



AMERICAN SOCIETY OF HEMATOLOGY

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7/31/08  
93 FR 44780  
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September 26, 2008

Michael Lesar  
Chief, Rulemaking, Directives, and Editing Branch  
Office of Administration,  
Mail Stop T-6D59  
U.S. Nuclear Regulatory Commission,  
Washington, DC 20555-0001

Re: NRC Security and Continued Use of Cesium-137 Chloride Sources Roundtable (Docket No. NRC-2008-0419, 73 FR 44780)

Dear Mr. Lesar,

The American Society of Hematology (ASH) appreciates this opportunity to review and provide input on the NRC Security and Continued Use of Cesium-137 Chloride Sources Roundtable Notice and Issue Paper (Docket No. NRC-2008-0419, 73 FR pp. 44780-44783) now open for comment. ASH represents over 11,000 U.S. clinicians and scientists committed to the study and treatment of blood and blood-related diseases. These diseases encompass malignant hematologic disorders such as leukemia, lymphoma, and myeloma; non-malignant conditions including anemia and hemophilia; and congenital disorders such as sickle cell anemia and thalassemia. In addition, hematologists have been pioneers in the fields of bone marrow transplantation, transfusion medicine, gene therapy, and development of many drugs for the prevention and treatment of heart attacks and strokes. The issue of the continued use of Cesium-137-containing irradiation devices is of particular importance and relevance to ASH members – research scientists as well as physicians.

ASH has serious concerns regarding the proposed recommendations to phase out irradiation devices containing Cesium-137 (Cs-137) radioisotope. While ASH agrees with the importance of minimizing risks of obtaining and misusing radioactive materials for the purpose of causing harm, the Society believes that the current proposal does not factor in the effective protections of these devices that are already in place, and that it is misguided in considering the alternative sources of irradiation as economically and practically viable. ASH urges the NRC to consider the competing risks of compromising patient care and basic research that leads to development of clinical treatments for patients, and asks the NRC to modify the final draft of its recommendations to include these comments.

Irradiation of blood components needs to be readily available for best medical care, and irradiation devices containing Cs-137 radioisotope are

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routinely used in hospitals and blood banks. Irradiation of blood components is the only proven way to prevent transfusion-associated graft versus host disease (TA-GVHD), which is usually fatal. Some patients are at increased risk of TA-GVHD, such as those receiving blood donated by relatives or patients with leukemia or other cancers, patients who have received bone marrow or solid organ transplants, patients with some types of immunodeficiency syndromes, premature infants, and patients receiving specific drugs for diseases such as Lupus. Because of the potentially high risk and because of danger of transfusing a non-irradiated blood unit to a patient at increased risk of TA-GVHD, many hospitals irradiate all transfused blood except in medical emergencies. Since irradiation reduces the shelf life of blood products, it is usually performed on a per-need basis, and is requested around the clock. Because of the need to urgently and rapidly irradiate blood in hospital blood banks, any change in irradiation sources should consider these issues. ASH is concerned that replacing the Cs-137-containing devices will impact the availability of irradiated products for emergent situations, which can result in devastating consequences for patients.

Although X-ray irradiators were proposed as an alternative to Cs-137-containing irradiation devices for blood irradiation, they have not been as reliable. They often malfunction, requiring frequent and costly maintenance and a backup irradiation device. Moreover, X-ray irradiators are not an effective alternative for crucial transplantation research involving animal models. Researchers and clinician-scientists use Cs-137-containing irradiation devices dozens times a day in research institutions and hospitals all over the United States to study many important biological processes and clinical interventions. For example, animal research on bone marrow transplantation, the development of the immune system and the body's response to infection or cancer, just to name a few, utilizes Cs-137-based irradiation daily. Any changes that would limit the access to or the availability of these devices will detrimentally affect this important research. X-ray irradiators are not a viable alternative for this kind of research, since they are much harder to calibrate for animals, and the dose has much greater variability throughout the compartment. Additionally, this kind of substitution would require re-validation of many research models of disease that have already been established. It would not be feasible to utilize clinical linear accelerators in the hospitals, as it would require the transport of animals out of research space, finding expensive time on expensive instruments, and making sure that patient care was not compromised.

Other suggested alternative sources of irradiation also do not seem to be viable both economically and practically. For example, Cobalt-60 (Co-60) has a shorter half-life than Cs-137, so Co-60 source would need to be replaced more frequently, which can be financially prohibitive. Co-60-containing devices would also require twice as much shielding as Cs-137 irradiators, thus doubling their size and weight as well as making them more expensive. The dimensions of such devices may prohibit their convenient location, which is usually in a place available for rapid access near the rest of the blood bank or a research animal facility. ASH is very concerned that the alternatives that were suggested in the recommendations to the NRC are not economically, practically, or scientifically viable; and any change in the availability of Cs-137-containing devices

without an acceptable alternative would be detrimental to vital patient care and fundamental research.

ASH is also concerned that NRC recommendations were made without having complete information about the impact of new regulations concerning physical access to the irradiators containing Cs-137. All individuals with access must now have a background check and be fingerprinted prior to being allowed access to irradiators, which increases their security and minimizes the risk of their misuse. In some research areas, a few certified individuals are performing all irradiation. ASH urges the NRC to base any future regulations concerning access or availability of Cs-137-containing devices on operational and scientific basis for their efficacy in order to minimize disruption in vital areas of medicine and research.

Thank you for the opportunity to submit these comments. Please contact ASH Scientific Affairs Manager, Ulyana Vjugina, at (202) 552-4935 or [uvjugina@hematology.org](mailto:uvjugina@hematology.org) for any additional information.

Sincerely,

A handwritten signature in black ink that reads "Kenneth Kaushansky". The signature is written in a cursive style with a large, sweeping loop at the end.

Dr. Kenneth Kaushansky  
President