



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, DC 20555 - 0001**

October 16, 2012

The Honorable Allison M. Macfarlane
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

**SUBJECT: SECY-12-0064, RECOMMENDATIONS FOR POLICY AND TECHNICAL
DIRECTION TO REVISE RADIATION PROTECTION REGULATIONS AND
GUIDANCE**

Dear Chairman MacFarlane:

During the 595th meeting, June 6 – 8, 2012, and the 598th meeting, October 4 - 5, 2012, of the Advisory Committee on Reactor Safeguards, we reviewed SECY-12-0064, "*Recommendations for Policy and Technical Direction to Revise Radiation Protection Regulations and Guidance.*" SECY-12-0064 requests Commission approval of the staff recommendations for revisions to the U.S. Nuclear Regulatory Commission (NRC) regulations and guidance for radiation protection considering the 2007 recommendations of the International Commission on Radiation Protection (ICRP) Publication 103.

Our Radiation Protection & Nuclear Materials Subcommittee also reviewed this matter during meetings on April 27, 2012, and September 18, 2012. During these meetings we had the benefit of discussions with representatives of the NRC staff. We also had the benefit of the documents referenced.

CONCLUSIONS AND RECOMMENDATIONS

1. Rulemaking to revise the limits for occupational radiation exposure as proposed by the staff in option 3 of SECY-12-0064 should not be undertaken.
2. The staff should proceed with the improvements in the NRC's regulations and guidance that update the scientific bases for calculating exposures and making these calculations consistent throughout the regulations.
3. The staff should develop improvements in the NRC guidance for those segments of the regulated community that would benefit from more effective implementation of ALARA¹ strategies and programs to comply with regulatory requirements.

¹ As Low As is Reasonably Achievable – See Appendix

4. The staff should continue discussions with stakeholders on alternative approaches to deal with individual protection at, or near, the current dose limit. Additionally, discussions should continue regarding dose limits for the lens of the eye and the embryo/fetus radiation exposures. A rationale and approach to improve reporting occupational exposure by industry segments not currently reporting should be developed.

BACKGROUND

In SRM-SECY-08-0197, “*Options to Revise Radiation Protection Regulations and Guidance with Respect to the 2007 Recommendations of the International Commission on Radiological Protection*,” dated April 2, 2009, the Commission approved the staff recommendation to begin engagement with stakeholders and interested parties to initiate development of the regulatory basis for possible revision of the NRC’s radiation protection regulations, as appropriate and where scientifically justified, to achieve greater alignment with the 2007 ICRP recommendations.

Following the Commission’s direction in SRM-SECY-08-0197, the NRC staff has engaged in numerous activities focused on aligning requirements with the current ICRP recommendations. These efforts have led to the identification of the policy issues in SECY-12-0064 where options are presented and direction is requested from the Commission to guide the development of the regulatory basis for a general revision of NRC’s radiation protection regulations.

Specifically, the staff recommends Option 3 in SECY-12-0064 which requests guidance from the Commission on the following issues:

- Updating Methodologies and Terminologies in Dose Assessments
- Revising the Limits for Occupational Total Effective Dose Equivalent
- Revising the Dose Limit for the Lens of the Eye
- Revising the Dose Limit for Exposure to the Embryo/Fetus
- ALARA Planning
- Protection of the Environment
- Units of Radiation Exposure and Dose
- Reporting of Occupational Exposure
- Revisions to 10 CFR Part 50, Appendix I

On the specific topic of a standard of 2 rem/yr (20 mSv/yr) vs 5 rem/yr (50 mSv/yr) plus ALARA – the staff states in SECY-12-0064:

“The current 10 CFR Part 20 occupational Total Effective Dose Equivalent (TEDE) limit is 5 rem per year (50 mSv). The international recommendations have, since 1990, incorporated a limit of 10 rem (100 mSv) over a 5 year period, with a maximum of 5 rem (50 mSv) in any one year. Some agencies, such as those of the International Atomic Energy Agency (IAEA), have adopted these limits. The trend internationally is to further simplify the limit to a single value of 2 rem (20 mSv), as evidenced in the drafting of the Euratom Basic Safety Standards Directive in the European Union.

The National Council on Radiation Protection and Measurements has also offered views in favor of changing the dose limit.

DISCUSSION

The ACRS supports the staff's recommendations in SECY-12-0064 to update the scientific bases for calculating doses and making these calculations consistent throughout the regulations.

A decision to change dose limits should be based on demonstrated health and safety benefits and consideration of negative, unintended safety consequences. The ACRS has considered the staff's recommendation in SECY-12-0064 to conform with the ICRP recommendation and concluded that these changes should not be implemented.

