



DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
2000 NAVY PENTAGON
WASHINGTON, DC 20350-2000

IN REPLY REFER TO

5104
N455A/15U132357
March 11, 2015

Ms. Cardelia Maupin
Office of Nuclear Material Safety and Safeguards
Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Ms. Maupin:

SUBJECT: DOCKET ID NRC-20009-0279; DRAFT 10 CFR PART 20

Ref: (a) 10 CFR Part 20, Standards for Protection Against Radiation
(b) Federal Register, Vol. 52, No. 17, January 27, 1987
(c) Federal Register, Vol. 79, No. 143, July 25, 2014

I am forwarding the Naval Radiation Safety Committee comments on the subject CFR revision. The comments are as follows:

a. Update 10 CFR Part 20 to Align with ICRP Publication 103 Methodology and Terminology: Reference (a) is primarily based on the 1977 recommendations of the ICRP (Publication 26 and associated reports). ICRP updated methodologies for dose assessment in 1991 (ICRP Publication 60 and associated reports) and again in 2007 (Publication 103). Additionally, some radiation dose terminology is different between reference (a) and the more recent ICRP publications.

b. (Q1-2) The NRC asked what time period should be considered for adoption of ICRP Publication 103 dose assessment terminology and methodology.

c. Navy Comments: Reference (b), commonly referred to as the 1987 Presidential Guidance to Federal Agencies for Occupational Radiation Exposure, should be updated prior to incorporating any updated ICRP recommendations in regulations. Reference (b) is intended to ensure alignment among Federal agencies on the regulation of radiation exposure, including dose assessment terminology and methodology. A special subcommittee of the Interagency Steering Committee on Radiation Standards (ISCORS) was tasked in 2013 to update reference (b). The ISCORS effort to update reference (b) should be completed prior to updating reference (a) to ensure consistency in regulation across the Federal radiation protection community.

10 CFR 20 should be aligned with the ICRP Publication 60 methodologies and terminologies prior to considering alignment with ICRP Publication 103. While the ICRP Publication 60 recommendations are complete and in widespread usage by radiation protection organizations around the world, ICRP has yet to issue updated dose coefficients based on the ICRP Publication 103 recommendations. Therefore, it is premature to incorporate the ICRP Publication 103 recommendations into radiation protection regulations. The Navy is already working to incorporate the ICRP Publication 60 recommendations into Navy radiation protection requirements.

a. Occupational Dose Limit for the Lens of the Eye: In Publication 118, the ICRP recommended reducing the limit on equivalent dose to the lens of the eye to 2 rem per year averaged over 5 consecutive years, not to exceed 5 rem in any one year. The current reference (a) and Navy limits for dose to the lens of the eye are 15 rem per year. In reference (c), NRC stated that consideration of lowering the exposure limit for the lens of the eye to 5 rem per year is appropriate.

(1) (Q2-1) The NRC asked if closer alignment with or adoption of ICRP Publication 118 recommendations regarding dose limits for the lens of the eye is appropriate.

b. Navy Comments: Reference (b) should be updated prior to incorporating any updated ICRP recommendations in regulations. Reference (b) is intended to ensure alignment among Federal agencies on the regulation of radiation exposure, including radiation exposure limits. A special subcommittee of ISCORS was tasked in 2013 to update reference (b). The ISCORS effort to update reference (b) should be completed prior to updating reference (a) to ensure consistency in regulation across the Federal radiation protection community.

Further study is required prior to considering lowering the annual dose limit for the lens of eye to align with the 2012 recommendations of the ICRP. As discussed in ICRP Publication 118, the scientific basis for establishing if a threshold dose exists for cataract formation is uncertain and internally inconsistent. The studies of radiocataractogenesis do not use a consistent definition of a cataract nor is the biological mechanism of radiocataractogenesis well understood. Additionally, few studies of radiocataractogenesis in radiation

workers were evaluated. Further, the ICRP, on page 302 of Publication 118, concludes that radiation induction of cataracts is a deterministic tissue reaction, so minimization of radiocataractogenesis using the ICRP's stochastic dose limit is technically inconsistent.

a. NRC should commission a health study of workers occupationally chronically exposed to ionizing radiation to determine if any elevated risk of radiation-induced cataracts exists at current radiation exposure limits and to identify a reasonable estimate of a threshold dose for cataract formation, if any exists.

