

minimizing the release of radioactive materials to the environment.

Each applicant for a license to possess and use special nuclear material in a plutonium processing and fuel fabrication plant as defined in 10 CFR 70.4, "Special Nuclear Material," must satisfy the provisions of 10 CFR 70.23, "Requirements for the approval of applications." Paragraphs (a)(3) and (a)(4) of 10 CFR 70.23 require that the applicant's proposed equipment, facility, and procedures be adequate to protect health and minimize danger to life or property.

II. Further Information

The NRC staff is soliciting comments on DG-3034. Comments may be accompanied by relevant information or supporting data, and should mention DG-3034 in the subject line. Comments submitted in writing or in electronic form will be made available to the public in their entirety through the NRC's Agencywide Documents Access and Management System (ADAMS).

Personal information will not be removed from your comments. You may submit comments by any of the following methods:

1. *Mail comments to:* Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

2. *E-mail comments to:* NRCREP@nrc.gov.

3. *Hand-deliver comments to:* Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

4. *Fax comments to:* Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission at (301) 415-5144.

Requests for technical information about DG-3034 may be directed to Timothy Johnson at (301) 492-3121 or e-mail to *Timothy.Johnson@nrc.gov*.

Comments would be most helpful if received by October 1, 2008. Comments received after that date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

Electronic copies of DG-3034 are available through the NRC's public Web site under Draft Regulatory Guides in the "Regulatory Guides" collection of

the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/doc-collections/>. Electronic copies are also available in ADAMS (<http://www.nrc.gov/reading-rm/adams.html>), under Accession No. ML081080479.

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR), which is located at 11555 Rockville Pike, Rockville, Maryland. The PDR's mailing address is USNRC PDR, Washington, DC 20555-0001. The PDR can also be reached by telephone at (301) 415-4737 or (800) 397-4205, by fax at (301) 415-3548, and by e-mail to *PDR@nrc.gov*.

Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

Dated at Rockville, Maryland, this 25th day of July, 2008.

For the Nuclear Regulatory Commission.

Harriet Karagiannis,

Acting Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

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NUCLEAR REGULATORY COMMISSION

[NRC-2008-0419]

Request for Comments on the Security and Continued Use of Cesium-137 Chloride Sources and Notice of Public Meeting

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of Public Meeting and a request for comment.

SUMMARY: The NRC is conducting a public meeting to solicit early public input on major issues associated with the use of certain forms of cesium chloride (CsCl) currently used by NRC and Agreement State-licensees. To aid in that process, the NRC is requesting comments on the issues discussed in this notice. While the NRC has not initiated rulemaking on this subject, we are utilizing the conventionally established rulemaking comment channels. Additionally, the NRC is requesting names of individuals to participate at the public meeting in a roundtable discussion of the issues discussed in Sections II and III of this notice.

DATES: *Comment Dates:*

1. Comments on this notice should be submitted by September 30, 2008. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure

consideration only for comments received on or before this date.

2. Nominations for participation in the roundtable discussion should be submitted by September 1, 2008.

Public Meeting Dates: The NRC will also take public comments on the issues raised in this notice at a public meeting on September 29-30, 2008. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information.

ADDRESSES: Members of the public are invited and encouraged to submit comments by mail to Michael Lesar, Chief, Rulemaking, Directives, and Editing Branch, Office of Administration, Mail Stop T-6D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

You may also submit comments electronically at <http://www.regulations.gov>; search on docket ID: NRC-2008-0419.

To ensure efficient and complete comment resolution, comments should include references to the section and page numbers of the document to which the comment applies, if possible. When commenting on the CsCl issues presented in this notice, please exercise caution with regard to site-specific security-related information. Comments will be made available to the public in their entirety; personal information, such as your name, address, telephone number, e-mail address, etc. will not be removed from your submission.

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

Regulations.gov: Documents related to this notice, including public comments, are accessible at <http://www.regulations.gov>, by searching on docket ID: NRC-2008-0419.