NRC regulations provide for the development and implementation for robust and effective ALARA programs. The important program elements for ALARA are provided in the Appendix. The staff stated that the current U.S. regulations [5 rem/yr (50 mSv/yr) plus ALARA] provide adequate protection of health and safety if the regulations as defined in 10 CFR 20.1003 are followed.

The staff provided excellent documentation showing that existing NRC regulations are being followed by the nuclear power industry (reactors and fuel cycle facilities) and that worker doses are below the current 5 rem (50 mSv) annual limit.

There is disagreement among professional organizations involved in radiation protection regarding the health and safety benefits of reducing the dose limit from 5 rem (50 mSv) to 2 rem (20 mSv) per year. In the absence of a clear and well demonstrated benefit, we disagree with lowering the dose limits.

Reduction of the limit from 5 rem/yr (50 mSv/yr) to 2 rem/yr (20 mSv/yr) will constrain some licensees to manage occupational radiation doses to levels below the 2 rem/yr (20 mSv/yr) limit. A typical industry practice is to constrain exposures to no more than 80% of the regulatory limit. Achieving these lower dose levels will require fundamental changes in how utilities employ personnel for dose-intensive tasks such as reactor coolant pump and steam generator replacement or repair and vessel head maintenance. The lowering of dose limits may also result in the need for frequent authorizations to exceed the reduced dose limits.

Compliance with the lower dose limits could also have unintended negative consequences. For example, if nuclear plant maintenance or inspection activities requiring workers with special skills were curtailed or postponed to ensure compliance with the annual limit of 2 rem (20 mSv), plant safety margins could be eroded. Further, the lower dose limits could inhibit the response of workers to exigent circumstances.

Health Physics professionals and practitioners at U.S. nuclear power plants understand the current 10 CFR Part 20 limits and manage their plants and personnel through effective ALARA programs. They are well trained and experienced. Their efforts to reduce radiation exposure to personnel are reviewed daily, monthly and annually by licensee management, periodically by industry groups, such as the Institute of Nuclear Power Operations (INPO), and inspected by the NRC staff at their discretion.

The staff noted that stakeholders have identified compliance problems in other areas regulated by the NRC (medical diagnostics and treatment and radiography using sources). The staff should develop improvements in the NRC guidance for more effective implementation of strategies and programs in these segments of the regulated community to maintain doses that comply with regulatory requirements and are ALARA.

The staff should continue discussions with stakeholders on alternative approaches to deal with individual protection at or near the current dose limit. Additionally, discussions should continue regarding dose limits for the lens of the eye and the embryo/fetus radiation exposures. A rationale and approach to improve reporting occupational exposure by industry segments not currently reporting should be developed.

We conclude that the current framework, limits, and ALARA practices provide adequate assurance of worker health and safety as long as they are properly applied.

Sincerely,

/RA/

J. Sam Armijo
Chairman

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Additional Comments by ACRS Members William Shack, Dennis Bley, Michael Corradini, Joy Rempe, Jack Sieber, John Stetkar, and Dick Skillman

While we are in full agreement with our colleagues that ALARA programs are the most effective tool for controlling the risks of radiation exposure, the dose limit constraints on ALARA programs are important for limiting individual risk. There are two aspects of the individual risk that need to be considered: how it is estimated, and what is an acceptable level of risk. The choice of an individual dose limit ought to be based on a well founded understanding of the risk factors and a rational basis for the choice of an acceptable level of risk.

The SECY focuses on the ICRP estimates of risk ($\sim 5 \times 10^{-2}/\text{Sv}$ for fatal cancer), but notes that the National Academy BEIR studies and the UNSCEAR studies come to similar conclusions. The NCRP is not mentioned in the SECY, but it also reaches a similar conclusion for these estimates of risk. This risk value is about three times greater than the estimate used to develop the current dose limit. The Health Physics Society position is that below 50–100 mSv (which includes occupational and environmental exposures), risks of health effects are either too small to be observed or are nonexistent and that quantitative estimation of health risks should not be made below an individual dose of 50 mSv in one year or a lifetime dose of 100 mSv above that received from natural sources.

These risk estimates are subject to uncertainty and controversy. Despite the controversy, we believe that use of the estimates of radiation risk proposed by the ICRP, NCRP, UNSCEAR, and BEIR is appropriate and consistent with the preponderance of the evidence and relevant scientific judgment and should be the basis for the development of annual and cumulative dose limits to manage individual risk from occupational exposures.

