

POLICY ISSUE
(Information)

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SECY-08-0092

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: PLANS FOR REVIEW OF RADIATION PROTECTION REGULATIONS
IN LIGHT OF THE NEW INTERNATIONAL COMMISSION ON
RADIOLOGICAL PROTECTION RECOMMENDATIONS

PURPOSE:

The purpose of this paper is to inform the Commission of the ongoing review of the new recommendations of the International Commission on Radiological Protection (ICRP), and the U.S. Nuclear Regulatory Commission (NRC) staff plans to develop options for the revision of regulations and guidance related to radiation protection.

BACKGROUND:

The Commission has, through several Staff Requirement Memoranda (SRM), requested that the staff review the recommendations of the ICRP, ascertain if and how NRC radiological protection standards and methods are affected, and provide recommendations to the Commission on how best to implement necessary changes to these standards and methods. Most recently, in SRM-SECY-07-0155, "Denial of a Petition for Rulemaking to Reconcile NRC Generic Environmental Impact Statement for Nuclear Power Plant Operating License Renewal Applications with the National Academy of Sciences Health Risks from Exposure to Low Levels of Ionizing Radiation: Biological Effects of Ionizing Radiation VII, Seventh Ed., 2005 Report (PRM-51-11)," dated November 11, 2007, the Commission requested that staff provide recommendations to the Commission on whether the ICRP recommendations warrant making changes to NRC radiological protection standards and methods.

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This request was similar to Commission direction provided in SRM-SECY-01-0148, "Processes for Revision of 10 CFR Part 20 Regarding Adoption of ICRP Recommendations on Occupational Dose Limits and Dosimetric Models and Parameters," dated April 12, 2002, in which the Commission approved the staff's recommendation to not initiate consideration of changes to NRC "Standards for Protection Against Ionizing Radiation," Title 10 of the *Code of Federal Regulations* Part 20 (10 CFR Part 20), until the ICRP had completed its update of the ICRP recommendations.

The ICRP published its revised recommendations in December 2007, as ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection." These recommendations are the latest in the series published by the ICRP, with previous versions contained in ICRP Publication 60 (1990), ICRP Publication 26 (1977), and ICRP Publication 2 (1959). The final version of the revised recommendations is similar in most respects to the draft versions on which the NRC staff provided comments during the ICRP development process (2003-2007). The ICRP accepted many of the NRC comments. However, in some instances, ICRP did not accept NRC comments, especially those comments or suggestions related to ICRP reliance on unpublished information and the inclusion of a chapter on protection of the environment. Similar comments from other stakeholders were rejected as well.

The NRC "Standards for Protection Against Ionizing Radiation," 10 CFR Part 20, provides the fundamental radiological protection criteria for use by NRC licensees. Through the existing compatibility criteria, the Agreement States have requirements that are essentially identical to 10 CFR Part 20 for their licensees. The last revision to 10 CFR Part 20 was completed in 1991, and was based, among other things, upon the major 1977 recommendations of the ICRP, contained in ICRP Publication 26, and the public dose limit later reflected in ICRP Publication 60. Not all the recommendations contained in ICRP Publication 60 were incorporated into 10 CFR Part 20 in 1991 because those recommendations were not available during the public comment period.

Some portions of the regulatory framework were not considered or updated during the 1991 revision of 10 CFR Part 20; therefore the radiation protection concepts dating back to the 1959 recommendations (ICRP Publication 2) are still in use. While the vast majority of NRC and Agreement State licensees use the current 10 CFR Part 20 (ICRP 26) methodology, there are some licensees (primarily NRC fuel cycle licensees) that have requested and received, on a case-by-case basis, authorization to use the newer ICRP methodology (ICRP 66 and beyond) in their licensed activities. As a result there are three different sets of ICRP recommendations that are in use today by various licensees. The staff notes that this situation is similar for other U.S. Federal agencies where the same spectrum of requirements exists.

DISCUSSION:

The ICRP, in the 2007 recommendations, generally agrees with the main conclusions of the BEIR VII report: "Health Risks from Exposure to Low Levels of Ionizing Radiation." Specifically, there has been no significant change in risk estimates for radiation exposure from those used in support of ICRP Publication 60. The ICRP continues to recommend a rounded fatal cancer risk value of 5×10^{-2} per Sv (5×10^{-4} per rem). This value takes into account uncertainties in estimates of probability of fatal cancer used in radiation protection and assumes several factors derived from scientific and epidemiological studies for lifespan of the population, quality of the

radiation, total-body exposure, and linear response at low doses. It should be noted that the current risk estimates are greater than the value of 1.5×10^{-2} per Sv (1.5×10^{-4} per rem) upon which the 1977 recommendations in ICRP Publication 26 are based. The ICRP also continues to recommend the use of the linear no threshold (LNT) hypothesis for the development of prospective radiation control programs. The LNT hypothesis assumes that for incremental increases in radiation dose there is a linear, incremental increase in the probability of fatal cancer.

