

**Summary of Comments on the CsCl Draft Policy Statement and Staff Resolutions –
Submitted in Response to the *Federal Register* Notice (FRN) and
at the November 8-9, 2010 Public Meeting (PM)**

Comment Number	Comment	Resolution
E. Maher, Health Physics Society (HPS); ML102571401		
FRN 1-1	The HPS fundamentally supports the NRC Policy Statement, including strong endorsement for the NRC's call for the imperative development "of a pathway for the long term storage and disposal of these sources whether or not there are alternatives developed" and for the need for threat assessments, which are not necessarily available to HPS or general public, to provide input to the decision making as to when an appropriate amount of security and regulations has been accomplished.	No change was made. Agrees with Draft Policy Statement.
FRN 1-2	Category 3 CsCl sources should be included in the scope of sources covered by the NRC Policy Statement.	No change was made. The Commission directed the staff to address category 1 & 2 sources only.
FRN 1-3	Based on Comment (1), the Policy Statement should expand the discussion of the types and uses of CsCl sources beyond the three types discussed to include Category 3 CsCl sources, including a discussion of their importance for continued use... The HPS position that Category 3 sources should be included in the scope of the Policy Statement would expand these applications to include well logging and level gauge sources. The Background section should include the discussion of the uses of these sources including the opportunity for alternative technologies, including non-radioisotope alternatives, to replace CsCl for these applications.	No change was made. The Commission directed the staff to address category 1 & 2 sources only.

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FRN 1-4	<p>The Policy Statement should address the NRC's policy on research, development, and implementation of alternative technologies to Category 1, 2, and 3 CsCl sources, including non-radioisotope alternatives...</p> <p>The HPS considers it a major oversight for the NRC Policy Statement to only support the research and development of a radioisotope alternative to CsCl...</p> <p>...identify legislative and regulatory hurdles that impede the NRC's ability to consider and incorporate alternative technology development and availability into its mission.</p>	<p>Changes were made. Discussion of alternatives was added. Research for non-radioisotope alternatives is outside the scope of NRC's mission. Discussion was added regarding the 2010 Task Force Report and its Implementation Plan by the NRC; both include endorsement of alternative technologies.</p>
FRN 1-5	<p>The Policy Statement should provide more discussion to clarify the NRC's determination of sources that may pose a significant risk to "<i>society and the environment.</i>"</p> <p>Since the Code [IAEA Code of Conduct] does not provide a basis, either scientific or qualitative, for determining sources that could result in a significant societal or environmental risk, the NRC should discuss its basis for determining what sources meet this criteria.</p>	<p>No change was made. NRC performed various vulnerability assessments and assessed the potential threat of the different types of sources used in the U.S. to determine which sources could pose a significant risk if used malevolently by a terrorist. These sources were later also identified by the IAEA as those that should have increased security. NRC has instituted such security requirements in the U.S. (since 2005). As the Policy Statement states, if the U.S. threat environment were to change, the NRC is ready to issue additional security requirements, if necessary, to apply appropriate limitations for use of CsCl in its current form.</p>

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FRN 1-6	The Policy Statement should recognize the issuance of the Task Force's second report to Congress.	Changes were made. Discussion of Task Force Report was added.
G. Williams, US Dept of Veteran's Affairs, National Health Physics Program; ML103050059		
FRN 2-1	VHA reviewed the draft policy statement and does not have any comments or proposed changes to the statement. The policies and focus for Nuclear Regulatory Commission regulatory oversight and actions appear appropriate.	No change was made. Agrees with Draft Policy Statement.
D. Bryan, on Behalf of Self (Radiation Technology, Inc.); ML103350131		
FRN 3-1	The comments contained in this letter are specific only to the use of CsCl sealed sources in industrial fixed gauging devices.	No change was made. The activity level in industrial fixed gauges is less than that of category 1 & 2 sources. The commenter stated that they have no experience with Cat 1&2 sources. The Commission agreed with the staff recommendation to provide security enhancements for Category 1 & 2 sources only. Industrial fixed gauges are outside the scope of the policy statement.
FRN 3-2	<p>While the activity of CsCl sources used in fixed industrial gauging devices falls below either Category I or Category II limits, they in no way should pose a terrorist threat; however, they do present a radiological problem.</p> <p>Failure of these sources can contaminate the surrounding area and Cesium can be inhaled by personnel.</p>	No change was made. Based on the current threat environment and vulnerability assessments, the Commission agreed with the staff recommendation to provide security enhancements for Category 1 & 2 sources only. The policy statement states that current security requirements are adequate and the Commission will take further actions when needed.

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FRN 3-3	I would propose the following action ban the distribution of CsCI sources of any activity for use in industrial environments.	Changes were made. Discussion of potential for rulemaking was added. The policy statement states that current security requirements are adequate and the Commission will take further actions, including licensing changes (e.g., banning), when needed.
FRN 3-4	I would propose the following action Issue an advisory that all those sources still in use be replaced with sources utilizing more current technology; e.g., ceramic matrix.	Changes were made. Discussion of alternatives was added. Discussion was added regarding the 2010 Task Force Report and it's Implementation Plan by the NRC; both include endorsement of alternative technologies.
FRN 3-5	Authorize disposal in DOE approved sites.	Changes were made. Disposal issues were added, e.g., 2010 Task Force Report and DOE EIS, both of which address this comment.
S. Musolino and D. Coulter, Brookhaven National Lab (BNL) and PHROBUS, Inc.; ML103500395		
FRN 4-1	Brookhaven National Laboratory report, BNL-90329-2009: The purpose of this document is to describe best practices available to manage the security of radioactive materials (RAM) in medical centers, hospitals, and research facilities. This document outlines approaches for the licensees possessing these materials to undertake security audits to identify vulnerabilities in how these materials are stored or used, and to describe best practices to upgrade or enhance their security.	No change was made. Details implementing security technologies are outside the scope of the Policy Statement, The submission contains specific procedures and hardware solutions as recommendations for licensees to meet existing security requirements. The Policy Statement is a broad statement on principles, not on specific implementation procedures.

