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A merged organization of the American College of Nuclear Physicians and the American College of Nuclear Medicine.

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U.S. Nuclear Regulatory Commission
Dale E. Klein, Commissioner
Washington, DC 20555-0001

Re: Solicitation for Public Comment on Potential Changes to the Agency's Radiation Protection Regulations (Federal Register, Volume 74, Number 128, July 7, 2009)

Dear Dr. Klein:

The Society of Nuclear Medicine[1] (SNM) and the American College of Nuclear Medicine[2] (ACNM), wish to voice their opposition to the Nuclear Regulatory Commission's proposal to limit radiation worker annual doses to 20 mSv (2 rem).

We are generally opposed to the proposal because there is no clear scientific basis for a reduction in permissible worker radiation absorbed doses. The available radiobiology literature varies in the interpretation of the effects of low dose radiation and new investigations are challenging traditional theories. Under the current 50 mSv (5 rem) plus ALARA system, doses to radiation workers in medicine are being well controlled and on average are only a small fraction of the regulatory dose limit. While it appears that a change from a 50 mSv (5 rem) to a 20 mSv (2 rem) dose limitation system would affect only a relatively small portion of the medical radiation worker population, there is nevertheless a real possibility that this change will cause increased costs to patients and third party payers and, potentially, a decrease in the quality and availability of medical care. We find no basis for the implied claim that such increases in costs would result in any clear benefit to workers. For these reasons, we oppose a change in the current 50 mSv (5 rem) plus ALARA radiation dose limit to radiation workers. There is a very strong current societal emphasis on controlling medical costs**.** Reducing dose limits in a way that may increase costs and possibly decrease medical quality, without any demonstrable benefit to workers, is not reasonable at this time.

[1] SNM is an international scientific and professional organization founded in 1954 to promote the science, technology and practical application of nuclear medicine. Representing16,000 members including physicians, technologists and scientists specializing in the research and practice of nuclear medicine.
[2] The new American College of Nuclear Medicine (ACNM), a combined organization of the American College of Nuclear Physicians and the American College of Nuclear Medicine; officially formed on September 1, 2009. Both colleges brought over thirty years of service to its respective members. The College comprised of physicians and other nuclear medicine professionals dedicated to enhancing the practice of nuclear medicine through the study, education and improvement of clinical practice.

Our opinion is based on the following points, which are all relevant to the Society of Nuclear Medicine (SNM), American College of Nuclear Medicine (ACNM):

1. The conceptual basis for lowering the annual occupational dose limit, or the need for additional dose constraints, below 50 mSv (5 rem) is a matter of debate among fair minded members of the scientific community. While it is clear that among members of certain groups exposed to radiation, most notably the survivors of the Japanese atomic bomb attacks, increased levels of dose result in increased incidence of cancer above the naturally occurring baseline, it is unclear how to apply this result to low levels of dose and dose rate (as occur in diagnostic medical procedures and routine radiation worker doses).

    a. The original control group, above which functional responses were developed for the cohorts of increasing dose, included persons who received doses between zero and 100 mSv (10 rem).

    b. The dose rate at which the doses were received by the bomb survivors that resulted in increased cancer risks was very high. An attempt to correct for this in extrapolating effects from these populations to the low doses received at low dose rates in diagnostic medical procedures and routine radiation worker exposures involves the use of a "Dose and Dose Rate Effectiveness Factor" (DDREF), whose value has varied in different publications, and is currently recommended by the National Academy of Sciences (NAS)[1] to be 1.5, a factor which contains considerable inherent uncertainty.