In final form, the 2007 recommendations are in many respects similar to the previous ICRP recommendations published in ICRP Publication 60. In particular, the recommendations with respect to the numerical values of dose limits for occupational and public exposure are unchanged. The 2007 recommendations represent a consolidation of material from ICRP Publication 60, and a number of the subsequent publications, and are presented by the ICRP as a consistent and coherent approach to radiation protection in all controllable exposure situations. In doing so, an increased emphasis was placed on the application of optimization, and the use of "constraints" as a prospective planning tool in optimization. The ICRP used the term "reference level" for the corresponding concept when considering optimization of protection for existing exposure situations, and in emergencies. The 2007 recommendations also provided new tissue and radiation weighting factors, and reflect other incremental changes reflecting improvements in scientific understanding of the intake, distribution, and elimination of radioactive material from the body. The enclosure provides a comparison of the radiological protection criteria in ICRP Publication 26, Publication 60, Publication 103, and the current 10 CFR Part 20.

There are numerous places within the NRC regulations, guidance and regulatory compliance codes and models where radiation protection criteria or concepts are either explicitly stated or referenced, and there are significant differences between the various components of the NRC regulatory framework. The NRC "Standards for Protection Against Ionizing Radiation," 10 CFR Part 20 are based on the recommendations of the ICRP as published in ICRP Publication 26 (1977). However, other portions of the regulatory framework were not considered or updated during the 1991 revision of 10 CFR Part 20. These include, for example, portions of the regulations in 10 CFR Parts 30, 31, and 32; 10 CFR Part 50 and Part 50 Appendix I; and 10 CFR Part 61. As a result, some of the existing NRC regulatory framework uses radiation protection concepts dating back to the 1959 recommendations of the ICRP (ICRP Publication 2). For certain licensees, such as fuel cycle facilities that may encounter internal radiation exposures as part of the licensed activities, the licensees have requested, and the Commission approved (SRM-SECY-99-077), the use of scientific information, modeling, and approaches from ICRP Publication 66 and subsequent reports.

The NRC staff, as previously directed by the Commission (SECY 01-0148) is in the process of analyzing the NRC regulations and guidance to determine the areas in which the 2007 recommendations of the ICRP, and other scientific information, warrant a change and update. Specifically, the recommendations in ICRP Publication 103 do not warrant any changes to the Commission's decision in SRM-SECY-07-0155 that approved the staff's recommendation to deny the petition for rulemaking (PRM-51-11) to reconcile the NRC's generic environmental impact statement for nuclear power plant operating license renewal applications with the BEIR VII report. The staff will provide a detailed analysis of the NRC regulations and guidance, and options for possible revisions, to the Commission in December 2008. This effort will benefit from interactions with the Agreement States, the Organization of Agreement States, Conference

of Radiation Control Program Directors, the nuclear industry, and with our Federal partners at the U.S. Environmental Protection Agency (EPA), the U.S. Department of Energy (DOE), and other organizations. The staff also recognizes that the ICRP itself is still in the process of preparing updated dose conversion factors using the new tissue and radiation weighting factors, and updated metabolic models, and that these materials will only become available starting in 2011.

Other Federal agencies are also in the process of considering changes as a result of ICRP Publication 103. This was a topic during the spring 2008 meeting of the Interagency Steering Committee on Radiation Standards (ISCORS). During that meeting, EPA indicated that it was examining the new BEIR VII report and ICRP 103, with a view to updating the dose coefficients presently contained in Federal Guidance Report 11, and then the risk values presented in Federal Guidance Report 13. As a note, the EPA does not use the internationally-derived dose coefficients. Instead, the EPA creates U.S. specific dose coefficients based on U.S. census data. There have not been decisions made regarding an update to the Presidential Federal Guidance for Occupational Exposure, last issued in 1987. The DOE indicated during the ISCORS meeting that it was continuing with previous plans to update certain portions of their regulations to ICRP Publication 60, and that they had not yet considered changes related to ICRP Publication 103.

