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U.S. Nuclear Regulatory Commission
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Via electronic submission:

<http://www.regulations.gov/fdmspublic/component/main?main=SubmitComment&o=09000064805f846d>

RE: Docket NRC-2008-0419, 31 July 2008, "Request for Comments on the Security and Continued Use of Cesium-137 Chloride Sources and Notice of Public Meeting"

Dear FDA Dockets Manager:

Thank you for the opportunity to provide comments to the issues concerning cesium-137 sources in irradiators. A work group, consisting of AABB members who also represent the following blood organizations: America's Blood Centers (ABC), American Red Cross (ARC), and the Armed Services Blood Program, was formed to analyze the issues listed in the Federal Register notice, *Request for Comments on the Security and Continued Use of Cesium-137 Chloride Sources and Notice of Public Meeting*, July 31, 2008. Additional comments/statements will be submitted on behalf of the other blood organizations which we support.

AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. Our members include more than 1,800 hospital and community blood centers and transfusion and transplantation services as well as approximately 8,000 individuals involved in activities related to transfusion, cellular therapies and transplantation medicine. For over 50 years, AABB has established voluntary standards for, and accredited institutions involved in, these activities. AABB is focused on improving health through the advancement of science and the practice of transfusion medicine and related biological therapies, and developing and delivering programs and services to optimize patient and donor care and safety.

Blood components are irradiated to prevent transfusion associated-graft-versus-host disease (TAGVHD) for white blood cells in cellular blood components such as red cells or platelets. Once established, TAGVHD is usually fatal and untreatable. While not all patients require irradiated blood, those whose immune systems are compromised or receiving blood from immunologically similar donors, such as family members, are at particular risk of this complication. Hence, it is imperative to balance the risks and benefits of phasing out Cesium in favor of alternative strategies. Respondents to the 2007 National Blood Collection and Utilization Survey reported that 2,322,000 blood components were irradiated in 2006. Many of these are concentrated at institutions that take care of cancer patients.

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Att = J. Jankovick (JPJ2)

The comments are arranged in the following format:

Issue – language from the federal register reprinted.

Recommendation / Comment – rationale is included.

Background – information supporting the recommendation.

Issue No. 1 – Alternatives to the use of CsCl sources in compressed powder form

Issue No. 1.2 – Feasibility of the Use of Isotopes Other Than Cs-137

Q1.2-1. (a) Can cobalt-60 (Co-60) be substituted for radioactive CsCl for any applications? (b) If so, what types of applications? (c) If not, why not?

Q1.2-2. Can the shielding challenges for Co-60 be addressed by switching from lead shields to more effective tungsten or depleted uranium shielding?

Note: Consider that tungsten shielding is more expensive than lead and manufacturing depleted uranium shielding is a very specialized, expensive operation that requires NRC or Agreement State licensing for its entire lifecycle.

Q1.2-3. What are the attendant risks associated with Co-60 source transportation?

Note: Consider the shorter half-life (5.27 y) of Co-60 radiation sources would require that they be replaced more frequently than Cs-137, which entails the transportation of both fresh and used sources.

Comment: In addition to the significant obstacles addressed in Issue No. 2 below, we note that the sheer weight of cobalt-60 radiation equipment makes them an impractical solution, for many current installations. To compensate for the shorter half-life, most Cobalt irradiators are loaded with sources of higher radioactivity. To shield this higher source, greater amounts of lead shielding are required and hence, most free standing Cobalt irradiators have substantially greater weight. While many irradiators are currently located in blood centers, many more are in hospitals, often, not on basement or ground floor levels. Thus, to install a cobalt-60 irradiator on a level other than the basement would require significant facility structural modifications.

Issue No. 2 – Use of alternative technologies

Q2-1. Are X-ray generators already commercially available as substitutes for applications that do not require the gamma rays with Cs-137 and Co-60?

