents* to more closely align with the ICRP Publication 103 methodology and terminology. Adoption of the ICRP 103 methodology and terminology into 10 CFR Part 20 and/or 10 CFR Part 50, Appendix I will be a significant, unnecessary resource burden to the nuclear power with little to no improvement in worker or public radiological safety or to the protection of the environment.

Issue No. 2 - *Scope of Changes to NRC Guidance Documents Associated With 10 CFR Part 50, Appendix I in Terms of Regulatory Guide 1.109*

The nuclear power industry recommends that the NRC not undertake any scope of changes to revise 10 CFR Part 50 Appendix I to more closely align with the ICRP Publication 103 methodology and terminology. Adoption of the ICRP 103 methodology and terminology will be a significant, unnecessary resource burden that may require nuclear power licensees to make significant modifications to existing facilities, procedures and programs, software, training, record keeping and data reporting and will result in little, if any, improvement in public or environmental radiological safety. The guidance stated in 10 CFR Part 50 Appendix I are "design objectives" and not "radiation protection standards", therefore any change does not guarantee measurable benefit or increase in the health and safety of the public.

Additionally, the existing version of Regulatory Guide 1.109, "Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purposes of Evaluating Compliance with 10 CFR Part 50, Appendix I" provides licensees the opportunity to use dose calculation parameters and methods other than

[12] 79 FR 6509 "Environmental Radiation Protection Standards for Nuclear Power Reactors," Docket ID EPA-HQ-OAR-2013-0689 (2014.)

[13] 79 FR 43284 "Radiation Protection," Docket ID NRC-2009-0279 (2014.)

those proposed by the NRC in the Regulatory Guide.[14] This provision provides an adequate justification for licensees to deviate from standard models. As such, revision to 10 CFR Part 50 Appendix I is unnecessary.

Issue No. 3 - *Detailed Considerations for Revising 10 CFR Part 50, Appendix I*

The nuclear power industry recommends the NRC not change 10 CFR Part 50, Appendix I to align with ICRP 103 or make any of the detailed changes identified in the options detailed in Issue 3. At this time, it is not prudent to align the 10 CFR Part 50 Appendix I with the ICRP Publication 103 dose calculation methods as the existing regulatory framework provides adequate protection of the health and safety of workers, the public, and the environment. Implementing such changes would be a significant, unnecessary resource burden with no measurable benefit or increase in the health and safety of the public or the environment.

Issue No. 4 - *Metrication – Units of Radioactivity, Radiation Exposure, and Dose*

The nuclear power industry recommends that the NRC express units of radioactivity, radiation exposure and dose in either metric or English units, provided that the NRC allow licensees to continue to use traditional units for the performance of facility required regulatory functions and to report to the NRC using traditional units. The industry recognizes that some professional organizations, such as the Health Physics Society,[15] support exclusive use of SI units for measuring and reporting radiation exposure and dose. However, nuclear power licensees recognize several potentially negative unintended consequences that could result from such a change that are not considered by these professional organizations. The consequences include the potential for human error in recording and reporting data/calculating releases and the difficulty in comparing future reported data to the decades of existing data.

Cumulative Impact:

The cumulative effect of regulation (CER) resulting from the changes described in the ANPR for 10 CFR Part 50, Appendix I will place substantial resource burdens on licensees, while yielding little or no additional protection of the public or the environment. It is estimated that implementing the program/instrumentation/training revisions required for 10CFR 50, Appendix I changes could result in a cost of $400,000 per facility or roughly $25 million for the industry.

This burden will be further compounded should the potential changes to 40 CFR Part 190 proposed by the U.S. Environmental Protection Agency in its February 2, 2014, ANPR and the changes proposed in the ANPR for 10 CFR Part 20 be imposed on licensees. Costs associated with the implementation of these changes are not included in the above estimates.

In summary, based on our review of the ANPR and each of the five specific issues upon which the NRC is requesting comment, the nuclear power industry's overall recommendation is that no changes be made to the existing regulations. We conclude that the changes proposed by the NRC are unnecessary from a health and safety standpoint, are unlikely to be cost-beneficial, and will provide little to no incremental improvement in the health and safety of workers, the public or the environment.

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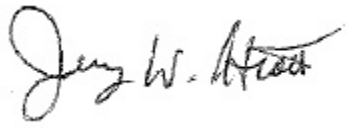
[14] Regulatory Guide 1.109, "Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purposes of Evaluating Compliance with 10 CFR Part 50, Appendix I, October 1977, p. 1.109-2.

[15] Health Physics Society Position Statement, PS025-0, "Exclusive Use of SI Units To Express Radiological Quantities." (2012).

However, notwithstanding our recommendation, should the Commission go forward with changes to 10 CFR Part 50, Appendix I we are providing comments that specifically address the issues raised within the ANPR.

We thank you for the opportunity to provide you with the nuclear energy industry's comments on the ANPR. If you have any questions or require additional information, please contact me.

Sincerely,



Jerry W. Hiatt, CHP

Attachment

Technical Response

To

"Reactor Effluents"

Docket ID NRC-2014-0044

A. Issue No. 1*: Closer Alignment of 10 CFR Part 20 and 10 CFR Part 50, Appendix I, With the Terminology and Methodology Recommendations of ICRP Publication 103.*

According the NRC Staff "Achieving a closer alignment between 10 CFR part 50, appendix I, and the ICRP Publication 103 recommendations would involve changing the underlying terminology and methodology for dose assessment in 10 CFR part 50, appendix I. This closer alignment, if adopted by the NRC, would pose several challenges for the NRC, including the need to revise guidance documents and implementing procedures, and updating computer codes. Likewise, a closer alignment would require licensees to retrain workers to use a new dose assessment system, revise implementing procedures and programs, and revise record keeping and data reporting practices. Therefore, the NRC is seeking to understand the impacts of more closely aligning 10 CFR part 50, appendix I, and associated guidance with the ICRP Publication 103 recommendations regarding terminology and methodology for dose assessments. The issues and options below are intended to elicit information and initiate a dialog with the public, the regulated community, and other stakeholders in future workshops and meetings."[1]

Introduction

The nuclear power industry recommends that the Nuclear Regulatory Commission (NRC) not revise 10 CFR Part 50, *Domestic Licensing of Production and Utilization Facilities*, Appendix I, *Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion "As Low as is Reasonably Achievable" for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents*[2] to more closely align with the ICRP Publication 103 methodology and terminology. Adoption of the ICRP 103 methodology and terminology into 10 CFR Part 20 and/or 10 CFR Part 50, Appendix I will be a significant, unnecessary resource burden to the nuclear industry with little to no improvement in worker or public radiological safety or to the protection of the environment.

As stated in 10 CFR 50.36a(a), the design objectives of 10 CFR Part 50, Appendix I, are not radiation protection standards, but are design criteria to ensure equipment designs maintain radioactive effluents As Low As is Reasonably Achievable (ALARA.) The NRC's regulation in 10 CFR 50.36a(b), which is referenced in Section IV of 10 CFR 50, Appendix I, invokes compatibility in balancing the need for operational flexibility while ensuring public health and safety. Per Federal Register Vol. 80, No. 85, dated Monday, May 4, 2015, page 25238, "The commission agreed with the NRC staff and the NRC's Advisory Committee on Reactor Safeguards (ACRS) 'that the current regulatory framework continues to provide adequate protection of the health and safety of the workers, the public, and the environment.' The commission further stated, '[f]rom a safety regulation perspective, ICRP Publication 103 proposes measures that go beyond what is needed to provide for adequate protection,'…"[3] Additionally, Federal Register Vol. 80, No. 85, dated Monday, May 4, 2015, page 25240, states "The 10 CFR Part 50, Appendix I, design objectives for plant systems are more restrictive than either the 1 mSv (100 mrem) per year dose[4] limit for members of the public in 10 CFR 20.1301(a), or the effluent concentration limits (ECLs) in 10 CFR Part 20, appendix B, Table 2, 'Effluent Concentrations,' which correspond to 0.5 mSv (50 mrem) per year."

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[1] 80 Fed. Reg. 25242

[2] 10 CFR Part 50, *Domestic Licensing of Production and Utilization Facilities*, Appendix I, *Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion "As Low as is Reasonably Achievable" for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents*

[3] Memorandum for SECY-08-0197, dated April 2, 2009, page 1

[4] Throughout this response, dose is use to mean dose equivalent (mrem)

The industry also agrees that "there is no evidence that the current set of radiation protection controls is not protective of the environment, and that the NRC should not develop separate radiation protection regulations for plant and animal species."[5] .

Any benefit to updating implementing procedures and computer programs is not justified by the associated costs. Effluent releases from the U.S. nuclear power industry historically have resulted in very low internal doses. A number of the changes in ICRP 103 are associated with the models used for calculating internal dose and changes to the tissue weighting factors. These changes will require re-analysis and assessment of existing facility design criteria and emergency plans (e.g. General Design Criteria 19 for control room habitability, emergency planning emergency action levels, etc.). These changes will also require revisions to a number of site procedures and computer software programs used for plant worker internal dose evaluations, effluent release calculations, and emergency planning dose assessment for members of the public.

Based on data from NUREG/CR-2907, Vol. 15, the thirty year trend for the commercial nuclear power plant (NPP) industry indicates a factor of 100 decrease per reactor in the quantity (curies) released from liquid effluents and a factor of 1000 decrease per reactor in the quanity of noble gas (curies) released from gaseous effluents. This decrease demonstrates that through resources and industry inititives placed in improved fuel, chemistry and plant management that effluent releases to ALARA levels are achieved, and that the operators of commercial plants are good stewards of the environment. Therefore, expending additional resources to change the dose modeling provides no benefit to the public or to the environment.

Option 1a: Do not change the basis of 10 CFR 50, Appendix I, and continue to use the existing requirements and NRC guidance.

"This option is based on current NRC regulations continuing to adequately protect the public, although 10 CFR Part 20 and 10 CFR Part 50, Appendix I, are based on different methods of assessing dose. Licensee compliance with 10 CFR Part 50, Appendix I, will continue to demonstrate that radioactive effluents to unrestricted areas are ALARA. If the NRC selects this option, the NRC may make minor revisions to update supporting NRC guidance, as most of such guidance was published in the late 1970s."[6]

Questions:

Question 1–1:

What are the advantages and disadvantages of the NRC selecting option 1a?

Response:

The nuclear industry strongly endorses option 1a, and has demonstrated its commitment to maintaining releases ALARA.

