Advisory Committee on the Medical Use of Isotopes (ACMUI)

Comments on the Nuclear Regulatory Commission (NCR)
Advanced Notice of Proposed Rulemaking (ANPR)
on Potential Changes to Radiation Protection Regulations

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Charge: To provide recommendations and answers to the specific questions and issues identified by NRC in the ANPR[1] in its development of a draft regulatory basis for possible revision of the NRC's radiation protection standards.

General Recommendations

Issue Paper 1 – The ACMUI supports updating 10 CFR Part 20 to align with the International Commission on Radiological Protection Publication (ICRP) 103 methodology and terminology.

Issue Paper 2 – The ACMUI supports change of the occupational dose limit for the lens of the eye to 50 mSv (5 rem).

Issue Paper 3 – The ACMUI does not support change of the dose limit for the embryo/fetus of a declared pregnant occupational worker from 5 mSv (500 mrem).

Issue Paper 4 – The ACMUI does not support revising or adding regulatory requirements regarding a licensee's as low as reasonably achievable (ALARA) program.

Issue Paper 5 – The ACMUI supports the change to use of the International System of Units (SI) in radiation protection regulations, but recognize the need by some licensees to have a transition period to move from the use of conventional units.

Issue Paper 6 – The ACMUI does not support expansion of additional categories of licensees that should be required to submit annual occupational exposure reports under 10 CFR 20.2206(a), except for considering the addition of a possession category for 100 curies of fluorine-18 under 10 CFR 20.2206(a)(7). .

Cumulative Effects of Regulation – The ACMUI recommends NRC use a similar implementation plan as was used for the last significant change of 10 CFR Part 20 in 1991[2] where the licensee could choose to implement the regulatory change anytime within a given time frame. The Committee recommends a time frame of at least three years to allow implementation of procedure, training, hardware, and software changes needed to implement the new regulatory requirements.

[1] 79 FR 43284, July 25, 2014, Docket ID NRC-2009-0279.
[2] 56 FR 23360, May 21, 1991

Issue Paper 1
Update 10 CFR Part 20 to Align with the International Commission on Radiological Protection Publication 103 Methodology and Terminology

Comments

The NRC's regulations currently use the term, "total effective dose equivalent (TEDE)," to represent the summation of doses received from external and internal radiation sources and thereby express the total stochastic radiation risk. As part of its development of the draft regulatory basis for the update of 10 CF Part 20, the NRC will consider revising the regulations in 10 CFR Part 20 and making associated changes to its other regulations to incorporate the ICRP term, "effective dose (ED)." ED, the tissue-weighted sum of the equivalent doses (i.e., the sum of the products of the tissue absorbed doses from different radiations R and the respective radiation weighting factors w_R) in all specified tissues and organs of the body, reflects the overall probability of radiogenic stochastic risk, namely, of cancer induction and genetic (germ-line) mutation. It takes into account the type of radiation (in terms of the radiation weighting factors w_R) and the nature (i.e., susceptibility to stochastic damage) of each organ or tissue irradiated (in terms of tissue weighting factors w_T). The concept of effective dose was originally proposed in 1975[3]. It was then included as "effective dose equivalent (H_E)" in ICRP publication 26[4]. In 1991, ICRP publication 60 shortened the name to "effective dose." (This quantity is sometimes incorrectly referred to as the "dose equivalent" because of the earlier name, and that misnomer in turn causes confusion with equivalent dose.) The tissue weighting factors were revised in 1990 (ICRP publication 60)[5] and 2007 (ICRP publication 103)[6] as updated radiation epidemiology data became available. It is recognized that the ED is misused at times, specifically, to estimate the stochastic risk to specific irradiated individuals. Nonetheless, ED is now the standard quantity used internationally as well as in the United States to express overall stochastic radiation risk[7]. The TEDE, still in place in current NRC regulations, is an outdated quantity and is no longer used or encountered other than in the NRC's regulatory literature and it is therefore **strongly recommended that the NRC revise its regulations in 10 CFR Part 20 and its other regulations to incorporate the ED in place of the TEDE.**

ICRP publication 103[6] superseded ICRP 26[4], and the dosimetry revisions from ICRP publication 26 to ICRP publication 103 included changes in the values of both the radiation and tissue weighting factors (w_R and w_T, respectively) used to calculate the ED. As noted, the tissue weighting factors were revised in 1990 (ICRP publication 60)[5] and 2007 (ICRP publication 103)[6]. **The NRC's draft regulatory basis will consider replacing the definition of weighting factor w_T in 10 CFR 20.1003 with the tissue weighting factors in Table 3 of ICRP Publication 103[6] and replacing the quality factors in Table 1004(b).1 and Table 1004(b).2 of 10 CFR 20.1004,**

[3] Jacobi W. The concept of effective dose - A proposal for the combination of organ doses. Radiat Environ Biophys 12: 101–109, 1975.
[4] 1977 Recommendations of the International Commission on Radiological Protection. Annals of the ICRP. ICRP publication 26 1 (1), 1977.
[5] 1990 Recommendations of the International Commission on Radiological Protection. Annals of the ICRP. ICRP publication 60 21 (1-3), 1991.
[6] 2007 Recommendations of the International Commission on Radiological Protection". Annals of the ICRP. ICRP publication 103 37 (2-4), 2007.
[7] Brenner DJ. Effective dose: A flawed concept that could and should be replaced. Br J Radiol 81: 521-3, 2008.

"Units of Radiation Dose," with the radiation weighting factors in Table 2 of ICRP Publication 103[8] together with other associated changes (e.g., replacing "dose equivalent" with the term "equivalent dose" and replacing TEDE with ED). The foregoing changes are strongly recommended.