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FRN 4-2	<p>Unpublished submittal of Editorial to Health Physics Journal, “Cesium Chloride: Dispersibility or Security?”, Nov. 29, 2010</p> <p>Specific Comments in the document:</p> <ul style="list-style-type: none"> • Changing cesium chloride to a different physical form does not eliminate the potential for malevolent dispersal; re-engineering the physical form will be costly, and its success debatable. • Any of the proposed alternatives to cesium chloride most likely will impose a significant economic impact, and present other serious drawbacks for clinical medicine and medical research. • The institution of the Increased Controls mitigated the risk of cesium chloride so that risk is only one of a continuum of terrorist threats. Although its potential impacts were not eliminated, the residual risk of this material is acceptable (or close to it), and proven opportunities exist for cost-effective improvements to security. 	<p>No change was made. The NRC did not receive any update from the commenter about the publication.</p> <p>The specific comments in the unpublished submittal are addressed as follows:</p> <ul style="list-style-type: none"> • No change made. Comment is about risk assessments which are addressed in the policy statement. • Policy Statement section “Uses of CsCI Sources” was expanded and clarified. • No change made. Comment is about risk assessments and security improvements that are addressed in the Policy Statement.
FRN 4-3	<p>Slide presentation presented at Public Meeting, November 8-9, 2010: Conclusion</p> <ul style="list-style-type: none"> • Changing physical form of Cs does not eliminate the potential impact from a dispersal (Re-engineering the physical form will be costly) 	Same answers as 4-2 above.

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	<ul style="list-style-type: none"> • Significant economic impact and effects to the medical industry and medical research to replace CsCl with alternatives (e.g., accelerator/x-ray technologies) • Residual risk for CsCl post-ICs is acceptable (or close to it) and opportunities exist for cost effective improvements to security. • 	
M. Gottesman, US Dept of Health & Human Services, National Institutes of Health (NIH); ML103500318		
FRN 5-1	With the implementation of increased controls and further security upgrades already accomplished to enhance the security of these irradiators, therefore, the NIH agrees with the NRC's draft policy statement that adequate protection of public health and safety is maintained.	No change was made. Agrees with Draft Policy Statement.
FRN 5-2	A short-sighted urgency to remove or replace cs-137 irradiators would unequivocally be detrimental to basic science.	Changes were made. Discussion of need for CsCl irradiators was expanded and clarified.
FRN 5-3	Regarding NRC's draft policy statement that "the development and use of alternative forms of cesium-137, while not required for adequate protection, is prudent", the NIH notes that, for biomedical research, the only alternative to practically consider is a cabinet x-ray device. Alternate chemical forms of Cs-137 are not currently deemed suitable for full scale replacement in sealed source irradiators.	Changes were made. Discussion of need for CsCl irradiators was expanded.

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FRN 5-4	Alternative technologies (i.e., linear accelerator) are vastly more expensive and require additional room shielding, a larger footprint, and a more complex maintenance and operation program.	Changes were made. Discussion of need for CsCl irradiators was expanded.
FRN 5-5	Basic science needs are currently being met using Cs-137 irradiators and to eliminate such a valuable tool to the NIH research mission would be devastating. Indeed, some research protocols would be forced to terminate; for example, a current cancer treatment with great promise.	Changes were made. Discussion of need for CsCl irradiators was expanded.
FRN 5-6	Transitioning to x-ray irradiators will cause a great number of research scientists time and effort to repeat previously-established experiments, and this cannot be understated.	Changes were made. Discussion of need for CsCl irradiators was expanded.
FRN 5-7	Quality science is a rigorous discipline, and changing technologies will require extensive testing in order to verify that the change will not alter an experimental outcome. There is known to be a radiobiological difference in effective dose between x-ray and monoenergetic (e.g., Cs-137) photon radiation.	Changes were made. Discussion of need for CsCl irradiators was expanded.
FRN 5-8	Such a transition [to x-ray irradiators] will also cause a major negative budgetary impact on the NIH and its grantees. The replacement expense is a cost that will need to be borne by the Institutes at a time when budgets are flat; already there have been major cuts to the NIH supplies, services and equipment operating budgets.	Changes were made. Discussion of need for CsCl irradiators was expanded.

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FRN 5-9	<p>There is currently no disposal outlet for cesium irradiators, and this causes an increased safety and security threat by placing these sources into a storage (as opposed to active use) mode. Faced with long-term storage of these irradiators, the NIH will not be able to reduce from the same level of enhanced access control already in place.</p>	<p>Changes were made. Disposal issues were added, e.g., 2010 Task Force Report and DOE EIS, both of which address this comment.</p>
FRN 5-10	<p>The NRC's draft policy statement on the protection of Cesium-137 Chloride sources gives credit to the biomedical research need for these irradiators. However, more text in the policy statement regarding the absolute need for Cs-137 irradiators would better underscore their useful and necessary contribution to the advancement of science at the NIH and elsewhere, since it is important to go on record with all of the reasons why alternative technologies cannot meet all of the needs of the biomedical research community.</p> <p>...the loss of Cs-137 irradiators would be a grave disservice.</p>	<p>Changes were made. Discussion of need for CsCl irradiators was expanded. Discussion of alternative technologies was added.</p>

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J. Evan Sadler, American Society of Hematology (ASH); ML103550227		
FRN 6-1	<p>ASH represents over 16,000 clinicians and scientist committed to the study and treatment of blood and blood-related diseases.</p> <p>The issue of the continued use of Cesium-137 Chloride (CsCl)- containing irradiation devices is of particular importance and relevance to ASH members – research scientists as well as physicians.</p> <p>With the implementation of increased controls and further security upgrades already in place to enhance the security of these irradiators, ASH believes that adequate protection of public health and safety has been achieved.</p>	Changes were made. Adequacy of security is discussed in the Draft Policy Statement and importance of irradiators in medicine and research has been clarified.
FRN 6-2	<p>ASH is concerned that hematology and blood marrow transplantation are not listed under the major areas of biomedical research that uses CsCl-containing irradiation devices.</p> <p>ASH recommends that the Draft Policy Statement be updated to include the following in the third paragraph of the "Uses of CsCl Sources" section as published in the Federal Register Notice NRC-2010-0209 p. 37486 (additional language underlined):</p> <p>In biomedical research, CsCl irradiation has been used for over 40 years in fields such as immunology, <u>hematology</u>, stem cell research, <u>bone marrow transplantation</u>, cancer research, in</p>	Suggested revisions were made.

