POLICY ISSUE
(Notation Vote)

November 24, 2008 SECY-08-0184

FOR: The Commissioners

FROM: R.W. Borchardt
Executive Director for Operations

SUBJECT: STRATEGY FOR THE SECURITY AND USE OF CESIUM-137 CHLORIDE SOURCES

PURPOSE:

To provide a strategy, regulatory options, and a recommended option regarding the security and future use of cesium-137 chloride (CsCl) sources. This paper does not address any new commitments.

SUMMARY:

On May 30, 2008, the Commission issued a Staff Requirements Memorandum (SRM) "Briefing on Materials Licensing and Security" directing that improving security of CsCl sources and consideration of the efficacy of existing technological alternatives should be a priority. The staff has worked with Federal partners, the Advisory Committee on the Medical Uses of Isotopes (ACMUI), the States, industry and various stakeholders to find solutions and provide recommendations, including identification of additional research needs, to the Commission on the path forward.

The staff has developed options for Commission consideration on a path forward based on information gathered from staff analysis, stakeholder inputs, a public workshop, site visits, and other sources. The focus of the recommendations includes sources in International Atomic Energy Agency (IAEA) Categories 1 and 2 which are used in three distinct modes of application: (a) blood sterilization, (b) bio-medical and industrial research, and (c) calibration of instrumentation and dosimetry.

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The stakeholder feedback received strongly indicates that near term replacement of devices or CsCl sources in existing blood, research, and calibration irradiators is not practicable and would be disproportionately detrimental to patient health, longstanding research, and emergency response capabilities. Furthermore, a clear strategy for the end-of-life management of these sources, which is the responsibility of the government, is not mature and likely will not be for some time. Therefore, the staff recommends continued security of these facilities through the use of increased controls and continued support of Federally-funded programs to harden the existing devices against intrusion. This recommendation supports the continued use and provides for adequate security of CsCl sources. The staff believes the feedback is compelling that banning of new devices using CsCl is not practicable at this time. Accordingly, staff recommends that for new licensees and existing licensees seeking a newly manufactured irradiator, the irradiator should be hardened at the manufacture point.

Regarding the long term replacement of CsCl, the industry feedback and literature indicates that an alternative chemical form of cesium could prove to be a suitable replacement, and would be preferable to other nuclides (Cobalt-60) or technologies (x-ray), primarily because of the energy spectrum. However, there is no apparent economic incentive for private industry to develop alternative chemical forms of large (>20 curies) cesium sources. Also, production capabilities of alternative chemical forms for large curie quantities have not been developed. The production environments are very complex due to the volatility of cesium-137 (Cs-137) during production. The staff recommends that the U.S. Nuclear Regulatory Commission (NRC) engage Federal partners and encourage efforts by the U.S. Government to research alternative forms. Since there is no current definition for dispersibility, to enable the long term replacement of CsCl, the staff also recommends the development of a common Federal agency set of criteria for dispersibility and other material properties as they relate to reducing the potential consequences of a radiological dispersion device (RDD).

This paper also responds to the Commission's direction to determine whether rulemaking is needed to address the definition of "radiation source" as defined in the Energy Policy Act of 2005 (EPAct). The staff concludes that additional rulemaking to address this definition is not needed at this time since existing regulations sufficiently address this definition and there is currently no compelling reason to amend these regulations.

BACKGROUND:

CsCl sources with activity levels in IAEA Categories 1 and 2 (i.e., above 27 curies) are widely used in self-shielded irradiators in three major modes of application: blood sterilization, bio-medical research, and calibration. CsCl is used because of the properties of Cs-137, including its desirable single (662 keV) energy spectrum, long half-life, low cost, and moderate shielding requirements relative to other nuclides. In the irradiators, the CsCl in a compressed powder form is doubly-encapsulated in a stainless steel capsule. This physical form is used because of its high specific activity (gamma emission per unit volume) and manufacturability; but it is highly soluble in water, and is dispersible in aerosol form, which presents security concerns.

The staff conducted a number of initiatives to assess the solubility/dispersibility issue, the adequacy of current security requirements, less soluble and dispersible chemical and physical forms for Cs-137, and the feasibility of utilizing alternate nuclides and alternate technologies without radioactive materials.

A significant element of the staff's initiatives was a public workshop, held on September 29-30, 2008, to solicit public input on major issues associated with the use of CsCl. The Workshop included active participation by 210 participants and the staff received 141 written comments. In advance of the Workshop, the staff published an Issues Paper in the *Federal Register* (73 FR44780) on five issues that were structured to initiate public comment. These five issues included (1) alternatives to the use of CsCl sources, (2) use of alternative technologies, (3) possible phase-out of CsCl sources, (4) additional requirements for enhanced security of CsCl sources, and (5) role of risk analysis in potential future CsCl requirements. The overwhelming majority of the written comments and discussion at the Workshop demonstrated the significant impediments and critical impacts to medical care, research, and calibration which would be associated with a potential phase-out of CsCl. The stakeholder feedback received strongly indicates that near term replacement of devices or CsCl sources in existing blood, research and calibration irradiators is not practicable and would be disproportionately detrimental to patient health, longstanding research, and emergency response capabilities. Given the range of uses of CsCl, one solution cannot apply to all applications or to all licensees uniformly. The transcripts of the Workshop are available in the Agencywide Documents and Management System (ADAMS) at ML082760548. The written comments can be found at: http://www.regulations.gov, NRC-2008-0419.

The NRC staff also conducted a series of visits to the manufacturers of CsCl irradiators and sources between December 2007 and April 2008. A cohesive set of conclusions emerged from the manufacturers: for development of high activity sources using less soluble and dispersible forms of Cs-137, a significant research effort is needed; scaling up from current small activity levels may not be technologically successful; and if security is to be enhanced, the NRC should work with the industry to identify cost effective feasible enhancements.

The staff requested that the ACMUI conduct an efficacy study to compare the use of CsCl irradiation to other technologies, particularly x-ray irradiation. On October 13, 2008, the ACMUI provided their report (see Enclosure) to the staff which delineated the use of gamma radiation in medical practice and research, described the limitations of x-ray irradiators and also provided recommendations to resolve security issues related to CsCl irradiators. The major conclusion is that the strong measures in place for ensuring security of CsCl sources in medical applications have reduced the vulnerability of these devices and should be acceptable as an alternative to removal or prohibition of these devices. The study concluded that x-ray machines could be a replacement for blood irradiation, but it is not clear from the available data that x-ray sources are biologically equivalent to CsCl irradiators because of the different energy spectrum. In addition, the report indicated that their use would present greatly increased expenses to programs that need the functionality and operational reliability of the irradiators. The ACMUI report indicated

that new X-ray irradiators have a purchase price listed at $250,000, a 3-year maintenance contract quoted at $66,000, and possible calibration costs may exceed $10,000 per year[1].

