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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: Issuance of Final Policy Statement on the Protection of Cesium-137 Chloride Sources.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) 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 becomes effective [Insert date of publication in the Federal Register].

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Enclosure

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 considers it prudent to express its views on the safe and secure use of these sources. CsCl sealed sources are used in many applications, 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 the replacement or elimination of CsCl sources.

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

[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.

the draft policy statement. NRC held a public meeting on November 8-9, 2010, to solicit 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, relevant to the draft policy statement and to the public meeting, accessible.

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 Final Policy statement contains expanded

[3] *See* Summary of Comments on the CsCl Draft Policy Statement and Staff Resolutions (ADAMS Accession number ML110750506).

discussions of the use of CsCl sources and of new developments in terms of security of CsCl, in addition to clarifications. Changes were also made to address the new developments including issuance of the 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 Radiation Source Protection and Security Task Force (Task Force) completed its quadrennial report (Task Force Report) to the President and Congress (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 (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, 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" (accessible at http://nepa.energy.gov/1653.htm). The Environmental Impact Statement (EIS) includes proposals for resolution of disposal issues for sealed sources, including CsCl sources. The Policy Statement recognizes DOE's issuance of the EIS and expresses the Commission's intent to interact with DOE to resolve the issue of waste disposal.

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

Statement of Policy

The U.S. Nuclear Regulatory Commission (NRC or Commission) 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 on the Safety and Security of Radioactive Sources.

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 risk significant 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 Code of Conduct on the Safety and Security of Radioactive Sources of the IAEA;
- 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 developments closely. In addition, the NRC recognizes that objective measures of

[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 to license and regulate by-product materials (radioisotopes), source materials (uranium and thorium), and certain quantities of special nuclear materials.

'solubility' and 'dispersibility' may need to be clarified as alternate forms of Cs-137 are developed by manufacturers;

- 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 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 security 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 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.

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 Web-Based Licensing and License Verification System, 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 risk-significant 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 reduced the vulnerability for malevolent use of radioactive sources, including CsCl sources. In addition, the NRC and Agreement States are supporting DOE's National Nuclear Security

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

Administration (NNSA) voluntary program to retrofit existing CsCl irradiators with 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 expert security guidance to licensees (assist visits) and table-top exercises 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) directed the NRC to establish and lead the Task Force to evaluate and provide recommendations to the President and Congress periodically relating to the security of radiation sources in the U.S. 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, 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 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 licensing for discontinuation of use. The Task

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

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 risk-significant 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 U.S. if the threat environment changes, which could warrant additional protective security measures.

Uses of CsCl Sources

CsCl sources comprise approximately 3 percent of the IAEA Category 1 and 2 quantity sources in the U.S. 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. 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 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 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. 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. Alternative technologies (e.g., cobalt-60 irradiators, linear accelerators, x-ray irradiators) are not as stable, more expensive, require more maintenance, are less suitable for accommodating research specimen, and require physical locations more robust than current irradiators. In addition, 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. Numerous research studies would be needed to ensure that alternative technologies would not compromise or adversely impact ongoing studies related to human health and health care.

The U.S. 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 U.S. 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 commercial 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. To resolve these issues, the NRC will continue to participate with its Federal and State partners and representatives of the private sector in initiatives to explore medium- and long term-solutions 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, 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, 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, Draft EIS)"[10] as required under the National Environmental Policy Act for public review and comment. DOE stated that in the coming years it plans to analyze public comments on its Draft EIS and finalize disposal alternative(s) for greater-than-Class C low-level radioactive waste, including CsCl sources. The Commission will actively interact with DOE in all phases of the process to establish a storage facility for permanent, safe and secure disposal of used and unwanted sources.

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 risk-significant sources used in medical, industrial, and research activities in the U.S. The

[9] Under specified circumstances, and pursuant to other authority and responsibility under the Atomic Energy Act of 1954, 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* the DOE EIS at http://www.gtcceis.anl.gov/

NRC encourages stakeholders to take an active role in source security and 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 are adequate and provide sufficient safeguards, the NRC recognizes that if the use of CsCl in its current form is to continue, 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 given that such events, while unlikely, cannot be dismissed. 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.

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

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 NRC's mission to conduct developmental research, the Commission 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 U.S. 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 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 risk-significant radiation sources more secure and less vulnerable to terrorists. The NRC has 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 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 closely. Regarding possible future regulatory actions affecting the use of Cs-137 irradiators in the three specific areas of application that benefit society, the NRC will solicit public input in the development of any rule or guidance for the use of CsCl devices. 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 its 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 __ day of _____, 2011.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook
Secretary of the Commission