Q2-2. Are X-ray tubes cost-effective considering the initial cost, operating costs, and requirements for more maintenance for periodic calibration and replacement than radioactive sources?

Q2-3. Is there any indication that the performance of the alternatives will change (improve or worsen) with respect to Cs-137?

Q2-4. Regarding the availability of alternative technologies, (a) what is the timeframe of future availability of each alternative, and (b) what is the cost for each of the alternative technologies (capital costs, operation costs, cost to users)?

Recommendation: Even though X-ray technology is available and is used by a small part of the blood community, there are significant logistical, operational and financial obstacles that will prevent an immediate or mass conversion to their use. Therefore, we recommend that

establishments not be required to convert to X-ray technology over any period of time that cannot ensure complete capacity to irradiate all products requiring treatment.

Background: This proposal should be considered in terms of balancing both risks and benefits of a proposed intervention, as well as costs and benefits. The risks of maintaining Cesium source irradiators are described in Radiation Source Use and Replacement (2008), National Research Council ISBN: 978-0-309-11014-3. The risks of removing Cesium source irradiators include the potential for inadequate treatment and development of TAGVHD to patients, if alternatives are either unavailable or not functioning. Currently, there are several establishments that utilize X-ray technology for the irradiation of blood products. The conversion to X-ray technology is problematic. While most centers have backup plans in the event that their irradiator becomes unavailable, these are rarely utilized since cesium irradiators are functionally so robust and durable. In contrast, the track record for the X-ray irradiators, while good, still has significantly more down time for X-ray source and power source replacement. In comparison, X-ray sources have down times of greater than 30-days (21.4%) as compared with 0-2-days (92.4%) for cesium source irradiators. In addition, decreased throughput capacity of some of the X-ray devices could lead to delay in providing patient therapy. In balancing the cost benefit ratio, the purchase of an X-ray irradiator would have to be considered a new unplanned cost, for most facilities own their cesium-137 irradiator and the annual operational cost of a cesium-137 irradiator (less than \$10,000 for 74.6% of survey respondents) is far less than an X-ray irradiator (61.5% of respondents less than \$10,000 but 84.6% do not cover X-ray tubes and power sources – the most frequently replaced parts which could cost up to \$40,000). Specifically, as outlined in Chapter 10 of the NRC document over the life expectancy of the X-ray equipment, one might expect to incur at least \$318,000 in additional service and maintenance costs per device. We posit that the costs outlined in Chapter 10, may be grossly underestimated since the reliability and throughput of existing X-ray devices may be sufficiently lower than cesium-137 irradiator, that the purchase of two X-ray irradiators to replace one cesium-137 irradiator may be necessitated. The requirements for dose mapping, validation, and training will remain.

The use of pathogen inactivation technology has significant potential to abrogate the need for blood product irradiation. However, such technology is not licensed for use in the United States and is not anticipated to be licensed in the immediate future.

Issue No. 3 – Possible phase-out of CsCl sources

3.1: Potential Rulemaking Issues and Justification for Regulatory Change

Q3.1-1. (a) What would be the medical consequences if CsCl was to be banned for medical (e.g., blood) irradiators? (b) What would be the impact to existing and future biomedical research using these devices? (c) Can alternative technologies be used for medical applications and/or biomedical research (research on animals and tissue?)

Q3.1-2. (a) What would be the consequences if CsCl was to be banned for irradiators that are used for industrial and calibration purposes? (b) What is the impact on existing American National Standards Institute (ANSI) standards and licensee conditions that require the use of Cs-137 for calibration purposes?

Q3.1-3. What would be the economic consequences to users if CsCl was to be banned?

Q3.1-4. What would be the economic consequences to vendors if CsCl was to be banned?

Q3.1-5. (a) Should the NRC discontinue all new licensing and importation of these sources and devices? (b) What is the regulatory basis? (c) Who (NRC, DHS, or jointly) should conduct the risk analysis?