There are important scientific quantities, concepts, and approaches that warrant consideration in order to position the NRC for a predictable and consistent regulatory basis for present and future uses. For example, while the NRC occupational dose limit of 5 rem (50 mSv) per year continues to align with the maximum value for any year recommended by the ICRP, there is no provision corresponding to the 20 mSv (2 rem) per year average given by ICRP. In the global community, the U.S. is virtually the only country that has not adopted some form of a 20 mSv (2 rem) per year occupational exposure limit. Furthermore, the biological and radiation weighting factors have been revised, and many of the metabolic models have likewise been updated.

The staff notes that the outdated nature of some of the NRC regulatory requirements and guidance may be seen as an issue by some in the consideration of licensing new reactors under 10 CFR Part 52. Staff has begun dialog with the nuclear industry on the implications and impacts of changes. In addition, the NRC and DOE are currently considering the design and construction of the next generation of nuclear power plants. As a result, there is a need to consider how current regulations and regulatory guidance should be revised to support the licensing of such new types of reactors. Moreover, the staff notes that there may be increased domestic and international pressure, stemming from the increasing globalization of the nuclear industry, to make changes to the current NRC radiation protection framework for radiation protection to align with those of the rest of the world. The staff notes that the increasing use of U.S. reactor designs in other countries, and the proposals for use of other designs in the U.S., and the increasing mobility of the global workforce, makes it increasingly important to have radiation protection requirements that are consistent with those used elsewhere.

Given the reasons above, the staff is considering making changes in upcoming individual rulemakings to use the newer ICRP methodology, where such changes may be appropriate, as the overall analysis of the regulatory framework continues. In this way, ICRP-related rulemakings will be handled in accordance with the current agency process for rulemaking prioritization. As an example, certain activities, such as consideration of the requirements for

design criteria for generally licensed devices that is underway now, could provide an opportunity to start making changes consistent with this future overall direction.

COMMITMENTS:

The staff plans to provide the Commission with options for possible revision of the overall regulatory framework by December 2008, which is consistent with previous Commission direction. The staff will, in parallel, consider, as appropriate, modifications utilizing the 2007 recommendations of the ICRP in rulemaking proposals being developed at this time.

RESOURCES:

The staff's consideration of options will take into account possible methods for organizing the work that would be necessary to update the radiation protection framework based on priority, resources, and the schedule of availability for the technical foundations and bases for making changes. The staff recognizes that the regulatory framework for radiation protection is extensive, and that a large resource effort over a number of years would be necessary to completely align all of the regulations, guidance, and supporting calculation codes and materials. In a subsequent options paper, that will be provided to the Commission in December 2008, the staff will describe the resources associated with each recommended option and identify those resources that are either budgeted or unbudgeted.

COORDINATION:

The Office of the General Counsel has reviewed this package and has no legal objection.

/RA Martin J. Virgilio for/

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Enclosure: Dose Limit Comparison Table

DOSE LIMIT COMPARISON CHART

Exposure Limits	ICRP 26 ¹	ICRP 60	ICRP 103	Part 20
Occupational	50 mSv (5rem)/yr (108) ²	20 mSv (2 rem)/yr, avged 5 yr 50 mSv (5 rem) in any year 100 mSv (10 rem) (total) in 5 yrs (166)	20mSv (2 rem)/yr, avged 5 yr 50 mSv (5 rem) in any year 100 mSv (10 rem)(total) in 5 yrs (183)	50 mSv (5 rem)/yr (§20.1201(a)(1)(i))
Public	5 mSv (0.5 mrem)/yr (119)	1mSv (0.1 rem)/yr Special circumstances of higher value, 5 yr average 1mSv (0.1 mrem) (192)	1 mSv (0.1 rem)/yr Special circumstances of higher value, 5 yr average 1mSv (0.1 rem) (191)	1 mSv (0.1 rem)/yr Up to 5 mSv (500 mrem)/yr with prior NRC authorization (§20.1301(a)&(d))
Fetal (Declared pregnant occupational workers)	≤ 15 mSv (1.5 rem) Working condition B (116)	2 mSv (200 mrem) to surface of abdomen for remainder of pregnancy, limit intakes 1/20 ALI (178)	1mSv (100 mrem) to the embryo/fetus (186)	5 mSv (0.5 rem) (§20.1208(a))

¹ ICRP-2 was mentioned in the body of the Commission paper but not included in this comparison because it was fundamentally different than the other reports. The external limit for occupational workers was 5(N-18) rem, where N=the worker's age. The internal dose was driven by the organ dose, which gave values of maximum permissible concentration based on organ dose rather than the effective dose. ICRP-2 did not contain any tissue or radiation weighting factors.