The transition from ICRP publication 26 to ICRP publication 103 also included changes in the underlying isotope-specific biokinetic models used to determine organ absorbed doses following intakes of radionuclides. Changes to the biokinetic models since ICRP publication 26 have included a new respiratory tract model (ICRP publication 66[9]) and, more recently, a new human alimentary tract (HAT) model (ICRP publication 100[10]). The biokinetic models can have a significant impact on calculated organ dose conversion factors (DCFs) (i.e., absorbed dose per unit activity administered or otherwise internalized; also known as dose coefficients) and thus on calculated EDs. The conversion to ICRP publication 103 biokinetic models would therefore not be without a certain "overhead": the current ICRP biokinetic models and DCFs may lead to revision of at least some the annual limits on intakes (ALIs), limits on derived air concentrations (DACs) etc in Appendix B to 10 CFR Part 20 and this, in turn, may have a financial impact on licensees and other stakeholders in order to comply with the revised limits. It is nonetheless **recommended that the NRC revise its regulations in 10 CFR Part 20 to incorporate the latest isotope-specific biokinetic models and associated DCFs in ICRP publication 103**.

The human body can now be realistically modeled as a complex set of mathematical and "voxel" phantoms as a result of advances in medical imaging and computer technology since the 1991 10 CFR Part 20 rulemaking. These advances have resulted in the development of age- and gender-specific reference computational phantoms for dosimetry in addition to adult males: 1-year-old, 5-year-old, and 10-year-old children and 15-year-old males and females[8,11]. The ICRP is considering the use of corresponding age- and gender-weighted DCFs for developing a set of environmental intakes of radionuclides. The NRC is likewise considering the use of the age- and gender-averaged approach to provide a more realistic representation of a member of the public that explicitly considers the presence of infants and children within the population. **The use of age- and gender-*averaged* DCFs, based on the set of ICRP reference computational phantoms, for establishing regulatory limits on environmental intakes of radionuclides is recommended. The use of age- and gender-*specific* DCFs for regulatory purposes should not be considered, however, as it is inappropriate for radiological protection of the general public and would excessively burden licensees.**

Specific Answers

Q1–1: *What are the implications of changing the NRC's regulations to specify ''total effective dose'' in place of the current term ''total effective dose equivalent?'' To the extent possible, please*

[8] 2007 Recommendations of the International Commission on Radiological Protection". Annals of the ICRP. ICRP publication 103 37 (2-4), 2007.
[9] Human Respiratory Tract Model for Radiological Protection. Annals of the ICRP. ICRP publication 66 24 (1-3), 1994.
[10] Human Alimentary Tract Model for Radiological Protection. Annals of the ICRP. ICRP publication 100 36 (1-2), 2006.
[11] Adult Reference Computational Phantoms. Annals of the ICRP. ICRP publication 110 39 (2), 2009.

provide specific implementation and operational cost information on the impacts of this change relative to licensee procedures, training, recordkeeping, and reporting. This information is necessary for the NRC to determine whether the imposition of such requirements on NRC licensees is justified.

A1–1: The ED is now the standard quantity used internationally as well as in the United States to express overall stochastic radiation risk. The TEDE is an outdated quantity and is no longer used or encountered other than in the NRC's regulatory literature. The ED and TEDE are, however, both metrics of overall stochastic risk and thus conceptually similar. They differ largely in technical detail: (a) the TEDE uses the quality factor, QF, while the ED uses the radiation weighting factor, w_R, to adjust for differences in linear energy transfer (LET) and in stochastic risk-related biological effectiveness among different radiations; (b) the TEDE and the ED use different tabulations of the tissue weighting factor, w_T, to adjust for differences in sensitivity to stochastic risks among different tissues. Transformation of TEDE, the current quantity, to ED, the proposed quantity, amounts to an arithmetic transformation, therefore. This, in turn, will require updating of software and/or hardcopy forms used to record and otherwise manage personnel exposures in a facility's radiation protection program. Any such updates are not without some financial and logistical impact but in this instance the impact should be minimal. Furthermore, the quantitative differences between the calculated TEDE and ED in specific instances are generally quite minor and generally should not impact a facility's operation. That is, an occupationally exposed individual who would exceed a regulatory MPD or an associated institutional action level if the dose were expressed in ED would also do so if it were expressed in TEDE. Likewise, an individual whose dose would not exceed a MPD or action level if the dose were expressed in ED would not exceed the MPD or action level if the dose were expressed in TEDE. Overall, replacing the TEDE with the ED in NRC regulation and thereby aligning the NRC's regulatory language with that use nationally and internationally is justified.

Q1–2: *If the NRC adopts the dose assessment terminology and methodology of ICRP Publication 103 (2007) in a future rulemaking, what time period should the NRC consider providing for implementation of the ICRP Publication 103 (2007) methodology and terminology?*

A1–2: As noted above, adoption by the NRC of the dose assessment terminology and methodology of ICRP Publication 103[12], in principle, should be logistically and conceptually straightforward. In practice, however, this conversion will involve updating of the applicable software and forms. The potential difficulties in updating, de-bugging, and testing and re-testing software, even for seemingly straightforward updates, should not be underestimated. For this reason, a minimum of three (3) years is recommended for implementation of the ICRP Publication 103[12] methodology and terminology.

Q1–3: *How should the calculation of effluent concentrations, currently in the 10 CFR part 20 radiation protection regulations, be modified to reflect advances in modeling that are now available? In particular, the NRC is interested in preliminary views on the age and gender averaged approach.*

[12] 2007 Recommendations of the International Commission on Radiological Protection". Annals of the ICRP. ICRP publication 103 37 (2-4), 2007.

A1–3: The calculation of effluent concentrations should be modified to reflect the latest set of ICRP reference computational phantoms[13,14] and regulatory limits on effluent concentrations should be based on age- and gender-*averaged* DCFs derived from these phantoms. For public health/regulatory purposes, the use of such average DCFs for establishing regulatory limits on effluent concentrations is logical, as the general public represents an average population composed of both genders and of a distribution of ages from newborns to adults. The use of age- and gender-*specific* DCFs for regulatory purposes should not be considered, however, as it is inappropriate for radiological protection of the general public and would be impractical to implement.

Q1–4: *Should the public dose limit of 0.5 mSv (50 mrem) continue to be the basis for the effluent concentration limits for the radionuclides in 10 CFR Part 20, appendix B, Table 2, Columns 1 and 2? Should it be reduced or otherwise modified?*

A1–4: As noted above, quantitative differences between the calculated TEDE and ED in specific instances are generally quite minor, despite the distinct sets of tissue weighting factors, w_Ts, used to calculate these respective quantities. Likewise, DCFs derived from the latest set of ICRP reference computational phantoms are not dramatically different from earlier DCFs. Accordingly, revision of a public dose limit of 0.5 mSv (50 mrem) as the basis for the effluent concentration limits for the radionuclides in 10 CFR Part 20, Appendix B, Table 2, Columns 1 and 2 is not warranted.