On September 12, 2008, the CsCl Subgroup of the Radiation Source Protection and Security Task Force (established under the EPAct) issued a report to the Task Force entitled "Report on Assessment of Feasibility of Phasing out the Use of CsCl in a Highly Dispersible Form." This report concluded that an immediate phase-out would not be feasible, but a step-wise phase-out could be feasible if a number of pre-conditions become available: (a) viable alternative technologies must be developed, (b) disposal pathway (including transportation containers and the disposal sites) must be established, and (c) sufficient time is scheduled for an orderly transition.

The staff also reviewed the recommendations of the report "Radiation Source Use and Replacement" prepared by the National Research Council of the National Academies (NA). The NA report (ML062190349) strongly emphasized replacement technologies for radioactive sources, particularly for CsCl. The report recommended that the U.S. Government should implement actions for eliminating IAEA Category 1 and 2 CsCl sources in the U.S. and, to the extent possible, elsewhere. The report suggested three actions to achieve such a goal: discontinue licensing new CsCl irradiator sources, put in place incentives for decommissioning existing sources, and prohibit the export of CsCl sources to other countries. Regarding implementation, the report indicated that NRC should consider the potential economic and social disruption that the change may cause. The report also stated that a research and development program would include "qualification of alternative matrices" for high-activity Cs-137 sources and production of those matrices to provide lower hazard Cs-137. The options in this paper address the recommendations of the NA report, including consideration of economic and social consequences for source replacement.

Regarding security enhancements at licensed facilities, subsequent to the terrorist events of September 11, 2001, the NRC and Agreement States issued additional requirements, in the form of Orders and new or amended rules, requiring licensees who possess risk-significant radioactive materials to implement increased security and control measures to reduce the risk of malevolent use and intentional unauthorized access to radioactive material. The additional requirements enhanced and supplemented existing regulations in 10 CFR 20.1801, "Security of Stored Material," and 10 CFR 20.1802, "Control of Material Not in Storage," which are primarily intended to prevent or mitigate unintended exposure to radiation. The components of security requirements currently in place for risk-significant quantities of Cs-137 include background checks, access controls, monitoring for and the detection of and response to unauthorized access, delay and deterrence of adversaries, and the tracking of transfers and shipments. In the future, an additional element may be added such as avoidance measures (i.e., phase-out of CsCl) when the technology becomes available. In addition, the existing import/export and National Source Tracking rules provide additional regulatory controls that increase knowledge and awareness of risk-significant radioactive material transactions and provide added assurance that such transactions are only made by authorized entities.

[1] Additional cost comparisons between CsCl and x-ray devices are available in the CsCl Subgroup's report to the Radiation Source Protection and Security Task Force and within the transcripts and written comments from the September 29-30, 2008, Stakeholder Workshop.

Several working groups, composed of NRC and Agreement State representatives, have been established to develop proposed rules intended to replace the existing security requirements.

There have been a limited number of research studies conducted on alternative, less soluble/dispersible forms of Cs-137. In 2008, the NRC's Office of Nuclear Regulatory Research and Office of International Programs published a draft Letter Report, "Initial Assessment of Alternative Materials for High Activity Cesium-137 Sources," prepared by Russian researchers from open-source scientific and technical publications. It concluded that the most promising materials are phosphate ceramics and cesium alumophosphate glass, and recommended development of a detailed scientific, engineering, and economic feasibility to assess further the possible replacement of CsCl with alternative materials.

The draft Letter Report was shared with technical staff within the Department of Homeland Security's (DHS) Domestic Nuclear Detection Office (DNDO), the U.S. Department of State, and the U.S. Department of Energy's (DOE) National Nuclear Security Administration (NNSA). A final version of the Letter Report that addresses comments received from these agencies is planned for publication in December 2008. Further development of alternative forms of Cs-137 to enhance security, as anticipatory research, would entail 4-5 years of development at an estimated cost between $500,000 and $1,000,000 per year.

An important consideration in moving forward on development of possible alternative material forms to cesium chloride is the reduction in risk to individuals, society, and the environment compared to cesium chloride. Selection of an alternative material should be based on technical analysis that demonstrates its superiority in mitigating consequences of malevolent use if the Cs-137 source was not safely managed or securely protected. This reduction needs to be quantified in terms of radiological dose to exposed persons during plume passage, emergency response, remediation, remediation costs and potential psychological impacts. The NRC staff is not aware of such analyses being conducted to date, and recommends that the Federal government undertake risk reduction and cost-benefit analyses of alternative materials to cesium chloride to inform decision making on replacement of CsCl.

The staff also established a website to inform the public of this NRC initiative, to facilitate public comment, and to provide background information to enhance public awareness of staff activities (http://www.nrc.gov/materials/miau/licensing.html#cesium).

DISCUSSION:

The following discussion presents the basic considerations, underlying all options, on the current and future use of CsCl.

Security and Control of Radioactive Sources

Based on the results of inspections for compliance with the increased security requirements, reviews of the effectiveness of the security orders, input from the September 2008 stakeholder meeting, and a review of current threat information, the staff believes that radioactive materials security has been greatly improved by the current security requirements, and that the risk of malicious use of the material has been reduced significantly. Staff reviewed the results of the

initial phase of inspections for compliance with the security orders, and, in conjunction with the Agreement States, conducted a review of the effectiveness of the implementation of the Increased Controls requirements. The staff's review concluded that licensees generally understood the requirements and implemented programs that met their intent, but there were specific areas where the requirements and guidance could be enhanced to increase licensee understanding and compliance. Neither the inspection results nor the review identified gaps in the requirements, or indicated a need for new security requirements. The results of these reviews will be provided to the working group developing the enhanced security measures proposed rule. The working group will consider this information and identify potential revisions to the requirements and guidance to address the identified issues.