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	<p>vivo immunology, systemic drug research, chromosome aberrations, DNA damage/repair, human genome, and genetic factors.</p>	
FRN 6-3	<p>ASH is concerned that the Draft Policy Statement does not sufficiently address the absolute need [and lack of viable alternatives] for CsCI-containing irradiation devices in biomedical research, nor does it explain that proposed alternative technologies cannot readily meet the needs of scientists performing this crucial research that benefits society...</p> <p>X-ray irradiators are not an effective or viable alternative to CsCI-containing irradiation devices.</p> <p>ASH recommends that the Draft Policy Statement be updated to include the following in the third paragraph of the "Uses of CsCI Sources" section as published in the Federal Register Notice NRC-2010-0209 p. 37486 (additional language underlined): In biomedical research...</p> <p>... For <u>the vast majority of biomedical</u> 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. <u>CsC1 sources are dependable, economical and relatively easy to use.</u> No alternative technologies that can effectively replace CsC1</p>	<p>Changes were made. Discussion of biomedical research was expanded to address recommended language.</p>

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	<p>sources for biomedical research, <u>including X-ray, linear accelerators and Cobalt-60 irradiators</u>, have yet been developed. <u>Any kind of substitution would require re-validation of many research models of disease that have already been established using CsCI-containing irradiation devices.</u></p>	
FRN 6-4	<p>ASH urges the NRC to solicit public input on the use of CsCI-containing irradiation sources <i>before</i> issuing any additional security requirements/limitations if the threat environment changes and/or suitable alternatives become available.</p> <p>ASH recommends that the following changes be made to the last bullet of the Statement of Policy as published in the Federal Register Notice NRC-2010-0209 p. 37485 (additional language underlined): 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 to apply appropriate limitations for the use of CsCI in its current form <u>or for its replacement with suitable alternatives without adverse effects on the three specific classes of applications that benefit society as described above.</u> The NRC will solicit stakeholder input prior to making any regulatory action on <u>the use of CsCI.</u></p>	<p>The Policy Statement addresses the comment by stating “In the event that changes in the threat environment necessitate regulatory action, the NRC, in partnership with its Agreement States will be ready to issue additional security requirements to apply appropriate limitations for the use of CsCI, as necessary”. For regulatory changes, NRC follows applicable rulemaking procedure, including solicitation of public and stakeholder inputs.</p>

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FRN 6-5	<p>ASH also recommends that the following changes be made to the last sentence of the Summary section published in the Federal Register Notice NRC-2010-0209 p. 37487 (additional language underlined): In the event that changes in the threat environment necessitate regulatory action, the NRC is ready to issue additional security requirements to apply appropriate limitations for the use of CsCl in its current forms or for its replacement with suitable alternatives <u>without adverse effects on the three specific classes of applications that benefit society as described above.</u> The NRC will solicit stakeholder input prior to making any regulatory action on the use of CsCl.</p>	Recommendation was added.
L. Thevenot, American Society for Radiation Oncology (ASTRO); ML103550238		
FRN 7-1	<p>ASTRO supports the Draft Policy Statement, but urges the NRC to proceed with caution as it finalizes the Statement. ASTRO wants the NRC to ensure that patient care and advances in biomedical research impacting patient care are not compromised by any policies imposed on the medical use and research applications of cesium chloride. ASTRO is the largest radiation oncology society in the world, with more than 10,000 members.</p>	No change was made. Agrees with Draft Policy Statement.
FRN 7-2	<p>ASTRO cautions that until alternate forms of cesium-137 are developed, tested and proven, that any decisions made by the NRC, agreement states, or other regulatory bodies to limit the use of cesium-137 may negatively impact patient care.</p>	Changes were made. Discussion of alternate technologies was added.

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FRN 7-3	Significantly, cesium-137 irradiators play an important role in medical research related to understanding and treating cancer and other serious illnesses as well as for developing countermeasures for radiologic terrorism.	Changes were made. Policy Statement section "Uses of CsCl Sources" was expanded and clarified.
FRN 7-4	ASTRO shares the NRC's concern that there is no disposal pathway available to licensees for retiring cesium irradiator sources and that stockpiling of sources in one location poses other security threats. Moreover, while some vendors and government programs provide for long-term storage of these sources, there is no permanent storage option. ASTRO cautions that until a clear disposal pathway has been established, changes to any of the rules surrounding the use of cesium irradiators should be put on hold pending careful consideration with relevant stakeholders.	Changes were made. Disposal issues were added, e.g., 2010 Task Force Report and DOE EIS, both of which address this comment.
FRN 7-5	ASTRO hopes that the final policy statement will acknowledge the importance of research in advancing patient care and avoids impairing or dismantling research capabilities.	Changes were made. Policy Statement section "Uses of CsCl Sources" was expanded and clarified.
J. Shlueter, Nuclear Energy Institute (NEI); ML103560077		
FRN 8-1	The industry expresses its overall support for the draft Policy Statement which recognizes that near term replacement of Category 1 and 2 Cesium-137 Chloride Sources is not practicable or necessary.	No change was made. Agrees with Draft Policy Statement.

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FRN 8-2	The draft Policy Statement also emphasizes the significant actions that the NRC and industry have taken to markedly enhance security of all Category 1 and 2 sources (including Cesium-137 Chloride sources) over the last several years - these efforts are to be applauded.	No change was made. Agrees with Draft Policy Statement.
FRN 8-3	The draft Policy Statement identifies the critical unresolved source storage, disposal, and transportation issues that would need to be fully vetted with all stakeholders and resolved prior to any decision to ban and replace Cesium-137 Chloride sources domestically.	Changes were made. Disposal issues were added, e.g., 2010 Task Force Report and DOE EIS, both of which address this comment.
FRN 8-4	Throughout the Draft Policy Statement, the focus appears to be relative to Category 1 and 2 Cesium-137 Chloride sources. However, the Statement of Policy section is silent with respect to the Category 1 and 2 focus and we believe clarifying this focus within that section would be appropriate and consistent with the remainder of the draft Policy Statement.	Changes were made. Added clarification.
FRN 8-5	In addition, the Statement of Policy section indicates that the development and use of alternative forms of cesium-137 is "prudent." Given the discussion during the November 8-9, 2010, public meeting and industry presentations regarding the significant and effective	Changes were made. The Policy Statement has been clarified with regard to the prudence of manufacturing alternative forms. Regarding the comment on adequacy of current security requirements and voluntary actions to enhance

