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NUCLEAR REGULATORY COMMISSION

[NRC-2010-0209]

Policy Statement of the U.S. Nuclear Regulatory Commission

on the Protection of Cesium-137 Chloride Sources

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is issuing a statement of policy on the protection of cesium-137 chloride (CsCl) sources. This statement sets forth the Commission's policy regarding secure uses of these sources at the present and states the Commission's readiness to respond with additional security requirements, if needed, should the threat environment change. The purpose of this policy statement is to delineate the Commission's expectations for security and safety of these sources.

DATES: This policy statement is effective July 25, 2011**.**

ADDRESSES: You can access publicly available documents related to this document using the following methods:

- **NRC's Public Document Room (PDR):** The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

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- **Federal Rulemaking Web Site:** Public comments and supporting materials related to this policy statement can be found at *http://www.regulations.gov* by searching on Docket ID **NRC-2010-0209.** Address questions about NRC dockets to Carol Gallagher, telephone: 301-492-3668; e-mail: *Carol.Gallagher@nrc.gov*.

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SUPPLEMENTARY INFORMATION:

I. Background

Certain radioactive sources, including CsCl sources, have been identified by the International Atomic Energy Agency (IAEA) *Code of Conduct on the Safety and Security of Radioactive Sources* (Code of Conduct) (see *http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004_web.pdf*) as sources that may

pose a significant risk to individuals, society, and the environment if improperly handled or used in a malicious act. Consequently, the NRC has required additional security measures for Category 1 and 2 sources and considers it prudent to express its views on the safe and secure use of CsCl sources. The CsCl sealed sources are used in many applications that have significant societal benefits, most commonly in irradiators, calibrators, and in devices for biological and medical research.

To develop its draft policy statement, the NRC initiated and completed a number of initiatives. A significant element of these initiatives was an Issue Paper which was published in the *Federal Register* on July 31, 2008 (73 FR 44780), and discussed with stakeholders in a public workshop held on September 29-30, 2008. The NRC also received numerous written comments on the Issues Paper. The oral and written comments as well as the transcript of the workshop, along with other relevant information, are accessible at *http://www.nrc.gov/materials/miau/licensing.html#cesium*. A study[1] on the use and replacement of radiation sources, conducted by the National Research Council of the National Academies in 2008, recommended eliminating Category 1 and 2 CsCl sources from use in the United States and to the extent possible elsewhere. The National Research Council also recommended that replacement of some sources with alternatives should be implemented with caution, ensuring that essential functions that the sources perform are preserved.

The NRC prepared a draft policy statement, which described issues related to safety and security associated with IAEA Category 1 and 2 CsCl sources[2]. The Draft Policy Statement was published for public comment in the *Federal Register* on June 29, 2010 (75 FR 37483). The intent of this document was to foster discussion about these issues and to solicit comments on the draft policy statement. The NRC held a public meeting on November 8-9, 2010, to solicit

[1] National Research Council of the National Academies, "Radiation Source Use and Replacement," The National Academies Press, Washington, DC, www.nap.org.

[2] An IAEA Category 1 cesium-137 source contains a minimum of 3000 Ci (100 TBq) and a Category 2 source contains a minimum of 30 Ci (1 TBq). See *http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004_web.pdf*.

comments on the Draft Policy Statement. The public meeting was announced in the *Federal Register* on September 29, 2010 (75 FR 60149), as well as in two NRC press releases issued June 28, 2010 (No. 10-117), and October 5, 2010 (No. 10-176). The public meeting included technical sessions with panel presentations, followed by facilitated discussion with the audience. The meeting was attended by the general public and representatives of licensees (users in the blood irradiation industry, biomedical research institutions, the pharmaceutical industry, and calibration laboratories), health and industry associations, source and device manufacturers, manufacturers of alternate technologies (x-ray and cobalt-60), and Federal and State government agencies. The NRC developed a public Web site, *http://www.nrc.gov/materials/miau/licensing.html#cc*, to make documents accessible relevant to the draft policy statement and to the public meeting.

