



# AMERICAN SOCIETY OF HEMATOLOGY

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## 2011

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Via Electronic Submission to Docket ID NRC-2010-0209 at [www.regulations.gov](http://www.regulations.gov)

Re: Request for Comments on the Draft Policy Statement on the  
Protection of Cesium-137 Chloride Sources [Docket ID NRC-2010-0209].

December 13, 2010

Dear Ms. Bladey:

The American Society of Hematology (ASH) appreciates this opportunity to review and provide input on the United States Nuclear Regulatory Commission's (NRC) Draft Policy Statement on the Protection of Cesium-137 Chloride Sources published in On June 29, 2010 in the Federal Register Vol. 75, No. 124, pp. 37483-37488 [Docket ID NRC-2010-0209]. ASH represents over 16,000 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 Chloride (CsCl)-containing irradiation devices is of particular importance and relevance to ASH members – research scientists as well as physicians. The CsCl-containing irradiation devices are considered to be the “gold standard” in providing an effective, reliable, dependable and very experimentally reproducible means of irradiation. With the implementation of increased controls and further security upgrades already in place to enhance the security of these irradiators, ASH believes that adequate protection of public health and safety has been achieved.

ASH applauds the NRC for providing an open forum for discussion of this important topic and seeking input from various stakeholders. ASH is pleased that the NRC recognizes the importance of continuous access to CsCl-containing irradiation devices for transfusion medicine and biomedical research. However, ASH has some concerns that it would like to share with the NRC, along with recommendations to update the Draft Policy Statement, listed below.

**Omission of Hematology and Blood Marrow Transplantation from List of Biomedical Research Areas that Use CsCl-Containing Irradiation Devices**

First, ASH is concerned that hematology and blood marrow transplantation are not listed under the major areas of biomedical research that uses CsCl-containing irradiation devices. Hematologists use CsCl-containing irradiation devices multiple 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, DNA damage/repair and the body's response to infection or cancer, just to name a few areas of hematology research, utilize CsCl-based irradiation daily.

***ASH Recommendation:***

ASH recommends that the Draft Policy Statement be updated to include the following in the third paragraph of the "Uses of CsCl Sources" section as published in the Federal Register Notice NRC-2010-0209 p. 37486 (additional language underlined):

In biomedical research, CsCl irradiation has been used for over 40 years in fields such as immunology, hematology, stem cell research, bone marrow transplantation, cancer research, in vivo immunology, systemic drug research, chromosome aberrations, DNA damage/repair, human genome, and genetic factors.

**Absolute Need for and Lack of Viable Alternatives for CsCl-Containing Irradiation Devices in Biomedical Research**

Secondly, ASH is concerned that the Draft Policy Statement does not sufficiently address the absolute need for CsCl-containing irradiation devices in biomedical research, nor does it explain that proposed alternative technologies cannot readily meet the needs of scientists performing this crucial research that benefits society.

Thus, X-ray irradiators are not an effective or viable alternative to CsCl-containing irradiation devices for crucial biomedical research such as transplantation and immunology research, for example. X-ray irradiators often malfunction, requiring frequent and costly maintenance and a backup irradiation device. They are much harder to calibrate for animals, and the dose depth has much greater variability throughout the compartment. The differences in chamber size and the irradiation time needed in order to achieve a uniform field in an X-ray irradiator are also limiting as compared to CsCl-containing irradiator.

Other suggested alternative sources of irradiation are also not viable both economically and practically. For example, Cobalt-60 (Co-60) has a shorter half-life than CsCl, 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 CsCl 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. Moreover, utilization of clinical linear accelerators would not be feasible, as it would require the transport of animals out of research space, finding expensive time on expensive instruments, and overcoming the resultant logistical problems to ensure that patient care is not compromised.

Any kind of substitution would require re-validation of many research models of disease that have already been established using CsCl-containing irradiation devices over the last few decades. It would be devastating to the biomedical research community, resulting in an immeasurable setback for science and medicine.

***ASH Recommendation:***

ASH recommends that the Draft Policy Statement be updated to include the following in the third paragraph of the “Uses of CsCl Sources” section as published in the Federal Register Notice NRC-2010-0209 p. 37486 (additional language underlined):

In biomedical research...

... For the vast majority of biomedical research there are no alternatives to Cs-137 irradiation because of the unique properties of Cs-137 radiation, such as high dose rates with uniform fields of linear energy transfer. CsCl sources are dependable, economical and relatively easy to use. No alternative technologies that can effectively replace CsCl sources for biomedical research, including X-ray, linear accelerators and Cobalt-60 irradiators, have yet been developed. Any kind of substitution would require re-validation of many research models of disease that have already been established using CsCl-containing irradiation devices.

**Need for Stakeholder Input Prior to Issuing Additional Security Requirements or Limitations**

Finally, ASH urges the NRC to solicit public input on the use of CsCl-containing irradiation sources *before* issuing any additional security requirements/limitations if the threat environment changes and/or suitable alternatives become available.

***ASH Recommendations:***

ASH recommends that the following changes be made to the last bullet of the Statement of Policy as published in the Federal Register Notice NRC-2010-0209 p. 37485 (additional language underlined):

American Society of Hematology – Comments on the Draft Policy Statement on the Protection of Cesium-137 Chloride Sources [Docket ID NRC-2010-0209]

The NRC monitors the threat environment and maintains awareness of international and domestic security efforts. In the event that changes in the threat environment necessitate regulatory action, the NRC is ready to issue additional security requirements to apply appropriate limitations for the use of CsCl in its current form or for its replacement with suitable alternatives without adverse effects on the three specific classes of applications that benefit society as described above. The NRC will solicit stakeholder input prior to making any regulatory action on the use of CsCl.

ASH also recommends that the following changes be made to the last sentence of the Summary section published in the Federal Register Notice NRC-2010-0209 p. 37487 (additional language underlined)

In the event that changes in the threat environment necessitate regulatory action, the NRC is ready to issue additional security requirements to apply appropriate limitations for the use of CsCl in its current forms or for its replacement with suitable alternatives without adverse effects on the three specific classes of applications that benefit society as described above. The NRC will solicit stakeholder input prior to making any regulatory action on the use of CsCl.

The American Society of Hematology will be happy to provide further information and be a resource for the NRC. Please contact ASH Scientific Affairs Manager, Ulyana V. Desiderio, PhD, at (202) 776-0544 or [udesiderio@hematology.org](mailto:udesiderio@hematology.org) for any additional information.

Sincerely yours,



J. Evan Sadler, MD, PhD

President