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	<p>security controls in place today and the limited risk reduction that could be realized by alternative forms of Cs-137, the prudence of the development of alternative forms is unclear.</p>	<p>security further, the Policy Statement states that “While the current security requirements are adequate and provide sufficient safeguards, the NRC recognizes that if the use of CsCI 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...”</p>
FRN 8-6	<p>If in the future the NRC revisits this subject, any decision to ban the use of Cesium-137 Chloride Sources must be made in the context of the domestic and international implications of such a decision. Discontinuing the use of Cesium-137 Chloride Sources domestically will only increase their availability in countries with potentially less regulatory structure and security, thereby posing an increased public health and safety risk worldwide; particularly since no viable domestic long term storage or disposal option exists today. In addition, future discussions involving banning the use of Cs-137 must consider its widespread medical use.</p>	<p>Changes were made. Discussion of export was included in the Draft. Discussion of possible future regulatory actions was added.</p>

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R. Brown, Council on Radionuclides & Radiopharmaceuticals, Inc. (CORAR); ML103570364		
FRN 9-1	<p>CORAR members include the major manufacturers and distributors of radioactive chemicals, radioactive sources, and radiopharmaceuticals and research radionuclides... CORAR generally supports NRC's recognition of the critical importance of these sources in applications related to medical use and other industries, as well as the fact that the current regulatory framework along with efforts of NRC and licensees has been very effective in securing control of these sources.</p> <p>This is a great example of when NRC works closely with industry stakeholders to achieve an effective and reasonable approach on this issue that benefits everyone.</p>	No change was made. Agrees with Draft Policy Statement.
FRN 9-2	CORAR also agrees with NRC's position that replacement of these sources with alternatives is not practicable or necessary in the short term, due to the effectiveness of existing controls and the lack of disposal options.	No change was made. Agrees with Draft Policy Statement.
FRN 9-3	The Background section of the Draft Policy states that NRC and licensee measures have ensured the security of Category 1 and 2 sources and states support of the recommendations of international community and references the IAEA Code of Conduct for the Safety and Security of Radioactive Sources. However, there is no specific discussion in the wording of the Statement of Policy to the effect that the scope of the Policy is limited to Category 1 and 2 sources and NRC should make this clear.	Changes were made. Statement limiting the scope of the Policy Statement to IAEA Cat. 1 & 2 sources was added.

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FRN 9-4	CORAR fully supports the Commission's view in the Draft Policy Statement that it imperative to develop a pathway for the long term storage and disposal of these sources. We also encourage NRC and other agencies to continue to engage stakeholders in the effort to find a solution.	No change was made. Agrees with Draft Policy Statement.
FRN 9-5	Why, as stated in the Statement of Policy, does NRC consider it "prudent" to develop and use alternative forms of Cs- 137 when previously in the Statement NRC states that sources are already adequately protected under current NRC requirements?	Changes were made. The Policy Statement has been clarified with regard to the prudence of manufacturing alternative forms. Regarding the comment on adequacy of current security requirements and voluntary actions to enhance security further, the Policy Statement states that "While the current security requirements are adequate and provide sufficient safeguards, the NRC recognizes that if the use of CsCI 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..."
FRN 9-6	While CORAR recognizes that the threat environment is subject to change, any potential security requirements that would result in an action to ban the use of these sources need to consider, in advance, the domestic implications as well as the unintended consequence of increasing their availability in countries with less rigorous or effective security arrangements in place.	Changes were made. Discussion of export was included in the Draft; no change was made. Discussion of future regulatory actions was added.

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A. Jones, Harvard University Radiation Safety Committee; ML110130221		
FRN 10-1	I submit this letter in support of the proposed Cesium-Chloride Policy Statement.	No change was made. Agrees with Draft Policy Statement.
FRN 10-2	The removal of instruments using ¹³⁷ Cs would severely limit current and future bio-medical research aimed at treating diseases such as cancer. Furthermore, this would cause a severe setback in ongoing research on the prevention of radiation effects due to accidents or terrorism, such as ongoing work at the University and its affiliated institutions on the medical countermeasures against radiation.	Changes were made. Discussion of biomedical research was expanded.
FRN 10-3	To further support the protection of this valuable scientific asset, the NRC should continue to encourage licensees to participate in the National Nuclear Security Administration program of voluntary security measures to enhance protection and management of these sources above those required by regulation. This combination of efforts serves to further support security while increasing the communication and sharing of best practices between licensees and regulators so that every effort is made to increase physical protections and to minimize the theft potential.	No change was made. Security was discussed in the Draft.
FRN 10-4	As noted in the Policy Statement, the NRC should encourage source and device manufacturers to continue work on design improvements to mitigate or minimize the radiological consequences of misuse or malevolent acts	No change was made. Regarding the comment on adequacy of current security requirements and voluntary actions to enhance security further, the Policy Statement states that “While

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	involving these sources.	the current security requirements are adequate and provide sufficient safeguards, the NRC recognizes that if the use of CsCI 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...”
FRN 10-5	The NRC should further study the solubility and dispersion of Cesium-Chloride, alternative forms Of ¹³⁷ Cs, and other IAEA Category 1 and 2 radioactive materials to better understand the comparative risks and advantages of alternative physical forms. This information would further inform the management and planning related to Category 1 and 2 sources.	No change was made. The response to FRN 10-4 applies.
FRN 10-6	As noted in the Policy Statement, a clear strategy needs to be defined to manage the disposition of these sources in a way that achieves security needs, minimizes radiation doses, and supports our national interests. In the short-term, this could be done by an enhanced Offsite Source Recovery Program that would provide safe and effective storage of disused sources while a long-term solution is developed.	Changes were made. Disposal issues were added, e.g., 2010 Task Force Report and DOE EIS, both of which address this comment.