Advantages:

- Resources (personnel and financial) can be better spent or saved for initiatives that increase worker, public, and environmental protection;

[5] Memorandum for SECY-08-0197, dated April 2, 2009, page 1

[6] 80 Fed. Reg. 25243 .

- Industry can focus on risk significant work vs. being distracted with implementation of significant upgrades that provides no added increase in protection to workers, the public, or the environment; and
- Maintaining the current regulation and basis provides a consistent comparison of data to decades from past performance.

10 CFR 50.34a requires applicants for construction permits to provide a description of the preliminary design of equipment that will be used to maintain control over radioactive materials in liquid effluents, as well as an estimate of the quantity of radionuclides expected to be released annually to unrestricted areas in liquid effluents. Section 50.34a also requires applicants for operating and combined licenses to describe equipment and procedures for the control of liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, as well as any revised estimate of liquid effluent releases. Per SECY 08-0197, Section C (a), page 4, the design objectives and related guidance could be left as they are since there is no necessary connection between Appendix I design objectives and Part 20 dose limits to the public, since Appendix I is not a radiation protection standard. Per SECY 08-0197 "The Appendix I design objectives are an 'ALARA design basis' requirement. If the design objectives of Appendix I are met, it constitutes a demonstration that effluents and dose to the public are ALARA and no additional efforts are required to reduce effluent release rates. As a result there is no need to link the two, as Part 20 and Appendix I address different regulatory objectives."[7]

The industry recognizes and agrees with the statement within ICRP 103, Executive Summary, section (e) and (f) page 12.

> "The distribution of risks to different organs/tissues is judged to have changed somewhat since Publication 60, particularly with respect to the risks of breast cancer and heritable disease. However, assuming a linear response to low doses, the combined detriment due to excess cancer and heritable effects remains unchanged at around 5% per Sv. Embodied in this current estimate is the use of a dose and dose-rate effectiveness factor for solid cancers which is unchanged at a value of 2."
>
> "The Commission's extensive review of the health effects of ionizing radiation has, however, not indicated that any fundamental changes are needed to the system of radiation protection."

Licensees have designed, constructed, and currently operate reactors to meet 10 CFR 50, Appendix I design and operation objectives. These objectives for 10 CFR Part 50, Appendix I, are conservative and control dose to levels well below the regulatory limits, (i.e. they achieve their intended purpose -- ALARA.) Per the NRC, the regulations provide adequate protection and ICRP 103 provides measures that go beyond what is needed for adequate protection.

Additionally, tissue weighting factors were introduced in ICRP 26 and the values have fluctuated with each subsequent ICRP publication. Some of the values published in ICRP 60 increased when compared to ICRP 26 and then decreased with the issuance of ICRP 103. Additionally, some of the values listed in ICRP 26 remain conservative when compared to the values listed in ICRP 60 and ICRP 103. Recognizing that 10CFR50 Appendix I is a design standard not a dose protection standard; it is impractical to spend considerable resources addressing the fluctuating values as the ICRP values are revised, especially when ALARA has already been achieved and maintained via the current regulatory standard.

Industry has maintained effluents ALARA and incorporation of ICRP 103 tissue weighting factors will add no additional protection to members of the public or the environment. These proposed regulatory

[7] SECY 08-0197, Enclosure 3, Section 3, p.4.

changes would consume significant resources for no added gain in protection. Leaving the regulations unchanged allows for resources to be used for initiatives that could improve overall safety while meeting the requirements of 10 CFR 50.36a (b), which "invokes compatibility in balancing the need for operational flexibility while still ensuring public health and safety."

Disadvantages:

- 10 CFR Part 50, Appendix I design objectives would remain based on total body and critical organ dose concepts and models which are based on the recommendations of ICRP 2; and
- The objection that ICRP 2 is no longer taught in U.S. universities as a dose assessment methodology requiring utilities to train new personnel on an outdated (but still effective) methodology has been offered by the NRC.[8] However, the dose modeling is imbedded into the methods contained within US NRC Regulatory Guide 1.109, and licensee Off Site Dose Calculation Manual (ODCM) documents. As such, maintaining the use of the older ICRP method requires only training to the license basis.

Option 1b: Revise the terminology and methodology for dose assessments in 10 CFR Part 50, Appendix I, to more closely align with the recommendations of ICRP Publication 103

"This approach would ensure a consistent application of regulatory criteria between 10 CFR Part 20 and 10 CFR Part 50, Appendix I. This option would offer the opportunity to use to a common regulatory basis for calculating and reporting doses."

Note: The following questions are based upon the NRC selecting option 1b.

Questions:

Question 1–2:

What are the advantages and disadvantages of more closely aligning the 10 CFR Part 50, Appendix I, terminology and methodology for dose assessments with those of the ICRP Publication 103 recommendations?

Response:

The nuclear power industry does not recommend option 1b. However, to be complete with our review, the following is provided as a response to Question 1-2.

Advantages:

- Reduction in potential confusion by using one dose concept and model vs. using different dose concepts and models.

Disadvantages

- This change would require significant resources, including potential costly plant modifications. Resources will be required to review monitor setpoints and change software, procedures, training programs, etc., for no added gain in protection. Appendix I is a design objective not a protection standard and by demonstrating that doses are ALARA; the design objectives are met.

[8] SECY 08-0197 Enclosure 3, Page 2.

Question 1–3*:*

At this time, the NRC is contemplating a parallel rulemaking effort, one for 10 CFR Part 20 and one for 10 CFR Part 50, Appendix I, with a common effective or compliance date for both rules. What are the advantages or disadvantages of the NRC conducting such a parallel rulemaking effort?

Response

Implementing 10 CFR Part 20 and 10 CFR Part 50, Appendix I in parallel with commensurate effective dates of compliance has positive and negative consequences. The following list summarizes the advantages and disadvantages associated with parallel rule implementation.

Advantages:

- It is cost effective to implement both rules in addressing software revisions, procedure changes, training requirements, instrument/equipment upgrades, etc. concurrently rather than as separate tasks;
- The overall length of time necessary to implement both rules in parallel will provide the additional time that may be required to address potential equipment modifications and change management for impacted personnel;
- Dual implementation would provide for improved consistency between 10 CFR 20 and 10 CFR 50 Appendix I;
- Concurrent implementation facilitates streamlining of radiation dose assessment practices (e.g., liquid and gaseous effluents, ODCM dose calculations, 40 CFR 190 dose assessments, etc.) and radiation protection procedures used in in meeting dose projection calculations; and
- Dual implementation may offer additional operational latitude and flexibility in the development of Regulatory Guides, NUREGS, and/or Regulatory Issue Summary (RIS) type documents by the NRC.

Disadvantages:

- Parallel implementation would require significant concurrent involvement from multiple departmental resources (e.g., radiation protection, chemistry, radwaste, etc.) over an extensive time period to support the rule changes;
- There is no need or inherent benefit in executing 10 CFR 20 and 10 CFR 50 Appendix I rule changes concurrently. The past 22 years of nuclear power plant operating experience demonstrate that operating under existing 10 CFR 20 and 10 CFR 50 Appendix I with different bases continue to maintain doses ALARA and provide an adequate level of safety and health to the public and the environment;
- Dual implementation with the same effective dates would require a longer implementation period; and
- Delays in some areas could result from regulatory guidance that may not be as readily available if one rule is implemented independent of the other. Bases and other documents supporting 10 CFR 20 and 10 CFR 50 Appendix I have different requirements which could present challenges to completing required revisions or creating new documents in parallel sequence.

Question 1–4:

What are the backfitting implications of applying option 1b to 10 CFR Part 50 licensees? What are the issue finality implications of applying option 1b to those persons who hold NRC approvals under 10 CFR Part 52 (*e.g.,* combined license holders and applicants, a holder of a standard design certification)?

Response:

I. As stated in the following sections imposition of Option 1b on Part 50 Licensees would constitute backfitting as defined in 10 CFR § 50.109

"Backfitting" is a change to the power plant itself, the design of the plant, or the procedures and organization necessary to design, construct, or operate the plant, due to a new or amended NRC regulation or interpretation. The NRC's rule applicable to commercial power reactors defines backfitting as:

> [T]he modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position.[9]

Once a new or amended requirement is identified as a backfit, the NRC must demonstrate – through a "systematic and documented analysis" – that the change will result in a substantial increase in the overall protection of public health and safety or the common defense and security. If the NRC determines that the change will result in a "substantial increase," it must then make a finding that the direct and indirect costs of implementation are justified in view of the increased protection. [10] Generally, a backfit may not be imposed unless these findings are made.

Option 1b would meet the § 50.109(a) definition of backfitting because the contemplated amendment to Appendix I would cause Part 50 licensees to modify the "procedures or organization required to design, construct or operate a facility." For example, the ANPR acknowledges that:

> Achieving a closer alignment between 10 CFR 50, Appendix I, and the ICRP Publication 103 recommendations would involve changing the underlying terminology and methodology for dose assessment in 10 CFR 50, Appendix I. This closer alignment, if adopted by the NRC, would pose several challenges for the NRC, including the need to revise guidance documents and implementing procedures, and updating computer codes. Likewise, a closer alignment would require licensees to retrain workers and use a new dose assessment system, revise implementing procedures and programs, and revise record keeping and data reporting practices.[11]

As recognized in the ANPR, Option 1b would require changes to licensee implementing procedures and programs that are required to operate nuclear power plants. Examples of these procedures include the Offsite Dose Calculation Manual, technical procedures which implement Regulatory Guide 1.21 programs (i.e. Radiological Effluent Release Report), radiological liquid and gaseous effluent sampling procedures, and effluent monitor instrument setpoint procedures. Given Appendix I provides "design objectives for light-water-cooled nuclear powers licensed under 10 CFR 50 or part 52," it is also possible that costly design and hardware changes may be required if the Appendix I rule changes were applied to operating plants.

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[9] 10 CFR § 50.109(a)(1).

[10] *See* 10 CFR § 50.109(a)(2), (a)(3), (c). This analysis is sometimes referred to as the "cost-justified, substantial increase" analysis.

[11] 80 Fed. Reg. 25242 (emphasis added).

Further, industry agrees with the Commission when the Commission previously recognized that the proposed changes would constitute backfits. For example, the ANPR describes the direction provided to the staff in SRM-SECY-08-0197, stating:

> The Commission agreed with the NRC staff and the NRC's Advisory Committee on Reactor Safeguards (ACRS) "that the current regulatory framework continues to provide adequate protection of the health and safety of workers, the public, and the environment." The Commission further stated, "[f]rom a safety regulation perspective, ICRP Publication 103 proposes measures that go beyond what is needed to provide for adequate protection," and that "[t]his point should be emphasized when engaging stakeholders and interested parties, and thereby focus the discussion on discerning the benefits and burdens associated with revising the radiation protection regulatory framework," which includes 10 CFR 50, Appendix I.[12]

The Commission's discussion of the adequate protection implications of the proposed changes, as well as its direction that the staff focus on "discerning the benefits and burdens" of modifying the regulatory framework, indicates that the Commission viewed the proposed changes as backfits and must meet the requirements in § 50.109.

