May 24, 2010

MEMORANDUM TO: R. W. Borchardt
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary **/RA/**

SUBJECT: STAFF REQUIREMENTS – COMSECY-09-0029 – DRAFT POLICY STATEMENT ON THE PROTECTION OF CESIUM-137 CHLORIDE SOURCES

The Commission has approved the publication of the draft Policy Statement in the Federal Register subject to the attached edits.

Any additional efforts to enhance security for these sources should consider whether there are benefits of further risk reduction given the NRC's actions to date and the current threat environment.

Staff should continue its effort to maintain awareness of advances in research related to alternative forms of CsCl.

Staff should continue interaction with other federal and state partners to facilitate a disposal solution.

Attachment:
As stated

cc: Chairman Jaczko
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
CFO
OCA
OPA

Attachment

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

The NRC's Role in Ensuring Security for Radioactive Materials

The U.S. Nuclear Regulatory Commission (NRC or Commission) has the responsibility to license and regulate the civilian use of radioactive materials for commercial, industrial, academic, and medical purposes in a manner that ~~uses to~~ protects public health and safety and promotes the common defense and security. The NRC and its predecessor, the Atomic Energy Commission, have regulated the use of radioactive materials since 1946. The use of radioactive materials is regulated by NRC and 37 states, known as Agreement States. Agreement States enter into agreements with the NRC under Section 274 of the Atomic Energy Act to license and regulate the use of byproduct material within their borders.

~~In fulfilling its mission, t~~The security and control of radiation sources is an essential part of ~~one of the top priorities for~~ the NRC's mission. The NRC's efforts in this regard continue to be effective~~;~~ , and there have been no security incidents involving risk-significant radiation sources. After September 11, 2001, the NRC imposed additional security requirements. In addition, the National Nuclear Security Administration (NNSA) has initiated a program to enhance security voluntarily beyond these requirements. One type of radioactive source, cesium-137 chloride (CsCl), has been the focus of increased attention in the U.S. because these sources are extensively used in a wide range of applications in medicine, industry, and research and, while unlikely, due to the physical and chemical characteristics of CsCl, these sources could be used by terrorists in a radiological dispersal device (RDD) or "dirty bomb."

The NRC supports and implements the recommendations of the international community regarding the safe use and protection of radioactive materials. In 2004, the International Atomic Energy Agency (IAEA) issued the *Code of Conduct for the Safety and Security of Radioactive Sources* (the Code), which prescribes a legislative framework, regulatory programs, and import/export provisions to achieve and maintain a high level of safety and security of radioactive sources. The U.S. Government is committed to the implementation of the Code. The Code applies to all radioactive sources that could pose a significant risk ~~(i.e., cause deterministic health effects)~~ to individuals, society, and the environment. The Code establishes five categories of radioactive sources based on their potential to cause severe deterministic health effects if not managed in a safe and secure manner. Consistent with the Code, the NRC and the Agreement States have established national requirements for the enhanced security for Category 1 and 2 quantities of radioactive material, which, if misused, could pose a significant risk to individuals, society, and the environment. ~~The U.S. has established national requirements for the enhanced security of IAEA Category 1 and 2 radioactive sources.~~

To maintain security of sources, the Energy Policy Act of 2005 (EPAct) directed the NRC to establish and lead the Radiation Source Protection and Security Task Force (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 EPAct named 12 Federal agencies to the Task Force. In addition to the named agencies, the NRC invited the U.S. Department of Health and Human Services and the White House Office of Science and Technology Policy to participate. To accomplish the mission in view of the regulatory responsibilities divided in the U.S. between the NRC and the Agreement States, the Task Force also invited a representatives of the Organization of Agreement States and the Conference of Radiation Control Program Directors to participate as a non-voting members. NRC has coordinated with these partners consistent with its regulatory role, to enhance the security of sources, including CsCl. The Task Force issued its first report in 2006,[1] and is scheduled to issue another report in 2010. The NRC's policy on security requirements, for radioactive sources, are is aligned with the recommendations of the first Task Force report.

Statement of Policy

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 the public health and safety is maintained if CsCl sources are managed in accordance with the security requirements of the NRC and the Agreement States. 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 International Atomic Energy Agency;
- While these sources are adequately protected under the current NRC requirements, To continue the use of CsCl in its current form, source and device manufacturers should strive to implement design improvements could be made that further mitigate or minimize the radiological consequences of misuse or malevolent acts involving the sources, and that reduce the probability of such acts being successfully carried out;
- The development and use of alternative forms of cesium-137, while not required for adequate protection, is prudent desirable and the NRC intends to monitor these developments closely. In addition the NRC recognizes that measures to verify effectiveness of the alternatives for solubility and dispersibility must be established to support future decision-making on this matter;
- CsCl enables three specific classes of applications that benefit society: (a) blood sterilization, (b) bio-medical and industrial research, and (c) calibration of instrumentation and dosimetry;
- The societal benefits that CsCl sources currently provide must be maintained in the future with any alternative forms of cesium-137, or with alternative technologies;
- 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

1 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, NRC Reference No. ML062190349.

storage and disposal of these sources whether or not there are alternatives 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 is ready to issue additional security requirements ~~and regulations regarding~~ to apply appropriate limitations for the use of CsCl in its current form ~~, should changes in the national threat environment necessitate it~~.