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FRN 10-7	In recognizing the global concern and need to tightly control these sources, the US should work with the International Atomic Energy Agency to properly inventory all such sources and implement the stringent US source safety and security standards throughout the world.	No change was made. The NRC and other federal agencies continue to work with the IAEA and other countries in implementing security requirements for IAEA Category 1 and 2 sources.
J. Klinger, Illinois Emergency Management Agency (IEMA); ML110180071		
FRN 11-1	The Agency supports the efforts made by the U.S. Nuclear Regulatory Commission (NRC) regarding safety, security and control of high risk Cesium Chloride (CsCl) sources.	No change was made. Agrees with Draft Policy Statement.
FRN 11-2	The NRC did not state what specific additional security requirements the NRC intends to implement and how the Agreement States will implement such. It may be difficult operationally and legally for some Agreement States to implement such limitations in a prompt manner when they are not aware of what the limitations are and when the need appears to be cause for immediate action.	No change was made; this process issue is outside the scope of the Policy Statement. This issue is being addressed by the on-going 10 CFR Part 37 rulemaking process.
FRN 11-3	The NRC should consider limited use of these sources where other sources or other nonradioactive alternatives are available. There are certain types of devices (e.g., fixed gauges) that currently have alternative source approvals. Yet the CsCl is still an option for these uses. Where there are current alternatives, the NRC should prohibit such use of CsCl in these devices. In addition, while new sources are not being actively approved, current source	Changes were made. Discussion of alternative technologies and seeking stakeholder input into future requirements was added. The Commission did not direct the staff to prohibit use of CsCl.

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	registrations/licenses allow the continued distribution of existing CsCI sources. This should be restricted where applicable.	
FRN 11-4	If additional requirements need to be implemented specifically for CsCI, these requirements should be added to the 10 CFR Part 37 proposed rule. The significance of such requirements should not be implemented through guidance or policies especially if the NRC considers this to be a matter of common defense and security.	No change was made; this process issue is outside the scope of the Policy Statement. This issue is being addressed by the on-going 10 CFR Part 37 rulemaking process.
FRN 11-5	The Agency agrees that the development and implementation of the web-based licensing and License Verification System will enhance the security of these sources. Additionally, the physical security enhancements voluntarily incorporated into existing irradiators and designed into newly manufactured products also greatly reduce the vulnerability of obtaining these sources through malevolent acts. These physical security enhancements should be mandatory, not voluntary.	No change was made. Based on the vulnerability assessments of these sources, there is not a need to require these security enhancements to be required. Regarding the comment on adequacy of current security requirements and voluntary actions to enhance security further, the Policy Statement states that “While the current security requirements are adequate and provide sufficient safeguards, the NRC recognizes that if the use of CsCI 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...”

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FRN 11-6	<p>The GTRI offers additional measures of security enhancements, which include removal of unwanted sources; installation of remote monitoring systems, access control devices, motion detector sensors and cameras; deployment of in-device delay mechanisms, tie downs and hardened doors/rooms for various devices containing radioactive source; and offers alarm response training and table top exercises for licensees and first responders. These federally funded programs should be heavily promoted throughout the licensing community.</p>	<p>No change was made. Regarding the comment on adequacy of current security requirements and voluntary actions to enhance security further, the Policy Statement states that “While the current security requirements are adequate and provide sufficient safeguards, the NRC recognizes that if the use of CsCI 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...” The Policy Statement is issued for all stakeholders; the ‘licensing community’ is included among the stakeholders.</p>
FRN 11-7	<p>There are no alternatives to replace the use of the CsCI sources and that there are no disposal options available puts licensees in a difficult situation. The Agency agrees with the need for source design improvements to mitigate or minimize the radiological consequences if these sources are misused and for the development of alternative products to replace these sources.</p> <p>The Agency agrees that standards/definitions for new chemical and physical forms used in CsCI source construction need to be defined by NRC prior to manufacturing such sources and approval by NRC and</p>	<p>Changes were made to address the use of alternatives and disposal. Agrees with Draft Policy Statement.</p>

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	Agreement States performing Sealed Source and Device Evaluations.	
FRN 11-8	Disposal options must also be actively explored for existing sources, including consideration of interim storage at existing federal facilities.	Changes were made. Disposal issues were added, e.g., 2010 Task Force Report and DOE EIS, both of which address this comment.
November 8, 2011 Public Meeting Transcript: ML103360214 Issue No. 1: NRC's Role, Licensee's Responsibilities		
Panel Presentation: E. Maher, Health Physics Society (HPS)		
PM-1	First of all, fundamentally we agree with virtually everything the Commission has done. We agree that they have done a great job in the draft policy statement. And we want to compliment the Commission on that work.	No change was made. Agrees with Draft Policy Statement.
PM-2	The first one is the consideration of the Category 3 sources, which were categorically excluded from the policy statement. We believe that there are Category 3 sources that should deserve consideration. Since Category 3 was included by IAEA, we believe that it should also be considered under the policy statement.	No change was made. The Commission directed the staff to address category 1 & 2 sources only.
PM-3	We like to see in the draft policy statement or the policy statement going forward that a discussion of well logging sources and level gauge sources, how they might be protected better.	No change was made. The Commission directed the staff to address category 1 & 2 sources only.

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PM-4	And also on the alternative technologies, what types of technologies are there to substitute for Category 3 sources for those uses.	No change was made. The Commission directed the staff to address category1 & 2 sources only.
PM-5	<p>The position to use alternative technologies is provided in the Energy Policy Act of 2005. And it says directing it to promote the replacement of risk significant radioactive sources. Although that is discussed in background in the draft policy statement, we feel that this needs to be incorporated in the licensing process directly.</p> <p>What we would like to see at some point, that a licensee who is applying for a license for cesium chloride source, that in the application addressed why they did not use a non-radioactive source alternative technology.</p> <p>So right now the draft policy does not incorporate any alternative technology in the licensing process. And we do believe that needs to occur.</p>	Changes were made. Discussion of the 2010 Task Force Report and its Implementation Plan by the NRC were added which address both alternative radioactive technologies and non-radioactive technologies.
Audience Discussion: K. Nelson, Mayo Clinic		
PM-6	...that led me to ask myself why Part 37 was really even necessary. And I think I have heard a little bit now from Terry and Steve about some of the issues. And perhaps it might be useful, then, if Part 37 is required. And I do think it's a little bit more prescriptive than the orders that originally came out. You might want to consider addressing that in your policy statement.	No change was made. Comment is outside of the scope of the Policy Statement. This issue is being addressed by the on-going 10 CFR Part 37 rulemaking process.