NRC's Public Document Room (PDR): The public may examine and have copied for a fee, publicly available documents at the NRC's PDR, Public File Area O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC's Agencywide Document Access and Management System (ADAMS): Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to *pdr.resource@nrc.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. John P. Jankovich, Office of Federal and State Materials and Environmental Management Programs, telephone (301) 415-7904, e-mail

john.jankovich@nrc.gov, or Dr. Cynthia Jones, Office of Nuclear Security and Incident Response, telephone (301) 415-0298, e-mail cynthia.jones@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Certain radioactive 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. Federal agencies have performed recent risk and consequence studies that show it may be prudent to require additional security features for licensed facilities that use certain radioactive material, including CsCl sources. CsCl sealed sources are used in many applications, most commonly in irradiators, calibrators, and in devices for biological and medical research. A recent National Academy of Sciences study (NAS report) has recommended the replacement or elimination of CsCl sources (see http://www.nap.edu/catalog.php?record_id=11976).

The NRC is seeking early public input on the major issues associated with any potential regulatory actions involving CsCl that would reduce the risk to individuals, society, and the environment if such material were used in a malicious act. As a first step, the NRC has prepared an Issues Paper, contained in Section III of this notice, which describes issues and alternatives related to the overall concerns associated with IAEA Category 1 and 2 CsCl sources.¹ The intent of this paper is to foster discussion about these issues and alternatives before any regulatory actions by NRC or the Agreement States are initiated. The NRC will also utilize a public Web site, <http://www.nrc.gov/materials/miau/licensing.html> to make documents relevant to the Issues Paper available to the public. The content of the Issues Paper is contained in Section III of this notice.

¹An 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.

II. Request for Written and Electronic Comments and Plans for a Public Meeting

The NRC is soliciting comments on the items presented in the Issues Paper. Comments may be submitted either in writing or electronically as indicated under the **ADDRESSES** heading. In addition, the NRC is holding a facilitated public meeting at the Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, Maryland on September 29-30, 2008, on the issues discussed in Section III of this notice. This Issues Paper provides background and topics of discussion on the major issues that will be the subject of the public meeting.

During the public meeting, NRC will conduct individual roundtable panel discussions, with opportunity for audience participation, on each issue contained in Section III of this notice. NRC is seeking the names of individuals interested in participating on these panels. Nominations by interested individuals or organizations should include the name of the proposed panel member, the issues they are interested in discussing, view point(s) on the issue(s), and affiliation (if any). Roundtable panel participants will be selected with the goal of providing balanced view points on each of the various issues. Please see the **ADDRESSES** section to submit nominations by September 1, 2008.

In addition to inviting public comments on the issues presented in Section III of this notice, the NRC is also soliciting specific comments related to: (1) Quantitative information on the costs and benefits resulting from consideration of the factors described in the Issues Paper; (2) operational data on radiation exposures (increased or reduced) that might result from implementing any of the options described in the Issues Paper; (3) whether the presented issues are addressed comprehensively; and (4) whether other options should be considered, including quantitative information on the costs and benefits for these other options. The Commission believes that stakeholder comments will help to quantify the potential impact of these proposed changes and will assist the NRC as potential regulatory action(s) are developed.

Based on the comments received in both written and electronic form, and at the public meeting, the Commission will then be in a better position to evaluate whether to proceed with the development of a proposed rulemaking or take some other regulatory action. If

the Commission decides to proceed with a proposed rulemaking, additional information will be published in the **Federal Register** for public review and comment.

III. Issues Paper on the Use of CsCl Sources at NRC- and Agreement State-Licensed Facilities

Introduction

Section A of this Issues Paper describes some general considerations recently raised concerning the use of certain CsCl sources at NRC- and Agreement State-licensed facilities. Section B of the paper discusses the various alternatives and major issues that need to be addressed before commencing any regulatory activities related to the use of CsCl sources in the U.S.

A. Background

The Energy Policy Act of 2005 (EPAct) required the establishment of an interagency Radiation Source Protection and Security Task Force (Task Force) to be chaired by the NRC. The Task Force was charged with: (1) Evaluating and providing recommendations relating to the security of radiation sources in the United States from potential terrorist threats, including acts of sabotage, theft, or use of a radiological source in a radiological dispersal device; and (2) providing recommendations for appropriate regulatory and legislative changes to Congress and the President.