~~The policy issues are addressed in detail below.~~ **Background**

Security and Control of Radioactive Sources **[removed BOLD and added underline]**

Strong measures and regulatory requirements 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 ~~revised~~ materials protection and security regulatory requirements that reflect the experience gained through implementation of existing requirements. ~~It is expected that a proposed rule will be published for public comment by early 2010.~~

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. 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, and import/export licensees and high risk radioactive sources.

The ~~strong~~ measures described above are in place to ensure the security of all Category 1 and 2 radioactive sources, including CsCl sources. These measures have reduced the vulnerability of CsCl sources. In addition, the NRC and Agreement States are supporting the U.S. Department of Energy's (DOE's) ~~National Nuclear Security Administration's (~~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 ~~overall~~ WMD countermeasure effort is ~~outreach and~~ 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 an event at a licensee's site.

The NRC supports the security initiatives of international organizations (e.g., IAEA), and other countries, as well as the initiatives of U.S. Federal agencies aimed to further increase the protection of high risk sources 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, warranting additional protective measures.

~~The additional security measures required by the NRC and Agreement States and implemented by licensees, along with the continuing coordination with other Federal partners on additional voluntary enhancement and communications initiatives, have significantly improved the security of these sources.~~

Uses of CsCl Sources **[removed BOLD and added underline]**

CsCl sources comprise approximately 3% of the IAEA Category 1 and 2 quantity sources in the U.S.~~, and~~ Many in the medical and scientific communities indicate that these CsCl sources are important due to their application in blood sterilization, bio-medical and industrial research, and calibration of instrumentation and dosimetry especially for critical reactor and first responder equipment ~~crucial functions of our society~~. ~~These sources are widely used in blood sterilization, bio-medical research, and calibration.~~ CsCl is used for these applications because of the properties of the nuclide cesium-137 (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. ~~; but it~~ However, the powder is highly soluble and dispersible, which presents security concerns.

~~Blood irradiation, conducted at blood centers, hospitals, and university medical centers, results in significant health benefits to patients.~~ Blood irradiation is medically essential to prevent transfusion-associated Graft-Versus-Host disease, and some hospitals use only irradiated blood. ~~Without irradiated blood, immuno-deficient and immuno-suppressed patients could potentially suffer death.~~ CsCl blood irradiators are used in over 90% of all blood irradiation because they ~~devices~~ are the most reliable and efficient blood sterilization devices currently available.

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 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.

The U.S. and international systems of radiation measurements are based on the energy spectrum of Cs-137. All American National Standards Institute (ANSI) standards and their associated test-and-evaluation protocols for radiation detection, instrumentation, and personal dosimetry rely on the use of Cs-137. 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. 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. These instruments are sent to secondary and tertiary laboratories that ~~who~~, 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 correctly and is traceable to NIST. ~~Consequently, maintaining the current CsCl technology is important, but replacement with other less soluble/dispersible forms of Cs-137 could be acceptable for calibration applications.~~

Ensuring Secure Disposal for Disused CsCl Sources **[removed BOLD and added underline]**

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. ~~Currently, there is no disposal capability for such commercial sources.~~ 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 ~~and frequency~~. The Commission considers it imperative to develop a pathway for the long term storage and disposal of these sources because long term storage at licensee facilities increases the potential for safety and security issues ~~perpetuates the security issues associated with CsCl~~. To resolve these issues, the NRC ~~has participated and~~ will continue to participate with its ~~other~~ 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 ~~whether or not there are alternatives developed~~.

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.[2] At the present time, no final decision has been made to proceed with approval, funding, and operation of a disposal facility~~, but if such a decision were made, DOE anticipates that such a disposal facility would not be available until around 2015-2020~~. The Commission will actively support DOE in all phases of the process to establish a storage facility for permanent, safe and secure storage of used and unwanted sources.

The NRC's Perspective on Further Security Enhancements **[removed BOLD and added underline]**

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 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 ~~The~~ NRC ~~welcomes efforts~~ will work with other federal agencies to~~ward~~ further enhance~~ing~~ the secure use of Cs-137 sources.~~ in a cost-effective manner without affecting the commercial, industrial, academic, and medical processes that depend upon these sources~~. The NRC recognizes that it is prudent to maintain awareness of the status of research to identify alternative forms of CsCl. NRC will remain cognizant of these issues and and appropriately consider whether there are safety and security benefits to further risk reduction. As part of 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 ~~if necessary, based on a change to~~ this environment change. Just as it did following the events following September 11, 2001, the NRC is prepared to take immediate action such as issuance of additional security requirements with ~~or~~ orders or ~~and will initiate~~ rulemaking to address such security-related issues, if necessary.