² Paragraph number from the ICRP report cited as a reference source

	ICRP 26	ICRP 60	ICRP 103	Part 20
Exposure Limits (continued)				
Medical Caregivers	---	Medical exposure, no limit, constraints considered, no value suggested (139 & S35)	5 mSv (500 mrem) per episode 20 mSv (2 rem)/yr max. constraint (322)	5mSv (0.5 rem) (§20.1301(c)(1))

	ICRP 26	ICRP 60	ICRP 103	Part 20
Organ Limits				
Worker	500 mSv (50 rem) organ dose 300 mSv (30 rem) lens (103)	-- ³ 150 mSv (15 rem) lens (172) 500 mSv (50 rem) skin over 1 cm ² (173) 500 mSv (50 rem) hands & feet (Table 6)	-- ⁴ 150 mSv (15 rem) lens 500 mSv (50 rem) skin over 1 cm ² 500 mSv (50 rem) hands & feet (Table 6)	500 mSv (50 rem) organ dose 150 mSv (15 rem) lens 500 mSv (50 rem) skin over 10 cm ² (§20.1201(a)(1)& (2))
Public	50 mSv (5 rem) organ dose (126)	--- rem hands and feet 50 mSv (5 rem) skin over 1 cm ² 150 mSv (1.5 rem) lens (194 and Table 6)	--- rem hands and feet 50 mSv (5 rem) skin over 1 cm ² 150 mSv (1.5 rem) lens (Table 6)	-- ⁵

³ Restrictions of intakes to the annual limit on intake will ensure that the lifetime equivalent dose in any single organ, except lens of the eye and skin, will not be such as to result in deterministic effects (175).

⁴ Control of stochastic effects will avoid the occurrence of most, and probably all, tissue reactions (95).

⁵ Organs with weighting factors are limited by the public dose requirement that their Total Effective Dose Equivalent (TEDE; from internal and external exposure) is not to exceed 1 mSv (0.1 rem)

Issue	ICRP 26	ICRP 60	ICRP 103	Part 20
Tissue Weighting Factors, w_T				
Gonads	0.25	0.20	0.08	0.25
Breast	0.15	0.05	0.12	0.15
Red bone marrow	0.12	0.12	0.12	0.12
Lung	0.12	0.12	0.12	0.12
Thyroid	0.03	0.05	0.04	0.03
Bone surfaces	0.03	0.01	0.01	0.03
Colon	-	0.12	0.12	-
Stomach	-	0.12	0.12	-
Bladder	-	0.05	0.04	-
Oesophagus	-	0.05	0.04	-
Liver	-	0.05	0.04	-
Brain	-	-	0.01	-
Kidney	-	-	-	-
Salivary Glands	-	-	0.01	-
Skin	-	0.01	0.01	-
Remainder	0.30 ⁶ (105)	0.05 ⁷ (Table 2 and S-2)	0.12 ⁸ (Table B.2 and B.3.5)	0.30 ⁹ (§20.1003)

⁶ The remainder is composed in part of the following additional tissues and organs: stomach, salivary glands, lower large intestine, and liver. When the gastrointestinal tract is irradiated, the stomach, small intestine, lower large intestine and upper large intestine are treated as four separate organs and be included in the remainder tissues.

⁷ The remainder is composed of the following additional tissues and organs: adrenals, brain, upper large intestine, small intestine, kidney, muscle, pancreas, spleen, thymus, and uterus.

⁸ The remainder is composed of the following additional tissues and organs: adipose tissue, adrenals, connective tissue, extrathoracic airways, gall bladder, heart wall, kidney, lymphatic nodes, muscle, pancreas, prostate, small intestine wall, spleen, thymus, and uterus/cervix.

⁹ 0.30 results from 0.06 for each of the 5 “remainder” organs (excluding the skin and lens of the eye) that receive the highest dose.

Issue	ICRP 26	ICRP 60	ICRP 103	Part 20
Radiation Weighting Factors, w_R				
Photons, all energies	1	1	1	1
Electrons and muons, all energies	1	1	1	1
Neutrons, all (unknown) energies	10	Step function	continuous function	10
< 10 keV		5	2.5	2 to 2.5
10 - 100 keV		10	2.5 to 10	2.5 to 7.5
100 - 2 MeV		20	10 to 20	7.5 to 11
2 to 20 MeV		10	7 to 17.5	8 to 9
> 20 MeV		5	5 to 7	3.5 to 8
Protons, energy > 2 MeV	10	5	2	10
Alpha particles, fission fragments heavy nuclei	20 (20)	20 (Table 1 and S-1)	20 (Table 2)	20 (Tables 1004(b) 1 & 2)