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Issue 2: US Regulatory Requirements for Security		
Panel Presentation: J. Ring, Harvard University		
PM-7	I'm Joe Ring from Harvard. I want to start off by saying that we've gone through the proposed policy statement and we support the policy statement.	No change was made. Agrees with Draft Policy Statement.
PM-8	...the faculty said we don't have an alternative. We need cesium chloride because it's the basis of our science. With that, it becomes a scientific asset, ... That then makes this an issue not of security and not of regulation, but one of protecting an asset.	Changes were made. Discussion of biomedical research was expanded to address the comment.
Panel Presentation: T. Masse, US NRC		
PM-9	So what's the bottom line on threat? The bottom line is that there is a credible, general terrorist threat to NRC license facilities and radioactive materials. However, at this time there is no specific credible threat to licensees, to materials or to CsCl.	No change was made. The threat environment is addressed.
Issue 3: Design Improvements and Alternatives		
Panel Presentation: R. Sylvester, America's Blood Centers		
PM-10	America's Blood Centers is actually a trade organization representing the not-for-profit independent community blood centers. We have a total of 76 member centers that collect over nine million donations, 600 blood center locations and transfusions for 2.5 million blood recipients. So we represent	No change was made. Agrees with Draft Policy Statement.

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	<p>half of the U.S. blood supply and the 25 percent of the Canadian blood supply.</p> <p>The draft policy statement which is what this workshop is about ABC and its members concur with the statements. We believe that to continue to have access to cesium chloride is very important for the public health. We agree that improvement designs are prudent. Alternative forms for cesium chloride would be great as long as we can have it at the same price and that it will last the same amount of time. And then a pathway to safely dispose of cesium is a must because right now it just doesn't exist.</p>	
<p>Panel Presentation: C. Ribaldo, National Institutes of Health (NIH)</p>		
PM-11	<p>the NRC's draft policy statement as far as we at NIH are concerned, this does represent the evolution of the scrutiny and increased security over cesium irradiators.</p>	<p>No change was made. Agrees with Draft Policy Statement.</p>
PM-12	<p>So the NRC's draft policy statement on the protection of cesium chloride sources gives credit to the biomedical research needed for these irradiators. There's a paragraph in there. One paragraph is devoted to this topic. Here it is right here. One sentence speaks to that absolute need for cesium chloride in biomedical research and it's quoted from the draft policy statement here.</p> <p>However, we believe much more needs to be said. More text in the NRC policy statement regarding the absolute need for</p>	<p>Changes were made. Discussion of use of CsCI was expanded.</p>

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	cesium chloride would better address the needs of the biomedical research community.	
PM-13	<p>In addition to other reasons you'll hear later, for example, waste disposal concerns, it's important I believe to go on record with more reasons why alternative technologies cannot readily meet all of the needs of NIH scientists. And it's not just the single reason here of uniform linear energy transfer.</p> <p>...there is a cross section of researchers for whom the cesium irradiators cannot be replaced by alternate technologies.</p>	<p>Changes were made. Disposal issues were added, e.g., 2010 Task Force Report and DOE EIS, both of which address this comment.</p> <p>Discussion of the need for Cs-137 was expanded.</p>
PM-14	The NIH agrees with the NRC policy statement in that the extensive safeguards already in place to protect cesium irradiators from malevolent use combined with the successful shift in researchers' security mindset negates national security need to remove cesium irradiators completely from their useful and necessary contribution to biomedical research.	No change was made. Agrees with Draft Policy Statement.
November 9, 2011 Public Meeting Transcript: ML103360218 Issue 4: Alternate Forms of Cs-137		
Panel Presentation: J. Schrader, REVISS		
PM- 15	...we have been able to show a reduction in dispersibility of materials to essentially 100% for cesium chloride to approximately 5% for both glass and ceramic. For solubility,	Changes were made to clarify NRC position on alternative forms and on the development of dispersibility criteria.

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	<p>we've also achieve results of approximately 5% for both glass and ceramic versus the cesium chloride 100%.</p> <p>We would also like help with feedback on the acceptability of standards expected for solubility, leachability and dispersibility.</p>	
<p>Panel Presentation: S. Musolino, Brookhaven National Laboratory (BNL)</p>		
PM-16	<p>cesium chloride is important to medicine and medical research. And currently there is no alternative. Accelerators and x-ray machines are expensive. They're much less reliable and more costly to maintain. Machines also take up a lot more space for things like chillers and associated equipment and space is a premium in hospitals. So many of the hospitals are finding this technology undesirable from a space aspect alone. There will be a financial impact on the medical community no matter what alternative is chosen...</p> <p>...a less dispersible form does not negate the risk of a potentially large clean up and economic cost. It depends on the device design as well. And radioactive materials other than cesium chloride can cause large scale environmental impacts under the right conditions. So I think our main focus should be security because the increased controls have vastly reduced the risk of a terrorist incident of radioactive materials. . .we've made a huge risk reduction in this area.</p>	<p>Changes were made. Discussion of the need for Cs-137 was expanded. Disposal issues were added, e.g., 2010 Task Force Report and DOE EIS, both of which address this comment.</p> <p>Regarding the comment on adequacy of current security requirements and voluntary actions to enhance security further, the Policy Statement states that "While the current security requirements are adequate and provide sufficient safeguards, the NRC recognizes that if the use of CsCl in its current form is to continue, the NRC encourages the source and device manufacturers to implement design improvements that further mitigate or</p>

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		minimize the radiological consequences of misuse or malevolent acts involving these sources...”
PM-17	changing the physical form of cesium does not eliminate the potential impact from a dispersal. Re-engineering the physical form will be costly. Significant economic impacts and effects to the medical industry will result to replace cesium with any alternative such as an accelerator x-ray technology. The residual risk of cesium chloride following the implementation of the ICs is at least in my personal line acceptable or close to it. And opportunities exist for cost effective improvements to security.	Changes were made. Discussion of the need for Cs-137 was expanded. Disposal issues were added, e.g., 2010 Task Force Report and DOE EIS, both of which address this comment.
Audience Discussion: J. Schrader, REVISS		
PM-18	I'm thinking if we can develop a good alternative to the cesium chloride in either a glass, ceramic, pollucite type suspension it would probably be a smart idea to go that direction with going forward and then maintain the current cesium sources that we have, cesium chlorides and establish security on the systems. And then as they approach the end of their life and they're removed, they'll be replaced with new machines that have this new type material in them. That would also give us the benefit of being able to maybe redesign the device to hold a larger source so that we could have the same characteristics.	Changes were made to clarify NRC position on alternative forms and on the development of dispersibility criteria.

