YALE-NEW HAVEN HOSPITAL
RADIATION SAFETY OFFICE

October 13, 2008

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Washington, D.C. 20555-0001

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RULES AND DIRECTIVES BRANCH USNRC

Re: Security and Continued use of Cesium-137 Chloride Sources [NRC 2008-0419]

Dear Mr. Lesar,

Yale-New Haven Hospital would like to offer the following comments in response to the NRC's notice [NRC-2008-0419], published in the Federal Register on July 31, 2008 regarding the consideration of additional security measures related to devices using Cesium-137 Chloride sources for irradiation purposes.

Here at the Yale Medical Center, Cesium-137 (Cs-137) irradiators are used on a daily basis for both clinical and research uses. Clinically, Cs-137 irradiation is used to treat blood components to prevent graft versus host disease. For immuno-compromised patients, this is a life saving procedure that allows them to receive blood products safely. X-ray alternatives exist, but they currently do not have the dependability, reproducibility and throughput capabilities compared to Cs-137 blood irradiators.

Cesium-137 irradiators are also used in many research applications in immunology, radiation biology and many other areas of biomedical research. In these applications, while x-ray devices may be substituted, in most cases, the characteristic radiations emitted by Cs-137 cannot be duplicated by x-ray alternatives. Switching to an x-ray alternative might set back research programs for many years while the radiation characteristics of the x-ray alternative are examined and characterized for each research model.

Cesium-137 irradiators are essential due to their simple operational characteristics. The Cs-137 source has a reasonably long half-life of 30 years and requires only a 2.3% decay correction on an annual basis to maintain dose calibration. The irradiation system only requires a simple timing mechanism and a simple moving sample chamber or source exposure mechanism. A simple turntable mechanism usually rotates the specimen to ensure the item is uniformly irradiated. The Cs-137 gamma rays are energetic enough that they are not significantly self-attenuated by biological specimens, which further improve dose homogeneity. These characteristics make the Cs-137 irradiator a dependable workhorse for clinical operations. They have very little down time and due to their relative simplicity, they are readily repaired with inexpensive replacement components.

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The alternatives, either x-ray or Cobalt-60 (Co-60) based, are significantly inferior to Cs-137 irradiators. The x-ray alternatives are much more complicated. The irradiation source degrades with use and must be periodically replaced at much greater expense and downtime as compared with Cs-137 irradiators. In addition, dose homogeneity and sample throughput is not comparable to Cs-137, due to lower effective photon energy and greater self-attenuation. The filtration needed to harden the x-ray beam in an effort to match the radiological characteristics of Cs-137, significantly drops the achievable dose rates and drives up the loading on the x-ray tube. This reduces its working lifespan. Additionally, x-ray based irradiators require warm-up runs and greater quality assurance work to ensure their dose reproducibility. Cobalt-60 alternatives require a 12.3% annual adjustment for decay and require source reloading 4 to 5 times as frequently. This increases operational and disposal costs considerably for this alternative. In addition, the higher photon energies of Co-60 require a considerably more massive irradiator shielding system that might require locating the unit on a ground floor, which could make the facility more vulnerable.

We believe the NRC must consider the fact that licensees are now well aware of the increased concerns regarding Cesium Chloride (CsCl) based irradiators. Many licensees would readily switch to Cs-137 irradiators that were based on ceramic or glass matrix sources, if they were currently available. Unfortunately, the availability of alternatives to CsCl sources is at least 5 years away. We are currently in the process of constructing a new blood bank facility and the irradiation facility will soon be placed into a much more secure environment. We firmly believe that other licensees will also be considering similar design considerations for their future irradiation facilities. With the existing increased controls already implemented and future improvements in security such as hardened facilities, hardened irradiator retrofit kits, irradiator intrusion detection alarms and alternatives to CsCl, we believe that it would be inappropriate to remove Cs-137 irradiators.

If Cs-137 irradiators were removed from service at this time, there are currently no disposal options available. The only option would be to return the sources to the manufacturer at considerable expense and facility replacement cost. Licensees would most probably be required to assume additional disposal expenses whenever an ultimate disposal option is identified.

For the above reasons, we believe that the NRC should consider the following actions to reduce the threats posed by CsCl based irradiators:

1. Promote alternative Cs-137 source technologies. The reduced specific activity of ceramic or glass based alternatives is not a limiting factor. Most existing irradiator designs could be modified to accept safer replacement sources without compromising their performance capabilities. If the NRC takes drastic actions against Cs-137 irradiation facilities at this time, production facilities may refuse to invest in alternative technologies, due to the loss of the Cs-137 irradiator market.

2. In the interim period, until replacement Cs-137 source technologies become available, existing irradiators should be hardened and fitted with tamper alarms.

3. Encourage existing licensees to further harden existing irradiator facilities, by architectural modifications whenever possible, during renovation projects.

4. Establish architectural security requirements for newly licensed irradiation facilities, at least until safer Cs-137 technologies become available.

In summary, Cs-137 irradiators are an important tool for clinical and research purposes. Alternatives to Cs-137 cannot completely replace the functions of Cs-137 irradiators. The most important step in ensuring that these devices are not targets for malicious acts is the recognition of the potential threat they initially posed. The NRC has already taken the step of implementing increased controls and that has significantly improved the security for these devices. Additionally, licensees have recognized the security concerns and have taken additional measures, above the required increased controls, to improve the security of these devices. Reasonable additional measures, as suggested above can further enhance the security levels and make these devices much less attractive for those with terrorist intent. However, complete elimination of Cs-137 irradiation facilities is not a reasonable option. The loss of the benefits these devices currently provide to our patients and society will only result in detriment to our efforts and benefit only those with malevolent intent.

Sincerely,

Michael J. Bohan
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Radiation Safety Officer/
Medical Health Physicist

Cc: Edward L. Snyder, M.D., Director, YNHH Blood Bank
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