[13] 2007 Recommendations of the International Commission on Radiological Protection". Annals of the ICRP. ICRP publication 103 37 (2-4), 2007.

[14] Adult Reference Computational Phantoms. Annals of the ICRP. ICRP publication 110 39 (2), 2009.

Issue Paper 2
Occupational Dose Limit for the Lens of the Eye

Comments

The ACMUI supports change of the occupational dose limit for the lens of the eye to 50 mSv (5 rem). This reduction of lens dose limit is anticipated to have minimal on medical licensees or on licensees that support medical use of byproduct material (support licensees), except for several radiation personnel populations. Those personnel who work with byproduct materials and related instrumentation and are exposed to non-uniform radiation fields such that their eye doses are higher than their whole-body doses may require additional eye shielding and/or personal dosimeters to specifically measure lens dose. Certain personnel whose eyes are exposed to radiation from byproduct materials and fluoroscopic x-ray sources, such as interventional physicians involved in radioembolic therapy of liver tumors, may be impacted by this dose limit reduction.

Specific Answers

Q2–1: *Is closer alignment with or adoption of the ICRP Publication 118 (2012) recommendations regarding the dose limits to the lens of the eye appropriate given the scientific information now available?*

A2-1: Yes. Recent human epidemiological studies have suggested that opacification of the lens of the eye, or a "radiation cataract", may occur at significantly lower doses of ionizing radiation than previously estimated. These include studies of Chernobyl nuclear reactor accident cleanup workers as well as radiologic technologists, interventional radiologists, and cardiologists. Of course, individual genetic and other differences in radiosensitivity among various exposed individuals may explain the variation in reported timing of the onset of cataract, degree of lens opacification, and subsequent progression to visual disability.

Q2–2: *How should the impact of a radiation-induced cataract be viewed in comparison with other potential radiation effects?*

A2-2: Unlike other potential radiation effects (fatal cancer, non-fatal cancer, or hereditary effects), radiation-induced eye lens injuries involve reduced transparency of the lens (cataract), which can be effectively treated by surgery. However, prevention (rather than treatment) should be the goal.

There are three predominant forms of cataract, nuclear, cortical, and posterior sub-capsular, defined on the basis of the anatomical location in the eye lens. Ionizing radiation is generally (though not exclusively) associated with posterior sub-capsular opacities, while age-related cataracts are most commonly found in the nuclear region and cortical cataracts are commonly found in diabetic patients. Treatment of cataract involves surgical removal of the opacified lens, leaving the capsule that contains it intact, and insertion of a plastic lens.

Q2–3: *What mechanisms could be applied to keep the cumulative exposure to the lens of the eye below the threshold of 0.50 Gy (50 rad)?*

A2-3: Personnel only exposed to byproduct materials – Mechanisms to minimize exposure to the lens of the eye are the same as those employed for all external exposure to the personnel – time, distance and shielding. As noted in NRC Inspection Procedure 83533[15], licensees need to evaluate radiation fields for dose gradients and have procedures in place to monitor non-uniform radiation fields. In regard to medical licensees or support licensees, personnel who do repair or maintenance of cyclotrons may be impacted the most by reduction of the lens occupational dose limit.

Personnel exposed to byproduct materials and x-ray sources – Due to non-uniformity of radiation fields, personnel involved in fluoroscopic x-ray procedures will also be impacted by reduction of the lens occupational dose limit regulated by State radiation control programs which adopted the 150 mSv (15 rem) occupation lens dose limit. Interventional radiologists performing Y-90 microsphere therapies and perhaps some cardiologists who still perform intravascular brachytherapy procedures are the cohorts of byproduct material and x-ray personnel affected, more so by their overall x-ray radiation exposures rather than those from the byproduct material they use.

For fluoroscopic x-ray personnel, there are 3 categories of eye protectors that can be applied to keep the cumulative exposure to the lens of the eye below the cataractogenesis threshold of 0.5 Gy (50 rad). It is important to point out, however, that these protective measures should be implemented along with maintaining x-ray fluoroscopy equipment (used to guide Y-90 radioembolization procedures) in optimum operating condition in order to minimize radiation exposure to the personnel.

The 3 categories of shielding for fluoroscopically-guided interventional radioembolization procedures are as follows:

1) Portable/moveable transparent scatter-shielding (leaded glass) screen, commonly suspended from the ceiling. These devices protect the entire head, and not just the eyes.

2) Protective eyewear (e.g. leaded glasses) for personal use. These come in a variety of choices that can be individualized for the individual's correct optical prescription, comfort and performance.

3) Personal protection suit that is made up of leaded acrylic face shield (protecting the eye) and apron (replacing the heavy lead apparel), with the operator is connected to the suit through a lightweight magnetic vest that the operator wears. The overhead, suspended design floats lead in front of the user instead of requiring them to wear it and has 1.00-mm lead-equivalent thickness protecting the body compared to the 0.5-mm thickness of older-style lead aprons.

For physicians and trainees who are directly involved with the interventional radioembolization procedures that use fluoroscopy (interventional radiology), the use of eye protection should be "mandatory". For the ancillary staffs in the interventional radiology suite (nurses, technologists, etc.) that are within a high-scatter X-ray radiation field and at least 3 feet away from the table (with

[15] NRC Inspection Manual, Inspection Procedure 83533, Part 52, External Occupational Exposure Control and Personal Dosimetry, Issue Date 10/27/10.

an estimated exposure typically 10-fold less than those at the table), the use of eye protection should be "recommended".

Q2–4: *What methods should be allowed for measurement or assessment of the dose to the lens of the eye?*

A2-4: The current most widely used method for measuring or assessing the dose to the lens of the eye is a body dosimeter which is worn at the point of highest exposure. For personnel only working with byproduct material, lens dose estimated from the body dosimeter is a conservative measure if radiation fields are fairly uniform. If there is significant non-uniformity in the radiation field in terms of the body versus the eye dosimeters, those personnel may need to utilize "eye-specific" dosimeters usually worn with a head strap above the eyebrows and near the eyes, to provide better measure of the lens dose.

