November 20, 2014

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

Re: Radiation Protection; Advance Notice of Proposed Rulemaking Docket ID NRC-2009-0279

Dear Chairman Macfarlane:

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) appreciates the opportunity to respond to the Commission’s request for comments regarding the possible amendment of regulations related to the medical use of byproduct material. SNMMI’s more than 18,000 members set the standard for molecular imaging and nuclear medicine practice through the creation of clinical guidelines, sharing evidence-based medicine through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy research and practice. SNMMI is pleased to offer comments on specific topics detailed below.

A. 10 CFR Part 20 to Align With ICRP Publication 103 Methodology and Terminology

This issue involves the alignment of the NRC regulations with the methodology and terminology as described in ICRP Publication 103. To date, the NRC has utilized the methodology as described in International Commission on Radiological Protection (ICRP) Report 26 and the definition of effective dose equivalent and total effective dose equivalent (EDE and TEDE) as opposed to effective dose and total effective dose (ED and TED) as described in ICRP Report 103. SNMMI recommends the adoption of the current methodology and terminology associate with ED and TED as this is consistent with current publications in this regard even it may involve some level of effort to implement these changes.

Although it may take some time to consistently implement such a change to “total effective dose” within the field of nuclear medicine, it should be relatively straightforward. In the comparison of various clinical procedures, ED is already the method of choice within the field, and thus practitioners are clearly conversant with the concept. Most of the implementation issues would involve occupational radiation safety such as the modeling of annual limits on intake (ALI) dose exposure to radioactive gas, the estimation biodistribution studies after the administration of therapeutic radiopharmaceuticals (e.g. $^{131}$I) to patients and in the reporting of personnel dose estimates, particularly when it involves a combination of both external and internal exposure. Changing to ED rather than effective dose equivalent (EDE) will involve some modifications of models, but these should be straightforward and should be manageable in a reasonable amount of time.

If the NRC adopts the dose assessment terminology a 2-3 year implementation period is reasonable. Although these modifications should be relatively straightforward, it will be necessary to develop, validate and implement these changes.

Although these calculations of effluent concentration are very important, their impact on nuclear medicine should be minimal. Therefore, SNMMI does not offer an opinion on these matters.
Regarding the public dose limit of 0.5 mSv continue to be the basis for effluent concentrations limits, it is recommended that the current limit be maintained using TED rather than the total effective dose equivalent (TEDE).

B. Occupational Dose Limit for the Lens of the Eye
It is the opinion of this committee that the proposed decrease in occupational dose limit for the lens of the eye should likely be lowered to new standards as proposed by the ICRP publication “ICRP statement on Tissue Reactions in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context.” New information regarding the threshold for cataracts appears to be lower than previously thought and should be acted upon. Despite cataracts being a surgically correctable disease, unlike most other radiation induced morbidities, it is felt that the efforts to reduce such disease can and should be enacted in its prevention.

Current standard radiation protection efforts may not be sufficient to assess the dose to the limits to the eye, and additional efforts may be needed to reveal the most appropriate methods for dose monitoring (additional badges or meters). This may require additional resources and efforts to be enacted by those at the highest risk of exposure, including possible additional personnel dosimetry and monitoring.

It appears that some of the radiation workers at the greatest risk for lens of the eye exposure are already taking precautions to reduce exposure. Many interventional radiation workers (interventional radiology and cardiology) wear leaded glasses as a standard of practice. Methods of detection to the lens of the eye in these populations may require additional modeling to adjust for the dose reduction from such protective equipment, as compared to the non-interventionist who may not be wearing such protective equipment routinely.

There is felt to be a low risk of significant operational impact if the dose to the lens of the eye is lowered to newly proposed levels. There may be some additional cost in radiation monitoring equipment, such as additional badges, as well as in protection equipment. But, it is felt that a majority of the radiation workers with the highest risk to such exposures commonly already have protection equipment, such as protective eyewear, and already incorporate precautions regarding radiation exposure. There is a possibility that a worker who currently approaches dose limits to the eye, may become limited in the volume of fluoroscopy his or her practice. But it is felt that with possible further training and protection measures that this would not be common in a majority of practices. Additional information on what average doses to the lens of the eyes may be needed to be collected to allow for a more informed position.

All state regulatory programs would be expected to follow any changes in the current dose limits to the lens of the eye to the newly proposed limits. Agreement states should be allowed to use more restrictive requirements as is the current practice, as their regulatory agencies deem appropriate.

C. Dose Limit for Embryo/Fetus of a Declared Pregnant Occupational Worker
It is the opinion of this committee that the proposed changes to decrease the dose limit for the embryo/fetus of a declared occupational worker could cause significant impact to both the worker and operational costs. Certainly, many pregnant radiation workers will feel hesitant to declare pregnancy to her employer if there is risk that the worker will be limited in hours able to be worked, which may negatively affect their income during the pregnancy. Operational costs may be increased as additional staff is needed to be hired or work overtime in order to make up for the time limits that may affect the pregnant radiation worker.
It has been shown that certain periods during pregnancy are more likely to be sensitive to ionizing radiation, such as the 10 – 17 week period. It is the opinion of this committee that if changes are made that decrease the allowed dose limit, that efforts should be made to try and reduce the dose limit during the periods that would have the most impact. This however is limited by the workers right to self-declare, which may not happen until after the most radiosensitive time of the pregnancy has passed. Subsequently, if the worker declares after the most sensitive portion of the pregnancy is over, then she may be adding excessive work/dose limits and operational costs that will add no benefit to the remainder of the pregnancy.