Recommendation: We recommend that the continued use of CsCl irradiators for irradiating blood components be permitted, but with modifications to ensure greater security of the source. CsCl irradiators are the primary technology used for irradiation of blood components in the US. Many are located in blood centers but more are located in hospitals and, in fact, many free standing Children's hospitals have them. Available alternatives are potentially less reliable (mechanical issues and decreased throughput) and will result in delays in providing patient therapies. The economic impact on current blood community licensees will be significant if CsCl irradiators are banned (please see response to Issue No. 2). The recent NRC publication (RIS 2008-17) outlined additional validated steps that can be taken to further restrict access to CsCl irradiator sources. The NRC should first take time to evaluate the effectiveness of these measures before initiating further recommendations or rulemaking.

Background:

Prior to decommissioning a cesium source irradiator, the new irradiator would have to be installed and validated. Space within most establishments is at a premium with very little to spare for installation of a new irradiator. If the irradiator is an X-ray device, facility modifications would have to be made before installation (i.e., water cooling systems are required for some devices). The unplanned costs and facility modifications to install X-ray technology would necessitate that many smaller establishments rely on X-ray equipment, such as linear accelerators utilized by therapeutic radiology departments within the establishment or contract out the service. Either of these options would result in a delay for processing the unit(s), thus negatively affecting the care provided to those who are in critical need of blood components, or put the recipient at risk in the event that transfusions were to be initiated prior to availability of irradiated components.

Most challenging are proposals that would require a rapid replacement of current cesium sources. Proposals calling for replacement in the immediate future face the following challenges:

- Limited number of current suppliers of alternative technologies with limited current inventory and limited manufacturing capacity to replace 400-700 units, currently in use. Furthermore, the total number of units would likely have to increase to create greater back-up capacity in light of the known greater down time of X-ray units.
- Limited capacity to validate the installation, operational and performance qualifications of newly placed instruments. For example, dose mapping for new X-ray irradiators often require a week or more per instrument.
- Limited capacity to remove current units. Currently, the largest manufacturer, Best Theratronics, has few specially equipped trucks capable of transporting units.
- The current system for decommissioning Cesium units requires government approval that historically has required a prolonged period (months) for approvals.
- Disposing of the source is also problematic. Currently, this requires disposal in a government approved site.
- Decommissioning costs alone historically exceed \$25,000 which does not include the establishment's time for coordinating transportation, security, and federal agencies. However, with the removal of older shipping containers (as of 01 October 2008) and limited capacity for long-term storage, the decommissioning costs are expected to exceed \$100,000.

NRC publication (RIS 2008-17) supports the voluntary program for security enhancements for self-contained irradiators containing CsCl sources. To propose rules/regulations before adequate time has elapsed for an analysis of the effectiveness of the program would be irresponsible and contradictory to NRC's support. Achieving the desired outcome from hardening the irradiators would be far less of an economic hardship for establishments and manufactures while maintaining the continuity of quality healthcare and national security.

Issue No. 3.2: Transportation and Storage Issues Associated With Removal of CsCl Sources from Licensee Facilities

Q3.2-1. (a) Are there transportation packages available for transportation? (a) Who should bear the transportation costs?

Q3.2-2. (a) How could the current CsCl sources be disposed given that CsCl is defined as a "Greater Than Class C" source and currently has no disposal mechanism in the U.S.? (b) If disposal was made available by DOE, what would be the cost of disposal?

Q3.2-3. (a) Where could the decommissioned sources be stored? (b) What disposition options are needed in the United States?

Recommendation: All costs associated with new regulations that ban the use of CsCl Sources due to homeland security concerns should be borne by an agency of the federal government – the Department of Homeland Security seems to be an appropriate budget to use.