For personnel performing fluoroscopic x-ray procedures, a collar body dosimeter placed outside any radiation protective garments provides an estimate the lens dose. If there is significant non-uniformity in the radiation field in terms of the collar versus the lens-of- eye, those personnel may likewise need to utilize "eye specific" dosimeters unless that non-uniformity is due to eye shields with a known shielding reduction factor.

Q2–5: *What methods should be allowed for recording dose to the lens of the eye when the eyes are protected?*

A2-5: For personnel doing fluoroscopic x-ray procedures, it would be reasonable to apply the industry reported estimates for the shielding reduction factor to the lens of the eye for the 3 categories of eye protectors: 1) scatter-shielding transparent screen, 2) personal leaded eye glasses, and 3) personal protection suit with a face shield. Direct monitoring of eye dose, for example, by use of small semi-conductor detectors clipped onto eye glasses, would be an ideal approach, but there are currently limited data on this method.

In a relatively busy interventional suite at a major inner city academic institution, the estimated annual dose to the lens of the eye without the use of eye protection ranges from 40 to 80 mSv (4 to 8 rem). It is estimated that the use of a personal leaded glasses alone would reduce the lens dose rate by a factor of 5 to 10, and scatter-shielding screens alone would reduce the dose rate by a factor of 5 to 25. Use of both glasses and shields simultaneously may reduce the dose rate by a factor of 25 or more. Recent whole-body and lens personal protection suits with a face shield, with 1-mm lead equivalence, may decrease the dose rate by a significantly higher factor, albeit at a much greater operational cost.

Q2–6: *What are the potential operational impacts of lowering the annual occupational dose to the lens of the eye from the current NRC regulatory standard of 150 mSv (15 rem) to 50 mSv (5 rem)? Would a reduction in the occupational dose limit for the lens of the eye require changes in*

programs, procedures, practices (e.g., increased use of protective eyewear), or in-room shielding? If so, please describe these changes, including any potential implementation and operational costs.

A2-6: The potential operational impact of lowering the annual occupational dose to the lens of the eye from 150 mSv (15 rem) to 50 mSv (5 rem) would certainly require changes in fluoroscopic x-ray safety programs, making the use of an eye protector shield or personal glasses a "mandatory" practice for interventional physicians/trainees and "recommended" for the ancillary staff. This would have implications on operational costs and on enforcement for x-ray safety programs.

Regarding costs, the portable/moveable transparent scatter-shielding screen option is estimated to cost less than $10,000 per shield, the personal leaded glasses may cost approximately $400/person, and the personal protection suit with a face shield may cost nearly $70,000 per unit; for 2 operators in the room, it would require the purchase of 2 units per interventional room.

Q2–7: *What are the potential impacts on State regulatory programs of a reduction in the occupational dose limit to the lens of the eye from the current NRC regulatory standard of 150 mSv (15 rem) to 50 mSv (5 rem)?*

A2-7: Regarding enforcement, it starts with implementing the change through the institutional Radiation Safety Committee and its Human Use Subcommittee and subsequent enforcement by the institution's Environmental Health Services and Radiation Safety Officer. Of course, these changes would have implications for State radiation control programs that changed their occupational lens dose limit to 150 mSv (15 rem), and perhaps on annual inspection and QA programs of The Joint Commission and Centers for Medicare & Medicaid Services (CMS).

Issue Paper 3
Dose Limit for the Embryo/Fetus of a Declared Pregnant Occupational Worker

Comments

The ACMUI recommends that the dose limit to the embryo/fetus (i.e., for the total dose of the duration of the pregnancy) of a declared pregnant woman not be changed from the current limit of 5 mSv (500 mrem) [10 CFR 20.1208]. The Committee's recommendation is based on the following considerations.

Scientific Basis of Risk

The risk of cancer from in utero radiation exposure is a controversial subject. Exposure to ionizing radiation represents an oncogenic risk, but the magnitude of the risk is unclear. The risks cannot be estimated accurately because of conflicting data and an inability to make precise risk estimates[16].

Recent publications and analyses indicate that the apparent risk is lower for the irradiated embryo than the irradiated child, and that there may be no increased carcinogenic risk from diagnostic radiological studies[17]. The Radiation Effects Research Foundation (RERF) continues to track the mortality and cancer incidence among survivors of the 1945 atomic bombings of Hiroshima and Nagasaki, including those who were exposed in utero and during early childhood. A recent RERF article[18] concluded both the in utero and early childhood groups exhibited statistically significant dose-related increases in incidence rates of solid cancers, but the apparent difference in excess absolute rates (EARs) of childhood and adult cancer incidence between the two groups suggests that lifetime risks following in utero exposure may be considerably lower than for early childhood exposure. Further follow-up is needed.

An additional, practical argument against a 100-mrem regulatory dose limit is that it would be within the range of variability encountered among natural background doses accrued annually across the United States. A regulatory dose limit within this range would thus be problematic, as it would be difficult to reliably distinguish an actual excess 100-mrem dose from the background dose itself.

The ACMUI does not support a lowering of the NRC dose limit from 5 mSv (500 mrem) to 1 mSv (100 mrem) based on the current scientific knowledge of stochastic risk to the embryo/fetus of a declared pregnant woman.

Alignment with Recommended Standards

[16] Brent, R.L. and Mettler, F.A., "Letters – Pregnancy Policy," American Journal of Roentgenology. 2004;182: 819-822.
[17] Brent, R.L., "Saving lives and changing family histories: appropriate counseling of pregnant women and men and women of reproductive age, concerning the risk of diagnostic radiation exposures during and before pregnancy," American Journal of Obstetrics & Gynecology (January 2009).
[18] Preston DL, Cullings H, Suyama A, et al., "Solid cancer incidence in atomic bomb survivors exposed in utero or as young children." J Natl Cancer Inst 2008;100:428-36.