On August 15, 2006, the NRC provided the President and Congress with the first Report documenting the efforts of the Task Force. The report included 10 recommendations and 13 actions to improve source security in the U.S. (see <http://www.nrc.gov/reading-rm/doc-collections/congress-docs/correspondence/2006/president-08-15-2006.pdf>). Recommendation 12-2 from this report focused on the security of IAEA Category 1 and 2 radioactive sources containing CsCl. Specifically, this recommendation stated that:

“The Task Force recommends that high priority be given to conducting a study within 2 years to assess the feasibility of phasing out the use of CsCl in a highly dispersible form. This study should consider the availability of alternative technologies for the scope of current uses, safe and secure disposal of existing material, and international safety and security implications.”

Section 651 of the EPAct also required that the NRC enter into an arrangement with the National Academy of Sciences (NAS) through which NAS would review the civilian uses of radionuclide radiation sources and study potential

replacements for sources that pose a high risk to public health or safety in the event of an accident or attack. Considering technical and economic feasibility and risks to workers, the NAS was asked to report findings and recommendations on options for implementing the identified replacements. The NAS completed its review in February 2008 (see http://www.nap.edu/catalog.php?record_id=11976) and stated that cesium-137 in the form of CsCl is a greater concern than other radiation sources based on its dispersibility and its presence in populated areas across the country. In view of the overall liabilities associated with radioactive CsCl and the alternatives that are available now or possible in the future to replace these radiation sources, the NAS report concluded that high-activity CsCl sources should be replaced. The NAS also recommended that "Replacement of some radionuclide radiation sources with alternatives should be implemented with caution, ensuring that the essential functions that the radionuclide radiation sources perform are preserved." The NAS also suggested options for implementing the replacement, including discontinuation of licensing of new CsCl irradiator sources and devices, prohibiting the export of CsCl to other countries and incentives to decommission existing sources and devices.

Accordingly, the NRC is providing the following key points for consideration and discussion in order to obtain stakeholder input before making any regulatory enhancements for the continued use of CsCl sources.

B. Issues for Discussion

The following format is used in the presentation of the issues that follow. Each issue is assigned a number, a short title, and a list of questions and factors for consideration. These issues, questions and factors are not meant to be a complete or final list, but are intended to initiate discussion. Interested stakeholders are welcome to recommend additions, deletions, or modifications to the key issues for consideration and propose implementation considerations. These issues and factors will serve as the basis for discussion at the public meeting. All public feedback will be used in developing implementation options for Commission consideration. Meeting participants and commenters are strongly encouraged to read the NAS report before the public meeting or providing comments.

Issue No. 1—Alternatives to the Use of Cesium Chloride (CsCl) Sources

The majority of self-shielded irradiators used in industrial operations, instrument calibration, and biological/medical research, are constructed with CsCl sources because of the suitable properties of cesium-137 such as long half-life, low cost, and moderate shielding requirements relative to other radionuclides. Currently, the physical form of CsCl in sources with activity levels under consideration (*i.e.*, IAEA Category 1 and 2) is compressed powder. The compressed powder form is used because of its high specific activity (high gamma emission per unit volume) making it feasible to manufacture high-activity sources in a relatively small volume.

In considering Issue No. 1, alternatives to the use of CsCl sources in compressed powder form, there are two main issues that should be considered and discussed. Issue 1.1: Feasibility of the use of other chemical or physical forms of cesium-137 (Cs-137) and Issue 1.2: Feasibility of the use of isotopes other than Cs-137. Each of these issues is presented below.

Issue No. 1.1: Feasibility of the Use of Other Forms of Cs-137

Q1.1–1. Are manufacturers currently considering the use of other forms of cesium (other than CsCl)? If yes, what are such considerations?

Q1.1–2. Is the use of other forms of cesium feasible? If so, please describe desired methods and discuss any benefits or obstacles (*e.g.*, intended function of source, costs, timeframe).

Q1.1–3. (a) Would the effect of density loading with different forms of cesium preclude their use in existing devices? (b) Would it require modification of existing devices?