Background: Blood establishments do not have the means to recover any costs associated with converting their existing CsCl irradiators to an alternative technology. Currently, establishments budget years in advance – based on knowledge of the half-life of the Cs-137 source – in order to afford new equipment at the appropriate time. Blood centers are uniformly not-for-profit and do not have significant economic reserves. Furthermore, passing through costs is a challenge since hospitals have no way of recuperating this form of expenditure, since hospitals are reimbursed by DRG of patient's served, not by their expenses engendered. (see, for example AABB reimbursement guide:

http://www.aabb.org/Documents/Programs_and_Services/Billing_and_Reimbursement_Initiative/s/reimbguidev071017.pdf. In addition to the economic consequences for converting to X-ray technology addressed in issue number 2, there are other economic consequences in regards to decommissioning the cesium-137 irradiator. Decommissioning a cesium-137 irradiator takes on average about three (3) months, if an approved agency to remove the irradiator can be contracted. There has been a lot of complaints reported that it is difficult to find an acceptable agency due to the relatively few authorized transportation companies

With respect to transportation, Best Theratronics, that has over 700 Cesium instruments in use, noted that they have a limited number of trucks and trained personnel capable of handling such sources. Greater risk may be engendered by rushing into decommissioning with inadequately trained personnel, than in leaving the units intact.

3.3: Consideration of Government Incentives and Voluntary Actions by Industry and Manufacturers

Q3.3-1. Should the Federal Government Issue incentives to implement replacements?

Q3.3-2. (a) Are there feasible incentives to shift users away from radioactive CsCl for users? (b) Manufacturers?

Q3.3–3. (a) *What incentives should the Federal Government provide to licensees to decommission their existing sources or devices because the devices still have use value?* (b) *For licensees that are defined as “not-for-profit” (e.g., hospitals), what type of incentives could be made available to change technologies?*

Q3.3–4. *How can the Federal government compensate licensees when they are forced to decommission these sources? Should compensation include the cost of the replacement technology? Decommissioning?*

Recommendation: We recommend that CsCl irradiators remain an approved technology for irradiating blood components. Federal Government funding/reimbursement for converting technologies must be made available if CsCl irradiators are phased out or banned.

Background: The current economic status of blood establishments (the vast majority of whom are not-for-profit hospitals and blood centers) necessitate that the Federal Government provides reimbursement/economic relief for this endeavor. The Off-Site Source Recovery Project (OSRP), a US Government activity sponsored by the National Nuclear Security Administration's (NNSA) Office of Global Threat Reduction, is responsible for the removal of excess, unwanted, abandoned, or orphan radioactive sealed sources. However, the funding and capacity of this organization is not sufficient to accommodate all of the cesium-137 irradiators currently in use. If establishments are mandated to decommission their cesium-137 irradiators within a specified period of time, additional funding and resources must be provided to OSRP or a mechanism and funding to reimburse an establishment must be implemented.

In addition to subsidizing the decommissioning of the cesium-137 irradiators, the Federal Government should provide monetary reimbursement or incentives to establishments for converting to an alternative technology. The present medical reimbursement mechanism does not provide blood establishments with a means to recover any costs associated with a switch out of cesium source irradiators – expenditures for the equipment, installation, training, and any facility modifications required. Establishments budget years in advance – based on knowledge of the half-life of the cesium-137 source – in order to afford new equipment at the appropriate time. Since blood establishments are uniformly nonprofit, they rarely have significant economic reserves. The current economic status of blood establishments necessitate that the Federal Government provides economic relief for this endeavor, that we currently estimate in excess of \$250,000 per irradiator.

Issue No. 4 – Additional Requirements for Enhanced Security of CsCl Sources

Q4.1. *Should the NRC and Agreement States require more stringent security measures than those currently mandated (e.g., should additional requirements be implemented for IAEA Category 1 and 2 sources)?*

Note: *The current requirements for increased security of certain high-risk radioactive sources in the U.S. are: (a) Compensatory Measures for panoramic irradiators; (b) Additional Security Measures for manufacturers and distributors; (c) Increased Controls for licensees with Category 1 and 2 devices and sources; (d) Fingerprinting for access to radioactive material (see <http://www.nrc.gov/security/byproduct/orders.html>).*

Q4.2. *Should the NRC and Agreement States require more stringent security measures for lower than Category 2 CsCl sources and devices (e.g., Category 3 sources)?*

Q4.3. Would additional security requirements for CsCl create a disincentive for owning them?