In SECY-12-0064[19], the NRC staff recommended an option to develop the detailed draft language for changes to 10 CFR 20 that would achieve a greater degree of alignment with current scientific information, and with international recommendations and standards. The NRC Advisory Committee on Reactor Safety Guards (ACRS) recommended that rulemaking to revise limits for occupational radiation exposure not be taken[20]. The Commission disapproved the staff's recommendation in Option 3 to develop the regulatory basis to reduce the occupational total effective dose equivalent[21]. However, both the ACRS and the Commissioners supported staff's continued discussion on dose limits for the embryo/fetus radiation exposure.

The National Council on Radiation Protection and Measurements (NRCP) recommends a dose limit of 0.5 mSv (50 mrem) equivalent dose in a month once pregnancy is known[22]. The NCRP recently updated and expanded its recommendations regarding radiation exposure to pregnant and potentially pregnant women[23]. This NCRP report concluded that formal declaration of a pregnancy by a pregnant worker permits supervisors, if necessary, to take steps to control occupational exposure to radiation to less than that normally received, and that any risks from occupational exposure are considered minimal as long as the regulatory dose limits are met. This NCRP report does not recommend a change from the previous 1993 recommendation for the dose limit to the embryo/fetus of a declared pregnant woman[24].

Commissioner Magwood commented that alignment with international standards and practices is not, in and of itself, an appropriate goal for the NRC[25]. The ACMUI agrees with Commissioner Magwood's comment, especially in light of the NCRP's continued recommendation for a dose limit of 0.5 mSv (50 mrem) equivalent dose in a month once pregnancy is known, which is consistent with the current 10 CFR 20.1208 limit.

Applications of Public Dose Limits and Individual Dose Limits

The NRC regulations require licensees to demonstrate compliance with dose limits for individual members of the public by considering the individual likely to receive the highest dose or for an individual continuously exposed [10 CFR 20.1302 and Appendix B Table 2]. These unrealistic circumstances, along with the low dose limit of 1 mSv (100 mrem), relieves licensees from having to consider what possible exposures each member of the public may receive from other licensees. Essentially, the NRC public dose limits are applied as design criteria. In the case where a member of the public may be more specifically identified and their exposure individually controlled and deemed appropriate, NRC allows use of an individual dose limit of 5 mSv (500

[19] NRC SECY-12-0064, "Recommendations for Policy and Technical Direction to Revise Radiation Protection Regulations and Guidance" (April 25, 2012).
[20] NRC Advisory Committee on Reactor Safeguards, "Letter on SECY-12-0064" (October 16, 2012).
[21] NRC SRM-SECY-12-0064, "Staff Requirements - SECY-12-0064" (December 17, 2012).
[22] NCRP (1993). National Council on Radiation Protection and Measurements. "Limitations of Exposure to Ionizing Radiation," NCRP Report No. 116 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).
[23] NCRP (2013). National Council on Radiation Protection and Measurements. "Preconception and Prenatal Exposure: Health Effects and Protective Guidance," NCRP Report No. 174 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).
[24] **NOTE:** Description of the NRCP 174 dose limit recommendation was incorrect in "Issue Paper 3 – Dose Limit for the Embryo/Fetus of a Declared Pregnant Occupational Worker," (79 FR 43293, July 25, 2014).
[25] NRC Commission Voting Record, "Staff Requirements - SECY-12-0064" (December 17, 2012).

mrem) [10 CFR 20.1301(d)]. This regulation provides the following three criteria that the NRC requires to approve an increase in the public dose limit from 100 mrem to 500 mrem: (1) "the need for and expected duration of operations in excess of the limit"; (2) "the licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit"; and (3) "the procedures to be followed to maintain the dose as low as is reasonably achievable".

In the case of a declared pregnant worker, the radiation worker is specifically identified, may be required to be individually monitored [10 CFR 20.1502], and may have other occupational exposures included for the current calendar year [10 CFR 20.2104]. The pregnant worker's exposure is individually controlled by virtue of her radiation worker training and the licensee's ALARA program.

The ACMUI does not consider it appropriate to apply a dose limit used as a design criterion for an unidentified individual who may be unaware of possible radiation exposure to an identified and often monitored radiation worker who is pregnant.

Specific Answers

Q3–1: *Are there any significant anticipated impacts associated with reducing the dose limit to the embryo/fetus of a declared pregnant woman, including operational impacts? What are the potential implementation and operational costs?*

A3–1: Several negative impacts associated with reducing the dose limit to the embryo/fetus of a declared pregnant woman were described in SECY-12-0064[26]:

> "Several stakeholders indicated that a more restrictive limit could result in an increase in individuals choosing not to declare their pregnancy, in order to ensure their continued employment. This issue was raised specifically in the medical context, where it was stated that medical students, residents, etc. would not want to have any impacts on achieving their degree and requirements. Some stakeholders went so far as to suggest that the requirements could result in an inappropriate bias in the selection of female applicants. Statements were also made that there could be an increase in non-compliance, with individuals choosing not to wear proper dosimetry, etc.

The ICRP notes that changes in a declared pregnant woman's radiation work responsibilities carries with it an ethical consideration in that another worker will have to incur additional radiation exposure because a co-worker became pregnant[27].

Q3–2: *Are there any benefits or impacts associated with applying the reduced dose limit over the entire gestation period, or only to the period after declaration?*

[26] NRC SECY-12-0064, "Recommendations for Policy and Technical Direction to Revise Radiation Protection Regulations and Guidance" (April 25, 2012).
[27] ICRP (2000). International Commission on Radiological Protection. Pregnancy and Medical Radiation, ICRP Publication 84, Ann. ICRP 30(1) (Elsevier, New York).

A3–2: Based on experience since 1991, the ACMUI recommends that no change be made to the current 10 CFR 20.1208(a) requirement to ensure the dose limit is applied to the entire pregnancy.

Q3–3: *Are there any anticipated implementation impacts on recordkeeping if the dose limit to the embryo/fetus is lowered to 1 mSv (100 mrem)? What are the potential implementation and operational costs?*

A3–3: NRC requires each licensee to use individual monitoring devices for adults likely to exceed 10% of their occupational total effective dose equivalent (TEDE), and for minors and declared pregnant women likely to exceed 1 mSv (100 mrem) TEDE. The requirement for a licensee to consider prior occupational exposure would be extremely difficult to demonstrate a reduced embryo/fetus dose limit for a worker who was not required to be assigned an individual monitoring device.