The NRC received written comments and a number of oral comments from the panelists and the audience at the public meeting. The majority of the comments supported the Draft Policy Statement. Many commenters recommended expanding the narrative regarding the areas of use of CsCl sources, as well as recommendations to clarify statements in the policy. The comments and the submissions provided valuable information for the formulation of this Policy Statement regarding the use of CsCl sources, security issues, and the diversity of impacts that licensees could experience as a result of potential further regulatory requirements. In addition, there were recommendations to include the IAEA Category 3 CsCl sources in certain selected types of use. All of the written and oral comments were considered when finalizing the Policy Statement[3]. None of the comments resulted in changes to the basic principles that are in the Policy Statement. The changes to the Draft Policy Statement are limited. In response to public comments, the Policy Statement contains expanded discussions of the use of CsCl sources in addition to clarifications. Changes were also made to address the

[3] *See* Summary of Comments on the CsCl Draft Policy Statement and Staff Resolutions (ADAMS Accession No. ML110750506).

new developments including issuance of the Radiation Source Protection and Security Task Force's (Task Force) quadrennial report (Task Force Report) and its implementation plan, and publication of the draft environmental impact statement by the U.S. Department of Energy (DOE).

In August 2010, the Task Force completed its quadrennial Task Force Report to the President and Congress (ADAMS Accession No. ML102230141). The Task Force Report addressed the security of all radioactive sources, but singled out the issue of CsCl sources in several of the recommendations. As a follow-up to the Task Force Report, the NRC developed an implementation plan for the Task Force Report (ADAMS Accession No. ML103050432) in December 2010. The NRC implementation plan defined the recommendations as tasks to be completed by the Task Force within the framework of their upcoming activities including the issue of CsCl sources. The Policy Statement is consistent with the conclusions and the recommendations of the Task Force Report.

Disposal of CsCl sources is addressed in the Policy Statement. Regarding disposal of radioactive materials, the DOE published, in February 2011, for public comment a "Draft Environmental Impact Statement for the Disposal of Greater-Than-Class C (GTCC) Low-Level Radioactive Waste and GTCC-Like Waste" (see http://nepa.energy.gov/1653.htm). The Draft Environmental Impact Statement (DEIS) includes proposals for resolution of disposal issues for sealed sources, including CsCl sources. The Policy Statement recognizes the DOE's issuance of the DEIS and expresses the Commission's intent to monitor the DOE as it makes a decision on a GTCC disposal facility which will require an NRC license.

II. Policy Statement of the U.S. Nuclear Regulatory Commission on the Protection of Cesium-137 Chloride Sources

Statement of Policy

The NRC issues this Policy Statement to set forth its policy on the secure uses of sealed sources containing CsCl and to describe potential Commission actions if changes in the security threat environment necessitate regulatory action. The Policy Statement also delineates the Commission's expectations for the secure and safe use of CsCl sources with activity levels of Category 1 and 2 as characterized by the IAEA Code of Conduct.

It is the policy of the Commission that its mission of ensuring adequate protection of public health and safety, common defense and security, and the environment while enabling the use of radioactive materials for beneficial civilian purposes is best accomplished with respect to CsCl by implementing or promoting the following principles:

- The safety and security of IAEA Category 1 and 2 sources is an essential part of the NRC's mission;
- Licensees have the primary responsibility to securely manage and to protect sources in their possession from misuse, theft, and radiological sabotage;
- Adequate protection of public health and safety is maintained if CsCl sources are managed in accordance with the safety and security requirements of the NRC and the Agreement States.[4] These requirements are based on vulnerability assessments of the various sources and follow the principles of the IAEA Code of Conduct;
- While these sources are adequately protected under the current NRC requirements, design improvements could be made that further mitigate or minimize the radiological consequences;
- The development and use of alternative forms of cesium-137 (Cs-137), while not required for adequate protection, are prudent and the NRC intends to monitor these