II. The Exceptions to the Backfitting Rule Do Not Apply to the Changes Contemplated Under Option 1b

There are three exceptions to the backfitting rule.[13] Specifically, the "cost-justified-substantial-increase" analysis mentioned above need not be performed where the backfit involves:

- A modification necessary to bring a facility into compliance with a legally binding requirement (e.g., a license, rule, or order of the Commission), or into conformance with written commitments made by the licensee ("Compliance Exception");
- A regulatory action necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security ("Adequate Protection Exception #1"); or
- A regulatory action involving defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate ("Adequate Protection Exception #2").

None of these exceptions would apply to the changes proposed in Option 1b. First, the proposed amendments would modify long-standing provisions of 10 CFR 50 that have been incorporated into licensee programs, procedures, and technical specifications and are not necessary to bring licensees into compliance with existing requirements or commitments. Thus, the Compliance Exception would not apply.

Further, given the Commission and staff's characterization of the existing regulations and proposed changes, the amendment described in Option 1b would not fall within either of the "adequate protection" exceptions. For example, in SRM-SECY-08-0197 the Commission stated:

> "The Commission agrees with the staff and the [ACRS] that the current NRC regulatory framework continues to provide adequate protection of the health and safety of workers, the public, and the environment. From a safety regulation perspective, ICRP Publication 103 proposed measures that go beyond what is needed to provide for adequate protection. This point

[12] *Id.* at 25,238, *quoting* Staff Requirements – SECY-08-0197 – Options to Revise Radiation Protection Regulations and Guidance With Respect to the 2007 Recommendations of the International Commission on Radiological Protection (April 2, 2009) (emphasis added).

[13] *See* 10 CFR § 50.109(a)(4)(i)-(iii).

should be emphasized when engaging stakeholders and interested parties, and thereby focus the discussion on discerning the benefits and burdens associated with revising the radiation protection regulatory framework. For example, while licensees voluntarily develop and implement internal constraints, the regulatory imposition of these constraints is an overreaching insertion of regulatory standards into the licensee's management of its radiation protection program.

The Commission agrees with the ACRS that there is no evidence that the current set of radiation protection controls is not protective of the environment, and that the NRC should not develop separate radiation protection regulations for plant and animal species. The staff should continue to monitor international developments in this regard and keep the Commission informed."[14]

Since the Commission has concluded that the ICRP 103 recommendations "go beyond what is needed to provide adequate protection," the backfits proposed in Option 1b would not be required to ensure that nuclear power facilities provide adequate protection of public health and safety. Thus, Adequate Protection Exemption #1 would not apply.

Further, the ANPR states:

> "[T]he dose calculation methodologies in 10 CFR 50, Appendix I (based on ICRP Publication 2), result in a total body dose, while the dose calculation methodologies in ICRP Publication 103 result in an effective dose. Although both calculation methodologies result in an estimate of the dose to an individual, different assumptions are used in each calculation. As a result, the estimated doses to the individual will be different, but the differences are not expected to be significant with respect to radiological protection for members of the public. A more exact estimate of the differences in dose estimates between the two calculation methodologies will be available once all of the dose coefficients for ICRP Publication 103 are published, which is currently scheduled for 2015. A summary of the differences in the dose estimates between ICRP Publication 2 and ICRP Publication 103 methodologies is expected to be included in the regulatory basis document."[15]

Since adopting the ICRP 103 dose calculation methodologies will not likely result in differences in estimated doses nor be a significant change in radiological protection, it is also unlikely that the Commission would determine that the amendments to align Appendix I with the ICRP 103 methodologies are necessary to "defin[e] or redefine[e] what level of protection to the public health and safety or common defense and security should be regarded as adequate." Thus, based on the information available at this time, it is unlikely that the Adequate Protection Exemption #2 would apply.

While we believe it is clear that none of the exceptions to the backfitting rule would apply to the changes contemplated in Option 1b, we recognize that in promulgating the 1991 revisions to 10 CFR Part 20 the Commission noted:

> [E]ven had the [backfitting] analysis not concluded that the amendment to Part 20 in this final rule provide a substantial increase in the overall public health and safety, it could have gone forward with the rule because the changes made to Part 20 also amount to a redefinition of the

[14] Staff Requirements – SECY-08-0197 – Options to Revise Radiation Protection Regulations and Guidance With Respect to the 2007 Recommendations of the International Commission on Radiological Protection (April 2, 2009); *see also*, 80 Fed. Reg. 25,238.

[15] 80 Fed. Reg. 25239.

> level of adequate protection and the backfit rule's substantial increase in protection and cost justification standards do not apply to a redefinition of adequate protection.[16]

However there are important distinctions between the 1991 Part 20 rulemaking and the rulemaking contemplated here. First, it is important to point out that Appendix I does not impose radiation protection standards. Instead, Appendix I provides design objectives and limiting conditions for operation that are used by reactor licensees to ensure that effluent releases are kept "As Low as is Reasonably Achievable" (ALARA). In turn, ALARA means:

> "[M]aking every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest."[17]

Per the denoted reference "It is well-settled that the Commission may not consider costs when deciding whether to impose or enforce a requirement necessary to provide adequate protection of public health and safety."[18] The Commission may, however, consider costs when deciding whether to impose requirements that are not necessary for the purposes of adequate protection. Thus, by definition, ALARA limits – which expressly consider the economics of improvements in relation to their benefits – go beyond what is required for adequate protection of public health and safety. Further, given the restrictions on the consideration of cost imposed by *UCS v. NRC*, redefining adequate protection to align with an ALARA limit such as those proposed in Appendix I would seem to be inconsistent with the definition of ALARA.

It is also important to note that in 1991 the Commission concluded that the revisions to the radiation protection standards in Part 20 would provide improved public health protection by virtue of:

- Reducing the annual worker dose limit from 12 rems/year to 5 rems/year;
- Imposing a specific dose limit for the embryo/fetus (no specific limit for the embryo/fetus existed prior to the 1991 rule change;)
- Updating the radionuclide intake limits based upon current scientific data, including substantially lower limits for several radionuclides such as uranium; and
- Creating a requirement for licensees to develop and implement ALARA programs and procedures (prior to 1991, except for LLRW effluent releases subject to Appendix I of 10 CFR Part 50, the regulations "exhorted" licensees to keep radiation exposures "ALARA," but didn't expressly require it.)[19]

In contrast, here the Commission seems to be acknowledging that the proposed changes would not provide an appreciable improvement in public health and safety, and the ANPR indicates that differences

[16] 56 Fed. Reg. 23389; May 21, 1991.

[17] 10 CFR § 20.1003.

[18] *Union of Concerned Scientists v. U.S. Nuclear Regulatory Commission*, 824 F.2d 108 (D.C. Cir. 1987) ("*UCS v. NRC*").

[19] *See* 51 Fed. Reg. 30,872

in estimated doses to individuals resulting from adoption of the ICRP 103 methodologies "are not expected to be significant with respect to radiological protection for members of the public."[20]

III. Changes Contemplated in Option 1b are Unlikely to Yield a "Cost-Justified, Substantial Increase" in the Overall Protection of Public Health and Safety or the Common Defense and Security

As discussed above, after determining that a proposed amendment to the agency's regulations meets the definition of a backfit and that none of the three exceptions to the rule apply, it is necessary to determine whether the proposed amendment will yield a "substantial increase in the overall protection of the public health and safety or the common defense and security." The NRC's guidance on addressing the "substantial increase" question is provided in "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Rev. 4. NUREG/BR-0058 provides one quantitative method to determine whether a proposed backfit will yield a "substantial increase" in public health and safety. This method, known as a Safety Goal Evaluation, is focused primarily on reactor accidents and uses reduction in Core Damage Frequency (CDF) as the primary quantitative metric to assess the safety benefit associated with a proposed backfit.[21] This approach to a Safety Goal Evaluation will not be useful here, however, because the contemplated changes to Appendix I address dose calculation methodology, not changes aimed at impacting plant accident risk (i.e., CDF and CCFP).

That said, there are several recent examples where the NRC staff has used other methods to perform quantitative assessments by comparing the estimated benefits of a proposed backfit more directly to the Commission's Quantitative Health Objectives (QHO). [22] These methods allowed the staff to evaluate the benefits of proposed regulatory changes in a quantitative fashion, despite the fact that the changes being considered would not directly affect CDF. Although in the past the NRC has evaluated changes to the radiation protection requirements in 10 CFR Part 20 using qualitative information, the staff should consider whether a quantitative analysis is possible using an approach that will allow the staff to compare the health and safety benefits of the proposed changes to the Commission's QHOs.

If the staff determines that the safety benefit of the proposed changes to Appendix I cannot be evaluated quantitatively, the qualitative analysis used should consider the following:

- The statement in the ANPR indicating differences in estimated doses that would result from adoption of ICRP 103 "are not expected to be significant with respect to radiological protection for members of the public"[23] and any work performed to more thoroughly examine the impact of adopting ICRP 103 on estimated doses;
- The long-term decreasing trend in the amount of radioactive material released in both gaseous and liquid effluents from commercial nuclear power reactors over the past three-plus decades; and

[20] 80 Fed. Reg. 25,240

[21] NUREG/BR-0058, at Section 3.0 "Safety Goal Evaluation for Operation of Nuclear Power Plants." NUREG/BR-0058 also describes use of conditional containment failure probability (CCFP) in conjunction with changes in CDF.

[22] *See, e.g.,* "Staff Evaluation and Recommendations for Japan Lessons-Learned Tier 3 Issue on Expedited Transfer of Spent Fuel," COMSECY-13-0030 (Nov. 12, 2013); "Evaluation of the Containment Protection & Release Reduction for Mark I and Mark II Boiling Water Reactors Rulemaking Activities," SECY-15-0085 (June 18, 2015).

[23] 80 Fed. Reg. 25,240.