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Audience Discussion: M. Shepherd, JL Shepherd & Associates		
PM-19	I think that using an integrated approach if the new technology becomes available, the manufacturers phase it in to the new devices is probably the most logical and cost effective way to go because of all the security that people have invested in their chloride irradiators. And I think that is better for the users also.	Changes were made to clarify NRC position on new technologies.
PM-20	It's very, very hard to put costs on things. But I think we don't need to reach a point if there's less dispersibility and for the Brookhaven, it depends on what the approach is even if we go to the expense, there will be still the dispersibility if it's in an RDD. We need to take a sane approach to doing this and not just jump on it, we have a hardened cesium, let's replace all of it within the next ten-year approach. I don't think that would be beneficial for anybody.	Changes were made to clarify NRC position on alternative forms and on the development of dispersibility criteria.
Audience Discussion: M. Goldberg, Argonne National Laboratory (ANL)		
PM-21	I'm Margaret Goldberg from Argonne National Lab. I just wanted to add a comment regarding the chemical form of the cesium. The dispersibility is certainly one issue regarding cesium chloride, but one other concern that we consider is the solubility. So when you go to a different form of cesium and it decreases solubility that is important. Cesium chloride is obviously very soluble. It's also very deliquescent. So even if it doesn't rain after an NRDB, it was just in a humid environment, we would have mobility of cesium as a chloride whereas you wouldn't get in some of the	Changes were made to clarify NRC position on alternative forms and on the development of dispersibility and solubility criteria.

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	<p>other forms. I just wanted to add I think it is important to still consider the chemical form.</p>	
<p>Audience Discussion: S. Musolino, Brookhaven National Laboratory (BNL)</p>		
PM-22	<p>I agree with that [PM-18], but the issue that remains in my mind is that cesium chloride right now is a very hard target and while there's a long-term desire to replace the form which certainly I would not disagree with either, we still have to keep in mind it's sitting in a hard target now and the NRC has achieved their objectives of security with the cesium. Even if you find that cesium may be extremely expensive to replace ten years down the line, I still think there's a viability to it with proper security.</p>	<p>Regarding the comment on current security requirements and voluntary actions to enhance security further, the Policy Statement states that "While the current security requirements are adequate and provide sufficient safeguards, the NRC recognizes that if the use of CsCl in its current form is to continue, the NRC encourages the source and device manufacturers to implement design improvements that further mitigate or minimize the radiological consequences of misuse or malevolent acts involving these sources..."</p>
<p>Issue No. 5: Fields of use for Cs-137 Sources: Blood Irradiation, Biomedical Research, Calibration</p>		
<p>Panel Presentation: S. Leitman, National Institutes of Health (NIH)</p>		
PM-23	<p>...the cesium chloride irradiators remain the most reliable and efficient means to accomplish blood irradiation. Other options, X-ray, are improving.</p> <p>The safety and security of cesium chloride sources has been markedly strengthened in the past two years through initiatives recommended and started by the NRC for which</p>	<p>Changes were made. Policy Statement section "Uses of CsCl Sources" was expanded and clarified.</p>

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	we as blood bankers would like to thank the NRC because we do feel much more safe, that these sources are much more safe now.	
Panel Presentation: K. Nelson, Mayo Clinic		
PM-24	I think one of the important messages that I would want to leave for the commissioners and the people that participate in the Task Force is that we are all in favor for looking at alternative methods, such as we heard from John in the previous session about different types of cesium that might be useful. But when we compare cesium with X-rays, for large facilities, we see that there could be a significant patient impact. And so when we are discussing this, please remember that changes that you might make, such as immediately removing cesium chloride, will have a profound impact on patient care settings. And I think that is very important to remember.	Changes were made. Policy Statement section “Uses of CsCI Sources” was expanded and clarified. Discussion of the 2010 Task Force Report and its Implementation Plan by the NRC were added which address both alternative radioactive technologies and non-radioactive technologies.
Panel Presentation: R. Minniti, National Institute of Standards and Technology (NIST)		
PM-25	I mean to show the network of calibration facilities in the U.S. So this network starts at NIST. And then, as you see, these standards are disseminated through the red dots, which correspond to secondary calibration facilities. And these later calibrate instruments for the end users. So, as you see, it is a complete network throughout the whole country and relies on the use of cesium irradiators. In addition, there are lots of national and international	Changes were made. Discussion of calibration was expanded.

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	protocols and document standards and guidelines that rely on cesium.	
Audience Discussion: W. Lew, University of California San Francisco (UCSF)		
PM-26	I just want to make a comment, too, that I concur on the NRC and the other agencies' need for the common defense. So I look forward to encouraging through the NRC the funding process to get the private sector, perhaps get the national labs, academics, whatever it takes, to develop machines. Maybe I will come up with that breakthrough so we could have the excellent machine source radiation and perhaps through the information provided by the last speaker. Thank you. Thank you very much. I want to just express my deep appreciation for the NRC making this forum available for UCSF.	Changes were made. Discussion of the 2010 Task Force Report and its Implementation Plan by the NRC were added which address both alternative radioactive technologies and non-radioactive technologies.
Audience Discussion: K. Nelson, Mayo Clinic		
PM-27	You know, I had a particular focus coming to this meeting. And that was in trying to ensure that my message regarding the use of cesium chloride for blood irradiation was heard. I thought that the policy statement did a fairly good job of doing that, acknowledging that we can't switch cesium chloride right now for a number of very important applications, you know, but we are going to continue to look at alternative sources. And I have no concern over that. I was concerned, however, regarding the 2010 Task Force report and the comments that I think we heard from John yesterday regarding that. They seem to be a little bit more	Changes were made. Discussion of the 2010 Task Force Report and its Implementation Plan by the NRC were added which address both alternative radioactive technologies and non-radioactive technologies.