[4] Agreement States are those States that have entered into an agreement with the NRC to assume authority under Section 274b of the Atomic Energy Act of 1954, as amended, to license and regulate by-product materials (radioisotopes), source materials (uranium and thorium), and certain quantities of special nuclear materials.

developments closely. In addition, the NRC recognizes that objective measures of 'solubility' and 'dispersibility' may need to be clarified as alternate forms of Cs-137 are developed by manufacturers;

- The CsCl sources enable three specific classes of applications that benefit society: (a) blood irradiation, (b) bio-medical and industrial research, and (c) calibration of instrumentation and dosimetry;
- The NRC recognizes that currently there is no disposal capability for such commercial sources. The NRC considers it imperative to develop a pathway for the long-term storage and disposal of these sources whether or not alternative forms are developed; and
- The NRC monitors the threat environment and maintains awareness of international and domestic security efforts. In the event that changes in the threat environment necessitate regulatory action, the NRC, in partnership with its Agreement States, would issue additional security requirements, if necessary, to apply appropriate limitations for the use of CsCl in its current form.

Security and Control of Radioactive Sources

Effective regulatory requirements and strong measures are currently in place for ensuring security and control of radioactive sources. After the terrorist events of September 11, 2001, the NRC and Agreement States issued security requirements mandating that licensees who possess IAEA Category 1 or 2 quantities of radioactive materials 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 Title 10 of the *Code of Federal Regulations* (10 CFR), Section 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.

Current security requirements include access controls and background checks for personnel; monitoring, detecting and responding to unauthorized access; delay; advance coordination with local law enforcement; and the tracking of transfers and shipments. The security requirements require licensees to establish and implement trustworthiness and reliability standards to determine who will have unescorted access to the radioactive material. An individual's trustworthiness and reliability is based upon a background investigation. The NRC and Agreement States have jointly developed materials protection and security regulatory requirements that reflect the experience gained through implementation of existing requirements.

In addition, the NRC has implemented new regulatory requirements for import/export licensing and for reporting to the National Source Tracking System (NSTS), which increase accountability of Category 1 and 2 radioactive material transactions and help to ensure that such transactions are only made by authorized entities.[5] The NRC developed and maintains the NSTS, which provides information on sources from the time of manufacture through transportation and use to end-of-life disposition. The NSTS and other systems under development, such as the Web-Based Licensing and License Verification System which will permit verification of a license to possess radioactive sources, are key components of a comprehensive program for the security and control of radioactive materials. When complete, these systems will include information on all NRC, Agreement State, import/export licensees, and IAEA Category 1 and 2 radioactive sources.[6]

The measures described above are in place to ensure the security of all Category 1 and 2 radioactive sources, including CsCl sources. Over the past six years, these measures have

[5] *See* 10 CFR 20.2207.
[6] *See* http://www.nrc.gov/security/byproduct/nsts.html.

reduced the vulnerability for malevolent use of radioactive sources, including CsCl sources. In addition, the NRC and Agreement States are supporting the DOE's National Nuclear Security Administration (NNSA) voluntary program to retrofit existing CsCl irradiators with additional physical security enhancements and to incorporate these improvements into the designs of newly manufactured units. These modifications extend beyond current regulatory requirements. These efforts are often complemented by assist visits and tabletop exercises by NNSA experts at licensee facilities that allow participants to share best practices.

The NRC and Agreement States also support the Federal Bureau of Investigation's ongoing Weapons of Mass Destruction (WMD) countermeasure effort to reach out to certain communities of licensees (including the CsCl irradiator licensee community). A critical aspect of this WMD countermeasure effort is information sharing through visits to licensees. These visits encourage communication and allow regulators, law enforcement, and licensees to gain an understanding of a licensee's security arrangements and how and when law enforcement would be engaged if there were a threat or a security event at a licensee's site.