    c. More cancers in the Japanese survivor population were observed and reported between the reports of the Biological Effects of Ionizing Radiation (BEIR) III (1980)[2] and BEIR V (1990)[3] Committees. This was interpreted by the NAS and the International Commission on Radiological Protection (ICRP)[4] to suggest a change in the slope of the line relating radiation exposure to excess cancer risk. On the other hand, the same data set led the French Academy of the Sciences[5] to express "doubts on the validity of using the Linear, No Threshold (LNT) hypothesis for evaluating the carcinogenic risk of low doses (< 100 mSv) and even more so for very low doses (< 10 mSv). The LNT concept can be a useful pragmatic tool for assessing rules in radioprotection for doses above 10 mSv; however since it is not based on biological concepts of our current knowledge, it should not be used without precaution for assessing by extrapolation the risks associated with low and even more so, with very low doses (< 10 mSv), especially for benefit-risk assessments imposed on radiologists. Considering the same body of data the Health Physics Society[6] has stated that "There is substantial and convincing scientific evidence for health risks at high dose. Below [100 mSv] 10 rem … risks of health effects are either too small to be observed or are non-existent." All of these organizations may be reasonably described as "fair minded" in the discussion of these issues, and there are clear differences of opinion on how to interpret the same set of results in their application to the low dose range.

d. Current radiobiological research is uncovering new information related to radiation effects which is relevant to the interpretations discussed here, but which is difficult to interpret. Clear and reproducible data show effects known as "hormesis"[7] in certain systems and experimental conditions (low levels of radiation may have some beneficial effects, possibly through stimulus of radiation repair mechanisms, e.g., "adaptive response"[8]), while other experiments clearly and reproducibly show that radiation responses are seen in cells not exposed to radiation ("bystander effects"[9], "genomic instability"[10]). Our understanding of radiation biology is clearly undergoing change, and the outcome of all of this research is not clear.

2. Epidemiologic studies focusing intently on finding radiation effects in the (very large) nuclear medicine patient population for decades after their nuclear medicine studies have found no statistically significant correlations of dose and effect[11,12].

3. In the current radiation protection environment, the annual allowable occupational dose limit of 50 mSv (5 rem), coupled with the use of the regulatory requirement of maintaining doses As Low As Reasonably Achievable (ALARA), have maintained the *de facto* limit considerably below 50 mSv (5 rem). Approximately 30 years ago, in 1980, approximately 1.3 million workers were employed in occupations involving exposure to radiation. On average, a worker received 200 mrem to whole body for this year and half of the workers received no measurable dose at all[13]. We have obtained data from two large medical centers regarding the measured radiation doses for radiation workers in recent years (Appendix). There are very few individuals (~0.3%) with doses above 20 mSv (2 rem). Nuclear medicine physicians and technologists routinely receive radiation doses significantly below 20 mSv (2 rem), and only a few individuals, principally workers in nuclear pharmacies or cyclotrons approach or exceed 20 mSv (2 rem).

4. Overall, the number of persons in the nuclear medicine worker population who will regularly exceed a 20 mSv (2 rem) annual dose limit appears to be small. However, a fair number will exceed 10 mSv (1 rem) or 5 mSv (500 mrem), and assuming that ALARA action levels are lowered with a lowering of the regulatory limit, many more of these workers may unnecessarily become of concern to the radiation safety program staff.

5. Other workers may need to be trained to ensure that accidental overexposures do not occur, and some of these workers, such as radiochemists and nuclear pharmacists, are expensive to train. In radiology and cardiology, the highest doses are routinely received by interventionalists whose subspecialist skills cannot be duplicated by others in the primary specialty. In interventional procedures, experience is essential to optimize quality medical performance. These interventionalists are mostly quite aware of how to minimize radiation dose during their procedures, but they work with complex cases that may require long imaging sessions. Forcing them to further reduce exposures could result in a lower quality of medical care for these patients, either by cutting the procedures prematurely short or by substituting less experienced personnel. Hiring and training more interventionalists would

mean an increase in medical costs. In areas where there are only enough cases to support one such professional, an increase in demand could mean that patients would have to travel to larger cities to get needed care. Many of these cases are emergencies, and distant travel is not a viable option; the patients may simply not get the quality care that they need. Or the dedicated physicians with doses near the new, lower limits may simply choose to cease wearing their monitoring badges out of fear of the regulatory issues complicating their ability to provide care, thus defeating the intent of the regulation.