The NNSA conducted security assessments over the last two years at NRC and Agreement State licensee facilities, many of which are hospitals and universities that use research and blood irradiators. The NNSA assessments did identify cost-effective measures licensees could implement to enhance their physical protection programs by using enhanced control, monitoring, detection, and delay to increase the potential of a successful response to an unauthorized access event. In some cases, NNSA also installed recommended security upgrades at no cost to the facility. In addition to the NNSA security assessments, NNSA and DNDO have initiated a joint "hardening" project for irradiators containing CsCl sources; this Federally-funded initiative is supported by the NRC and the Agreement States. This project has identified relatively simple and cost effective hardening measures that can be retrofitted to existing irradiators and incorporated into the design of newly manufactured irradiators that will provide additional delay for unauthorized access to the CsCl sources. A pilot installation phase is currently underway and a national implementation plan is expected in early 2009. Although the current security measures are effective and have reduced the risk of malicious use of the CsCl sources, the NNSA and DNDO initiatives will provide meaningful enhancements to the security of irradiators containing risk-significant CsCl sources. The working group developing the enhanced security measures proposed rule is also considering enhancements to security of devices containing CsCl sources.

Blood Irradiators

Blood sterilization by irradiation, conducted at blood centers, hospitals and university medical centers, results in significant health benefits to patients. Irradiation of blood is medically essential to prevent transfusion associated graft versus host disease. Without irradiated blood, hematology and oncology patients would suffer potential death. In 2004, over 2.5 million blood components were irradiated. ACMUI reported that 15-40% of the blood used in the U.S. is irradiated; stakeholders indicated that some hospitals use 100% irradiated blood. CsCl blood irradiators are used in over 90% of all applications because the devices are the most reliable, efficient, and require low maintenance. X-ray is an alternative form of irradiation which is also available for blood sterilization; however, stakeholders have indicated that X-ray irradiators create hardship for the sterilization industry because of their significant limitations compared to CsCl irradiators, such as low reliability, slow throughput, high initial costs, high operating costs, high maintenance requirements, and shorter working life.

Research Irradiators

In biomedical research, CsCl irradiation has been used for over 40 years in fields such as immunology, stem cell research, cancer research, in vivo immunology, systemic drug research, chromosome aberrations, DNA damage/repair, human genome and genetic factors. For example, in DNA research more then 7,400 papers have been published using CsCl irradiation, and more than 700 researchers use CsCl irradiators at a single major U.S. research institution. If CsCl irradiation was to be replaced with another source of irradiation, the results of this research would no longer be scientifically replicable since the specific interactions from CsCl irradiation interactions are integral to the studies. The response of biological systems to the specific radiation is well established. The response of cells and tissues varies with radiation type and energy.

For most research, there are no alternatives to Cs-137 irradiation because the experiments require high doses at high dose rates with uniform fields of linear energy transfer (LET) radiation. To proceed with biomedical research, comparison studies will have to be conducted in order to correlate research using an alternative source to the existing CsCl based data sets and could compromise the continuity of biomedical research. Future results could not be directly compared to many years of established data. Significant time (many years) and effort would be needed to determine and validate radiation doses and deliveries from alternative sources.

Calibration

The U.S. national system and international systems of radiation measurements are based on the energy spectrum of Cs-137. All ANSI standards and their associated test-and-evaluation protocols for radiation detection and personal dosimetry rely on the use of Cs-137. Cs-137 was selected over 40 years ago as the basis of international calibration because of the optimal single energy spectrum of this nuclide and its long half-life. The National Institute of Standards and Technology (NIST) maintain the national measurement standards and calibrate the instruments for secondary laboratories. These instruments are disseminated to secondary and tertiary laboratories who, in turn, calibrate the instruments for the end users. This network of facilities ensures that every radiation detection instrument that is used in the country measures correctly and is traceable to NIST. In addition, U.S. accreditation programs, such as those managed by the Health Physics Society, the DOE, and the National Voluntary Laboratory Accreditation Program, also rely on the use of Cs-137. As an example, the calibration program of the U.S. Armed Forces performs annual calibration of approximately 150,000 survey meters which all must be traceable to the NIST standard. In addition, all DHS-related standards for calibration of first responder and emergency response equipment such as personnel self-reading dosimeters, portal monitors and portable survey instruments also require the use of Cs-137 for calibration purposes. Most of the laboratories involved in the calibration networks are in civilian, government, military, and national laboratories, all of which have high levels of security. Approximately 250,000 radiation-measuring instruments and millions of dosimeters are traceable to the spectrum of Cs-137. This traceability is ensured through periodic proficiency tests and calibrations. Replacing the current CsCl technology with other less soluble/dispersible forms of Cs-137 could be acceptable for calibration applications because the Cs-137 spectrum would be maintained. However, until a new chemical/physical form of Cs-137 becomes available, calibration facilities will have to rely on devices containing CsCl.

The Table below notes the proportion of CsCl used within the primary applications at the present time.

Application	IAEA Category	# of Licensees	# of Devices	% of Total Curies
Blood Irradiators	1-2	327	575	33.65
Research Irradiators	1-2	265	526	66.00
Calibrators	2	61	104	0.35

In summary, alternatives could be possible but are not currently available. It is not certain whether it will be viable to produce less-dispersible/soluble forms of Cs-137 for high activity sources needed in CsCl irradiators. A clear strategy for end-of-life management of these sources must be developed and significant research and development effort is needed to make viable alternative technologies widely and cost-effectively available. The current status of source development does not indicate assurances that less-soluble and dispersible forms of Cs-137 could be developed. NRC could work closely with domestic Federal and international partners: (a) to enhance security regardless of any option, and (b) to conduct research to develop viable resolution of the solubility/dispersibility issue.

As part of the staff's efforts to address CsCl sources, the Commission directed (in SRM dated February 6, 2006) the staff to determine whether rulemaking is needed to address the definition of "radiation source" as defined in Section 651 of EPAct. The EPAct's definition of radiation source[2] is consistent with existing NRC regulations in Appendix E to 10 CFR Part 20 for nationally tracked sources, Appendix P to 10 CFR Part 110 for imports and exports, and Appendix I to 10 CFR Part 73 (effective February 23, 2009) for Category 1 and 2 radioactive materials. Given that existing regulations address the term "radiation source" as it is defined in the EPAct, and that there is currently no compelling reason to amend these regulations, the staff does not believe that any additional regulations are needed for the definition of a radiation source at this time.