To maintain security of sources, the Energy Policy Act of 2005 (EPAct) established the Task Force on Radiation Source Protection and Security to be chaired by the Chairperson of the Commission (or designee). The purpose of the Task Force is to evaluate and provide recommendations to the President and Congress periodically relating to the security of radiation sources in the United States from potential terrorist threats, including acts of sabotage, theft, or use of a radiation source in a radiological dispersal device. The Task Force consists of representatives from 14 Federal agencies (11 of which were specified in the EPAct), the Organization of Agreement States, and the Conference of Radiation Control Program Directors. The Task Force issued its first report[7] in 2006 and its quadrennial report[8] in 2010. The 2010

[7] Report to the President and the U.S. Congress Under Public Law 109-58, The Energy Policy Act of 2005, The Radiation Source Protection and Security Task Force Report, ADAMS Accession No. ML062190349.

[8] Report to the President and the U.S. Congress Under Public Law 109-58, The Energy Policy Act of 2005, The

Task Force Report, in a number of its recommendations, addressed the following issues associated with CsCl sources: export, end-of-life management, options for disposal, voluntary replacement with alternative technologies, and potential discontinuation of use of CsCl sources, contingent upon the viability of alternative technologies and consideration of the threat environment. The Task Force also developed a plan to implement the recommendations of the report. The NRC's policy for CsCl sources is consistent with the recommendations of the Task Force reports.

The NRC supports the security initiatives of international organizations (e.g., IAEA), and other countries, as well as the initiatives of Federal agencies aimed to further increase the protection of IAEA Category 1 and 2 sources both domestically and overseas (e.g., NNSA's Global Threat Reduction Initiative). The NRC participates in the development of such protective measures in various international forums and will consider their applicability for use within the United States if the threat environment changes, which could warrant additional protective security measures.

Uses of CsCl Sources

The CsCl sources comprise approximately 3 percent of the IAEA Category 1 and 2 sources in the United States. In comments at the public meetings and in written submissions, members of the medical and scientific communities stated that these CsCl sources are essential due to their applications in blood irradiation, bio-medical and industrial research, and calibration of instrumentation and dosimetry, especially for critical reactor and first responder equipment. The CsCl is used for these applications because of the properties of the nuclide Cs-137, including its desirable single energy spectrum (662 keV), long half-life, low cost, and moderate shielding requirements relative to other nuclides. The CsCl used in these applications is in a

2010 Radiation Source Protection and Security Task Force Report, ADAMS Accession No. ML102230141.

compressed powder form that is doubly-encapsulated in two stainless steel capsules to ensure safety and security in normal use. This physical form is used because of its high specific activity (gamma emission per unit volume) and manufacturability. However, the powder is highly soluble and potentially dispersible, which could present security concerns if not properly secured and used in a malevolent manner.

Blood irradiation is medically essential to prevent transfusion-associated Graft-Versus-Host disease and the vast majority of hospitals use only irradiated blood. The CsCl blood irradiators are used to irradiate over 90 percent of all irradiated blood because CsCl blood irradiators are the most reliable and efficient blood irradiation devices currently available.

In biomedical research, CsCl irradiation has been used for over 40 years in fields such as immunology, hematology, stem cell research, bone marrow transplantation, cancer research, in-vivo immunology, systemic drug research, chromosome aberrations, DNA damage/repair, human genome, and genetic factors. According to members of the medical community, the continuation of such research is crucial for advancing patient care, and for studies on medical countermeasures against radiation effects for the protection of the public, first responders and military personnel. For most research, there are no alternatives to Cs-137 irradiation because of the unique properties of Cs-137 radiation, such as high dose rates with uniform fields of linear energy transfer. No alternative technologies that can effectively replace CsCl sources for biomedical research have yet been developed. Based on decades of use, including trial use of certain x-ray machines for irradiation, the biomedical research community considers the Cs-137 irradiators optimal for providing effective, reliable, dependable, economical, and experimentally reproducible means of required health care equipment needed for research. According to the medical community, the results of previous research with Cs-137 irradiators cannot be compared to results obtained from other types of irradiation due to differences in the energy spectra and dose distribution of the radiation sources. Conversion factors between biomedical

experimental results of x-ray versus gamma-rays do not exist. The use of alternative technologies would necessitate extensive research to re-validate research models of diseases that have already been established using irradiation devices containing Cs-137.

