October 14, 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


Dear Mr. Lesar:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 38,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Nuclear Regulatory Commission’s (NRC) request for comments on the security and continued use of cesium-137 chloride (CsCl) sources.

A recent National Academy of Sciences study recommends the replacement or elimination of CsCl due to its potential risk to individuals, society and the environment if improperly handled or used in a malicious act. While we understand the NRC’s concerns, the AHA urges the Commission to proceed cautiously as it considers these complex issues, particularly the medical use and research applications of CsCl, so as not to adversely impact patient care and advances in biomedical research.

Blood irradiation is medically necessary for some patients to prevent transfusion-associated graft versus host disease. CsCl blood irradiators are the most reliable, efficient and low-maintenance tools available. Hospitals that have blood donation centers or treat significant numbers of immuno-compromised patients often own such irradiators. CsCl irradiators also play an important role in medical research related to understanding and treating cancer and other serious illnesses. They also are used to develop countermeasures for radiologic terrorism.

As discussed at the NRC’s Stakeholder Workshop on September 29 and 30, there is no available technology for producing irradiators with Cs-137 in any form other than CsCl that could be available for practical use in the near future. Other types of irradiators, such as Cobalt-60, require considerable and costly additional shielding. They also require reloading every five years (compared to every 30 years for CsCl irradiators), which significantly raises transportation and security vulnerabilities for decommissioned and new sources.
X-ray irradiators, which have been promoted as a viable alternative to CsCl, are not as efficient or reliable, and their efficacy is questionable. X-ray irradiators also are associated with higher maintenance costs. Further, current U.S. manufacturing capacity for X-ray blood irradiators is limited. The wait time to purchase an X-ray blood irradiator is more than six months, and we expect that this would worsen if the NRC were to uniformly require the removal of CsCl irradiators from hospitals and research institutions. Finally, replacing a CsCl irradiator with an X-ray irradiator is an extremely expensive proposition and would create a financial hardship for many hospitals. The additional cost includes not only the purchase of a new machine, but also the costs to decommission the CsCl irradiator and operate the new machine on an annual basis.

The AHA strongly believes that the recently increased security requirements in place at hospitals that possess CsCl irradiators are adequate to prevent potential misuse or malicious intent. The NRC’s recent security-related orders call for a high level of security around irradiators. Currently, they are required to be located in locked, hardened and nearly impenetrable rooms. Users of the equipment are required to be fingerprinted and have background checks conducted by the Federal Bureau of Investigation. Facilities utilize biometric entry security systems and 24-hour security video surveillance to ensure the safety of the irradiators. If video monitoring fails, guards are deployed to the area. Further, hospitals can take advantage of the Department of Homeland Security and Department of Energy’s voluntary “hardening program” to further enhance the security of CsCl irradiators by making design modifications that further protect against unauthorized access to the sealed sources.

For these reasons, the AHA believes that there is no need for the NRC to move forward with rulemaking that would limit or eliminate the use of CsCl. As long as hospitals have sufficient controls in place to assure the security of the equipment, existing CsCl irradiators should be allowed to continue operation. If the NRC ultimately mandates replacement, the AHA recommends that it start with a ban on the purchase of new irradiators and that hospitals with existing irradiators be allowed a reasonable and adequate time period for removal and replacement of existing machines. In addition, financial resources must be provided to hospitals to offset the significant costs that would be incurred.

Thank you again for the opportunity to comment. If you have any questions, please feel free to contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President