Option 1. Enhance security and issue a Commission Policy Statement

Under Option 1, both the fundamental elements of security and the normalcy of CsCl use in all three modes of application (i.e., blood irradiation, bio-medical research, and calibration) are maintained. This option recognizes that significant impediments exist to any potential phase out of CsCl and that there is insufficient information available to develop a technical basis for rulemaking. This option initiates a path forward toward further enhancing security of CsCl and resolving the impediments identified by the stakeholders.

The staff would continue to work with domestic and international partners to respond to a changing risk environment as well as to promote technological developments. Under this option, the Commission would issue a Policy Statement to delineate the Commission's emphasis on security for CsCl sources, and specify the Commission's vision for future developments in the safe and secure use of CsCl sources. The Policy Statement would reflect

[2] RADIATION SOURCE – The term 'radiation source' means "(A) a Category 1 Source or a Category 2 Source, as defined in the Code of Conduct;" and "(B) any other material that poses a threat such that the material is subject to this section, as determined by the Commission, by regulation, other than spent nuclear fuel and special nuclear materials [Public Law 109-58-Aug. 8, 2005, 119 STAT.803]."

the Commission's desire to facilitate additional actions aimed at reducing the risk of CsCl and work toward solutions to challenges which need to be addressed in order to support a potential phase out. In addition, NRC would conduct, in cooperation with Federal, State, and international partners, a number of specific actions to continuously assess and enhance the security program, including protective strategies, evaluation and response to threats, and encouragement of technological developments for alternative forms of CsCl.

Specific actions to be conducted by the NRC staff to enhance security:

- Assess implementation of voluntary hardening program for blood and research irradiators and consider making it a requirement for existing devices through rulemaking.
- Attain industry consensus for new blood irradiators to be delivered with hardening. There are two vendors of blood irradiators in the U.S. A limited number of new units are ordered each year. Both vendors have expressed intent informally to harden new units. Thus, a consensus can be realistically achieved.
- Work with NNSA and DNDO on potential hardening (to increase delay) for CsCl calibrators and assess potential security enhancements.
- Continue to monitor the threat environment and issue new security requirements as may be necessitated by emerging risks.
- Assess whether additional requirements are needed (e.g. tamper-proofing) through the ongoing enhanced security rulemaking process. Consider using this rulemaking to seek stakeholder input on strategies to mitigate the insider threat.
- Interact with IAEA and other international partners to promote and enhance CsCl security.
- Engage Federal partners in the (a) the development of a common Federal agency set of criteria for dispersibility and other material properties as it relates to mitigating the consequences of an RDD, and (b) anticipatory research for less soluble/dispersible forms of Cs-137, preceded by risk and cost-benefit analyses for reducing consequences from the current use of CsCl.
- Develop a strategy for end-of-life management of CsCl sources.

The staff would develop a Commission Policy Statement that would address the following issues:

- Articulate current security requirements and processes for performance evaluation, monitoring, and improvement. This would re-emphasize for the public the current state of security requirements.
- Articulate the Commission's role in ensuring public health and safety and promoting common defense and security for radioactive materials under NRC jurisdiction.
- Articulate the uses of CsCl.
- Articulate why alternative forms would be desired.
- Encourage active development of alternative forms.
- Articulate the role and need for continued involvement from Federal partners and stakeholders in security enhancements and technology development to reduce the risks of high activity CsCl sources.
- Define the role of risk and cost/benefit in regulatory decision making.

The implementation period for Option 1 is relatively short. Some of the actions can be started immediately, such as for the security of the largest sources and additional actions continuing for two years for remaining high risk CsCl sources. All actions, except long term research, under NRC lead could be completed within two years.

Advantages of Option 1:

- Prompt actions, security activities are consistent with current NRC program planning.
- No impact on blood irradiation practices.
- Uninterrupted continuity of bio-medical research.
- Adherence to current calibration practices.
- Low cost impact to government and licensees.
- Consistent with the majority of stakeholder feedback.
- Policy Statement would provide clear articulation of the Commission's policy.
- Could spur the development of alternative forms/technologies by industry.
- Would solicit further stakeholder input for additional technical information and solutions to current impediment.
- Would allow continued active stakeholder input.
- Would engage Federal partners in the (a) the development of a common Federal agency set of criteria for dispersibility and other material properties as it relates to mitigating the consequences of an RDD, and (b) anticipatory research for less soluble/dispersible forms of Cs-137 that includes a cost-benefit analysis of reducing consequences from the current use of CsCl.

Disadvantages of Option 1:

- The current form of CsCl would not be changed.
- No apparent economic incentive for private industry to develop alternative chemical forms of CsCl.
- The actions taken are not in full in accordance with some report recommendations (e.g. NA report).

<u>Option 2. Rulemaking to ban CsCl in soluble/dispersible form for blood irradiators, and maintain use of CsCl for research and calibration</u>

Under Option 2, the NRC staff would initiate a process that would lead to phasing out CsCl in dispersible/soluble form in blood irradiators and replace it in existing and new devices with ceramic/glass form. Replacement of the current form of CsCl would be feasible when two pre-conditions are resolved: (a) non-soluble/dispersible forms become available requiring a research and development process to successfully scale up the activity level from 20-50 to 1,000-2,000 curies per source on a commercial basis, and (b) a disposal pathway is established to transport and store the existing sources that are to be replaced. Replacement of existing sources is feasible for the models manufactured by two of the three irradiator vendors (Best Theratronics and J.L. Shepherd and Associates), and not feasible for the third vendor (Pharmalucense who does not distribute new units any longer, but maintains existing units only, about 25% of the blood irradiators currently in use).

Specific actions to be conducted by the NRC staff:

- Establish acceptance criteria for dispersibility because currently there are no objective, quantifiable techniques which would define and measure dispersibility. Dispersibility of ceramic or vitrified forms of Cs-137 changes over time in a radiation environment; thus, the acceptance criteria must also account for such a change.
- Interact with Federal partners to facilitate the availability of the disposal pathway.
- Interact with Federal partners to fund research to develop non-dispersible/non-soluble form.
- Initiate rulemaking to require non-dispersible/non-soluble material for CsCl sources or develop incentives for voluntary licensee actions.
- Interact with IAEA and other international partners to promote and enhance CsCl security.