- The fact that estimated doses to the public attributable to effluent releases from commercial nuclear power reactors are already very low.[24]

Given the very low estimated public doses attributable to effluent releases from commercial nuclear power reactors, we believe that the changes contemplated in Option 1b would yield very little, if any, safety benefit. If, however, the NRC can show that the proposed changes pass the "substantial increase" test, the backfitting rule requires a demonstration that "the direct and indirect costs of implementation . . . are justified in view of this increased protection."[25] Given the seemingly small safety benefits associated with Option 1b, it is unlikely that it could be justified in light of the costs described in our responses to questions 1-5, 1-6, and 1-7.

IV. Issue Finality

10 CFR Part 52 contains multiple "issue finality" provisions that are similar to the backfitting provision applicable to Part 50 licensees. Portions of these "issue finality" provisions are discussed briefly below.

Early Site Permit Holders (10 CFR § 52.39)

Section 52.39(a) states, in part:

> Notwithstanding any provision in 10 CFR 50.109, while an early site permit is in effect under §§ 52.27 or 52.33, the Commission may not change or impose new site characteristics, design parameters, or terms and conditions, including emergency planning requirements, on the early site permit unless the Commission:
>
> (i) Determines that a modification is necessary to bring the permit or the site into compliance with the Commission's regulations and orders applicable and in effect at the time the permit was issued;
>
> (ii) Determines the modification is necessary to assure adequate protection of the public health and safety or the common defense and security;
>
> (iii) Determines that a modification is necessary based on an update under paragraph (b) of this section; or
>
> (iv) Issues a variance requested under paragraph (d) of this section.

If Option 1b is implemented and modifications to Appendix I are applied to Early Site Permit holders, it is possible that those changes could result in changes to design parameters or terms and conditions of the permit. In that case, the restrictions provided in § 52.39(a) would apply. At this stage it is difficult to more fully assess the applicability of § 52.39. However, given the discussion of backfitting provided above, imposition of Option 1b would not satisfy either § 52.39(a)(i) or (ii). If Option 1b is pursued, the NRC staff should carefully consider how the rule will apply to and impact Early Site Permit holders.

Standard Design Certifications (10 CFR § 52.63)

Section 52.63(a)(1) states, in part:

> (a)(1) Notwithstanding any provision in 10 CFR 50.109, while a standard design certification rule is in effect under §§ 52.55 or 52.61, the Commission may not modify, rescind, or impose new

[24] "Doses to the public due to effluents from NPPs are less than 0.1% (one-tenth of one percent) of what the average person receives each year from all sources of radiation." NUREG/CR-2907, "Radioactive Effluents from Nuclear Power Plants, Annual Report 2009," at pg. 2-6.

[25] 10 CFR § 50.109(a).

> requirements on the certification information, whether on its own motion, or in response to a petition from any person, unless the Commission determines in a rulemaking that the change:
>
> (i) Is necessary either to bring the certification information or the referencing plants into compliance with the Commission's regulations applicable and in effect at the time the certification was issued;
>
> (ii) Is necessary to provide adequate protection of the public health and safety or the common defense and security;
>
> (iii) Reduces unnecessary regulatory burden and maintains protection to public health and safety and the common defense and security;
>
> (iv) Provides the detailed design information to be verified under those inspections, tests, analyses, and acceptance criteria (ITAAC) which are directed at certification information (*i.e.*, design acceptance criteria);
>
> (v) Is necessary to correct material errors in the certification information;
>
> (vi) Substantially increases overall safety, reliability, or security of facility design, construction, or operation, and the direct and indirect costs of implementation of the rule change are justified in view of this increased safety, reliability, or security; or
>
> (vii) Contributes to increased standardization of the certification information.

The prohibition described in § 52.63(a)(1) would apply if the proposed changes to Appendix I would modify, rescind, or impose new requirements on the certification information. If so, the changes could be permitted only if one of the conditions in § 52.63(a)(1)(i)-(vii) were satisfied. As described above, it is unlikely that Option 1b would satisfy the "cost-justified, substantial increase" requirement imposed by § 50.109. Thus, it is also unlikely that Option 1b would satisfy § 52.63(a)(1)(vi). Likewise, § 52.63(a)(1)(i) and (ii) would not apply for the same reasons that the compliance and adequate protection exceptions to the backfitting rule would not be satisfied. There is no indication that the changes contemplated in Option 1b would contribute to standardization (§ 52.63(a)(1)(vii)) or correct any material errors in certification information (§ 52.63(a)(1)(v)). Finally, as described above and elsewhere in these comments, the changes contemplated in Option 1b would actually increase, rather than decrease, burden on licensees (§ 52.63(a)(1)(iii)). Although it is difficult to precisely assess whether § 52.63 would apply to the changes under consideration in Option 1b at this point, it seems unlikely that any impacts on certification information could be justified under that provision.

Combined License Holders (10 CFR § 52.98)

Section 52.98(a) states, in part:

> (a) After issuance of a combined license, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, the inspections, tests, analyses, and acceptance criteria contained in the license which are not derived from a referenced standard design certification or manufacturing license, except in accordance with the provisions of § 52.103 or § 50.109 of this chapter, as applicable.

If the changes proposed in Option 1b were enforced on combined license holders and resulted in a change to the terms or conditions of the license itself, or the design of the facility, the restriction in § 50.98 would apply. Such a change could only be imposed in accordance with the provisions of § 50.109. For the reasons discussed above, it is unlikely that imposition of Option 1b could be justified pursuant to § 50.109.

Question 1–5:

What cost savings would be realized over the life of the operational programs if dose calculation methods (for 10 CFR Part 20 and 10 CFR Part 50, Appendix I) are standardized?

Response:

Changing the underlying dose methodologies would not lead to any cost savings over the life of the operational programs. As noted above, change would result in a large resource burden to the nuclear industry licensees with little to no improvement to worker, public, or environmental safety. Since compliance is driven by licensees' Off Site Dose Calculation Manuals (ODCM), the fact that the calculations are not based on the same ICRP model is transparent to the individuals implementing the license requirements. Changing to ICRP Publication 103 tissue weighting factors and other concepts would require ODCM changes, procedure changes, training, computer program changes and associated verification and validation. The learning curve for those implementing the new methods to understand the updated guidance may result in diversion of resources from other safety focus areas.

The nuclear industry feels strongly that the NRC Commissioners should direct resources to those changes that are necessary to substantially improve worker and public health and safety and those which will streamline regulatory processes. SECY-15-015, Project AIM 2020, recommends that the NRC achieve the highest standards of performance with a balanced perspective of the significance of the activity, focusing on the right things. There is no net benefit from changing the methodology in 10CFR 50 Appendix I to ICRP publication 103 dose methods, yet the cost would be significant. The nuclear industry sees no balance in the cost without benefit.

Question 1–6:

What operational impacts and costs (per reactor unit) would be incurred by licensees (*e.g.,* in updating licensee programs, procedures, computer codes, training)?

Response:

The operational impacts are significant, with changes estimated to exceed $400,000 per operating site. An initial evaluation reveals that this change would divert resources from other important safety functions to address these changes. A detailed cost to implement such a change must be performed but as noted by the question, the costs include licensing basis changes, complete revision to the ODCM calculation methodology, procedures, hardware, computer codes, setpoint calculation review, and plant staff training. These costly changes would affect many levels of plant management without a net positive benefit and would impact an industry that is already experiencing economic reasons to close plants.

Question 1–7:

Would licensee costs and the operational impacts of complying with a revised 10 CFR Part 50, Appendix I, be similar for both BWRs and PWRs?

Response:

There would be no substantial difference in costs between BWRs and PWRs for complying with a revised 10 CFR Part 50.

Question 1–8:

Should all of the conforming changes to the dose based criteria in 10 CFR Part 50 (*e.g.,* the TEDE criteria in 10 CFR 50.34(a)(1)(ii), 10 CFR 50.67, and Appendix A, "General Design Criteria for Nuclear Power

Plants," Criterion 19, "Control Room") be changed coincident with the changes to 10 CFR Part 50, Appendix I, or should conforming changes to other Parts of the regulations be conducted in a separate, later rulemaking?

Response:

A separate rulemaking would be needed that is not coincident with the 10 CFR Part 50 Appendix I change. Changes to all the dose based criteria in 10CFR 50 will require re-analysis and assessment of existing facility design criteria and emergency plans (e.g. General Design Criteria 19 for control room habitability, emergency planning emergency action levels, etc.). These changes will also require revisions to a number of site procedures and computer software used for plant worker internal dose evaluations, effluent release calculations, and emergency planning dose assessment for members of the public. Changes will extend to the emergency plan, scenario development, and dose calculation methods in the dose modeling software for emergencies. A wholesale change in the design basis is not warranted by safety, but would result in a significant burden for reanalysis, and, quite possibly, costly modifications that do not add any margin of safety to the workers or the public.

Question 1–9*:*

Should the NRC expand the number of age groups from 4 to 6 as recommended in ICRP Publication 103.

Response:

The primary purpose of the 4 age groups is to address differences in consumption of food products. *Generally* the dose factors do not vary among the age groups as much as the consumption rates which impacts the total amount of radioactive material entering the body. For example in the USNRC Regulatory Guide 1.109 model, the infant receives dose only via the animal milk ingestion (a nursing infant is not considered), potable water, inhalation and ground plane pathways.

Per the discussion on "maximum individual" in US NRC Regulatory Guide 1.109, pages 1 and 2 the assumption is that protecting the hypothetical individual receiving the maximum dose adequately protects the rest of the public. The maximum individual consumption rates are given in US NRC Regulatory Guide 1.109 Table E-5; however these are stated as recommended usage values for the maximum exposed individual, "***in lieu of site-specific data.***"

Demographics and consumption habits have changed since the development of the Regulatory Guide; however, at issue is whether or not the NRC will continue to use the maximum individual as described in Regulatory Guide 1.109 as a means of implementing Appendix I design objectives. A question to consider is if the maximum individual concept is retained by the NRC, how will compliance with Appendix I be demonstrated?

The third paragraph of the abstract of ICRP Pub 101a[26] states, "The Commission recognizes that the level of detail afforded by its provision of dose coefficients for six age categories is not necessary in making prospective assessments of dose, given the inherent uncertainties usually associated with estimating dose to the public and with identification of the representative person. It now recommends the use of three age categories for estimating annual dose to the representative person for prospective assessments. These categories are 0 - 5 years (infant), 6 - 15 years (child), and 16 - 70 years (adult). For practical implementation of this recommendation, dose coefficients and habit data for a 1-year-old infant, a 10-year-old child, and an adult should be used to represent the three age categories."

[26] ICRP Publication 101a, "Assessing Dose of the Representative Person for the Purpose of the Radiation Protection of the Public." ICRP Publication 101a. Ann. ICRP 36 (3), 2006.

