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RULES AND DIRECTIVES BRANCH USNRC

Cynthia G. Jones, Ph.D.
Sr. Technical Advisor for Nuclear Security
U.S. Nuclear Regulatory Commission
Office of Nuclear Security & Incident Response
Mail Stop T4–D22A
Washington, DC 20555–0001

Re: Public Comments on the Security and Continued Use of Cesium-137 Chloride Sources

Dear Dr. Jones:

The Georgetown University (GU) Medical Center is a "not-for-profit" institution which includes the Lombardi Comprehensive Cancer Center. A National Cancer Institute (NCI) Comprehensive Cancer Center designation is the highest ranking given to a center meeting strict criteria including, a strong core of basic laboratory research in several fields, the ability to translate those research findings into clinical therapies that can one day be used to treat patients, a program of high-priority clinical trials, and a commitment to community service and outreach activities related to cancer prevention and control. On behalf of the GU Radiation Safety Committee, I appreciate the opportunity to provide our response to the NRC Request for Comments on the issue referenced above. Since GU Hospital is a separate NRC Licensee, our responses will be restricted to the biomedical research performed at the GU Medical Center.

Issue No. 1.1: Feasibility of the Use of Other Forms of Cs-137
During the public workshop, Oak Ridge National Laboratory (ORNL) provided a presentation stating that they have experience developing alternate source forms (Cs pollucite and Cf cermet), and that ORNL is available to assist in the development and/or evaluation of alternate source forms. We strongly recommend that the United States pursue assisting Mayak, Russia, in the development of an alternate form of cesium as a replacement for cesium chloride (CsCl) (*i.e.,* in a glass or ceramic matrix). The assistance, if requested, should be both technological and financial.

Issue No. 1.2: Feasibility of the Use of Isotopes Other Than Cs-137
The use of cobalt-60 (Co-60) as a substitute for CsCl would not be desirable for the following reasons:

- The shorter half-life (5.27 y) of Co-60 sources would require that they be replaced approximately six times more frequently;
- Multiple source exchanges would increase the financial burden to all "not-for-profit" institutions (source purchase, transportation, disposal, etc.);
- It is not clear whether current irradiators could accommodate a Co-60 source. If the irradiators could accommodate Co-60, approximately twice the amount of shielding is necessary and current facilities are not designed to accommodate the increased weight;
- Significant expense would be incurred to locate a suitable new facility, perform a structural engineering review, install sufficient shielding, and, relocate the increased controls; and,
- With the reductions in the amount and availability of grant funding, it is not clear whether funding would be available for the purchase of an alternative source irradiator.

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Issue No. 1.2: Feasibility of the Use of Isotopes Other Than Cs-137 (continued)

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?

No. As stated in the Request for Comments, tungsten shielding is more expensive than lead and manufacturing depleted uranium shielding is a very specialized, expensive operation that requires NRC licensing for its entire lifecycle. As stated above, current facilities are not designed to accommodate the excess weight of increased shielding. Significant expense would be incurred to locate a suitable new facility, perform a structural engineering review, and install increased room shielding or purchase a new Co-60 irradiator.

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

Increased source exchanges (approximately six times more frequently than CsCl) require increased transportation frequency which inherently results in an increased risk for accidents or malevolent events. Increased security during transportation also increases the personnel and financial resources required to minimize and/or mitigate those risks. If the activity of the Co-60 sources are greater or equal to the Radioactive Materials Quantities of Concern, Additional Security Measures would be required (involving NRC, Licensees, Carriers, etc.).

Issue No. 3—Possible Phase-Out of CsCl Sources

Issue No. 3.1: Potential Rulemaking Issues and Justification for Regulatory Change

Q3.1–1. (b) What would be the impact to existing and future biomedical research using these devices?

The Research Irradiator Facility (RIF) is utilized by researchers approximately 25% of the work week, by approximately 31 researchers (with active grants). A number of other researchers have stated that they have grants pending approval and a few have grants they are planning to submit. A vast majority of the biomedical research is ongoing and cumulative, utilizing previously obtained CsCl data. Phasing out CsCl would terminate the vital cancer research projects at the Lombardi Comprehensive Cancer Center. The current research areas include radiation-induced signal transduction, molecular targeting for radiation sensitization of cancer cells, poly (ADP-ribose) polymerase (PARP) activation in apoptosis, roles of oncogenes in radiation resistance, and DNA damage and repair. All of these are directly related to underlying mechanisms of cancer formation or treatment.

