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June 22, 2015

Secretary,
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

Rulemaking.Comments@nrc.gov

RE: Docket ID NRC- 2009-0279

Madame Secretary;

We appreciate the opportunity to respond to your request regarding proposed rulemaking impacting current radiation protection regulations. We also applaud your efforts to harmonize radiation protection regulations with current ICRP recommendations and the IAEA Basic Safety Standards used outside of this country.

However we do have some concerns with some of the elements of the proposed rulemaking which we will outline below. The basis for most of the regulatory changes is the theoretical increase in the occurrence of a biological effect, e.g., cancer or cataracts. With the possible exception of ocular exposure, none of the changes are supported by current biological evidence.

Comments on the Rationale for Regulatory Changes

As mentioned in NRC-generated documentation associated with this proposed rulemaking, "Issue Paper 4 – Individual Protection-ALARA Planning", in addition to meeting regulatory limits, NRC requires its licensees to apply ALARA principles in practices using byproduct material. Current limits are based on the risk of a fatal cancer in comparison to the average annual risk of accidental death associated with working in 'safe' industries. This corresponded to an annual mortality risk level of approximately 1 person in 10,000 workers which was roughly correlated to an annual exposure of 10 mSv.

The difficulty in comparing accumulated radiation dose to risk levels in other industries is that radiation dose is used as a surrogate to risk and individuals have varying sensitivities to radiation as well as other physical, environmental and chemical agents. This makes direct comparisons with other industries problematic. The perception of industries considered safe will vary with time and a better understanding of the risks involved with that industry.

Also, as indicated in the document, ICRP 103 recommends using constraints as a starting point for optimization. In ICRP methodology, constraints serve as an upper bound on the annual dose that members of the public could receive and should not be considered as 'limits'. The NRC defines constraints as a value above which specific licensee actions are required.

It appears the use of NUREG-0713, Volume 33, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities: Forty-Fifth Annual Report", is used to justify lower occupational exposure limits. This study only involves the following industries: commercial nuclear power reactors and test reactor facilities; industrial radiographers; fuel processors, fabricators and reprocessors; manufacturing and distribution of byproduct material; independent spent fuel storage installations; facilities for land disposal of low-level waste; and geologic repositories for high-level waste. Medical facilities were not included in this report. The annual effective dose for a US commercial nuclear power plant worker is approximately 1 mSv. The annual effective dose for a typical nuclear medicine technologist working in a busy department will be several times higher than this level. Additionally, the annual effective dose for a physician performing fluoroscopy guided interventions will be many times higher than the average commercial nuclear power plant worker. The greatest amount of occupational exposure in a medical facility occurs with staff exposed to x-rays; even in facilities with good radiation safety awareness and programs.

Recommendation: Based on this assessment, we believe the available data used is inadequate for a regulatory change and recommend that the NRC should work with agreement state programs to determine current exposure patterns in different medical facilities before new occupational exposure limits are promulgated.

Comments on the Reduction of Current Occupational Whole Body Exposure Limits

In medical facilities radiation exposure occurs with the use of byproduct material and x-rays. Individual states regulate x-ray use and are using the current NRC limit to cover all occupationally exposed workers. As already referenced in a letter received by NRC on this topic from the Organization of Agreement States and dated July 31, 2011, "Changing 10 CFR Part 20 to lower the exposure limits for RAM users might result in a dual limitation system in the states ... this would be troublesome and cumbersome."

If a single exposure limit were used for all users of medical radiation, annual dose to interventionalists such as IR physicians, vascular surgeons, neuroradiologists, heart cath physicians and certain GI physicians as well as some allied health staff assisting physicians performing interventional procedures, could exceed the ICRP 103 recommendation of 20 mSv annually. Even though various equipment and administrative controls are in place to reduce patient and staff exposure, the trend of increased interventional procedures in lieu of surgery and the increase in complexity of procedures has caused a general increase in annual dose to these groups. A reduction in the occupational dose limit for medical facilities could result in patients not receiving life-saving care due to interventionalists not being able to practice because they are at or near the annual limit.

Recommendation:

Maintain the current whole body radiation dose limit at 50 mSv per year. There is no biologic evidence to support lowering the dose limit and lowering the limit for healthcare workers may detrimentally impact patient care.

Comments on the Reduction of Current Lens of the Eye Exposure Limits

In the past decade, several scientific papers have been published purporting an increase in cataracts in radiation workers, predominantly post-scapular cataracts. Although most are not case-controlled studies, it appears current limits may not be sufficient. In light of this evidence, Mayo Clinic has instituted a policy that for all employees whose collar badge dosimeter could, or is likely to, exceed 50 mSv, leaded eyewear will be recommended.

Recommendation:

Maintain the current lens of the eye radiation dose limit at 15 mSv per year until the NRC performs a thorough review of the scientific literature and radiation protection community consensus to determine the numerical value of a lower dose limit.

Comments on the Reduction of Embryo/Fetal Limits

The proposed reduction of the embryo/fetal dose limit for a declared pregnant worker from 5 mSv to 1 mSv is not supported by biologic data. Most licensees clearly understand the importance of reducing embryo/fetal exposure and are proactive in their efforts. For example, not allowing pregnant staff to handle or administer therapeutic amounts of radionuclides or working with liquid radioiodines. In addition, large programs with more specialized work areas (e.g., general, cardiac, or PET) may be able to rotate a pregnant technologists into an area with lower exposure risk.

In reviewing the radiation exposures of Mayo Clinic nuclear medicine staff that have become pregnant in the past 15 years, their cumulative gestational period exposures have ranged from 0 mSv to 4 mSv. However, even with our proactive efforts and occasionally reassigning work assignments, 14 pregnant nuclear medicine staff exceeded 1 mSv. Exposure to pregnant nuclear medicine technologists at other institutions without this flexibility could result in an even larger percentage of pregnant staff exceeding 1 mSv during their gestation period.

Most nuclear medicine departments are staffed by females of child-bearing age, removing even one individual from the staff rotation may detrimentally impact patient care and increase health care costs without a concomitant increase in safety.

Recommendations:

Maintain the current embryo/fetal dose limit at 5 mSv during the gestation period. Ensure other practical dose reduction strategies are in place.

Please feel free to contact us should you have any questions.

Sincerely,

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RulemakingComments Resource

From: Sturchio, Glenn M., Ph.D. <Sturchio.Glenn@mayo.edu>
Sent: Monday, June 22, 2015 11:16 AM
To: RulemakingComments Resource
Cc: Nelson, Kevin L., Ph.D.; Sturchio, Glenn M., Ph.D.
Subject: [External_Sender] Comments regarding proposed changes in radiation dose limits - Docket ID NRC-2009-0279
Attachments: NRC Dose Limit Reduction Response June 2015.doc

Good Morning:

Please find attached comments from Mayo Clinic regarding proposed rulemaking on changes to radiation dose limits.

Thank you,
Glenn

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