Note that the paragraph indicates that there is no real advantage from a radiation protection standpoint of using 6 age groups, but, rather, suggests:

> *"dose coefficients and habit data for a 1-year-old infant, a 10-year-old child, and an adult should be used to represent the three age categories dose coefficients and habit data for a 1-year-old infant, a 10-year-old child, and an adult should be used to represent the three age categories."*

This also appears to be reasonable solution as the dose factors and consumption rates of USNRC Regulatory Guide 1.109 varies little between the teen and adult.

As such, the nuclear industry does not see any appreciable advantage in expanding the number of age groups to 6 classifications. Such age distinctions would be of value in assessing a single or small group exposure for certain cases, if needed.

B. Issue No. 2: *Scope of Changes to NRC Guidance Documents Associated With 10 CFR Part 50, Appendix I in Terms of Regulatory Guide 1.109*

"In the event of a revision of the 10 CFR part 50, appendix I, regulations, the NRC would need to consider making revisions to several guidance documents associated with the 10 CFR part 50, appendix I, regulations. In Enclosure 3 of SECY–08–0197, the NRC staff examined a tiered approach reflecting increasing levels of complexity of a revision to the associated guidance documents. The discussion in SECY–08–0197 considered three options for revising those guidance documents associated with 10 CFR part 50, appendix I. The NRC staff notes that the primary guidance document, RG 1.109, has not been updated since 1977. The following options and questions are intended to elicit information and initiate a dialog with the public, the regulated community, and other stakeholders in future workshops and meetings."

Introduction

The nuclear power industry recommends that the NRC not revise 10 CFR Part 50 Appendix I to more closely align with the ICRP Publication 103 methodology and terminology. Adoption of the ICRP 103 methodology and terminology will be a significant, unnecessary resource burden that may require nuclear power licensees to make significant modifications to existing facilities, procedures and programs, software, training, record keeping and data reporting and will result in little, if any, improvement in public radiological safety. The guidance stated in 10 CFR Part 50 Appendix I are "design objectives" and not "radiation protection standards", therefore any change does not guarantee measurable benefit or increase in the health and safety of the public.

10 CFR Part 50.34a, "*Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors*", states:

> *The guides set out in appendix I to this part provide numerical guidance on design objectives for light-water-cooled nuclear power reactors to meet the requirements that radioactive material in effluents released to unrestricted areas be kept as low as is reasonably achievable. These numerical guides for design objectives and limiting conditions for operation are not to be construed as radiation protection standards.*

Current and proposed nuclear power licensees are designed and operated to keep radioactive effluent releases ALARA per the dose requirements of the 10 CFR Part 50 Appendix I design objectives. Additionally, as noted in the ANPR, "[f]rom a safety regulation perspective, ICRP Publication 103 proposes measures that go beyond what is needed to provide for adequate protection.[27]"

For consideration in Option 2a and Option 2c, Regulatory Guide (RG) 1.109 currently provides licensees the opportunity to use dose calculation parameters and methods other than those proposed by the NRC. RG 1.109, page 2, first paragraph, states:

> *…the applicant is encouraged to use information and data applicable to a specific region or site when possible. Where site-specific information and data is used, its justification should be documented for the NRC staff's review.*

And RG 1.109, page 2, third paragraph, states:

> *The models and assumptions described in Appendices A, B, C, and D of this guide are acceptable to the NRC staff for calculating doses to individuals and populations.* ***If other models are selected****, they should include the same*

[27] 80 Fed. Reg. 25238 (May 4, 2015.)

exposure pathways considered in the models described in this guide. The assumptions and methods used should be fully described and documented.

These statements provide an adequate justification for licensees to deviate from the RG 1.109 standard models and to use the methodologies contained within ICRP 103, if appropriate. Therefore, revision to 10 CFR Part 50 Appendix I is unnecessary.

Option 2a: Limited Scope Revision (no changes to the numerical values)

"Under this option, the proposed revision would include very limited changes to 10 CFR part 50, appendix I (e.g., to change the design objectives for total body dose only), and would involve very limited changes to only one regulatory guide (e.g., the dose coefficients in RG 1.109, Table B–1, "Dose Factors for Exposure to a Semi-Infinite Cloud of Noble Gases," and Tables E–6, "External Dose Factors for Standing on Contaminated Ground," to E–14, "Ingestion Dose Factors for Infant," only)."

Option 2b: Full Scope Revision

"Under this option, the NRC would consider a complete revision to 10 CFR Part 50, appendix I, and all NRC guidance documents, which would include a total of more than 30 regulatory guides, NUREGs, generic communications, and associated software programs. A full scope revision also involves evaluating new radwaste systems, updating dispersion models, new source terms, rewriting RG 1.109, RG 1.110, RG 1.111, and RG 1.112."

Option 2c: Expanded Scope Revision

"Under this option, the NRC would include more substantive changes to the regulations and applicable guidance documents than included in Option 2a and potentially substantially less than that listed in Option 2b."

Questions

Question 2–1:

Which Option (i.e., what scope of changes to NRC guidance documents) seems most appropriate, and are other options available?

Response:

Option 2a:

Option 2a is the most reasonable should a revision to 10 CFR Part 50 Appendix I be implemented. This option bounds licensees' commitment to the revision. Fewer personnel resources would be required for procedure revisions and training. Option 2a also provides a limited scope revision to the sites' Off-Site Dose Calculation Manual (ODCM). This would require fewer resources to implement the change as monitoring equipment is unlikely to need upgrading. Software modifications would likely only entail updates to data tables/fields, and not source code. Additionally, historical data and trending would also be maintained.

The industry recommends that any revision to RG 1.109 take into account proposed changes to the EPA's 40 CFR Part 190[28] and other research studies that are currently ongoing. Specifically, with respect to the consideration of different age groups defined by ICRP recommendations, any revision to RG 1.109 would need to align with potential future changes associated with the EPA 40 CFR Part 190 ANPR[29]. Should EPA move forward with rulemaking to 40 CFR Part 190 to align with ICRP 103, the potential exists for compliance issues when one regulation requires dose to infant, child, teen, and adult, and another

[28] 79 FR 6509 Docket ID EPA-HQ-OAR-2013-0689 (2014.)

[29] Federal Register Vol. 79, No. 23, dated Tuesday, February 4, 2014

requires dose to 1-year old, 10-year old, and adult. Additional guidance beyond what is currently provided would be required to ensure regulatory compliance. Also, should EPA eliminate the dose based standard in favor of a risk based standard (counter to industry and other professional organization recommendations) additional compliance issues may become problematic.

Option 2b:

Option 2b is the least reasonable and impractical should a revision to 10 CFR Part 50 Appendix I be implemented. This option is expansive and requires significant resource commitment from licensees and the NRC while yielding little or no additional protection to the health and safety of the public. This option would require a dedicated project team for each site or utility that would be needed for activities such as procedure revisions, personnel training, full-scope revision to site ODCM, software and equipment modifications, etc. and could potentially lead to an increase in human performance errors.

This option is not practical due to the large volume of regulatory guidance documents that would require revision. The personnel and resource requirements cannot be justified for the little or no benefit that would be gained in protecting the health and safety of the public or the environment.

Option 2c:

The industry finds commenting on a revision to 10 CFR Part 50 Appendix I using Option 2c nearly impossible to due to a lack of specific details. This option considers a scope spanning all possibilities between Option 2a and Option 2b, and thus cannot be quantified with any accuracy. Therefore, the nuclear power industry recommends that the NRC better define the expanded scope proposed in Option 2c. The scope should be bound within the following

1. NRC provide explicit guidance on:
    a. other acceptable dose calculation methods beyond RG 1.109.
    b. how to obtain site-specific data and parameters.

    OR

2. NRC revise RG 1.109 beyond Tables B-1 and E-6 to E-14 to include the following RG 1.109 tables to incorporate updated scientific data:
    a. A-1 Bioaccumulation factors,
    b. A-2 Shore-width factors,
    c. D-1 Transport times in the food distribution system,
    d. E-1 Stable element transfer data
    e. E-2 Nuclide transfer parameters for goat's milk
    f. E-3 Animal consumption rates
    g. E-4 U_{ap} to be used for average individual
    h. E-5 U_{ap} to be used for maximum exposed individual
    i. Other tables, input parameters, or dose calculation methods as necessary based on updated scientific research.

Question 2–2:

What are the advantages and disadvantages of each of the three options?

Response:

No Revision

Advantages:

- Will not change "design objectives" for current radioactive waste treatment systems previously designed under 10 CFR 50 Appendix I;
- Using "other methods" is already allowed by NRC guidance (see the "Introduction" to our response;)
- Requires no additional resource burden to licensees for little or no measurable increase in health and safety of the public and the environment; and
- Allows for easier data comparison of future dose results (and hence performance) to past performance by reporting doses in a consistent manner.

Disadvantages:

- May not align with possible revision to 10 CFR Part 20 or 40 CFR Part 190; and
- Need for continued training on ICRP 2 methodology to the extent that the methodology is used as the basis for ODCM calculations.

Option 2a: Limited Scope Revision

Advantages:

- Fewer resources required for procedure revisions, training, software and equipment modifications, etc.; and
- Reduced scope revision to site ODCM.

Disadvantages:

- Inputs to dose calculations having inconsistent bases (i.e. using updated dose coefficients but old consumption rates;) and
- Need for continued training on ICRP 2 methodology to the extent that the methodology is used as the basis for ODCM calculations.

Option 2b: Full Scope Revision

Advantages:

- Aligns the basis of 10 CFR Part 50 Appendix I and related documents.

Disadvantages:

- Significant personnel resources required for procedure revisions, training, software and equipment modifications, etc., potentially leading to an increase in human performance errors;
- Significant time commitment required; and
- Loss of consistency with historical trends

Option 2c: Expanded Scope Revision

Option 2c cannot be adequately evaluated as proposed for advantages and disadvantages due to the lack of detail.

C. Issue No. 3: *Detailed Considerations for Revising 10 CFR Part 50, Appendix I*

"The questions in this section explore some of the specific technical details that may be associated with revising the design objectives. The NRC staff has identified the following options for potential revisions to the 10 CFR Part 50, Appendix I. It should be noted that the various options below are not considered to be mutually exclusive; that is, the NRC may consider one or more of these options, or various combinations of these options:"

Introduction

As stated in SECY-08-0197, "current regulations provide adequate protection of public health and safety and are well understood by licensees, and that the impacts of changing the regulatory framework are not balanced by the benefits of updating scientific information and enhancing international consistency"[30]. Additionally, Enclosure 3 to SECY 08-0197, also states that "the implementation of Part 50 Appendix I design objectives is not an issue for power reactors because their use is well established and the industry has extensive operational experience in demonstrating compliance.[31]" Regulatory compliance is documented in NUREG/CR-2907, Vol. 15, *Radioactive Effluents from Nuclear Power Plants,* where *c*ompliance is demonstrated below with figures 3.15 and 3.18 (from NUREG/CR-2907) displaying this improving trend graphically:[32]

[30] SECY 08-0197, dated Dec. 18, 2008, p.4...