The current NRC limit is inconsistent with the positions of the ICRP, NCRP, and HPS since it has no limit on cumulative dose. We believe the staff should continue to consider the impacts of moving to a position more consistent with the current consensus on radiation risk management.

The regulations apply to a diverse range of industries and activities, from power plants with on-site NRC inspectors to small radiography firms to hospitals where nuclear medicine procedures are performed. Some of these activities are using well-conceived and monitored ALARA programs that control doses well below the 50 mSv/yr limit. Others have less formal programs that generally control doses to somewhat below the limit. Still others appear to have other priorities, and their controls are less effective.

The staff currently proposes options either for a limit of 20 mSv/yr, or the ICRP limits, or to retain the 50 mSv/yr limit with “constraints” (essentially reportable trigger values as the limit is approached). The staff should investigate alternative approaches that could offer the flexibility to tailor compliance programs to the needs of the diverse activities that fall under the regulation. For example, one possibility would be to offer both a fixed deterministic option and a risk-informed option, from which a licensee could choose (analogous to the NFPA-805 process).

REFERENCES

1. SECY-12-0064, "Recommendations for Policy and Technical Direction to Revise Radiation Protection and Guidance," April 25, 2012 (ML121020115)
2. ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection," March 2007
3. SRM-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 (ML090920103)

APPENDIX

Dose management can best be accomplished with an effective ALARA program

A robust ALARA program is the best tool to maintain worker exposure As Low As Reasonable Achievable (ALARA). Rather than emphasizing a reduction in a dose limit (Total Effective Dose Equivalent), one should evaluate all work activities involving radioactive materials using the definition of ALARA in 10 CFR 20.1003 and related guidance, which states:

“ALARA (acronym for ‘as low as is reasonably achievable,’) means making 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.”

Radiation exposure limits and radioactive material release limits are clear. In 10 CFR Part 20, “Standards for Protection Against Radiation,” § 20.1302(b) requires that:

“A licensee shall show compliance with the annual dose limit in § 20.1301 by (1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or (2) Demonstrating that (i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of Appendix B to §§ 20.1001-20.2401; and (ii) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.”

In addition, 10 CFR 20.1101(b) requires that:

“The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).”

Regulatory Guide 8.37, “ALARA Levels for Effluents from Materials Facilities,” provides a principle source for ALARA guidance. As noted, “This regulatory guide provides guidance on designing an acceptable program for establishing and maintaining ALARA levels for gaseous and liquid effluents at materials facilities. Materials facilities are those facilities at which the possession or use of source, byproduct, or special nuclear material is licensed under 10 CFR Parts 30, 40, 60, 61, and 70.”

In addition, Regulatory Guide 8.37 states, “NRC licensees have taken actions to maintain doses to both workers and members of the public ALARA under the admonition contained in 10 CFR 20.1(c), which requires that licensees “make every reasonable effort” to maintain doses and effluents ALARA. NRC licensees have generally reduced doses to relatively small fractions of

the dose limits. Therefore, the NRC staff does not expect that most licensees will need to make significant changes to procedures, operations, and equipment in order to be in compliance with the requirements of 10 CFR 20.1101(b). However, for those licensees who have not previously developed a radiation protection program that includes written procedures and policies as well as a commitment to ALARA, additional steps may be necessary to demonstrate compliance with requirements now explicit in 10 CFR Part 20 to maintain doses ALARA.”

Additional guidance on ALARA programs can be found in other regulatory guides. While these guides deal primarily with occupational exposure and may be specific to one type of licensee, they contain programmatic information that may be useful to all licensees. They are as follows:

- Regulatory Guide 8.10, “*Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable.*” This guide delineates the components of an ALARA program.
- Regulatory Guide 8.18, “*Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable.*”
- Regulatory Guide 8.31, “*Information Relevant to Ensuring that Occupational Radiation Exposures at Uranium Mills Will Be As Low As Is Reasonably Achievable.*”
- Regulatory Guide 10.8, “*Guide for the Preparation of Applications for Medical Use Programs*” Section 1.3 and Appendix G deal specifically with ALARA programs for medical facilities.

In addition to NRC Regulatory Guides, there is a robust body of information regarding ALARA and its application in the peer reviewed scientific literature. Other regulatory- and industry-developed guidance is readily available and widely used in ALARA program planning and execution.

Significant reductions in radiation exposure of workers and releases of radioactive materials associated with licensed activities can be accomplished by focusing not on dose limits but on ALARA practices that better assure a systematic and proactive approach to limiting doses and releases.

Letter to the Honorable Allison M. Macfarlane, NRC Chairman, from J. Sam Armijo, ACRS Chairman, dated October 16, 2012

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