The implementation period for Option 2 is relatively long. Development of an alternative form Cs-137, if accomplished, is estimated to take at least 4-5 years and the viability of the alternative is not assured. Consequently, the replacement program could begin after the 4^{th} or 5^{th} year (or when the disposal pathway becomes available). Establishment of a disposal site is estimated to take 4 years or more.

Advantages of Option 2:

- Reduces risk (real or perceived) associated with soluble/dispersible forms of CsCl in one major use.
- Acceptable to all users (including research and calibration).
- Consistent with NA Report recommendations.
- No effects on 2 of the 3 major areas of use in bio-medical research irradiators and in calibration.
- Regulatory requirement may stimulate industry to develop technological alternatives.
- May be coupled with government incentives.

Disadvantages of Option 2:

- Risk that development of new form may not be successful.
- Implementation would start in the long term.
- May interrupt blood supply.
- May not be justified by risk consequences.
- A disposal pathway, i.e., transportation packages and disposal site, must be developed prior to implementation.
- Replacement constitutes significant cost impact on industry.
- Installation of hardening makes replacement more complicated and costly.
- Some irradiators (Pharmalucense units) are not suitable for replacement.
- Would only address approximately 1/3 of the CsCl currently in use.
- There is cost impact on the Government if incentives are used.
- Congressional action (to solve disposal issue) may be needed.
- Insufficient information to develop a technical basis for rulemaking at this time.

- The changes would affect only the domestic use of CsCl, its use in other countries will not be changed.

Option 3. Rulemaking to ban soluble/dispersible form of CsCl (for all applications)

Option 3 would extend the ban, discussed above in Option 2, to all 3 major areas of use and would require the use of alternative forms of Cs-137. The above pre-conditions (as listed in the CsCl Subgroup's report, discussed in the Background section of this paper) must also be met for implementation of the ban. The specific actions to be conducted by the NRC staff are also identical, but on a larger scale.

Advantages of Option 3 (The advantages of Option 2 apply, with additional advantages below):

- The solubility/dispersibility issue would be addressed.
- The unique role of the Cs-137 energy spectrum in bio-medical research and calibration would be preserved.
- Regulatory requirement may stimulate industry to develop technological alternatives with limited research costs to government.

Disadvantages of Option 3 (the disadvantages of Option 2 apply, with additional disadvantages below):

- Huge cost impact on industry.
- Grandfathering existing units would stretch out the implementation for decades.
- Without a grandfathering clause, some irradiators (Pharmalucense units) would have to be replaced before the end of their working life.
- The changes would affect only the domestic use of CsCl, its use in other countries will not be changed.

RECOMMENDATIONS:

The staff recommends that the Commission approve Option 1. The recommendation is based on an assessment of the advantages, disadvantages, and implementation period of the three Options and the information gathered from staff analysis, stakeholder inputs, a public workshop, site visits, and other sources. Option 1 also accounts for the fact that viable alternatives may not be successfully developed, however, research on alternative forms of Cs-137, lays the foundation for a path forward that may reduce the risks associated with CsCl sources.

RESOURCES:

The actions proposed in the Options above have resource impacts both on the NRC, the Agreement States, other Federal agencies, and the industry.

NRC Staff Resource Requirements:

Option 1

- Direct staff activities related to security issues as listed above (no impact because within current budget activities) 0.0 FTE

- Staff activities to develop criteria for dispersibility 1.0 FTE
- Staff activities for rulemaking (no impact because Option 1 will be part of on-going rulemaking process) 0.0 FTE
- Development of the Policy Statement 2.0 FTE
- Stakeholder outreach for development of Policy Statement $120K

Option 2

- Staff activities to develop criteria for dispersibility 1.0 FTE
- Rulemaking activities
    - Year 1, Establish technical basis for rulemaking 2.5 FTE
    - Stakeholder outreach $240K
    - Year 2, rule development 2.0 FTE
    - Year 3, rule development 2.2 FTE

Option 3

- Identical to Option 2 with significantly larger scope for establishing the technical basis for rulemaking, with the addition of FTE 1.5 FTE

For the above options, if anticipatory research is to be conducted by the NRC, the staff estimated that an annual funding of $500k to $1 million would be necessary each year for a period of 4-5 years.

The work and resources identified above are new initiatives and were not known when the FY 2009 and FY 2010 budgets were prepared. Upon Commission approval and direction, the staff will develop detailed resource estimates for NRC activities and work with the Office of the Chief Financial Officer to immediately identify available resources and submit a high priority funding plan for approval that supports the approved regulatory Option.

COORDINATION:

The Office of General Counsel reviewed this paper and has no legal objection. The Office of the Chief Financial Officer reviewed this paper and has no objection.

AGREEMENT STATE COORDINATION:

The NRC staff coordinated this strategy with the Organization of Agreement States (OAS), Inc. On November 5, 2008, the OAS indicated that the OAS Board "…supports the NRC staff recommendation that the Commission approve Option 1 as discussed in the draft document. It recognizes the collaborative actions taken to date to improve security and oversight of these sources, while allowing continuation of the current uses of CsCl in blood irradiation, research and calibration. At the same time, it would make clear that there is a need for continued cooperation between Federal, State, and international partners to continuously enhance security, evaluate threats and encourage development towards alternative technologies.

We believe that it is imperative to develop a viable alternative technology and a disposal option for these sources before considering the phase-out of them. Therefore, we are opposed to rulemaking as outlined in Options 2 and 3 at this time."

/RA Martin J. Virgilio Acting For/

R. W. Borchardt
Executive Director
for Operations

Enclosure:
Advisory Committee on the Medical Uses
of Isotopes Report on ^{137}CsCl Irradiators

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Advisory Committee on the Medical Uses
of Isotopes Report on ^{137}CsCl Irradiators

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Advisory Committee on the Medical Uses of Isotopes's Report on ^{137}CsCl Irradiators

Summary

After studying the issues, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) came to the following conclusions:

1. Irradiators are necessary for medical practice and medical research.
2. It is not clear from the available data that x-ray sources are biologically equivalent to ^{137}CsCl irradiators.
3. Alternatives to the ^{137}CsCl irradiators currently in operation present greatly increased expense to programs that need the functionality and operational reliability of the irradiators.
4. The recommendation of the National Research Council (NRC) of the National Academies to eliminate the use of irradiators that employ ^{137}CsCl was based on the situation at the time of their study. Since that time, security of medical irradiators units has been substantially strengthened in three ways:
    a. Increased security of persons with access. The December 2005 NRC orders increased the security requirements for all persons having unescorted access to ^{137}CsCl irradiators, including background checks, personal reference checks, and fingerprinting checks against the FBI fingerprint database.
    b. Increased security of the facilities housing the units, including high-security locks on facility door, multiple doors with locks for access, motion sensors, video cameras monitored by facility security, preplanning with local law enforcement, database encryption, and secured facility schematics, and drawings.
    c. Increased security of the units themselves, including locks on source access panels and entry points.