The identification of factors associated with the responses of mammalian cells to ionizing radiation has been a major focus of research in radiation biology. More specifically, the ability to predict "radiation sensitivity" or "radiation resistance" of tumors relative to normal tissue tolerance has been identified as an important goal of clinically-related radiobiological investigation. Furthermore, understanding of the cascades leading to gene expression in response to ionizing radiation may permit future improvement of therapeutic interventions.

Recent insights into the molecular bases underlying cellular radiation response have been dramatic. Signal transduction pathways have been implicated in important roles in cellular responses to ionizing radiation. Induction of gene expression by these cascades under various conditions has been shown to result in cell cycle arrest, activation of DNA repair processes, and activation of apoptosis.

Q3.1–1. (c) Can alternative technologies be used for medical applications and/or biomedical research (research on animals and tissue?) .

Currently for most radiation biology protocols (low dose, DNA repair and animal studies) there are no suitable alternative technologies. These must be developed prior to eliminating the use of CsCl.

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

Without a reasonable alternative, biomedical research would be severely impacted. Some of the studies expand on decades of previous research using cesium irradiators. Prior to changing to an alternative technology, when it becomes available, parallel studies must be performed to ensure that the revised research protocols produce valid results. This is currently not funded and may not be possible in all cases.

Currently at GU Medical Center there are 15 active research grants requiring the use of the RIF. The granting agencies are the National Institutes of Health (NIH), National Aeronautics and Space Administration (NASA), Department of Defense (DOD), and pharmaceutical companies (pharm).

- NIH 9 grants for a total of $4,347,135 (Annual Average of $483,015)
- NASA 1 grant for a total of $1,359,244 (Annual Average of $339,811)
- DOD 3 grants for a total of $1,387,009 (Annual Average of $462,336)
- Pharm 2 grants for a total of $186,926 (Annual Average of $93,463)

The total active grant funding is $7,280,314. There are also 5 grants that have been submitted and are pending approval. The total pending grant funding is $10,428,440. All these grants rely on the use of the RIF, and should CsCl be banned, these allocated funds would be lost.

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

Q3.2–1. (b) Who should bear the transportation costs?

Licensees were required to bear the financial burden of implementing the ICs (including the FBI identification and criminal history checks). If CsCl sources are banned, and required to be transported before the end of their useful life, financial assistance should be provided.

Issue No. 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?

Yes, especially for "not-for-profit" institutions.

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

No, not currently.

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?

There needs to be an alternative technology prior to offering any incentives.

(b) For licensees that are defined as "not-for-profit" (e.g., hospitals), what type of incentives could be made available to change technologies?

If an alternative technology becomes available, financial incentives would be desirable.

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

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

We feel that the implementation of the current requirements for increased security of certain high-risk radioactive sources in the U.S. are sufficient.

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

No, not at fixed facilities.

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

It depends on what the additional requirements are, how easy they are to implement, and the additional cost.

Issue No. 5—Role of Risk Analysis in Potential Future CsCl Requirements

Q5.1. (a) How should the NRC determine the economic and social disruptions/impacts to the public, licensees, and the environment?

As always, the NRC should perform a cost benefit analysis bearing in mind that the public benefits from the many uses of CsCl (including blood irradiators and cancer research). Immediate suspension of the use of CsCl would disrupt the availability of blood for patient transfusions, and could delay new discoveries in cancer detection or treatment. First Responders and radiation workers benefit from the use of CsCl for the calibration of their radiation survey instruments. These are some of the tangible benefits to society.

Since the implementation of the ICs, the risk of CsCl sources being successfully obtained, manipulated and diverted for malicious purposes, is reduced but unquantifiable. We urge the NRC to carefully consider all of the quantifiable risks and costs, and verify that the future of cancer research and the subsequent benefits to society are not decreased by any potential actions.

(b) How should these factors be measured in decision making?

We support the comments made by Richard Toohey, PhD, president of the Health Physics Society, urging a careful and thoughtful approach in making decisions on the recommendations of the National Academy of Sciences (NAS) report on CsCl utilization and possible source replacement. Additional stakeholder input should be obtained in stakeholder meetings or task groups which include many of the organizations that attended the workshop.

Sincerely,

Catalina E. Kovats

Digitally signed by Catalina E. Kovats
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