Q1.1–4. Is it feasible that high-activity (*e.g.*, IAEA Category 1 and 2) cesium sources will be available in alternative material forms? If so, what is the estimated timeframe for manufacturing?

Q1.1–5. Since all the CsCl is manufactured in Mayak, Russia, is it known if the cesium source producer can modify its production process?

Q1.1–6. Would other entities (in the U.S. or worldwide) engage in manufacturing sources with alternative forms of Cs-137?

Issue No. 1.2: Feasibility of the Use of Isotopes Other Than Cs-137

Q1.2–1. (a) Can cobalt-60 (Co-60) be substituted for radioactive CsCl for any applications? (b) If so, what types of applications? (c) If not, why not?

Q1.2–2. Can the shielding challenges for Co-60 be addressed by switching

from lead shields to more effective tungsten or depleted uranium shielding?

Note: Consider that tungsten shielding is more expensive than lead and manufacturing depleted uranium shielding is a very specialized, expensive operation that requires NRC or Agreement State licensing for its entire lifecycle.

Q1.2–3. What are the attendant risks associated with Co-60 source transportation?

Note: Consider the shorter half-life (5.27 y) of Co-60 radiation sources would require that they be replaced more frequently than Cs-137, which entails the transportation of both fresh and used sources.

Issue No. 2—Use of Alternative Technologies

An alternative technology is defined in the context of this document as a technological process that provides the same societal benefits as the devices that utilize CsCl at the present time, but without the use of radionuclides. Some of the potentially feasible alternative technologies include such processes as x-ray irradiators or electron beam irradiators. Previous reports, such as those prepared by the Radiation Source Protection and Security Task Force and the NAS, referenced above, addressed the issue of alternative technologies to a limited extent. A more extensive examination of the feasibility of these and other alternative technologies is needed.

Therefore, in considering Issue No. 2, use of alternative technologies, there are four main issues that should be considered and discussed:

Q2–1. Are X-ray generators already commercially available as substitutes for applications that do not require the gamma rays with Cs-137 and Co-60?

Q2–2. Are X-ray tubes cost-effective considering the initial cost, operating costs, and requirements for more maintenance for periodic calibration and replacement than radioactive sources?

Q2–3. Is there any indication that the performance of the alternatives will change (improve or worsen) with respect to Cs-137?

Q2–4. Regarding the availability of alternative technologies, (a) what is the timeframe of future availability of each alternative, and (b) what is the cost for each of the alternative technologies (capital costs, operation costs, cost to users)?

Issue No. 3—Possible Phase-Out of CsCl Sources

Discontinuation of the further use of CsCl sources with activity levels in IAEA Category 1 and 2 was

recommended for consideration by the Radiation Source Protection and Security Task Force and by the NAS, referenced above.

Both reports recognize the important role that devices, containing such sources, fulfill in serving public health, research and instrument calibration at the present time. But the reports also considered the potential risks associated with these sources and, consequently, recommended phasing out their future use. NRC has not made any decision in this regard, but as a follow-up to the recommendations, NRC is seeking additional information that would provide relevant information for its decisionmaking process.

In considering Issue No. 3, possible phase-out of CsCl sources, there are four main issues that should be considered and discussed: Issue 3.1: Potential rulemaking issues and justification for regulatory change; Issue 3.2: Transportation and storage issues associated with removal of CsCl sources from licensee facilities; Issue 3.3: Consideration of government incentives and voluntary actions by industry and manufacturers; and Issue 3.4: Impact of U.S. changes to regulating CsCl on the international community. Each of these issues are presented below.

Issue No. 3.1: Potential Rulemaking Issues and Justification for Regulatory Change

Q3.1-1. (a) What would be the medical consequences if CsCl was to be banned for medical (e.g., blood) irradiators? (b) What would be the impact to existing and future biomedical research using these devices? (c) Can alternative technologies be used for medical applications and/or biomedical research (research on animals and tissue?)

Q3.1-2. (a) What would be the consequences if CsCl was to be banned for irradiators that are used for industrial and calibration purposes? (b) What is the impact on existing American National Standards Institute (ANSI) standards and licensee conditions that require the use of Cs-137 for calibration purposes?