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	<p>aggressive in their statements regarding removal of cesium chloride at a more accelerated rate. And so my message again would be I think that the policy statement is good. It allows some flexibility. But I am concerned that the other members of the Task Force may not understand the need currently for cesium chloride and why we just can't stop using cesium chloride.</p>	
<p>Audience Discussion: S. Leitman, National Institutes of Health (NIH)</p>		
PM-28	<p>I think the draft policy statement got it right. In preparation for this meeting, I thought the language was good. And it listed the reasons for which cesium chloride is such a useful radionuclide for these medical and research and calibration purposes.</p>	<p>No change was made. Agrees with Draft Policy Statement.</p>
<p>Audience Discussion: R. Minniti, National Institute of Standards and Technology (NIST)</p>		
PM-29	<p>I guess the only thing I would add is that in the case of calibration of instruments, cesium is needed because of what I said in the talk, the fact that it is a mono-energetic, potent source. And if there is going to be a replacement, it would have to be another form of cesium. We could not use an X-ray source because of what I explained before. An X-ray provides a broad energy spectrum. So, other than that, I don't have anything else to add.</p>	<p>Changes were made. Discussion of calibration was expanded.</p>

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Issue No. 6: Status of Disposal		
Panel Presentation: A. Edelman, Office of Environmental Management, DOE		
PM-30	<p>The Department of Energy is indeed working on coming up with a disposal methodology, disposal approach for greater than class C waste that includes cesium chloride sources. The policy statement mentions that there are two impediments to disposal. One is the high cost for disposal of cesium chloride sources and also the lack of a disposal facility. I am hoping that as a result of DOE efforts that we will be able to at least solve one of those two problems, come up with a disposal facility for future disposal of cesium chloride sources.</p> <p>About 25 percent of that waste total is from sources of about 8 and a half percent, or 1,000 cubic meters, coming from cesium chloride sources. The other you need about 1,800 cubic meters from sealed sources, about 15 percent.</p>	Changes were made. Disposal issues were added regarding DOE's EIS.
PM-31	<p>We need NRC to evaluate the EIS to look at the methodologies, the conceptual designs we have developed and determine whether or not those can be approved under existing conceptual design and what type of regulations we need to be developed.</p> <p>One comment I have on the draft policy is that right now the draft policy focuses on the Commission to actively support the storage of greater than class C waste. And I would like to see that extended to not only support the storage of greater</p>	Changes were made. The Policy Statement states "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 storage of waste other than "greater than class C" is outside the scope of the Policy Statement.

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	<p>than class C waste but also the disposal of class C waste. And that is something that we are really going to need NRC because we are not going to be able to get there without NRC's approval and licensing of the facility.</p>	
<p>Panel Presentation: K. Nelson, Mayo Clinic</p>		
PM-32	<p>Well, as mentioned previously and in the draft policy statement, there are no disposal options for commercial cesium chloride since the closure of Barnwell, South Carolina in July 2008 for out-of-compact waste. We just heard an excellent presentation about what DOE is planning to do for greater than class C waste in their EIS, environmental impact statement. There may be a commercial option with waste control specialists in Texas. And I will talk a little bit more about that in a couple of slides. But, although I keep telling myself this is a process and a long process, it just seems that there is a lack of political will to move this forward.</p>	<p>Changes were made. Disposal issues were added regarding DOE's EIS.</p>
PM-33	<p>We, being the Health Physics Society, have a position statement on continued federal and state is needed for better control of radioactive sources. And if you are interested in getting this position statement, contact me. And I am certainly happy to send it to you.</p> <p>The specific items that we identified under waste in this position statement included that we want Congress to take</p>	<p>Changes were made. Disposal issues were added regarding DOE's EIS. Interaction among federal, state and professional organizations is addressed in the discussion of the 2010 Task Force Report and its Implementation Plan.</p>

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	<p>some action to ensure accessibility and safe options for disposal of radioactive sources, especially category 1, 2, and 3 sources, which we -- well, we have been predominantly talking about category 1 and 2 sources at this workshop.</p> <p>We further recommended that federal and state agencies work with professional organizations, such as HPS or it could be AAPM, to develop and implement programs to better inform licensees on source disposal.</p>	
<p>Panel Presentation: R. Dansereau, New York State Health Department</p>		
PM-34	<p>We look at the NRC's draft policy statement as it relates to disposal. I think it is well-done because we talk about the need for long term developing a pathway for long-term storage as well as disposal.</p> <p>We look at the Task Force's challenges and recommendations related to disposal. They're really talking about disposal. They don't address the long-term storage issue.. But NRC has captured the need for the disposal. And we do see that for the presentation, DOE is working towards finding a solution and developing capacity for disposal.</p> <p>What I haven't heard much about is the potential to recycle cesium chloride. What happens to some of these disused sources where the capsule cannot be used further? Because they have decayed away to a level they are not useable. Is</p>	Changes were made. Disposal issues were added regarding DOE's EIS.

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	anybody looking at means to recycle the cesium chloride, rather than to start with virgin material or add more cesium chloride to what is available out there?	
Panel Presentation: J. Zarling, National Nuclear Security Administration (NNSA)/DOE		
PM-35	<p>We do work with NRC, as I said, to prioritize these recoveries based on location and activity. But this is not the only problem that we have. You know, disposal is one problem, but, actually, even moving the material to the disposal site is another problem.</p> <p>I wasn't here this morning to hear what Mary had to say. However, Los Alamos with the -- Los Alamos and GTRI are working on a new type B container. Right now there is a very limited number of type B containers in the United States that can move.</p> <p>...There's also a limited number of people that can work on the devices as well.</p>	Changes were made. Disposal issues were added, e.g., 2010 Task Force Report and DOE EIS, both of which address this comment including transportation issues.
Audience Discussion: S. Wagner, American Red Cross		
PM-36	Because there are a lot of irradiators that are beginning to get close to 30 years old. I imagine that the facilities may either want to replace them with similar sources or perhaps go to X-rays. But we can't just keep on accumulating these sources in these buildings that have certain lifetimes. There has to be some at least intermediate-term solution.	Changes were made. Disposal issues were added, e.g., 2010 Task Force Report and DOE EIS, both of which address this comment including transportation issues.