(1) (Q2-2) The NRC asked how radiation-induced cataracts should be viewed in comparison with other potential radiation health effects.

b. Navy Comment: All radiation-induced health effects are significant given the potentially life-altering consequences to the worker. However, NRC should give due consideration, when evaluating the technical basis for any change to radiation exposure limits for the lens of the eye, to the fact that many of the studies cited by ICRP as providing justification for a lower threshold dose for radiocataractogenesis include in the definition of cataracts ocular artifacts with no discernible vision impairment and which do not have a clear epidemiological linkage to future vision impairment.

(1) (Q2-3) The NRC asked what mechanisms could be applied to keep the lifetime cumulative exposure to the lens of the eye below the threshold of 0.50 Gy (50 rad).

c. Navy Comment: Establishing mechanisms to maintain cumulative lifetime exposure to the lens of the eye below 0.50 Gy (50 rad) would be inconsistent with the scientific consensus that radiocataractogenesis is a deterministic health effect. No mechanisms are currently required to ensure other deterministically-limited doses are maintained below a cumulative threshold value.

(1) (Q2-4) The NRC asked what methods should be allowed for measurement or assessment of dose to the lens of the eye.

d. Navy Comment: ICRP Publication 103 defines the tissue depth for monitoring of the lens of the eye as 3 mm and states monitoring at the traditional skin and extremities tissue depth of 0.07 mm is adequate for the lens of the eye. Therefore, a dosimeter calibrated and accredited to measure shallow dose at a tissue depth of 0.07 mm is sufficient for monitoring exposure to the lens of the eye. Not specifically monitoring the lens of the eye is technically acceptable when radiation surveys of the work area, taking into account the specific worker position for a task, demonstrate that the difference in radiation exposure between the reference dosimeter location and the lens of the eye will be within the variation criteria of ANSI/HPS N13.41-2011, Criteria for Performing Multiple Dosimetry.

e. Dose Limit for Embryo/Fetus of a Declared Pregnant Occupational Worker: Reference (a) requires licensees to ensure occupational radiation exposure to the embryo/fetus of a declared pregnant worker does not exceed 500 mrem during the entire pregnancy. ICRP Publication 103 recommends a dose limit of 100 mrem for declared pregnant radiation workers, the same as the ICRP's recommended annual dose limit for an unmonitored member of the public.

(1) (Q3-1) NRC asked if there are any significant impacts associated with reducing the dose limit to the embryo/fetus of a declared pregnant woman from 500 mrem to 100 mrem, as recommended in ICRP Publication 103.

f. Navy Comments: Reference (b) should be updated prior to incorporating any updated ICRP recommendations in regulations. Reference (b) is intended to ensure alignment among Federal agencies on the regulation of radiation exposure, including radiation exposure limits for the embryo/fetus. A special subcommittee of ISCORS was tasked in 2013 to update reference (b). The ISCORS effort to update reference (b) should be completed prior to updating reference (a) to ensure consistency in regulation across the Federal radiation protection community.