Q3–4: *Are there technological implementation issues, such as limits of detection, which would make adoption of the ICRP Publication 103 (2007) recommendation difficult in certain circumstances?*

A3–4: While the limit of detection for individual monitoring devices designed to measure deep effective dose equivalent (EDE) has improved in the past few decades, the levels being measured are of the order of daily background radiation levels and thus are more susceptible to inaccuracies introduced from varying background doses subtracted from the individual monitoring devices.

Reduction of the embryo/fetus dose limit would likely require a licensee to transition from relying only on the EDE measurement from individual monitoring devices to applying a correction factor to account for dose to the embryo/fetus based on a monitoring device attached at the pregnant woman's waist. ICRP states that its recommended dose limit applies to the fetal dose and it is not directly comparable to the dose measured on a personal dosimeter but can overestimate the fetal dose by a factor of 25 for nuclear medicine workers[28].

Q3–5: *Are there data on actual dose distributions to the embryo/fetus of a declared pregnant worker? What are the trends for these data?*

A3–5: The ACMUI does not know of a source of data other than that gathered by vendors providing individual monitoring devices. Based on our collective anecdotal knowledge, EDE measurements from individual monitoring devices assigned to declared pregnant women remain well below 5 mSv (500 mrem) over the gestation period.

[28] ICRP (2000). International Commission on Radiological Protection. Pregnancy and Medical Radiation, ICRP Publication 84, Ann. ICRP 30(1) (Elsevier, New York).

Issue Paper 4
Individual Protection – ALARA Planning

Comments

The current Part 20 requires ALARA but does not provide specific ALARA planning and implementation requirements and so allows licensees to design ALARA requirements that are appropriate to their enterprise. The best methodology would be to maintain the status quo and not impose any further prescriptive requirements. Defining what may be "reasonably achievable" is an inherently subjective process. The risks and safety cultures of different industries and different licensees within the same industry differ so much that providing the same compliance-based requirements on all licensees will not be effective. Furthermore, if the NRC does decide to impose prescriptive ALARA requirements on its own licensees, there should be greater flexibility provided to the Agreement States in promulgating their own regulations to keeping occupational doses ALARA. For this reason, any proposed ALARA should be Compatibility C.

Specific Answers

Q4–1: *What are the potential implications of adding specific ALARA planning and implementation requirements to the 10 CFR part 20 regulations? What changes to licensee radiation protection programs could be anticipated? What would be the potential implementation and operational costs?*

A4–1: No additional specific ALARA planning and implementation is needed for the overwhelming number, if not all, of the medical users of radioactive materials. These licensees rarely experience situations where workers' doses approach regulatory limits. Many of them already utilize administrative control levels (ACLs) to maintain doses ALARA. There are engineers who perform maintenance on commercial PET cyclotrons who routinely receive doses to the whole body and extremities that approach annual regulatory limits. However, it is not necessary to add specific ALARA planning and implementation requirements to the 10 CFR part 20 regulations. Safety cultures differ from licensee to licensee and there should be flexibility provided for the implementation of ALARA at each facility

There are classes of users of machine-produced radiation that may benefit from specific ALARA planning and implementation but they are state-regulated, rather than NRC-regulated.

Q4–2: *What regulatory language should be used for an additional ALARA planning requirement and what is the rationale for this language?*

A4–2: Safety cultures differ among licensees and there should be flexibility provided for the implementation of ALARA at each facility. It is important that licensee's ALARA programs be designed to be effective for each licensee and for each group of workers there. Specific ALARA planning requirements would simply add an additional regulatory burden without improving the implementation of the licensee's ALARA program.

Q4–3: *How does each of the described methodologies for addressing when an individual occupational worker approaches his or her cumulative dose for the year work for different classes of licensed uses (e.g., a worker at a nuclear reactor power plant versus an industrial radiographer versus medical personnel)? What are the benefits and impacts of the various approaches to ALARA planning on the various types of licenses?*

A4–2: It is very rare that medical personnel using radioactive materials approach a dose limit. There is no need for additional approaches to ALARA planning for these types of licenses, therefore. There are cases at commercial PET cyclotrons where the engineers do receive whole body and extremity doses that can approach regulatory limits. However, even for these cases, the best approach is to retain the current Part 20 ALARA requirement and leave it to the licensee to develop ALARA procedures that are consistent with its own specific safety culture.

Q4–4: *Should licensees be allowed to establish different ACLs for different groups of occupational workers? If so, what should be the basis for the various groupings?*

A4–4: Licensees should be allowed to establish different ACLs for different groups of occupational workers. The basis should be a review of the historical doses for these groups and a consideration of what is "reasonably achievable". The safety culture at each institution should form the basis for determining the appropriate ACL for each group.

Q4–5: *How do the different methodologies previously discussed impact the ability of licensees to best address radiation protection within their programs?*

A4–5: The current Part 20 requires ALARA but does not provide specific ALARA planning and implementation requirements and so allows licensees to design ALARA requirements that are appropriate to their business. The best methodology would be to maintain the status quo and not impose any additional prescriptive requirements.

Q4–6: *Other than the methodologies discussed in the preceding section, are there other ways to evaluate occupational lifetime cumulative exposures that should be considered?*

A4–6: Since the Commission has decided not to impose a lifetime limit for occupational exposure, there seems to be no good reason for establishing ALARA limits for workers whose lifetime exposure is approaching some arbitrary guideline.

Q4–7: *What are the potential impacts to licensees, contractors, and dosimetry vendors of amending 10 CFR 20.2104 to require a licensee to account for exposure from an occupational worker's concurrent employment with another licensee? Are there any dosimetry vendors that provide concurrent dose records? Should the NRC consider provisions that would require*

individual occupational workers to provide their occupational dose information in addition to requiring such information from licensees?

A4–7: The current 10 CFR Part 20 already has sufficient requirements for a licensee to determine the exposure form an occupational worker's concurrent employment with multiple licensees. It is the responsibility of licensees to work with their employees and the dosimetry vendors to facilitate their compliance with the requirements listed below.

10 CFR 20.1201(f) requires that a "licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person".

10 CFR 20.2104(a) requires that, "for each individual who is likely to receive an annual occupational dose requiring monitoring under § 20.1502, the licensee shall determine the occupational radiation dose received during the current year".

