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General Comment

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U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Comments on Security and Continued use of Cesium-137 Chloride Sources

Dear Mr. Lesar:

These comments are in response to the July 31, 2008 Federal Register Notice (NRC-2008-0419) inviting public comments on the issue of security and continued use of Cs-137 Chloride sources commonly used in transfusion medicine and research. As a member of the US Nuclear Regulatory Commission (NRC) Advisory Committee on Medical Use of Isotopes and as Radiation Safety Officer for a large tertiary care medical center, I have given considerable study and thought to this issue and offer the following comments.

1. The irradiation of blood products and research biological materials serve a clear and significant benefit to the public. Irradiation of blood products has advanced medicine and is required for transfusion into any immune compromised patient, for treatment of numerous cancers and for tissue and organ transplants. Irradiation of the blood products transfused into patients is required to prevent graft vs. host disease, a painful and potentially fatal condition that would prevent treatment of many patients if the blood could not be irradiated. Irradiation of biological material in biomedical research is required to compromise the immunity of cells and tissues in the development of new therapies for numerous diseases. Thus, irradiation of blood products and research materials is essential in modern medicine and research.

2. Due to a concern about the potential theft of Cs-137 sources for use in a dirty bomb, the National Research Council of the National Academies recommended that the NRC eliminate the use of irradiators that employ Cs-137 CsCl. In the meantime, NRC has required licensees to implement numerous changes in their operations to improve security of these sources. These changes alone have mitigated many of the concerns about potential theft of the Cs-137 CsCl sources and, in my opinion, have reduced the vulnerability to a negligible level. These changes include:
□□□□□□□□□ Increased security of the facilities housing the irradiators including high security locks on facility doors, intrusion alarms or equivalent, preplanning with local law enforcement, and increased security of facility information related to the irradiators,
□□□□□□□□□ Increased security screening of individuals who are granted access to the irradiators including trustworthiness and reliability determinations, background checks, local criminal records checks, fingerprinting, and FBI criminal records checks,
□□□□□□□□□ Increased administrative controls on escorting service and other personnel who require access to the irradiator facility,
□□□□□□□□□ In the near future increase the hardening of the irradiators to decrease the possibility of someone breaking into the irradiator shield to remove the Cs-137 CsCl sealed source, and
□□□□□□□□□ Future consideration by manufacturers to change the CsCl source to a solidified compound.

3. The Cs-137 CsCl irradiators could be replaced with irradiators that use electronically generated x-rays. One x-ray irradiator has been approved by FDA for irradiation of blood products, and several x-ray irradiators are available for use in research. Currently, several significant issues challenge the feasibility of using x-ray irradiators to replace all Cs-137 irradiators:
□□□□□□□□□ The literature contains conflicting reports about the efficacy of x-ray irradiation vs. irradiation with Cs-137. The primary difference between the x-rays and the gamma rays from Cs-137 is the energy of the radiation. The average x-ray energy is approximately 50 keV while the energy of the Cs-137 gamma rays is

660 keV. This major difference in energies has a significant impact on the way energy is deposited in the blood product. Similar challenges exist for use of x-ray irradiators in research.
□□□□□□□□□ The irradiator approved by FDA for use on blood products costs approximately $220,000. Disposal of the Cs-137 irradiator costs approximately $20,000 to $50,000. These costs present a greatly increased expense to hospitals and blood banks at a time when many are struggling financially due to reimbursement challenges. It is not uncommon for large medical centers to have more than one blood irradiator as well as several research irradiators. The financial impact of eliminating use of Cs-137 irradiators would quite significant.
□□□□□□□□□ Only one x-ray irradiator is currently approved by FDA for irradiation of blood products. Thus the capacity to replace all Cs-137 irradiators used to irradiate blood products even within the next several years is quite limited.
□□□□□□□□□ Cs-137 irradiators are rather trouble free. The most common maintenance problem is related to the drive mechanism that transfers the blood product or research material to the Cs-137 chamber where it is irradiated. Large medical centers have an engineering group that can repair such problems in short order. The Cs-137 source never needs to be changed although irradiation times are twice as long when the unit reaches an age of 30 years. The maintenance of x-ray irradiators is more troublesome and costly and requires replacement of the x-ray tube every few years at a current cost of approximately $10,000.
□□□□□□□□□ Thus, annual maintenance cost of x-ray irradiators is significantly greater than those of Cs-137 irradiators.

In conclusion, Cs-137 CsCl irradiators are used in a number of critical medical and important research applications. Alternatives to these irradiators are expensive, and required replacement would place a significant financial burden on blood banks and hospitals. Subsequent to the concerns expressed in the National Research Council□□□□□□□□□s report on Cs-137 CsCl irradiators, security of irradiators has been enhanced significantly, reducing the vulnerability of the Cs-137 sources to theft. Given the potential and real differences in efficacy, cost of replacement and maintenance costs, and given the mitigation of security concerns of Cs-137 CsCl irradiators, the continued use of Cs-137 CsCl irradiators is justified, and ordering *their replacement would not be in the best interest of the public.*

Thank you for the opportunity to comment.

Sincerely,

Richard J. Vetter, Ph.D. CHP
Radiation Safety Officer

cc: Radiation Safety Committee