Blood Systems

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RULES AND DIRECTIVES BRANCH USNRC

September 8, 2008

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

Re: Docket Number NRC-2008-0419

Dear Mr. Lesar:

The purpose of this letter is to submit comments to the U.S. NRC regarding the National Academies of Sciences (NAS) study that recommended the replacement or elimination of Cesium Chloride (CsCl) sources used in blood irradiators and other medical equipment.

Blood Systems, Inc. has multiple blood irradiators located in different facilities which use Cesium-137 as a sealed source. Each irradiator is located in a locked room with access permitted only by individuals who have been deemed trustworthy & reliable by Blood Systems and who have undergone the required FBI background checks. Any irradiators that are decommissioned are done so under U.S. NRC regulations. We feel the current safety measures in place are adequate to protect the public health from unwanted exposure.

Blood Systems, Inc also shares the concerns raised by the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) in the attached letter dated February 20, 2008. We would hope that all concerns are fully addressed before any rulemaking regarding the use of CsCl is initiated by the NRC.

Should you have any questions or require additional information, please contact Mark Georgescu at (480) 675-5643.

Sincerely,

Mary Beth Bassett
Vice President Quality Management/Regulatory Affairs
Blood Systems, Inc.

:mag
Attachment

E-RIDS = ADM-03
Add = J. Jankovich (JPJ2)

SUNSI Review Complete
Template = ADM-013

February 20, 2008

Robert J. Lewis, Director
Division of Material Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs
U.S. Nuclear Regulatory Commission
Two White Flint North
11545 Rockville Drive
Rockville, Maryland 20852-2738

Dear Mr. Lewis

The Advisory Committee on the Medical Use of Isotopes (ACMUI) appreciates the opportunity to comment on the report entitled "Radiation Source Use and Replacement" prepared by National Academy of Science (NAS). The report represents the results of a study, conducted by NAS under Section 651 of the Energy Policy Act of 2005, of the industrial, research, and commercial (including medical) uses of Category 1 and 2 radioactive sources to identify technically and economically feasible replacements for sources that pose a high risk to public health and safety in an accident or terrorist attack. The purpose of the ACMUI is to provide advice to NRC on policy and technical issues that arise in regulating the medical use of byproduct materials for diagnosis and therapy, and, in that capacity, our review of the NAS report was focused on the impact of its recommendations on the practice of medicine.

The ACMUI recognizes and appreciates the efforts put forth by NAS in preparing this this report. The ACMUI, however, has several concerns and comments regarding the report and its recommendations:

1. The report has suggested alternative replacements for CsCl, e.g., x-ray blood irradiators. However, the report does not address the efficacy of these alternative replacements for CsCl. Further study will need to be carried out on the alternatives to assure that these alternative replacements have the capacity for producing the desired result or effect and to identify any impacts. For example, a linac could be used to irradiate blood in the evening (when it is not being used to treat patients), but the hemotologists need the blood irradiated immediately before use, which is generally in the daytime, not in the evenings.

2. The report does not address increased or enhanced security methods as an alternative. Enhanced security features would provide a more cost effective means of providing security.

3. Terrorist threat exist worldwide. Elimination of CsCl needs to have a global solution, otherwise, the refurbished CsCl irradiator equipment will be sent to underdeveloped countries where the environment is potentially less secure, thus increasing the overall threat risk.

4. The report does not acknowledge the fact that the cost of replacement, decommissioning, and disposal of current CsCl technology, as well as, the

increased operating cost of the Xray alternatives will likely be passed on to patients, thereby increasing the already high cost of medical care. One estimate suggests that implementation of the x-ray alternative could increase costs by 177% in comparison to Cs while being less reliable.

5. The report does not address the fact that the tax incentives to replace CsCl technology would not work for most hospitals, which are generally not-for-profit.

6. The report does not adequately distinguish between Cs-131 and Cs-137. Cs-131 is a new and useful isotope which does not have the dispersal potential of Cs-137. However, both isotopes may be viewed as having the same threat risk by the public due to the word "Cesium". By not distinguishing between these two isotopes of Cesium, any action on CsCl based on this report could potentially deny the useful medical treatment of Cs-131 to the public.

7. The NAS report appears to have a bias against Gamma Knife Radiosurgery. The Gamma Knife has proven medical benefit. This technology provides very rapid, focused treatment versus the non-radioactive alternatives. However, the NAS report places the Gamma Knife in a negative light compared to the Linac xray alternatives. The successful Gamma Knife treatment method should not eliminated as it would deny needed medical treatment to patients.

8. ACMUI agrees with the NRC staff observation that there are significant environmental and worker risk of using Ethylene Oxide technology. These risks were the reason that Ethylene Oxide technology was eliminated and hence returning to the Ethylene Oxide technology would be a step backward. Further, Ethylene Oxide is used for sterilizing equipment and not for sterilizing blood.

ACMUI would be happy to elaborate on the above concerns, and any additional observations, resulting from our review with you, NAS, or Congress, at your convenience.

Sincerely

Nag

Dr. Subir Nag
ACMUI