10 CFR 20.2104(c) states that "in complying with the requirements of paragraphs (a) or (b) of this section, a licensee may—

(1) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year;

(2) Accept, as the record of cumulative radiation dose, an up-to-date NRC Form 4, or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee); and

(3) Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee) by telephone, telegram, electronic media, or letter. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established".

Issue Paper 5
Metrication – Units of Radiation Exposure and Dose

Comments

The SRM-SECY-12-0064 states that the regulations should maintain both traditional units and the International System of Units (SI).

To those who support a complete transition to SI units this can be seen as a regulatory constraint. The United States will unfortunately continue to use dual units while the rest of the world continues to use only SI units. The resistance to conversion within the US can perhaps best be defused by this statement in the Health Physics Society (HPS) Position Statement: Exclusive Use of SI Units to Express Radiological Quantities. (Adopted February 2012)

> "Nearly all countries in the world, many with well-established nuclear industries, have effected this transition successfully, without compromising health and safety, and have demonstrated that complete conversion to current international units is certainly practical and doable."

Even within the Commissioners SECY-12-0064 they state within section 7) Units of Radiation Exposure and Dose:

> "The same public communication and emergency response communication issue remain as they were in 1995. These issues were highlighted during the response to the Fukushima event, where there was confusion resulting from the use of different units."

This statement appears to be in conflict with the very essence of the NRC, as stated on the "About NRC" web page;

> "…to ensure the safe use of radioactive materials for beneficial civilian purposes while protecting people and the environment."

Confusion from different units during an emergency is contrary to the NRC's mission, especially when their use is avoidable. This would seem to be an unassailable reason as to why the NRC should convert. The SRM-SECY-12-0064 regulatory "constraint" is in place; that is 10 CFR Part 20 already contains both units. The following answers to the three questions will be answered within the following context. The use of both units will be used consistently throughout the regulations (with emphasis on the SI unit) as a means to effect the transition to the sole use of SI units in the future.

Specific Answers

Q5–1: *Will promulgation of amendments to the 10 CFR part 20 regulations with dose limits and other measurements shown in dual units, with the SI units shown first, followed by the traditional units in parentheses, cause an undue burden or hardship upon any licensee or class of licensees? If so, please explain and provide examples, including any potential implementation or operational costs.*

A5–1: To paraphrase the HPS statement above, there are no real burdens or hardships as everyone else outside of the US has already accomplished the transition to SI units. Consider the Chinese, not only did they complete the conversion but they also did it across two different alphabets, having converted SI units from the Latin alphabet to their Pure logographic alphabet.

SI in Chinese:
Bq = 放射性活度

Q5–2: *Should 10 CFR 20.2101(a) be revised to allow licensees the option of providing records in SI units or in traditional units? Should licensees be allowed to provide reports in the units used in licensee records? Should licensees be required to record and report in both sets of units? Please provide reasons why or why not.*

A5–2: 10 CFR 20.2101(a) should be revised so licensees always provide records in SI units, if desired they may also report in traditional units in parentheses. They should do the same when they provide reports, i.e., SI units first, if desired traditional units second and in parentheses. They may use both sets of units but it should not be required. Again what would be required is the use of SI units and if desired, traditional units in parentheses.

According to the Department of Transportation, currently within the U.S. over four million radioactive material packages and their related records are already prepared and shipped each year in this manner. Again, there is no real burden or hardship. Revising the regulations in this manner would be consistent with and facilitate the transition to SI units in the future.

Q5–3: *Should the NRC amend the appendices for 10 CFR Part 20 to show values in SI units only, in traditional units only, or in both sets of units? If both SI and traditional units are provided, which set of units should be considered as the regulatory standard? If only one set of units is specified, what would be the most effective means to provide the other set of units (e.g., in a separate guidance publication)? Please provide reasons why or why not.*

A5–3: To be consistent with SRM-SECY-12-0064 the appendices should be amended to show values in both units, with the SI unit considered as the regulatory standard.

Values in both sets of units could be easily displayed, especially in the electronic version of the regulation. While a printed version of the appendices with both set of units would be cumbersome, the real effect would be negligible, as the NRC web site has already demonstrated the advantages of the electronic version of the appendices. The electronic version of the appendices allows the regulatory information to be readily available, and in a form easier to find and far easier to read than the printed version. In addition it has already found a solution for the metrication conversion by listing the SI value with three significant digits, as it did with appendix A to 10 CFR Part 37. Additional reliance on the electronic version of the regulations is consistent with the Government Printing Office's own efforts to strive to keep all informed in the digital age.

The NRC has already taken a major step in the metrication conversion with the appendices. The last time they were revised the concentration values in traditional/traditional units, e.g., mCi/firkins* were converted to a hybrid of traditional and SI units, mCi/mL. Complete conversion to SI/SI units is the next logical step.

* The old traditional unit for volume used in the appendices is not known. A firkin which is a unit of volume was chosen as an example of an out-dated traditional unit.

Issue Paper 6
Reporting of Occupational Exposure

Comments

The ACMUI does not believe there is need to expand the number of license categories required to submit annual occupational exposure reports to the NRC because of the low average occupational doses associated with medical-use licensees and licensees which support them. One license category which may be considered for inclusion for annual occupational exposure reporting would be cyclotron production licensees producing and using fluorine-18 in quantities exceeding 100 curies.

The ACMUI does not believe that NRC should act as the nation's repository of occupational radiation exposure data, as the NRC does not have regulatory authority over all occupational radiation sources. While it would be helpful to gather all occupational radiation exposure data for all material licensees meeting the current 10 CFR 20.2206(a) criteria, the ACMUI cannot provide a specific recommendation as we do not know enough about the resources needed for Agreement States to gather these data nor the NRC's regulatory authority to require Agreement State material licensees to submit annual occupational exposure reports directly to the NRC.