The national and international systems of radiation measurements are based on the energy spectrum of Cs-137. All American National Standards Institute standards and their associated test-and-evaluation protocols for calibration of radiation detection, instrumentation, and personal dosimetry rely on the use of Cs-137. In addition, all U.S. Department of Homeland Security-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. Cs-137 was selected by the national and the international community as the basis of calibration because of the optimal single energy spectrum of this nuclide and its long half-life. The National Institute of Standards and Technology (NIST) maintains the national measurement standards and calibrates the instruments for secondary laboratories which require the use of Cs-137. These instruments are then sent to secondary and tertiary laboratories that, in turn, calibrate the instruments for end users. This network of facilities ensures that every radiation detection instrument that is used in the country measures radioactivity and identifies isotopes correctly and is traceable to NIST.

Ensuring Secure Disposal for Disused CsCl Sources

The disposal of CsCl radioactive sources, which are currently in use, is a challenge because of the high cost of disposal and the lack of commercial disposal facilities. The vast majority of the CsCl sources in use today are classified as greater-than-Class C low-level radioactive waste. Today, used and unwanted CsCl sources are stored safely and securely at the users' sites under the applicable NRC and Agreement State control and security requirements until options become available. To maintain source safety and security, the sites

are routinely inspected in accordance with established NRC and Agreement State inspection procedures. The Commission considers it imperative to develop a pathway for the long-term storage and disposal of these sources because extended storage at licensee facilities increases the potential for safety and security issues. The NRC will continue to monitor Federal and State activities and private sector initiatives as medium- and long-term solutions are explored to address the need for disposal and disposition of CsCl sources.

The Low-Level Radioactive Waste Policy Amendments Act of 1985 assigned responsibility for providing disposal of this type of waste to DOE. However, pending the availability of a disposal capability, the DOE is not responsible for accepting disused sources for storage, transportation or other activities related to disposal except under special circumstances.[9] In February 2011, the DOE published the "Draft Environmental Impact Statement for the Disposal of Greater-Than-Class C (GTCC) Low-Level Radioactive Waste and GTCC-Like Waste (DOE/EIS-0375D, DEIS)."[10] as required under the National Environmental Policy Act for public review and comment. The DOE stated that in the coming years it plans to analyze public comments on its DEIS and finalize disposal alternative(s) for greater-than-Class C low-level radioactive waste, including CsCl sources. The Commission will monitor DOE as it makes a decision on a GTCC disposal facility, which will require an NRC license.

The NRC's Perspective on Further Security Enhancements

The NRC believes that the current enhanced regulatory framework for security of radioactive sources has been very effective in enhancing and ensuring the security and control of IAEA Category 1 and 2 sources used in medical, industrial, and research activities in the United States. The NRC encourages stakeholders to take an active role in source security and

[9] Under specified circumstances, and pursuant to other authority and responsibility under the Atomic Energy Act of 1954, as amended, the DOE may recover excess or unwanted sealed sources (including CsCl sources) for reuse, storage or disposal that present threats to public health, safety or national security.