    Given these changes, we found that the National Research Council concerns do not currently apply as previously stated, and have been superseded by increased safeguards as required by the Nuclear Regulatory Commission and state regulatory authorities. Well-secured ^{137}CsCl irradiators present little security hazard.

Practicality of Alternatives to ^{137}CsCl Self-Shielded Irradiators*

Blood and Blood-Product Irradiation

Based on our survey of the literature and other publicly available information sources, the only medical x-ray irradiator that the U.S. Food and Drug Administration (FDA) has cleared to irradiate blood and blood products to prevent graft-versus-host disease is the

* Content taken from manuscript submitted to *Health Physics* June 17, 2008: Dodd, B and Vetter, R. "Replacement of ^{137}Cs Irradiators with X-Ray Irradiators"

Raycell (Best Theratronics 2008) originally manufactured and sold by Rad Source (Rad Source 2007a) as the unit model RS 3000. Other manufacturers may also be developing plans for new irradiators.

The first question regarding practicality of an x-ray machine to irradiate blood or blood products is whether there are any technical issues. Although the photon energy of x-ray machines is lower than those of ^{137}Cs, Janatpour et al. (2005) demonstrated that x-ray machines can deliver the necessary 25 Gy dose with sufficient uniformity and stability to meet FDA guidelines. The typical x-ray irradiator generates a filtered energy spectrum with a peak energy of approximately 160 kVp, compared to the monoenergetic 662 keV gamma rays from ^{137}Cs. While a radiation weighting factor of 1 is applied to both gamma rays and x rays for radiation protection purposes (NCRP 1993), the biological effectiveness of low energy photons is approximately twice that of 662 keV ^{137}Cs gamma rays (ICRU 1986). Consequently, a dose of 25 Gy delivered by an x-ray irradiator will not produce the same biological effect as 25 Gy from ^{137}Cs gamma rays. The significance of this difference in radiation effectiveness relevant to transfusion medicine and immunological research is unknown.

Regarding costs, the NRC study (2008) quoted about $180,000 for a new x-ray irradiator and an annual service agreement cost of just over $10,000. However, the actual cost of the x-ray system has increased. In May 2008 this manufacturer quoted a purchase price of $250,0000 and $66,000 for a 3-year maintenance contract including a routine service call and one set of replacement parts as needed. While the purchase price might be about the same as a ^{137}Cs irradiator, the annual maintenance cost with a service agreement may be much greater unless the owner has engineering capabilities to provide service and maintenance in-house. Also, the service contract does not include physics services. Depending on the number of set-ups, calibration costs may exceed $10,000 per year if outside physics services are required. In addition, there would be a one-time cost of installing a 240 volt line to the room for most of the x-ray units replacing a cesium irradiator.

Based on repair history of clinical x-ray machines, a user of an x-ray irradiator may experience a higher failure rate and require more service and down-time than a ^{137}CsCl irradiator. Since maintenance of an irradiated blood supply is important, purchasers of x-ray blood irradiators find it necessary to purchase an annual maintenance agreement. However, outside service can result in a facility being unable to perform life-saving irradiations for a time. For example, one owner experienced a service response and re-calibration time of two weeks. Both the upper and lower power supplies had to be replaced after a few years of operation. Therefore, blood banks and hospitals may need to plan for an alternative means of irradiation or an alternative supply of irradiated blood components to meet critical demand. Without ^{137}CsCl as an alternative, the facility may have to purchase two units to assure a continuous supply of irradiated blood.

Another factor to evaluate for practicality is the throughput of an x-ray irradiator. Two units of blood can be irradiated at one time with the Raycell, and irradiation time is about 5 min. This is sufficient for two blood centers contacted, which do about 30-100 units per month, and it is adequate for a clinic doing about 20 units per day. However, a significant workload like that at a large academic medical center with a throughput of 50-60 units per day may exceed the capabilities of a single x-ray unit. While it may seem that the exposure rate with the x-ray would keep up with the demand, the blood

irradiation is not continually as with an assembly line. Rather, units are irradiated as needed based on the clinical demand, in irregular intervals. Thus, the duration required for the irradiation becomes an important limiting factor. One potential buyer stated that about 48,000 blood products could be irradiated within the x-ray tubes' 2000-h warranty period (Blood Bank Talk 2007). For a site processing 50 units per day and assuming that procedures requiring irradiated blood happen mostly during normal work days, that would imply the need for a new tube each 3.7 years, adding considerably to the cost of the operation.

Since ^{137}Cs has a half-life of 30 years, it is not financially practical to replace those units that were installed within the last 15 years. Ease of use is comparable between the ^{137}CsCl irradiator and the x-ray irradiator.

One issue that has not been investigated is whether all the operating cesium irradiators could afford to replace the units, or whether some facilities will cease operation, depriving patients of irradiated blood and researchers a source of radiation.

Biomedical and Small Animal Irradiators

Ten x-ray irradiators are commercially available for cell, tissues and small animals, eight from three U.S. manufacturers and two irradiators from outside the U.S. A few will be discussed as being representative of the issues.

The **RS 2000** (Rad Source 2007b) has been sold by Rad Source since 1999, with about 15-20 units placed in Europe and Asia and 50-60 placed in the USA. Several users contacted seem satisfied with the device. The purchase price is little over $100,000, and a service agreement is around $10,000 per year. Apparently reliability has been good; however, owners should expect to refurbish or replace the power supply about every 4-5 years.

The Rad Source RS 2400 (Rad Source 2007c), operating between 80 and 160 kV, delivers a higher dose rate using a new technology emitter. This 4-pi x-ray source may have the capability of eventually delivering about 300 Gy min^{-1}, but the two RS 2400s operated considerably lower than this. The International Atomic Energy Agency is testing one of these units for its sterile insect programs. The dose rate and irradiation volume of the RS 2400 are much larger than those for the RS 2000 and may allow five 450-ml blood bags to be irradiated simultaneously at a dose rate about 45 Gy min^{-1}. However, the canister loading methodology may need some redesign before it would be practical for irradiation of blood. Rad Source expects to submit its application for FDA approval for irradiation of blood products with this device in 2008. The RS 2400 is expected to sell for about $200,000 - 250,000 with an annual service contract of about $20,000. To ensure a high degree of reliability and minimal down time, the service agreement will include a tube replacement every 2000 h.

