POLICY ISSUE
(Notation Vote)

November 24, 2008 SECY-08-0184

FOR: The Commissioners

FROM: R.W. Borchardt
Executive Director for Operations

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

PURPOSE:

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

SUMMARY:

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

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

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

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

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

BACKGROUND:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DISCUSSION:

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

Security and Control of Radioactive Sources

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

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

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

Blood Irradiators

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

Research Irradiators

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

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

Calibration

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

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

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

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

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

Option 1. Enhance security and issue a Commission Policy Statement

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

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

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

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

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

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

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

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

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

Advantages of Option 1:

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

Disadvantages of Option 1:

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

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

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

Specific actions to be conducted by the NRC staff:

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

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

Advantages of Option 2:

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

Disadvantages of Option 2:

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

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

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

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

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

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

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

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

RECOMMENDATIONS:

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

RESOURCES:

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

NRC Staff Resource Requirements:

Option 1

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

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

Option 2

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

Option 3

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

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

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

COORDINATION:

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

AGREEMENT STATE COORDINATION:

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

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

/RA Martin J. Virgilio Acting For/

R. W. Borchardt
Executive Director
for Operations

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

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

WITS200600067/EDATS: SECY-2008-0503 WITS200800255/EDATS: SECY-2008-0338 WITS200800253/EDATS: SECY-2008-0336

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OFC	FSME/DMSSA	FSME/DMSSA	FSME/DMSSA	FSME/DMSSA	NSIR	OCFO
NAME	JJankovich:ct	AMauer	TReis	RLewis	RZimmerman	JDyer (DJackson for)
DATE	10/30/08	10/30/08	10/30/08	11/07/08	11/05/08	11/06/08
OFC	OGC	OIP	RES	TechEd	FSME	EDO
NAME	BJones (GMizono for)	MDoane	BSheron	CPoland	CMiller	RWBorchardt /MJVirgilio for/
DATE	11/05/08	11/05/08	11/05/08	11/13/08	11/17/08	11/24/08

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