Recordkeeping is felt unlikely to be significantly impacted as there are currently already limits in place that must be followed and tracked. However, there may be an issue in the ability and limits of detection of current radiation monitoring equipment to be able to detect such low levels. If this is the case, then newer and more sophisticated monitoring devices may be needed by pregnant workers, which would likely then add more operational cost for the remainder of the pregnancy.

Additional information is needed in the dose distribution of the embryo/fetus. Clearly different radiation workers encounter various sources of radiation exposure, from external sources to possible inhalation of radioactive gases. These different sources of possible exposure would likely each require their own dose distribution calculation methods.

**D. Individual Protection—ALARA Planning**

It is the considered opinion of this committee that the proposed changes to ALARA Planning would result in negligible additional implementation and operational costs as the vast majority of licensees already maintain ALARA programs. Most agreement states already have some sort of ALARA language in their regulations in which case the addition of additional language would simply be a duplication of regulatory efforts. However, in cases where language is needed some adaptation of the following is offered as a starting point. The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA). The licensee shall review the radiation protection program content and implementation at the frequency specified in the license..

With respect to questions of dose methodology for individual occupational classes, we believe that it is in the best interest of the NRC to follow the proposed strategy of aligning with the language found in ICRP 103 (an average dose over a 5-year period of 20 mSv as an alternate concentration limits - ACL). We believe that this accurately communicates the desire to maintain ALARA doses, while still allowing the flexibility for a worker to receive up to 50 mSv in any one year pursuant to their specific occupational requirements. Additionally, we believe it highly advisable to allow occupational flexibility in the establishment ACL because not every group’s dose during regular work will be the same as other groups. For example, if one group received a dose significantly above their normal reported dose, but still below the ACL for all other groups, it could be a missed opportunity for further investigation; without which ALARA principles would not be appropriately applied.

As previously stated, we do not believe that the implementation of any proposed methodology would have a substantial impact on current programs. However, we recognize that as workers in medical and/ or academic settings that our doses are generally much lower than regulatory limits, especially when averaged over many years and that this might not be the case for other occupational categories.
It is our opinion that the NRC should consider provisions that would require individual workers to provide occupational dose information. The impact of such a requirement would result in a justifiable increase in administrative burden. However, given that no other ways to evaluate occupational lifetime cumulative exposures are known at this time, the benefits of keeping accurate records of personnel exposure far outweigh any enhanced administrative burden. Especially since Landauer or similar badge monitoring companies can provide concurrent dose records with the proper releases from the employee.

Finally, we believe that agreement states should be allowed to use more restrictive requirements in accordance with their own regulatory agencies. Failure to allow this casts doubt as to the purpose of being an agreement state.

E. Metrication—Units of Radiation Exposure and Dose
It is the considered opinion of this committee regarding the proposed changes in metrication that a concerted effort should be made to more closely align the units of the regulatory, reporting, and recording standards to those most commonly encountered by the scientific community, SI units. We recognize that a rapid and complete departure from traditional units is not advisable given the current level of unfamiliarity with SI units that may be encountered. We therefore, recommend adopting a policy of a slow transition period of five years during which time values would be published and accepted in both traditional and SI units and thereafter only in SI units. However, for the sake of uniformity the regulatory standard should change immediately to the globally recognized SI unit with clear instructions on forms and reports pertaining to mathematical unit conversion. From our perspective, as scientists and engineers in the US, we are already expected to communicate in SI units when publishing manuscripts in scholarly journals, as is the rest of the world. Therefore this change should not create a hardship and in fact the reverse is expected as the units of communication will be standardized. Additionally, the proposed transition period should allow for a streamlined conversion of metrication units and suitable adjustment period for effected personnel. Furthermore, where appropriate, we believe that the traditional units may be effectively presented as additional columns in tables, as addenda, or as separate guidance publications.

F. Reporting of Occupational Exposure
SNMMI questions the value of reporting of occupational exposures to a central database as this would involve significant additional effort for licensees to comply, introduce a potential loss of privacy on behalf of employees within nuclear medicine while the value of such a collection of data is uncertain. SNMMI does not recommend the reporting of such data, but if necessary would recommend that these reports be limited to certain categories of workers that of particular interest to the NRC.

The value of collecting occupational exposure information in one central database in nuclear medicine is unclear. More in depth knowledge of the duties of each employee would be necessary to be able to interpret any dosimetry evaluation.

Regarding agreement states and whether they should be required to adopt these regulations requiring reporting, SNMMI does not recommend that agreement states be required to comply with such regulations. The NRC may have specific plans on the reporting of these data but it may not meet the needs and subsequent allotment of resources of individual agreement states.

SNMMI does not recommend a gradual expansion of reporting categories, but if necessary would recommend that these reports be initially limited to those categories of workers for which the NRC expects to be informative. If the initial program is determined to be of value, the program then can be expanded.
SNMMI believe that expanding the occupational exposure reporting requirements program would have considerable costs associated with it as it would require additional filing and reporting on behalf of the licensee. It is unclear if the value of such reporting would outweigh the expense.

SNMMI is pleased to provide comments to the NRC on proposed revisions to 10 CFR Part 20. As always, SNMMI is ready to discuss any of its comments with the NRC. In this regard, please contact Susan Bunning, Director, Health Policy and Regulatory Affairs, by email at sbunning@snmmi.org or by phone at 703-326-1182.

Sincerely,

Virginia Pappas, CAE
Chief Executive Officer