Faxitron (2008) sells two irradiation systems, the RX-650 and the CP-160, with prices around $43,000 and $87,000 respectively. The Faxitron RX-650 operates at a peak energy of only 130 kVp. To achieve adequate uniformity of dose, Kennedy et al. (2004) had to irradiate the mice from several directions because of the attenuation of the lower energy radiation in the bodies of the mice. Woo and Nordal (2006) concluded that the Faxitron CP-160 could be useful for small animal research if radiation was delivered carefully to ensure accurate and uniform radiation dose. The authors stated that at a

distance of 33 cm the indicated beam diameter on the tray was 26 cm, whereas the part of the beam where the uniformity as within 10% was confined to a diameter of 16 cm.

Precision X-Ray Inc. (2005) sells four different biomedical and small animal x-ray irradiators with energies ranging from 160 kVp to 320 kVp. With 0.5 mm Cu and operating at 320 kV, the unit delivers a dose rate of 2 Gy/minute. The higher tube potential brings the RBE to the same value as the ^{137}Cs gamma ray beam. The price runs around $170,000, exclusive of the service contract.

Kimtron markets units similar to the Precision X-ray units, with four units operating between 160 kV and 450 kV. The prices appear comparable to similar units.

Gilardoni, an Italian company, sells the Radgil (Gilardoni 2000) with an energy of 200 kVp and a dose rate of about 1 Gy min^{-1} at a cost of about 94,000 Euros (~$146,000).

Hitachi (2008) manufactures the MBR-1520-3, which is a 150-kVp blood irradiator that can deliver doses from 15 to 35 Gy in 5-Gy increments. However, there is no indication of FDA approval for human use.

AAPM Survey of Users

The American Association of Physicists in Medicine (AAPM) conducted a survey of its members in August to assess their experience with irradiators. The results of the survey would be skewed toward hospital-based or university-based irradiators; however, for the information gathered, that should not affect the conclusions. The survey, since it was targeted at medical physicists and some health physicists, represents only a small part of the irradiators in use. Of the 363 respondents, 297 had irradiators, 84.6% of those used ^{137}Cs as the source, 9.3% used conventional x-ray units and 6% used medical linear accelerators (linacs). The ^{137}CsCl units represented the major vendors. Only 10% were purchased within the last two years, with 7% planning on replacing the units within the next 5 years.

A quarter of the ^{137}CsCl units had had some malfunction but most were repaired in less than 7 days. Of the x-ray units, 35% had malfunctions, with 44% being repaired within 7 days.

Only 40% of the cesium units were used for blood irradiation, with about 25% used for material irradiations and another 25% for animal irradiations. Of the x-ray units, half were for blood irradiation, while 19% were for material irradiation and 32% for animals. Forty percent of the medical linacs for the respondents were used predominantly for blood irradiation and 11% for animals.

This survey indicates that, while fairly reliable, conventional x-ray units and medical linacs account for a small minority of the irradiators in the field. They had slightly more downtime than ^{137}CsCl units. The cesium units have also been reliable and their users, in general, have no plans to replace them. Forced removal of the cesium irradiators would result in a very large loss of resources, both radiation sources and funds, not only for blood banks but research institutions as well.

Linear Accelerators

Medical linear accelerators (linacs) can and do provide irradiation for blood products and materials. While linacs can serve for animal irradiation, their use with mice presents some difficulties because of the build-up region in the dose that is on the order of the thickness of a mouse. Most facilities that use linacs for irradiation either are part of larger processing facilities (for example, medical product sterilization companies) or find time between patients (creating problems in scheduling and staffing) in a radiotherapy clinic because of the extremely large initial investment, about $2,000,000 for these units and the cost for maintenance of $200,000 per year. Night time irradiations pose additional staffing issues. Because of the costs, linacs are not a viable replacement for ^{137}CsCl irradiators for the vast majority of facilities.

Alternative Radionuclides

At the time of writing, the only reasonable alternative radionuclide source for irradiators would be ^{60}Co. This radionuclide is used in large industrial irradiators, but is not currently available for blood or research irradiators. The use of ^{60}Co would require frequent source change due to the much shorter half-life compared with ^{137}Cs (5.27 years compared with 30 years), and higher initial source activities to extend the useful life of the sources. The ^{60}Co also requires thicker shielding because of the higher energy (1.2 cm half-value layer in lead compared with 0.6 cm.) Since the half-value layer enters into shielding as an exponent, the difference in the thickness of shield required due to the differences in the values multiples rapidly. These two considerations would lead to high initial costs for a unit and frequent, repetitive costs for source replacement. Finally, there is no convincing evidence that the ^{60}Co sources of any form would pose less of a hazard than the ^{137}CsCl.

Further Considerations for Blood Irradiation

The subcommittee consulted 10 hematologists or oncologists and one clinical laboratory director. These included researchers at one of the nation's most prestigious blood disorder and hematologic cancer research centers having extensive use of ^{137}CsCl blood and small animal irradiators.

Most of the previous information, such as in the National Research Council report, focused use of irradiators at central blood banks.

Five of the 10 hematologists/oncologists reported that they regularly prescribe irradiated blood for transfusions. Of these, one said that up to 40% of all blood he prescribed was irradiated. The others estimated that 15% to 33% of all blood for transfusion was irradiated. They all mentioned that their patient population was the reason why they tended to prescribe more irradiated blood products than the nominal 10% that often is used for planning. Patients who are post transplant are one such category, although none of these physicians had many patients in this subset. The more common reason was the use of certain chemotherapeutics that severely affect the host immune system.

Although no surveyed physicians were aware of difference between ^{137}Cs irradiated blood vs. x-ray, all ten (including one physician who doesn't presently routinely give irradiated blood transfusions) stated a regulation to eliminate or reduce the availability of irradiated blood products, or access to ^{137}CsCl irradiators would represent a severe drawback in the hematology/oncology field of medical practice and research. One physician who prescribes irradiated blood 40% of the time said that hematologists and oncologist prescribe irradiated blood about 33% of the time and that figures which say that only around 10% of all transfused blood is irradiated are skewed by the trauma-related transfusions in hospital emergency rooms and for surgery-related transfusions. Oncologists might rely more on irradiated blood than other medical professionals.