[31] Ibid, Enclosure 3, p.7.

[32] NUREG/CR-2907, Vol. 15, dated August 2013, pp. 3-51 and 3.43.

Figure 3.15

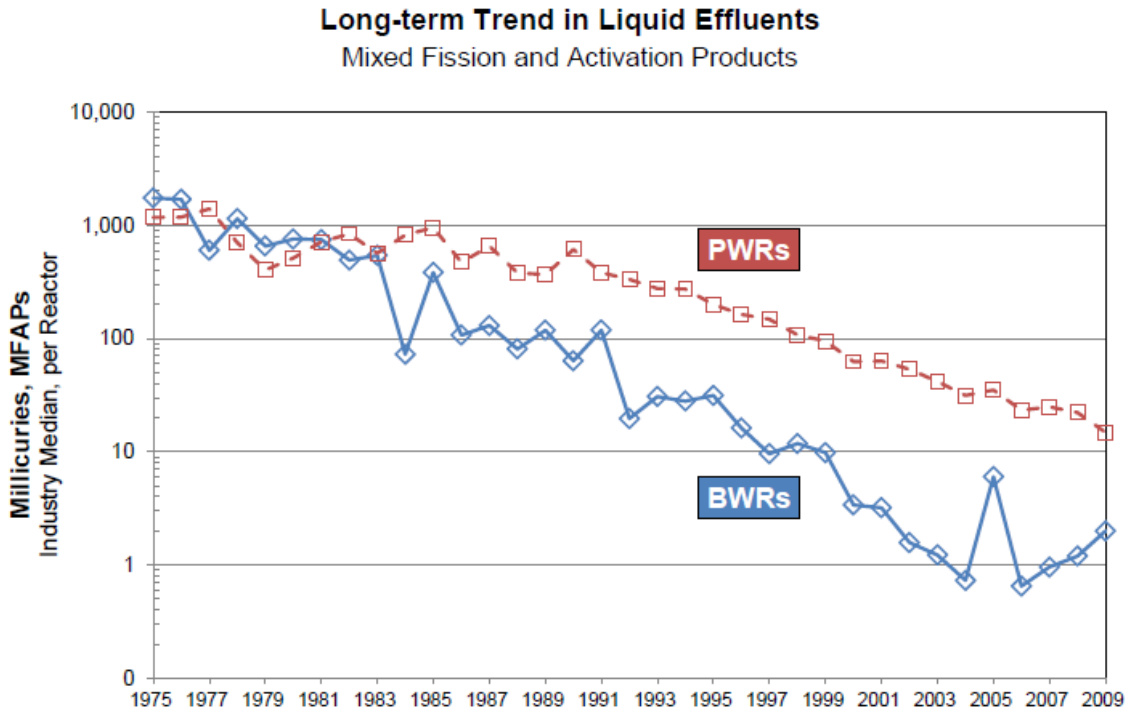
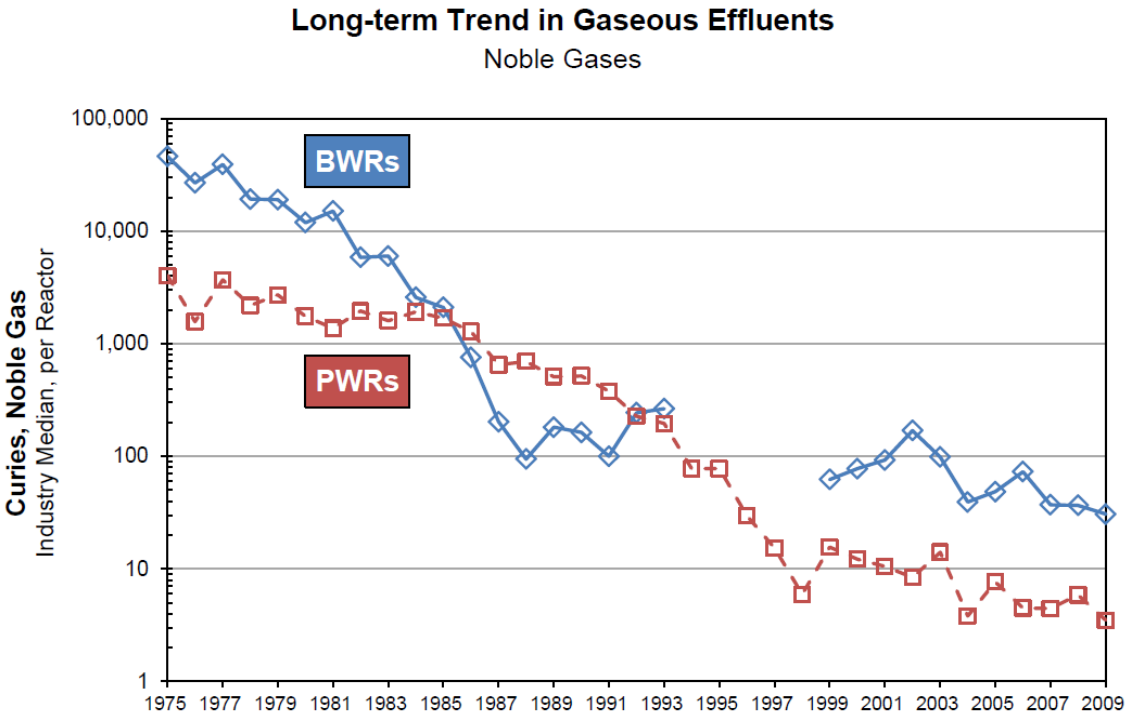


Figure 3.18



The figures above demonstrate that the median dose calculated from both liquid and gaseous releases is well below 1 millirem per year. Giving context to the significance of 1 millirem per year NUREG/CR-2907 provides:

The dose from radioactive effluents to the maximum exposed individual living near any U.S. NPP is less than the dose from any one of the following:

- *I week of skiing in the Rocky Mountains,*
- *4 weeks from the natural potassium in each person's body, or*
- *8 weeks to a homeowner residing in a brick or stone house.*[33]

This data and information demonstrates that the current regulations and NPP operations provide more than adequate protection to the members of the public. As such, the nuclear power industry recommends that the Nuclear Regulatory Commission (NRC) not revise 10 CFR Part 50, Appendix I to more closely align with the ICRP Publication 103 methodology and terminology. Adoption of the ICRP 103 methodology and terminology into 10 CFR Part 20 and/or 10 CFR Part 50, Appendix I will be a significant, unnecessary resource burden to the nuclear industry with little to no improvement in worker or public radiological safety or to the protection of the environment.

To fully respond to the ANPR, the remainder of this section contains the industry response regarding Issue 3, which contains some of the technical details involved in revising the design objectives. The options identified by the NRC are as follows:

Option 3a: Maintain the numerical values of the 10 CFR Part 50, Appendix I, design objectives as they are currently written without any modification.

Option 3b: Eliminate the use of organ dose as design objectives in 10 CFR Part 50, Appendix I, for liquid and gaseous effluents.

Option 3c: Eliminate the use of annual gamma and beta-air doses for gaseous effluents.

Option 3d: Update cost-benefit criteria in Section II.D of 10 CFR Part 50, Appendix I

Option 3e: Disposition of Docket RM–50–2, "Guides on Design Objectives for Light-Water-Cooled Nuclear Power Reactors," in the "Concluding Statement of Position of the Regulatory Staff," pp. 25–30 February 20, 1974)—the NRC staff would remove Docket RM–50–2 from 10 CFR Part 50, Appendix I, Section V, if the NRC staff determines that it is no longer applicable to any pending applications

NOTE: The following options for potential revisions to 10 CFR Part 50, Appendix I, are unrelated to the alignment with the ICRP Publication 103 terminology and methodology but have some implications for associated NRC guidance.

Option 3f: Light-water-cooled reactor provisions of 10 CFR Part 50, Appendix I—the NRC staff would expand scope of 10 CFR Part 50, Appendix I, to include designs other than Light-Water-Cooled Reactors.

Option 3g: Consolidation of NRC licensing guidance implementing 10 CFR Part 50, Appendix I—the NRC staff would consolidate some NRC guidance documents, if appropriate, and update the following RGs and NUREGs:

a. RG 1.21

b. RG 1.109

c. RG 1.206

[33] IBID, p. 3-54.

d. RG 4.15

e. NUREG–1301

f. NUREG–1302

g. NUREG–0133

h. NUREG–0543

i. NUREG/CR–4013—LADTAP

j. NUREG/CR–4653—GASPAR

k. NUREG–0800

Questions

Question 3–1:

Should the NRC focus on only those changes necessary to align 10 CFR Part 50, Appendix I, with ICRP Publication 103 dose calculation methods (*e.g.,* Issue 3, options 3a thru 3e) or should all of the specific changes identified in options 3a thru 3g be evaluated?

Response:

Industry's recommendation is that the NRC should not change 10 CFR Part 50, Appendix I to align with ICRP 103 or make any changes identified in options 3a thru 3g. At this time, it is not prudent to align the 10 CFR Part 50 Appendix I with the ICRP Publication 103 dose calculation methods as the existing regulatory framework provides adequate protection of the health and safety of workers, the public, and the environment. Implementing such changes would be a significant, unnecessary resource burden to licensees and the NRC with no measurable benefit or increase in the health and safety of the public or the environment.

Currently, 10 CFR 50, Appendix I contains design objectives that are based on ICRP 2 dosimetry models. This model expresses doses to the organ instead of expressing dose to a single body. ICRP refers to earlier publications, stating that "in the Commission's 1956 Recommendations (ICRP, 1957), limits on weekly and accumulated doses were set that corresponded to annual dose limits of [5 rem] for workers and [500 millirems] for the public". However, 10 CFR 50, Appendix I recommends significantly lower design and operational objectives in that:

- *The calculated total quantity of all radioactive material above background to be released from each reactor to unrestricted areas will not result in an estimated annual:*
    - *Dose or dose commitment from liquid effluents for any individual in an unrestricted area from all pathways of exposure in excess of 3 millirems to the total body or 10 millirems to any organ.*
    - *Air dose from gaseous effluents at any location near ground level which could be occupied by individuals in unrestricted areas in excess of 10 millirads for gamma radiation or 20 millirads for beta radiation.*
    - *External dose from gaseous effluents to any individual in an unrestricted area in excess of 5 millirems to the total body*
    - *and design objectives based upon a higher quantity of radioactive material above background to be released to the atmosphere than the quantity specified [above] will be deemed to meet the requirement for keeping levels of radioactive*

material in gaseous effluents as low as is reasonably achievable if the applicant provides reasonable assurance that the proposed higher quantity will not result in an estimated annual external dose from gaseous effluents to any individual in unrestricted areas in excess of 5 millirems to the total body or 15 millirems to the skin.