SNM and ACNM appreciate the opportunity to provide comments on this proposal. Thank you for your attention and consideration.

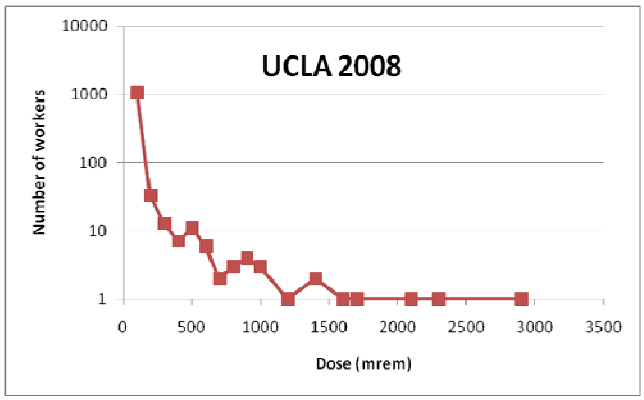
Sincerely,

Michael M. Graham, PhD, MD
President, SNM

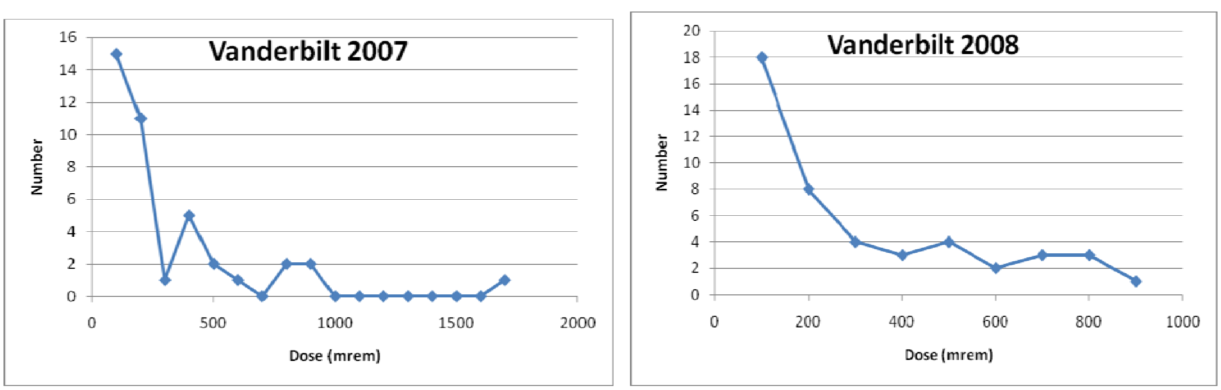
Jay A. Harolds, MD
President, American College of Nuclear Medicine

Appendix

Observed radiation worker exposures at two major medical centers. The plots show the numbers of workers who received doses at or below a given dose level. The data were grouped into bins, in 1 mSv (100 mrem) increments. Each point shows the number of persons who received annual doses equal to or less than that point. The first point is shown at 1 mSv (100 mrem), and represents the number of workers receiving between 0-1 mSv (1-100 mrem). The second point, at 2 mSv (200 mrem), represents the number of workers receiving between 1-2 mSv (100-200 mrem), and so on.



1. Histogram of radiation doses among radiation workers at UCLA Medical Center, Los Angeles California, all medical workers. Note: there are 3 individuals with reported dose above 20 mSv (2 rem) of 1157 workers = 0.3%.



2. Histograms of radiation doses among radiation workers at Vanderbilt Medical Center, Nashville, TN, nuclear medicine and nuclear pharmacy workers. Note: there are no individuals with doses above 20 mSv (2 rem), of ~45 workers.

References

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