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HEADQUARTERS UNITED STATES AIR FORCE
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FROM: AFMSA/SG3PB
1400 KEY BLVD, STE 400
ROSSLYN VA 22209-1554

SUBJECT: Request for Comments on the Security and Continued Use of Cesium-137 Chloride Sources and Notice of Public Meeting (FR Doc. E8-17545, NRC-2008-0419)

On behalf of the Office of the Air Force Surgeon General, we submit a response to the subject. Comments from our stakeholders have been consolidated and are attached.

The USAF has four IAEA Category 1 and 2 CsCl sources. Three are used for calibration and the other is used for blood irradiation. The calibration sources are used in unique research and the blood irradiator is vital to neonatal care. All are subject to increased controls and have military security features that exceed normal industry standards. Replacing them at this point does not appear to be practical, necessary or fiscally responsible.

Questions in this matter should be directed to Dr. Ram Bhat at 703-588-1049, telefax 703-588-5855, or electronic mail at ramachandra.bhat@pentagon.af.mil.

RKBhat

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Atch:
USAF Comments 20080926

1st Ind, AFMSA/SG3PB
Approved.

Craig L. Adams

CRAIG L. ADAMS, Lt Col, USAF, BSC
Chief, AF Radioisotope Committee Secretariat
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E-RIDS = ADM-03
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US AIR FORCE COMMENTS -20080926

NRC ISSUES	NRC QUESTIONS	USAF COMMENTS ON Cs-137	
		AS A CALIBRATOR	AS A BLOOD IRRADIATOR
Issue No. 1.1: Feasibility of the Use of Other Forms of Cs-137	*Q1.1–1. Are manufacturers currently considering the use of other forms of cesium (other than CsCl)? If yes, what are such considerations?*	N/A	N/A
	Q1.1–2. Is the use of other forms of cesium feasible? If so, please describe desired methods and discuss any benefits or obstacles (e.g., intended function of source, costs, timeframe).	The use of other forms of cesium is possible; however, changes in irradiation configurations, distances used or other considerations would be required with considerable loss of time and money in the process.	N/A
	Q1.1–3. (a) Would the effect of density loading with different forms of cesium preclude their use in existing devices? (b) Would it require modification of existing devices?	N/A	N/A
	Q1.1–4. Is it feasible that high-activity (e.g., IAEA Category 1 and 2) cesium sources will be available in alternative material forms? If so, what is the estimated timeframe for manufacturing?	N/A	N/A
	Q1.1–5. Since all the CsCl is manufactured in Mayak, Russia, is it known if the cesium source producer can modify its production process?	N/A	N/A
	Q1.1–6. Would other entities (in the U.S. or worldwide) engage in manufacturing sources with alternative forms of Cs-137?	N/A	N/A

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?*	Not in the dosimetry program, our primary use. The energy range for Co-60 is too high. The well-understood spectrum of Cs is the foundation of dosimetry standardization programs. This would cause additional issues with the self-shielded irradiators used within the program. These systems are used for daily quality control and initial TLD calibrations.	N/A
	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.	Yes. The irradiators currently used are self-shielded with Cs. A new facility may have to be built to accommodate Co-60.	N/A
	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 that Cs-137, which entails the transportation of both fresh and used sources.	More isotopes on the open road due to irradiators having to be refreshed more often than with Cs-137. More shielding required due to the higher energy of Co-60 over Cs-137.	N/A
Issue No. 2—Use of Alternatives 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?*	No. In some cases where the Cs-137 irradiator can be used with 24 hour supervision to achieve very low dose rates.	X-ray devices are currently available for the blood irradiation market.

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?	X-ray tubes would not provide the type, quantity and energy ranges needed for the dosimetry program.	Changing to an x-ray source at the current time is not cost effective as a device utilizing RAM is already in place and already has had money invested in it to meet current security requirements.
Q2–3: Is there any indication that the performance of the alternatives will change (improve or worsen) with respect to Cs-137?	The performance will worsen, the x-ray tube will operate at a lower energy.	X-ray sources can not achieve the dosimetric uniformity required in blood irradiation. The concerns inherent in the devices are related to dose rate achievable and reliability. When providing blood to a patient there is a very short, case specific, period of time in which the blood can be processed and transported once it is removed from refrigeration until it is placed in the patient. There is little margin for delay. Longer irradiation times detract from this margin. There is also an increased likelihood of device failure in x-ray based units. Without redundant systems this could lead to lack of irradiated blood when it is needed and henceforth the death of the patient. This is particularly important in the irradiation of blood products for neonatal patients. Blood in these cases cannot be irradiated prior to refrigeration.