- *The calculated annual total quantity of all radioactive iodine… [is limited to] 15 millirems to any organ.*[34]

The NRC has noted that ICRP 103 proposed measures that go beyond what is needed to provide adequate protection to the public. ICRP 103 recommends that a limit of "planned exposure" to the general public of 100 millirems in a year and notes that "In special circumstances, a higher value of effective dose could be allowed in a single year, provided that the average over 5 years does not exceed [100 millirems]." Table 8 note f provides further recommendation concerning annual planned exposures to members of the public: "the dose constraint should be less than [100 millirems] and a value of no more than about [30 millirems] would be appropriate". Even though differences between the current and former ICRP methodologies exist, the potential benefit from changing the dose calculation method is minimal, considering that the current regulatory framework provides adequate protection of the health and safety of workers, the public, and the environment. The current methodology is already addressed in the existing regulation which is understood by the industry. Any changes made to the current methodology would add unnecessary "Cumulative Effects" burdens with no apparent benefit.

With the understanding that industry does not support any of the proposed changes stated in the ANPR, should the NRC moves forward with changes to 3a through 3e, evaluation of all of the changes to the associated regulatory guidance of 3a through 3g will be necessary.

Question 3–2:

What significant impacts would be expected if 10 CFR Part 50, Appendix I, were revised to include all of the options (Issue 3, options 3a thru 3g)?

Response:

Significant impacts to nuclear facilities and supporting regulatory guidance would exist if 10 CFR 50 Appendix I were revised to include all of the options presented within Issue 3. Impacts include, but are not limited to, a significant revision of Offsite Dose Calculation Manuals, technical documents and program governing procedures. Additionally, the revisions would impart significant resource burden for utilities, considering the minimal benefit from the changes. Areas affected would include but not be limited to:

- Revising station procedures to include updated numerical values, new terminology and design objectives, and references to new regulatory documents. Costs include expending man-hours in identifying effected station procedures and incorporating changes;
- Revising Offsite Dose Calculation Manuals to include updated numerical values, new terminology and design objectives, and references to new regulatory documents. Costs include man-hours from the program owner in implementing changes and from personnel reviewing the changes;

[34] Title 10 Code of Federal Regulations Part 50, Appendix I, Section II

- Revising Final Safety Analysis Report to include updated numerical values, new terminology and design objectives, and references to new regulatory documents. Costs include man-hours from the program owner in implementing changes and from personnel reviewing the changes;
- Training for effluent personnel on new regulatory guidance documents and their design basis will be required. Costs include man-hours spent in training for effluent and training personnel, man-hours for updating training materials and subsequent approval, and the potential for human error with confusion from significant updates to programs. The training would necessarily include individuals from multiple disciplines including radiation protection, chemistry, radwaste, environmental, etc.;
- Software revisions and training needs associated with revising software and software requirements. Cost include man-hours from IT staff, training personnel, purchasing/upgrading new software, and the potential for human error with utilizing software with new design basis; and
- A loss of consistency with historical data. Additional analysis would be necessary to compare new data with old data for reporting purposes.

As detailed in the industry response to Issue No. 1, implementing required changes would not only present a human capital resource issues but a financial burden as well with a lower range estimated cost of $400,000 per site.

Question 3–3:

Given the scope of the regulatory and technical issues associated with making all of the specific changes identified in Issue 3, options 3a thru 3g, is there any merit in addressing selected options in future implementation phases of this rulemaking (or in separate rulemaking efforts)? If so, which of the options should be delayed?

Response:

There is no merit in addressing any of the proposed options 3a thru 3g for rulemaking now under consideration or in the foreseeable future. The potential benefit from changing 10 CFR 50, Appendix I is minimal considering that the current regulation provides adequate protection of the health and safety the public and the environment. Therefore, it is difficult to justify any revision to 10 CFR 50, Appendix I because it is not a safety standard and a revision would be a significant resource burden, as noted in response to question 3-2. As stated in Enclosure 3 to SECY 08-0197, "the Appendix I design objectives are an 'ALARA design basis' requirement. If the design objective of Appendix I are met, it constitutes a demonstration that effluents and doses to the public are ALARA and no additional efforts are required to reduce effluent release rates"[35]. The NRC has also noted that the ICRP 103 recommendations proposes measures go beyond what is needed to provide adequate protection.

With the understanding that industry does not support the proposed changes, it is also understood that if the NRC moves forward with changes to 3a and 3c, it would be appropriate to eliminate organ & air dose limits and replace the methodology with committed dose equivalent (CDE.) An additional factor to

[35]SECY 08-0197, dated Dec. 18, 2008, Enclosure 3, p.9.

consider is if changes are made the changes must align with any potential changes made by the EPA to 40CFR190 which is currently under review.[36]

Question 3–4:

Should licensees still report doses separately for organs, such as skin and thyroid, whenever airborne effluent releases are dominated by radioactive iodines and noble gases?

Response:

Based on the premise that additional rulemaking is not required and will not be implemented, the answer is "Yes," doses should continue to still be reported separately for organs as long as 40 CFR 190 requirements are stated in terms of organ dose. Currently, 10 CFR 50, Appendix I contains a dose criterion that is based on ICRP 2 dosimetry models. This model expresses doses to specific organs instead of expressing dose to a single body. The significance of this difference is minimal as the dose to the critical organ is reported; meaning that, taking into consideration tissue weighting factors, the highest dose contributor is reported. Even though differences between the methodologies exist, the potential benefit from changing the dose calculation method is minimal since the current regulatory framework provides adequate protection of the health and safety of workers, the public and the environment.

The NRC has noted that the ICRP 103 proposes measures that go beyond what is needed to provide adequate protection[37]. Additionally, as stated in Enclosure 3 to SECY 08-0197, "the implementation of Part 50 Appendix I design objectives is not an issue for power reactors because their use is well established and the industry has extensive operational experience in demonstrating compliance". Changing the method of reporting doses for organs would mean a loss of direct comparability with historical data.

However the industry recognizes that if changes are made to EPA's regulation 40 CFR 190, further evaluation of 10 CFR regulatory requirements will be necessary and the question of organ vs effective dose may arise. In the industry response to the ANPR for 40CFR190 industry recommended that should the EPA rulemaking proceed:

> *"Updating the dose limit in terms of effective dose is a logical solution. A single dose limit in terms of effective dose would provide regulatory consistency, particularly when considering a potential revision to the NRC's 10 CFR Part 20. By simply stating the limit in units of "effective dose", the most recent (e.g., ICRP 103) and, quite likely, potential future dosimetry methodology is, in effect, incorporated."* [38]

Question 3–5:

Should licensees continue to report skin doses, skin dose rates, total body dose rates, and organ doses (including thyroid doses) if organ doses are eliminated? Why or why not?

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[36] 79 FR 6509 Docket ID EPA-HQ-OAR-2013-0689 (2014.)

[37] SRM-SECY-08-0197 dated April 2, 2009.

[38] August 1, 2014, Jerry w. Hiatt (NEI) to EPA Docket Center "Industry Comments on the EPA Advanced Notice of Proposed Rulemaking for 40 CFR 190, 'Environmental Radiation Protection Standards for Nuclear Power Operations.".

Response:

The reporting of dose rates is not required. The instantaneous dose rate limits of nuclear power plant technical specifications are a means of limiting short term airborne concentrations, which in turn are based on controlling potential acute exposure. The technical specification dose rate limits are unrelated to the 10 CFR 50, Appendix I ALARA guidance and primarily serve as the bases for the noble gases process effluent radiation monitor setpoints. Finally, the reporting of ICRP 2 based cumulative organ, skin, total body doses and noble gas gamma beta and skin air dose should continue in order to provide a means of direct comparison with historical data.

Question 3–6:

Should the categories of releases described in 10 CFR Part 50, Appendix I (liquid activity, noble gases in gaseous releases, radioactive iodines, tritium, other nuclides in gaseous releases), be expanded or otherwise revised

Response:

No. The categories of 10 CFR 50, Appendix I design objectives are based on the necessity of designing and operating radioactive waste treatment systems for the different physical forms of effluents: liquids, noble gases and particulates (including radioiodines). As such, revision to the categories of releases is unnecessary.

Issue No. 4: Metrication – Units of Radioactivity, Radiation Exposure, and Dose

"The metrification policy addresses the units to be used to express radioactivity, radiation exposure, and dose."

Introduction

The nuclear industry recommends that the NRC express units of radioactivity, radiation exposure and dose in either metric or English units, provided that the NRC allow licensees to continue to use traditional units for the performance of facility required regulatory functions and report to the NRC using traditional units. It is recognized that some professional organizations, such as the Health Physics Society,[39] support exclusive use of SI units for measuring and reporting radiation exposure and dose. However, nuclear industry licensees recognize several potentially negative unintended consequences that could result from such a change that are not considered by these professional organizations. These include the significant potential for human error that could lead to negative impacts on worker protection and protection to members of the public.

Questions:

Question 4-1:

Should the annual radioactive effluent release reports [ARERR] contain both metric and English units (*e.g.,* metric units first, followed by English units in parentheses)? Would this be an undue burden or hardship, as identified in the Commission's 1996 review of the 1992 metrication policy (61 FR 31171; June 19, 1996)? Explain and provide examples.

Response:

While the nuclear energy industry supports regulation that expresses radiation and exposure in both traditional and SI units, we believe that regulations should allow licensees the option to continue to use and record doses in traditional units at nuclear energy facilities. We also recommend that licensee records should be reported to NRC and involved stakeholders in traditional units. Reporting in dual sets of units would cause an undue hardship upon nuclear energy industry licensees with little cost-benefit and provide no additional improvement of radiological protection to workers, the public or the environment. Indeed, unless significant stakeholder (e.g., public, media, etc.) education is provided the reporting in dual units could prove confusing to stakeholders and potentially lead to a reduction in stakeholder confidence.

