

February 15, 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  
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11545 Rockville Drive  
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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 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 hematologists 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 be 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



Dr. Subir Nag  
ACMUI