Specific Answers

Q6–1: *What criteria should the NRC use to identify additional categories of licensees that should be required to submit annual occupational exposure reports under 10 CFR 20.2206(a)?*

A6–1: The NRC states in the 2012 occupational radiation exposure report[29] that the principal uses of these data "…are to provide facts regarding routine occupational exposures to radiation and radioactive material that occur in connection with certain NRC-licensed activities." In addition, the NRC staff uses the data for the following purposes:

- Evaluation of licensee's radiation protection and as low as reasonably achievable (ALARA) efforts.
- Assist in evaluation of radiological risk and comparative analyses of radiation protection performance between license categories.
- Use as one metric by NRC Reactor Oversight Program to evaluate ALARA program effectiveness and for inspection planning purposes.
- Evaluate radiation exposure to transient individuals.
- Use for establishing priorities for NRC health physics resources.
- Provide facts for answering Congressional and administration inquiries and for answering public questions.
- Provide information that may be used to conduct epidemiologic studies.

[29] NUREG-0713, Vol. 34; http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0713/v34/

- Use in evaluating NRC radiation protection standards with respect to adopting the new ICRP 103 recommendations[30].

The NRC is able to address all of the foregoing purposes for those licensee categories which NRC is the sole radiation safety regulatory authority (e.g., reactors, fuel cycle facilities, and radioactive waste disposal facilities). These licensee categories are already required to submit annual occupational exposure reports under 10 CFR 20.2206(a). However, NRC is not able to address all of these purposes for all material licensees, including medical and medically-related licensees, as noted in NUREG-0713, Vol. 34, Section 2 "Limitations of the Data"[31]. The term, "medically-related licensees," used here refers to any material licensee providing radiopharmaceuticals, radiochemicals, radiation sources, and radiation services that medical licensees may use. The inclusion of additional categories of licensees required to submit annual occupational exposure reports to NRC is problematic as described in the answers below.

Q6–2: *What are the benefits of collecting occupational exposure information in one central database to assess the total annual occupational exposure of those individuals who work at more than one licensed facility or contractor facility during the calendar year and receive occupational exposures at these facilities?*

A6–2: The NRC requires licensees to determine for each individual who is likely to receive an annual occupational dose requiring monitoring [10 CFR 20.1502] that individual's occupational radiation dose received during the current year [10 CFR 20.2104] to document compliance with the NRC occupational dose limits [10 CFR 20 Subpart C]. The NRC may benefit from collecting annual occupational exposure information from more material licensees, including medical and medically-related licensees, in its evaluation of radiation exposure for transient workers, and perhaps in its evaluation of Agreement States radiation control programs. But as NRC states in NUREG-0713, Vol. 34[31], Section 2, "The average dose per individual, as well as the dose distributions shown for groups of licensees, also can be affected by the multiple reporting of individuals who were monitored by two or more licensees during the year."

The NRC defines occupational dose as [10 CRF 20.1003]:

> *"Occupational dose* means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, from voluntary participation in medical research programs, or as a member of the public."

Some material licensees, such as medical and medically-related licensees, will have individuals whose occupational exposure includes exposure to unlicensed sources of radiation (e.g., x-ray

[30] 2007 Recommendations of the International Commission on Radiological Protection". Annals of the ICRP. ICRP publication 103 37 (2-4), 2007.
[31] NUREG-0713, Vol. 34; http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0713/v34/

machines, accelerators, non-byproduct materials nor regulated by the NRC, etc.). If the purpose of a central database is to assess total annual occupational exposures for radiation workers, the NRC's limited regulatory authority would not make it the ideal federal entity to manage such a central database.

Q6–3: *Should Agreement States be required to adopt regulations that are compatible with the requirements in 10 CFR 20.2206?*

A6–3: No. This question really comes back to whether NRC should manage a central database collecting occupational exposure data. As noted in the NRC's Issue Paper 6, "Reporting of Occupational Exposure" (http://pbadupws.nrc.gov/docs/ML1408/ML14084A344.pdf), "More than seven times as many radioactive material licensees are regulated by Agreement States than those regulated by the NRC." The NRC and Agreement States regulatory authority comes from the Atomic Energy Act (AEA) of 1954, as Amended (http://pbadupws.nrc.gov/docs/ML1327/ML13274A489.pdf#page=23). The Occupational Safety & Health Administration (OSHA) and each State are regulatory authorities for occupational exposure to non-AEA radiation sources. The split of these regulatory authorities are summarized in this table. There are additional Federal and State entities that may not fall under these regulatory authorities in regard to occupational exposure to radiation.

Regulatory Authority for Occupational Exposure to Radiation

Regulator	Reactors/Fuel Cycle/Radioactive Waste Disposal	Radioactive Materials under AEA[1]	Radiation-Producing Machines/Non-AEA Radioactive Materials
Nuclear Regulatory Commission (NRC)	100 %	12.5 %	0 %
State[2]	0 %	87.5 %[3]	100 %[5]
Occupational Safety & Health Administration (OSHA)	0 %	0 %[4]	100 %[5]

[1] Atomic Energy Act of 1954, as Amended
[2] State can be one of the 50 States or a U.S. Territory
[3] State is required to be one of the 37 Agreement States
[4] As per OSHA regulation 29 CFR 1910.1096(p) and per Memorandum of Understanding between NRC and OSHA (http://pbadupws.nrc.gov/docs/ML1135/ML11354A432.pdf)
[5] As per OSHA Instruction STD 01-04-001 (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=1771)
NOTE: The NRC and OSHA do not have regulatory authority over certain other Federal and State entities.

Given the current split of regulatory authority, any consideration of establishing a central database for occupational exposure to radiation should address this split before requiring Agreement States to adopt regulations that are compatible with the requirements in 10 CFR 20.2206.

Q6–4: *Should the NRC consider a gradual expansion of the 10 CFR 20.2206 licensee reporting categories in a step-wise fashion (e.g., staggered compliance dates for different categories of licensees)? What are the advantages or disadvantages for this option?*

A6–4: No, as noted in the previous answers.

Q6–5: *What are the potential implementation and operational costs associated with expanding the occupational exposure reporting requirements?*

A6–5: The regulatory authority issue noted in **A6–3** needs to be addressed before investing in expansion of the NRC's occupational exposure reporting requirements. If expansion of this reporting was deemed worthwhile for only AEA-regulated activities, the listing of 99 license categories (41 license categories for medical and medically-related licensees) provides an indicator of the number of licensees potentially impacted.