Question 4-2:

What costs or other impacts to operational programs would be incurred if metrication was changed as described above?

Response:

In reality, while it may appear that the transition of units in the ARERR would be as simple as using a software transition package, the industry recognizes that to effectively use SI Units and reduce the potential for human error in making the required conversions, a true transition requires a total shift in the thought process of utility personnel involved in effluent monitoring and control and also in other offsite stakeholders.

[39] Health Physics Society Position Statement, PS025-0, "Exclusive Use of SI Units To Express Radiological Quantities." (2012).

As such, transition to the dual SI unit structure would require significant resources for licensees to address issues including:

- Significant revision of existing procedures (including effluent release permits, software changes, etc.);
- Re-training of personnel (e.g., radiation protection, radwaste, chemistry, licensing, etc.);
- Extensive education of the general public, the press, local and state government representatives, and other stakeholders in the meaning of the new units, (e.g., explaining why past ARERR's used units of micro-Curie [acknowledged as a very small number] but current reports would use units in the tens of thousands [i.e., 1 micro-Curie = 37,000 Becquerels.] Education would require the involvement of multiple industry resources (e.g., public relations, training material development and distribution; media contacts, etc.)
- Conversion of "read-outs" from radioactive effluent process instrumentation;
- Conversion of existing records and reporting computer software platforms to support the use of SI units; and
- Units in the Annual Radiological Environmental Operating Report (AREOR) would also need to be changed for consistency and prevention of potential confusion to stakeholders

It is expected that there will be substantial resource burdens on utilities and public officials to transition to SI units with limited benefits. When combined with the potential changes discussed in the ANPR for 10CFR20[40] and depending on the modifications required and outcome of training evaluations for these activities, it is estimated that the cost of transitioning to the SI structure could approach $3-5 million per facility to implement (excluding the impact on emergency preparedness related activities).

Question 4-3:

Should the requirements of 10 CFR 20.2101(a) and the guidance of RGs 1.21 and 4.15 be revised and integrated with those in 10 CFR Part 50, Appendix I, thereby allowing licensees to provide records and reports in SI units only?

Response:

While nuclear energy industry licensees support regulation that includes both traditional and SI units, the industry believes that such language should allow licensees the option to continue to use traditional units and to provide reports in those units. As such, no revision to 10 CFR Part 20.2101(a) and RGs 1.21 and 4.15 is required.

[40] March 24, 2015, Ellen Anderson (NEI) to Annette Vietti-Cook (NRC), "Industry Comments on the NRC ANPR for 10 CFR Part 20, Radiation Protection" (ML15083A063)

Cumulative Impact

"The NRC is specifically requesting comments on the cumulative effects that may result from potential amendments to 10 CFR Part 50, Appendix I, and revisions to the associated guidance documents."

Introduction

The cumulative effect of regulation (CER) resulting from the changes described in the ANPR for 10 CFR Part 50, Appendix I will place substantial resource burdens on licensees, while yielding little or no additional protection of the public or the environment. This burden will be further compounded should the potential changes to 40 CFR Part 190 proposed by the U.S. Environmental Protection Agency in its February 2, 2014, ANPR[41] and the changes proposed in the ANPR for 10 CFR Part 20[42] be imposed on licensees.

It is impossible at this time to forecast, schedule, or budget for all of these proposed actions until the U.S. EPA and the NRC determine and communicate their final intentions to revise those specific portions of their respective regulations. That said, current staffing levels at nuclear power facilities are established to provide protection for workers, the public, and the environment. These proposed changes to 10CFR50, Appendix I, along with the changes proposed by the U.S. EPA and the additional changes proposed by the NRC to Part 20, will require dedicated manpower and resources that are typically dedicated to worker, public and environmental protection activities.

Based on industry's review of the ANPR and each of the specific issues upon which the NRC is requesting comment, the nuclear power industry's overall recommendation is that no changes be made to the existing regulations. We conclude that the changes proposed by the NRC are unnecessary from a health and safety standpoint, are unlikely to be cost-beneficial, and will provide little to no incremental improvement in the health and safety of workers, public or environment.

This recommendation is consistent with recommendations contained in NEI's September 15, 2015 response[43] to the NRC's request for comments on the NRC's Common Prioritization and Re-baselining Initiatives discussed during a September 1, 2015 public meeting. NEI's response states:

> *In the Radiation Protection rulemaking, the goal is to achieve greater alignment between the NRC's radiation protection regulations and the 2007 recommendations of the International Commission on radiological protection. As discussed in our March 24, 2015 comment letter[44], we believe the rulemaking is unnecessary from a health and safety standpoint and will provide little to no incremental improvement in the health and safety of workers, public or environment.*
>
> *Similarly, the intent of the Dose Assessments for Radioactive Effluents rule is to align the NRC regulations governing dose assessments for radioactive effluents from nuclear power plant operations with the most recent terminology and dose-related methodology published by the International Commission on Radiological Protection (ICRP) contained in ICRP Publication 103 (2007).*

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[41] 79 FR 6509 "Environmental Radiation Protection Standards for Nuclear Power Reactors," Docket ID EPA-HQ-OAR-2013-0689 (2014).

[42] 79 FR 43284 "Radiation Protection," Docket ID NRC-2009-0279 (2014).

[43] September 15, 2015, John C. Butler (NEI) to Frederick D. Brown (NRC) "Industry Recommendations for NRC Project AIM 2020 Prioritization and Re-baselining Initiatives," p. 5.

[44] March 24, 2015, Ellen Anderson (NEI) to Annette Vietti-Cook (NRC), "Industry Comments on the NRC ANPR for 10 CFR Part 20, Radiation Protection" (ML15083A063)

In neither instance is there a safety basis for the identified changes yet the cost to implement these rules is estimated to exceed $3 million per facility. Moreover, implementation will require substantial effort by NRC and industry to revise approximately 50 regulatory guides.[45] *Based on the low value to safety and high burden imposed by these proposed rules, we recommend that both rulemakings be terminated*

Questions

Question 5–1:

If the NRC conducts a parallel rulemaking effort (amending its regulations in both 10 CFR Part 20 and 10 CFR Part 50, Appendix I), should there be a separate, later compliance date (*i.e.,* a period of time between the rules' effective date and a date when licensees must be in compliance with the rules)? If so, when should the compliance date be set, *e.g.,* 1 year after the effective date? Two years? Another length of time? Please explain the rationale or justification for any such compliance date.

Response:

Should parallel rulemaking on 10CFR20 and 10CFR50, Appendix I occur, the nuclear power industry recommends that the compliance date for 10CFR50, Appendix I be separate and significantly later than the compliance date for 10CFR20. The rationale for separate and subsequent implementation dates includes the reality that the majority of the same personnel resources will be involved in implementing both rulemakings. Each rulemaking will require actions, such as:

- Development of a comprehensive industry change management plan and individual facility-specific change management plans;
- Revision of compliance documents (e.g. technical specifications, etc.) and associated implementing procedures;
- Development and implementation of revised training programs (e.g. radiation protection, chemistry, radwaste, etc.);
- Modification or purchase of new computer software;
- Potential modification or purchase of new effluent monitoring instrumentation; and
- Reassessment of effluent- related resources and staffing levels to address industry participation in the review and comment on the development or revision of associated regulatory guides and other supporting documents.
- Actual industry experience with the 1991 revision to 10 CFR 20 indicate that it is likely that any revision to 10 CFR 20 may have unforeseen impacts on the interpretation and implementation of 10 CFR 50, Appendix I (e.g., aligning ODCM's to be consistent with both revisions.)

Please note that in addition to implementing these changes, individuals involved will also be engaged in the daily operation of their facilities. The implementation time interval would facilitate the focus of industry on continuing to maintain safe and efficient operations of the facilities.

Due to the above listed concurrent actions and should the rule changes occur in parallel, the industry recommends that the compliance date for changes to 10CFR50, Appendix I be set at a minimum three year period after the compliance date for changes to 10CFR20.

[45] http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise/divison-reg-guide.html

Question 5–2

What actions could be taken to reduce or minimize the implementation time?

Response:

The industry recommends that to reduce/minimize the implementation time for licensees, the NRC should complete, approve, and have available for stakeholder use all of the associated regulatory guidance documents (e.g., regulatory guides, NUREG's, etc.) prior to the implementation date for either 10CFR20 or 10CFR50, Appendix I. The availability of these documents is essential in providing licensees acceptable methods and justification for implementing revisions to existing program documents and policies.

Question 5–3:

What other requirements, regulations, or orders, whether issued or promulgated by the NRC or another Federal agency, may compete with, or take priority over implementing any potential changes to 10 CFR Part 50, Appendix I? If so, what are the consequences, including associated costs, and how should they be addressed?

Response:

The design objectives of 10 CFR Part 50, Appendix I, are not radiation protection standards, but are design criteria to ensure equipment designs maintain radioactive effluents ALARA. As such, requirements, regulations, or orders that impact actual radiation protection standards must take priority over implementing any potential Appendix I changes. While it is impossible to predict other future changes, those currently being proposed include:

- 40 CFR 190
- 10 CFR 20
- 10 CFR 37

The industry estimates that if changes go forward the estimated costs to implement 40 CFR 190 and 10 CFR 20, excluding facility modifications and/or emergency preparedness changes necessary to comply with regulatory requirements, could approach $25M and $200M, respectively.

Question 5–4:

If 10 CFR Part 50, Appendix I, is amended, what unintended consequences, including associated costs, may arise that would negate the benefits to revising it? What could be done to minimize unintended consequences?

Response:

The overall potential unintended consequences are difficult to predict until the actual changes in the regulation have been detailed (e.g., adoption of SI units.) However, possible unintended consequences resulting from the imposition of changes to 10CFR50, Appendix I could include:

- Increased potential for human errors in recording data/calculating releases;
- Possible human performance errors resulting from the re-assignment of experienced effluent personnel to address implementation of changes;
- Unintentional misreporting of required data to regulators and stakeholders due to errors in radiation unit conversions by licensees; and
- Difficulty in comparing reported data to previous decades of data which could lead to a reduction in public confidence (e.g., past reports were in small units such as micro-Curies while "new" reports would be in significantly larger units such as kilo-Becquerels.)

Should the NRC proceed with the changes discussed in the ANPR, we suggest prioritizing licensee implementation based on increased public/environmental protection, as well as forecasted resources required for implementation of each issue. Furthermore, reasonable implementation dates should be established in years, not months, taking into account the monetary and human resources necessary to implement the actions (training, document revisions, computer software revisions, equipment modifications, etc.) required to comply with each issue.