The NRC solicits stakeholder input into major issues associated with the use of CsCl. The ~~public workshop entitled~~ Public Workshop on the Security and Continued Use of Cesium-137 Chloride Sources that the NRC held in September 2008~~,~~ is an example of soliciting such input. The workshop was attended by a large number of stakeholders and, in addition to the oral presentations and comments, the NRC received a significant number of written submissions. The workshop 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 ~~may~~ experience as a ~~the~~ result of potential further regulatory requirements.

~~The NRC recognizes that enhancements to CsCl security could be achieved through both rulemaking and voluntary industry initiatives. Therefore,~~ While the current security requirements are adequate, 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. Similarly, ~~Furthermore,~~ the NRC supports efforts to develop alternate forms of Cs-

2 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.

137 that would further reduce the risk of malevolent use associated with CsCl. The National Research Council of the National Academies (NA) issued a report[3] that supported these efforts, ~~and~~ 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 would provide lowered security hazards.

The NRC recognizes that objective measures of 'solubility' and 'dispersibility' need to be defined before alternate ~~less-soluble and less-dispersible~~ forms of Cs-137 that are ~~(i.e.,~~ less-soluble and less-dispersible than the ~~CsCl in~~ compressed powder form~~)~~ can be developed. The Commission has already directed the NRC staff to work with Federal agencies to define these measures which must be readily expressible in physical and chemical terms and be demonstrated through well-defined test protocols. In addition, the criteria for the solubility and the dispersibility measures must be established at levels that ensure enhancement of security and reduction of risks of malevolent use. Consequently, the criteria must be developed and accepted by both the cognizant technical communities and the communities responsible for the Nation's security.

~~The NRC encourages the technical and security communities to work together in developing objective measures of solubility and dispersibility. Currently, there is only one objective measure of solubility in the U.S. and international standards, i.e., the measure of leachability in ANSI N43.6-2007 and ISO 2919-1999. A similar measure has yet to be developed for dispersibility. Furthermore, once a dispersibility measure is developed, government agencies responsible for security must establish quantified criteria, both for solubility and dispersibility, which would provide an adequate enhancement of security and reduction of risk for malevolent use.~~

While it is outside the scope of NRC's mission to conduct developmental research, the Commission encourages stakeholder research to develop alternative chemical forms for large activity Cs-137 sources. One of the recommendations made by the NA was to investigate the development of alternate chemical forms of Cs-137. The NRC believes that such research should engage cognizant Federal agencies and should consider the practicality of producing an end product that would maintain ~~provide~~ the security as well as the societal benefits of the current applications ~~use~~ of CsCl sources ~~in a secure and cost-effective way~~. ~~The NRC intends to work with domestic and international partners to establish acceptable levels of solubility and dispersibility. With such measures, production of alternative forms of Cs-137 would become a clearly defined goal for the source manufacturer and user communities.~~ The NRC considers that pursuit of alternate forms of cesium would provide benefits in the longer term, because the technology of manufacturing other forms of cesium is not yet available. Given the state of the current technology, NRC believes that, for the short term, it is more feasible to focus current security efforts on strengthening existing security of sources as necessary through cooperative efforts and voluntary initiatives of industries that currently manufacture and use irradiators with CsCl sources. While current NRC security requirements ensure the safety and security of these sources, it ~~It~~ has been shown through the voluntary NNSA security initiative program that further security enhancements and future design improvements further minimize the potential misuse or malevolent acts involving these sources.

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

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. The NRC has met this responsibility through imposition of additional security requirements. The NRC has articulated in the past that the use of alternative forms of Cs-137 is desirable. ~~While t~~The NRC's actions to date have resulted in strong security measures being established, and 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 requirements and considering a lack of a disposal capacity. ~~and would be detrimental to patient health, longstanding research, and emergency response capabilities. Furthermore, a~~ A clear strategy for the end-of-life management of these sources, which is the responsibility of the DOE ~~government~~, is not mature and likely will not be for some time. Many medical, research, and emergency response stakeholders have indicated that short term replacement would be detrimental. 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. The NRC will continue to work with its federal partners to ensure the safety and security of CsCl sources. In the event that changes in the threat environment necessitate regulatory action, t~~T~~he NRC is ready to ~~use its regulatory authority and~~ issue additional security requirements to apply appropriate ~~regarding~~ limitations for the use of CsCl in its current forms or ~~and~~ for its replacement with suitable alternatives~~, should changes in the threat environment necessitate it~~.