Q3.1-3. What would be the economic consequences to users if CsCl was to be banned?

Q3.1-4. What would be the economic consequences to vendors if CsCl was to be banned?

Q3.1-5. (a) Should the NRC discontinue all new licensing and importation of these sources and devices? (b) What is the regulatory basis? (c) Who (NRC, DHS, or jointly) should conduct the risk analysis?

Issue No. 3.2: Transportation and Storage Issues Associated With Removal of CsCl Sources From Licensee Facilities

Q3.2-1. (a) Are there transportation packages available for transportation? (a) Who should bear the transportation costs?

Q3.2-2. (a) How could the current CsCl sources be disposed given that CsCl is defined as a "Greater Than Class C" source and currently has no disposal mechanism in the U.S.? (b) If disposal was made available by DOE, what would be the cost of disposal?

Q3.2-3. (a) Where could the decommissioned sources be stored? (b) What disposition options are needed in the United States?

Issue No. 3.3: Consideration of Government Incentives and Voluntary Actions by Industry and Manufacturers

Q3.3-1. Should the Federal government issue incentives to implement replacements?

Q3.3-2. (a) Are there feasible incentives to shift users away from radioactive CsCl for users? (b) Manufacturers?

Q3.3-3. (a) What incentives should the Federal government provide to licensees to decommission their existing sources or devices because the devices still have use value? (b) For licensees that are defined as "not-for-profit" (e.g., hospitals), what type of incentives could be made available to change technologies?

Q3.3-4. How can the Federal government compensate licensees when they are forced to decommission these sources? Should compensation include the cost of the replacement technology? Decommissioning?

Issue No. 3.4: Impact of Potential U.S. Changes to Regulating CsCl on the International Community

Q3.4-1. How can the U.S. prevent recovered sources from decommissioned devices (or the devices themselves) from being sold outside the U.S.?

Q3.4-2. (a) If the U.S. decides to ban the use of CsCl sources, should the U.S. have a position in denying or eliminating after-market sales of CsCl irradiators outside the U.S.? (b) Would this be potentially denying medical care to developing countries?

Q3.4-3. What should the role of the International Atomic Energy Agency (IAEA) be in assisting the U.S. in ensuring the safe and secure use of CsCl sources and devices?

Issue No. 4—Additional Requirements for Enhanced Security of CsCl Sources

In considering Issue No. 4, additional requirements for enhanced security of CsCl sources, there are three main issues that should be considered and discussed:

Q4.1. Should the NRC and Agreement States require more stringent security measures than those currently mandated (e.g., should additional requirements be implemented for IAEA Category 1 and 2 sources)?

Note: The current requirements for increased security of certain high-risk radioactive sources in the U.S. are: (a) Compensatory Measures for panoramic irradiators; (b) Additional Security Measures for manufacturers and distributors; (c) Increased Controls for licensees with Category 1 and 2 devices and sources; (d) Fingerprinting for access to radioactive material (see <http://www.nrc.gov/security/byproduct/orders.html>).

Q4.2. Should the NRC and Agreement States require more stringent security measures for lower than Category 2 CsCl sources and devices (e.g., Category 3 sources)?

Q4.3. Would additional security requirements for CsCl create a disincentive for owning them?

Issue No. 5—Role of Risk Analysis in Potential Future CsCl Requirements

In considering Issue No. 5, the role of risk analysis in NRC and Agreement State requirements for CsCl, the main issues that should be considered and discussed:

Q5.1. (a) How should the NRC determine the economic and social disruptions/impacts to the public, licensees, and the environment? (b) How should these factors be measured in decision making?

Dated at Rockville, Maryland, this 24th day of July 2008.

For the Nuclear Regulatory Commission,
John P. Jankovich,
Team Leader, Office of Federal and State Materials and Environmental Management Programs.

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OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments and Notice of Public Hearing Concerning China's Compliance With WTO Commitments

AGENCY: Office of the United States Trade Representative.

ACTION: Request for comments and notice of public hearing concerning