	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)?	N/A	There is concern that an edict from the NRC requiring a transfer to x-ray based system will create a surge in the demand that may outpace supply and increase costs. In this case, current estimates on costs will significantly underestimate the relevant reality. Different facilities will also have variable costs based off of need to run water lines for cooling and the physical removal of existing devices and installation of new ones.
Issue No. 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?)*	N/A	X-ray sources can achieve the dosimetric uniformity required in blood irradiation. The concerns inherent in the devices are related to dose rate achievable and reliability. When providing blood to a patient there is a very short, case specific, period of time in which the blood can be processed and transported once it is removed from refrigeration until it is placed in the patient. There is little margin for delay. Longer irradiation times detract from this margin. There is also an increased likelihood of device failure in x-ray based units. Without redundant systems this could lead to lack of irradiated blood when it is needed and henceforth the death of the patient. This is particularly important in the irradiation of blood products for neonatal patients. Blood in these cases cannot be irradiated prior to refrigeration.

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?	(a) The entire personal dosimetry and equipment calibration programs of not only the USAF but also many commercial programs would have to be radically changed at great expense. This would include new facility construction, instrument design and calibration procedure changes, but also an increase in the health risk to workers using these instruments, etc. (b) It is assumed current federal standards would have to be re-written and new methods developed.	N/A
Q3.1–3. What would be the economic consequences to users if CsCl was to be banned?	No comment	USAF facilities are funded by taxpayers. The cost associated with providing uninterrupted neonatal blood irradiation service would be borne by them.
Q3.1–4. What would be the economic consequences to vendors if CsCl was to be banned?	N/A	N/A
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?	N/A	N/A

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?*	N/A	(a) Current availability of transportation supplies/contractors may not be able to meet demand follow an NRC order to replace all irradiators. (b) NRC via taxpayers.
	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?	N/A	N/A
	Q3.2–3: (a) Where could the decommissioned sources be stored? (b) What disposition options are needed in the United States?	N/A	N/A

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?*	N/A	The federal government should bear the cost of disposal and replacement for facilities with currently serviceable units. A pre-negotiated price with disposal contractors might be established. The transition period should be extended via justifiable waivers. Facilities may have an incentive to replace units early in the phase out period due to the current burden of increased controls for most sources.
	Q3.3–2. (a) Are there feasible incentives to shift users away from radioactive CsCl for users? (b) Manufacturers?	N/A	The desire to relax security requirements is an incentive already in place.
	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?	N/A	The desire to relax security requirements is an incentive already in place.

	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?	Yes	The federal government should bear the entire cost of decommissioning and replacing units at facilities with currently serviceable units. Minimization in costs could be obtained by having the NRC list reliable contractors who can perform work at a fixed price. The facility should have the option of finding a less expensive service. If the facility uses a contractor not listed by the NRC and the costs are more than the NRC fixed price option, the facility should bear the expense.
Issue No. 3.4: Impact of Potential U.S. Changes to Regulating CsCl on the International Community	*Q3.4–1. How can the U.S. prevent recovered sources from decommissioned devices (or the devices themselves) from being sold outside the U.S.?*	N/A	Sources should be permanently disposed of in the United States.
	Q3.4–2. (a) If the U.S. decides to ban the use of CsCl sources, should the U.S. have a position in denying or eliminating after-market sales of CsCl irradiators outside the U.S.? (b) Would this be potentially denying medical care to developing countries?	NA	If the purpose of the NRC mandate was to reduce threat, then no after-market sales should be permitted.
	Q3.4–3. What should the role of the International Atomic Energy Agency (IAEA) be in assisting the U.S. in ensuring the safe and secure use of CsCl sources and devices?	No comment	N/A

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).*	No. Major changes have already occurred at considerable expense so cost/benefit of added measures requires further study.	No. Current rules are sufficient.
	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)?	No.	No.
	Q4.3. Would additional security requirements for CsCl create a disincentive for owning them?	No.	Yes

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? (b) How should these factors be measured in decision making?*	N/A	No comment.