ICRP Publications 84 and 103 do not identify any increase in risk to the embryo/fetus due to radiation exposure when compared to past reviews of available scientific data and are consistent in stating that in utero radiation exposure risks are similar to

early childhood radiation exposure risks (approximately three times higher than the population as a whole). Additionally, although NRC states in reference (c) that National Council on Radiation Protection and Measurements (NCRP) Report 174 also recommends a 100 mrem limit for declared pregnant females, NCRP Report 174 does not recommend a reduced exposure limit and instead reaffirms the NCRP Report 116 recommendation of a 50 mrem per month limit (effectively a 500 mrem limit for the period of gestation). Further, the NCRP states in Report 174 that deterministic health effects to the embryo/fetus have not been identified at doses less than 10 rem and the evidence for stochastic health effects (i.e., elevated rates of cancer in offspring exposed in utero) is unclear, with some studies indicating risks are lower for the embryo/fetus than for children.

a. (Q3-2) NRC asked if there are benefits or impacts associated with applying the reduced dose limit to the embryo/fetus over the entire gestation period or only to the period after declaration.

b. Navy Comment: The ICRP is clear in Publication 103 that the recommended 100 mrem dose limit to the embryo/fetus only applies to the period after declaration and that normal occupational radiation protection standards are sufficient to protect the embryo/fetus prior to declaration. It would be very difficult to apply the 100 mrem dose limit to the entire period of gestation as it is easy for a radiation worker in the normal course of their duties to exceed 100 mrem in the period between when a radiation worker becomes pregnant and the worker declares the pregnancy to the organization. Applying the reduced dose limit to the entire pregnancy may require unnecessarily restricting the duties of female radiation workers of child-bearing age, particularly if there is no allowance for exceeding the limit prior to the worker's declaration. Additionally, if the current requirement in reference (a), section 1208(b), to maintain exposure to the embryo/fetus as uniform as possible is maintained, licensees may be required to implement exposure control levels for declared pregnant radiation workers of 10 mrem per month, which would significantly increase the difficulty of managing exposure to declared pregnant workers during normal assigned duties.

(1) (Q3-5) NRC asked for data on actual dose distributions to the embryo/fetus of a declared pregnant worker.

c. Navy Discussion: The Naval Nuclear Propulsion Program (NNPP) has had 7 declared pregnant workers at nuclear shipyards receive radiation exposures greater than 100 mrem since 2000 (approximately 1 percent of all declared pregnant workers over that time period), with the highest dose being 191 mrem. In all but 1 instance in which the embryo/fetus was assigned a dose greater than 100 mrem, all of the exposure was received prior to the worker declaring the pregnancy; in the other case, the embryo/fetus received 175 mrem prior to the worker's declaration and an additional 1 mrem of exposure after declaration. Since 2000, 23 percent of declared pregnant workers were not required to be monitored for radiation exposure during pregnancy, 38 percent were monitored and received no measurable dose, and 37 percent received measurable doses less than 100 mrem during the term of the pregnancy.

For additional perspective, since 2000, only 1 declared pregnant worker (less than 1 percent of all declared pregnant workers over that time period) at a NNPP Department of Energy site has received more than 100 mrem during the term of the pregnancy, with the total dose being 122 mrem. The worker received 101 mrem during the pregnancy prior to declaration. 24 percent of declared pregnant workers were not required to be monitored during the period of pregnancy and 43 percent were monitored but received no measurable exposure. The remainder all received doses less than 50 mrem.

a. Individual Protection - As Low As Reasonably Achievable Exposure Planning: The Navy has no comments on the questions posed by NRC in reference (c) on ALARA exposure planning.

b. Metrication - Units of Radiation Exposure and Dose: The Navy has no comments on implementation of metric units in reference (a).

c. Reporting of Occupational Exposure: The Navy has no comments on the questions posed by NRC in reference (c) for reporting of occupational radiation exposures.

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Thank you for the opportunity to comment and we look forward to discussing them with your staff or in an open forum. If you have any questions, please contact me at (703) 695-5259 or Dr. Lino Fragoso at (703) 695-5272.

Sincerely,

A handwritten signature in black ink, appearing to read 'DLMA', with a long horizontal stroke extending to the right.

D. W. FLETCHER, Ph.D.
Commander, MSC, U.S. Navy
Executive Secretary
Naval Radiation Safety
Committee

Copy to: Region II