One institution specializing in research on hematologic malignancies reported that four ^{137}CsCl irradiators are used by 250 authorized users at a frequency of about 30 to 40 times per day in support of about 20 research projects and eight active clinical trials. Although comparable x-ray systems could be obtained to replace the ^{137}CsCl irradiators, four physician/PhD researchers indicated that the change would require more than a year to develop the radiation response relationships between the radionuclide-source and x-ray source irradiators, and that impacts on ongoing funded research would be enormous.

None of the physicians or the lab director had knowledge of the radiobiological differences between samples irradiated by x-rays or monoenergetic photons from ^{137}Cs sources. Four of six hematologists had experience with both irradiator systems. Three also had experience also with linac irradiated blood before their institutions obtained dedicated blood irradiators.

^{137}Cesium Chloride Irradiator Security

Prior to the publication of the National Research Council report the U.S. Nuclear Regulatory Commission (NRC) has disseminated orders to licensees for increased controls on sources of radioactive material in quantities of concern. The "Orders Imposing Increased Controls" issued in December 2005 contain requirements based on the International Atomic Energy Agency Code of Conduct. These measures were required to safeguard radioactive sources from theft or other unauthorized use. These requirements include:

1. Limit access to approved individuals who need to use radioactive materials in performing work activities.
2. Perform background and trustworthiness checks on all employees with access.
3. Escort all service providers who need to access the radioactive source.
4. Document the monitoring of sources with means for detecting source removal.
5. Increase source monitoring during source delivery or shipment.
6. Respond immediately to any attempted theft, sabotage, or diversion of sources.
7. Develop a plan for assistance from supporting authorities in the event of theft, sabotage, or diversion.
8. Provide means for transmitting information between personnel and components used to detect an intrusion.
9. Notify the NRC Operations Center of any attempted theft of radioactive material.
10. Document any attempt at theft or diversion of radioactive material.

11. Use trusted carriers with package tracking systems, who maintain constant control during transit, and who maintain communication for response or assistance.
12. Notify the NRC 90 days prior to certain shipments.

To review the changes resulting from the NRC orders for increased controls, a site visit for one of the members of this subcommittee was arranged to a major medical center with four ^{137}CsCl blood irradiators. The visit found that the licensee maintained access control to the irradiators by the means required in the Order, including:

1. Allowing access only to approved personnel who had undergone a thorough FBI background check, fingerprinting, work history review, psychological review, and local law enforcement background check.
2. Allowing access only to persons needing and trained to use the irradiators properly.
3. Providing redundant enforced doors, locks, heavy walls, computer-coded key-card access, and continuous video monitoring of the halls, entry, and workspace occupied by the irradiator units.
4. Presenting documented procedures to ensure that authorized users support the institutions system to prevent unauthorized access and protect access information, drawings, schematics, maps, and facility floor plans from unauthorized use.
5. Coordinating with local law enforcement agencies for rapid response to any attempted intrusion or theft of radioactive material.

In addition, we found the irradiator systems to be outfitted with additional padlocks and security measures for preventing unauthorized access to radioactive sources inside the irradiators. The irradiators weigh 4000 to 5000 pounds and do not have wheels.

In summary, we found highly increased security of ^{137}CsCl irradiators and increased controls over access by authorized personnel at the institution. It would be very difficult, even for personnel with access permission, to attempt theft, diversion, or misuse of the ^{137}CsCl irradiator systems. The institution had implemented all requirements to enhance the security of ^{137}CsCl irradiator systems in a manner typical of such irradiators.

In addition to the increased security enhancements required by the NRC, an initiative by the Department of Energy (DOE), the Department of Homeland Security (DHS), and the Domestic Nuclear Detection Office will harden ^{137}CsCl irradiators throughout the United States to delay unauthorized access to ^{137}Cs sources. This has been a cooperative effort for the past 18 months. The demonstration project was completed in March of 2008 and the pilot project is currently being conducted in nine facilities. DOE and DHS anticipate that this pilot program will be completed later this year.

The pilot project is the actual enhancement of the irradiators in the field. The manufacturer will install additional material and make minor changes to the exterior of the irradiator to make it more difficult to remove the source(s). There are nine facilities that have volunteered to participate. The pilot will have two of the manufacturers visit the facility and add the enhancements to the irradiators. The pilot will demonstrate the ease and ability of performing these tasks in a “real world” environment. The pilot will also validate the costs to perform the retrofit. It is estimated that the cost will be $2,000 to 4,000 for each device. The DHS and the DOE will pay the manufacturers for the

enhancements. It is expected that the pilot will be successful and the project will be open to all of the devices currently licensed in the United States.

Alternative Forms for ^{137}Cesium Sources

The subcommittee considered whether this report should recommend to manufacturers of ^{137}CsCl irradiators that alternatives to the powder form of the source be pursued. However, as of this time, there is no convincing evidence that another form, particularly a solid form, would be safer. While a powder may be dispersed by a bomb, a solid poses a radiation hazard much greater than the dispersed powder. In addition, the manufacture of a solid source could pose a hazard to the workers making the sources.

Conclusions

1. Cesium-137 irradiators are used in a number of important medical and research applications. As the population of the United States ages, the use of irradiated blood products will escalate, producing an increased demand for the availability of this technology for patient safety. The need for medical irradiators is unquestionable.
2. Some investigators are concerned about the ways that differences in radiation quality between ^{137}CsCl irradiators and x-ray systems would affect experimental results on blood samples, small animals, separated T-cells and stem cells, and other biological media.
3. Alternatives to ^{137}CsCl irradiators are expensive, and forcing the switch to x-ray sources would place an unnecessary and great financial burden on blood banks and research institutions.
4. The ACMUI subcommittee believes that the ^{137}Cesium Chloride Irradiator Security Enhancements and Increased Controls and Security Inspections have provided strong measures for ensuring the safety and integrity of ^{137}CsCl sources in medical irradiators, have reduced the vulnerability of these devices as material suitable for malicious intent, and should prove to be acceptable as an alternative to removal or prohibition of these devices.

ACMUI ^{137}CsCl Irradiator Subcommittee

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