Recommendation: We recommend that any decision be delayed until adequate time is allotted for a study evaluating the effectiveness of RIS 2008-17 – installation of hardening measures by manufacturers to current CsCl irradiators.

Background: There is a project currently underway for the hardening of existing CsCl source irradiators. The hardening efforts would increase the time for unauthorized access to the source material to be greater than 60 minutes. The irradiator manufacturers will perform the hardening activities and are reimbursed by federal funds. In conjunction with the other increased security measures (e.g. fingerprinting, secure location, monitoring), these measures would significantly increase the safety and security of the source material. The increased security measures have been implemented by the blood establishments which currently utilize a CsCl source irradiator. Of note, several centers surveyed that recently purchased the X-ray irradiators cited current regulations as incentive for their choice of the alternative technology.

In addition, the NRC solicited specific comments related to:

Quantitative information on the costs and benefits resulting from consideration of the factors described in the Issues Paper.

AABB surveyed our Transfusion Services and Blood Banks members; of the 345 respondents, 195 irradiate blood products in-house with 147 (79.5%) using cesium-137 and 25 (13.5%) using X-ray technology. It was interesting to note that 118 (74.2%) use another facility as their backup and 23 (14.5%) do not have a backup mechanism. This correlates with the data that 75.4% of the respondents provide back up irradiator services for other facilities, the majority of the backup service is accomplished via cesium-137 irradiators.

Of the cesium-137 irradiator responses, 99 (76.2%) do not have plans to replace their current irradiator and those that plan to replace their irradiator (81.3%), plan to do it within the next 5 years – replacement is split between cesium-137 and X-ray. The majority (62.5%) cited regulatory/compliance concerns as the reason for replacing the current irradiator with source degradation and upgrade of equipment as the second reasons.

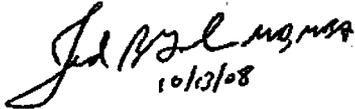
Operationally, the cesium-137 irradiator is more cost effective and reliable than the alternative, X-ray. An annual service contract cost less than \$10,000 for 74.6% of the respondents and 23% pay between \$10,000 and \$25,000. The down time of the irradiator is not significant with 92.4% down less than 2 days and 5% non-operational greater than 30 days. Those facilities that have decommissioned or moved an irradiator experienced a cost of less than \$25,000 (73.6%) and a time period of less than one month (70.6%) but it was reported to take greater than 3 months in some instances (13.7%).

X-ray irradiators on the average cost more to maintain. An annual service contract for an X-ray irradiator cost less than \$10,000 for 61.5% of the respondents but 38.5% pay \$10,000 to \$25,000. However, 84.6% of the service contracts do not include the replacement of the X-ray tube and/or power source which are the parts that are most prone to require frequent replacement. The cost to replace the X-ray tube and/or power source ranged from less than \$10,000 to \$40,000 (83.3%) with 16.7% reporting costs of greater than \$40,000. X-ray irradiators are non-operational more

often than a cesium-137 irradiator – 78.6% responded that their irradiator was non-operational 0-2 day annually with 21.4% non-operational greater than 30 days.

Please direct all questions regarding these comments or requests for additional information to Joseph L Giglio, Deputy Director Regulatory Affairs – AABB at 301-215-6515 or jgiglio@aabb.org.

Sincerely,

A handwritten signature in black ink that reads "Jed Gorlin, MD, MBA" with the date "10/2/08" written below it.

Jed Gorlin, MD, MBA
AABB Board of Directors