[10] *See* http://www.gtcceis.anl.gov/.

continue their efforts in maintaining the current security environment. As is necessary and practical, and in response to any change in the threat environment, the NRC will work with other Federal agencies to further enhance the secure use of Cs-137 sources. The NRC recognizes that it is prudent to maintain awareness of the status of research to identify alternative forms of CsCl. The NRC will remain cognizant of these issues and appropriately consider whether there are safety and security benefits to further risk reduction. As part of the NRC's responsibility to ensure the security of these sources, the NRC, in coordination with its Federal partners, continuously monitors the national threat environment and is prepared to take further regulatory actions should this environment change. Just as it did following the events of September 11, 2001, the NRC is prepared to take immediate action such as issuance of additional security requirements with Orders or rulemaking, to address such security-related issues, if necessary.

While the current security requirements and measures are adequate, the NRC encourages the source and device manufacturers to implement design improvements that further mitigate or minimize the radiological consequences of misuse or malevolent acts involving these sources. Accordingly, the NRC supports efforts by manufacturers to develop alternate forms of Cs-137 and to strengthen device modifications that could further reduce the risk of malevolent use associated with CsCl. The National Research Council of the National Academies issued a report[11] that supported these efforts, recommended that the NRC consider the potential economic and social disruption that changes to the CsCl requirements could cause, and supported a research and development program for alternative "matrices" for high-activity Cs-137 sources, which could provide lower security hazards.

The NRC recognizes that objective measures of 'solubility' and 'dispersibility' may need to be clarified as alternate forms of Cs-137 are developed by manufacturers. While it is outside the scope of the NRC's mission to conduct developmental research, the Commission

[11] National Research Council of the National Academies, "Radiation Source Use and Replacement," The National Academies Press, Washington, DC, www.nap.org.

encourages research to develop alternative chemical forms for large activity Cs-137 sources. Given the state of the current technology, and because a less dispersible form does not negate the risk or a potentially large cleanup and economic cost, the NRC believes that, for the near term, it is more appropriate to focus on continued enforcement of the United States security requirements and to mitigate risk through cooperative efforts and voluntary initiatives of industries that currently manufacture and use CsCl sources. While current NRC and Agreement State security requirements are in place to ensure the safety and security of these sources, additional voluntary security efforts by licensees and that of NNSA's security enhancement program help to enhance existing and future design improvements to further minimize the potential misuse or malevolent acts involving these sources.

Summary

The NRC is continually working with its domestic and international partners to assess, integrate, and improve its security programs, and to make radiation sources more secure and less vulnerable to terrorists. The NRC and the Agreement States have the responsibility to ensure the safe and secure use and control of radioactive sources, including CsCl sources. Both the NRC and the Agreement States have met this responsibility through imposition of additional security requirements. The actions of the NRC and the Agreement States to date have resulted in a strong security program. The NRC recognizes that near term replacement of devices or CsCl sources in existing blood, research, and calibration irradiators is not practicable or necessary due to implementation of the additional security requirements and lack of a disposal capacity. Many medical, research, and emergency response stakeholders have stated that short term replacement would be detrimental to existing medical programs, on-going biomedical research, and homeland response activities, respectively. Therefore, the NRC continues to believe that the security of these facilities should be maintained and enhanced as

practical through the implementation of the regulatory requirements and through voluntary actions such as the physical security enhancements of existing devices and future designs against intrusion. The NRC supports efforts to develop alternate forms of Cs-137 that would reduce the security risks and will monitor these developments. Regarding possible future regulatory actions affecting the use of IAEA Category 1 and 2 CsCl sources, the NRC would solicit public input in the development of any rule or guidance for the use of CsCl devices if additional security measures are considered. The NRC will continue to work with its Federal and State partners to ensure the safety and security of CsCl sources. In the event that changes in the threat environment necessitate regulatory action, the NRC, in partnership with the Agreement States, will be ready to issue additional security requirements to apply appropriate limitations for the use of CsCl, as necessary.

Dated at Rockville, Maryland this 19th day of July, 2011.

For the Nuclear Regulatory Commission.

/RA/

Annette L. Vietti-Cook,
Secretary of the Commission.