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CHAIRMAN

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The Honorable Christopher S. Bond
United States Senate
Washington, D.C. 20510-2603

Dear Senator Bond:

I am responding to your letter dated December 14, 1998, in which you transmitted concerns of constituents and interested parties with the Nuclear Regulatory Commission's (NRC) proposed revision of 10 CFR Part 35, "Medical Uses of Byproduct Material." Of particular concern is "the perception that the NRC continues to propose regulations in areas where there is no statistically significant radiation risk to workers, members of the public, or patients."

As you noted in your letter, on March 20, 1997, the Commission directed the revision and restructuring of Part 35 into a risk-informed and, where appropriate, more performance-based regulation. This direction was part of the Commission's overall decision to decrease oversight of lower-risk activities, such as diagnostic nuclear medicine, while retaining oversight of high-risk activities. This decision was consistent with the Commission's ongoing recognition of the low risks associated with diagnostic nuclear medicine. For example, the current Part 35 does not require reporting of most errors in the delivery of diagnostic nuclear medicine dosages (referred to as misadministrations) because of the relatively low level of radiation risk to the patient.

A "risk-based" approach to regulatory decision-making is one in which a safety decision is solely based on the numerical results of a risk assessment. This places heavier reliance on risk assessment results than currently may be practicable. A "risk-informed" approach to regulatory decision-making represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety. The Commission does not endorse risk-based regulation. In revising Part 35, the Commission is using risk insights from available risk information, considering it in relation to its completeness and reliability, and balancing these insights against other factors such as statutory requirements and stakeholder interests in formulating policy. In July 1998, the Commission approved publication of a proposed revision of Part 35 that focuses the regulations on those medical procedures that pose the highest risk, from a radiation safety standpoint, in keeping with the Commission's previous direction. During development of the specific provisions in the final rule, all of the public comments will be carefully considered to determine if additional improvements should be made to achieve this goal.

Originated by: [DFlack, NMSS]

The following are responses to your specific questions:

1. What information on risk did the Commission consider when it revised the regulations for diagnostic nuclear medicine procedures included in the revision of Part 35?

Prior to initiating the revision of the regulations for diagnostic nuclear medicine, the Commission thoroughly reviewed several extensive assessments, including the external review conducted by the National Academy of Sciences-Institute of Medicine (NAS-IOM), a 1993 NRC internal senior management review, and the Commission's Strategic Assessment and Rebaselining Project. During the development of the overall revision of Part 35, the NRC staff considered information on risk provided by members of the public and professional societies, professional medical standards of practice, and event databases maintained by NRC, to determine where oversight of lower-risk activities could be decreased and where there needed to be continuation, or even broadening, of the regulations governing higher-risk activities. Throughout the development of the proposed rule and associated guidance, public workshops were held and early opportunities for comment from potentially affected parties were provided, which were in addition to the normal notice and comment opportunities provided on published, proposed rulemakings. These interactions included significant discussions on the risk associated with medical uses of byproduct material.

2. Why did the Commission, after having spent $2.5 million, reject the National Academy of Sciences-Institute of Medicine report, which found that for nuclear medicine, the risk and probability of harm occurring to a patient or a member of the public is extraordinary low?

The NAS-IOM study was conducted because NRC sought an evaluation of whether the rules, policies, and procedures of the current regulatory framework for medical uses of byproduct material fulfilled the NRC's statutory responsibilities for public health and safety. The Commission was not persuaded by the NAS-IOM report's overall recommendation to Congress that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. The Commission continues to believe that public health will be best protected by continued NRC oversight over the use of byproduct material in nuclear medicine and radiation therapy.

The Commission's decision to not adopt the recommendations in the NAS-IOM report relative to jurisdictional changes that would be required under the Atomic Energy Act, was based, in part, on public comments received which opposed this aspect of the report. Other State and Federal agencies to which the jurisdiction would have fallen if the NRC adopted the recommendations (e.g., the Department of Health and Human Services, Food and Drug Administration), indicated to the NRC staff that they did not support these provisions. In addition, some of the earlier supporters of the IOM recommendations, reversed their previous positions based on the prospect of working with NRC to review and reduce the burden associated of the medical and materials use regulations. Although the Commission decided not to adopt the NAS-IOM study recommendations, the risk assessment information, including the information on comparative risks of ionizing radiation in medicine, in the report was considered during the rulemaking process. Note should be made that the NAS report concluded that "no

comprehensive raw data are available to make exact comparisons" between risks of medical modalities (pg. 124). In addition, both the NAS report and the NRC's Advisory Committee on the Medical Uses of Isotopes (May 8, 1997, Commission briefing) recognized that quantifying levels of risk in radiation medicine is problematic.

3. How can the Commission claim that the current proposed revision of Part 35 is "risk informed" if the Commission dismissed the NAS-IOM report and recommendations of the National Council on Radiation Protection and Measurements, and the 1993 internal management report? Please provide me with any data that contradicts the NAS-IOM or NCRP conclusions?

In taking a risk-informed (as contrasted with risk-based) approach to formulating the proposed revision of Part 35, The staff carefully considered the risk information in all three of the referenced documents during the process of identifying those procedures that pose the highest risk, from a radiation safety standpoint. This information, along with the information in the NRC's event databases and the input received during the enhanced participatory process, was then used to determine what requirements are necessary to ensure radiation safety during the medical use of byproduct material. Consideration of all of this information resulted in revision or deletion of certain requirements in the lower risk diagnostic area, for example the requirement to measure unit dosages was deleted.

In addition, the proposed rule was made available for a 120-day comment period, which ended on December 16, 1998. All the risk information received in writing during the public comment period, as well as the information received at the three facilitated public meetings held during the public comment period, will be carefully considered and used in making any necessary adjustments to the proposed rule.

During the development of the proposed rule the staff eliminated requirements in the current Part 35 that are contained elsewhere in the Commission's regulations, such as the radiation protection requirements in Part 20. Part 35 licensees will continue to be required to comply with these requirements, such as the ALARA provisions in Part 20, but the staff believes that there is no need to duplicate requirements. Part 20 contains *general* radiation protection requirements applicable to all licensees whereas Part 35 contains *specific* requirements unique to medical use licensees. This licensing approach is consistent with that used for other licensees such as industrial radiography (Part 34), commercial irradiators (Part 36), and well-logging (Part 39). While some may argue that Part 35 should not contain *any* requirements associated with low risk procedures, certain radiation protection-related requirements unique to medical use may be needed in Part 35 because of their contribution to risk reduction. For example, the proposed rule retains requirements to perform quality control tests on instrumentation used to measure the radioactivity of patient dosages prior to administration. Finally, although the NRC no longer collects data on recurring events involving most diagnostic nuclear medicine procedures since the NRC considers them "low risk," certain Part 35 medical use requirements remain necessary to ensure adequate protection of the workers, patients and public.

Information on risk will continue to be an important consideration during development of the specific provisions in the final rule. The Commission has directed that the final rulemaking package include a discussion of risk assessment, including pros and cons. It is the Commission's firm intention that the revised regulations are both needed for the safe use of byproduct material in medicine and do not inhibit the practice of nuclear medicine.

If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

Shirley Ann Jackson

Shirley Ann Jackson