American Association of Physicists in Medicine

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October 15, 2008

Mr. Michael Lesar
Chief
Rulemaking, Directives, and Editing Branch
Office of Administration
Mail Stop T-6D59
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTN: Rulemakings and Adjudications Staff

SUBJECT: Request for Comments on the Security and Continued Use of Cesium-137 Chloride Sources and Notice of Public Meeting; NRC-2008-0419] [*See* 73 FR 44780 (July 31, 2008) and 73 FR 5580 (September 26, 2008).]

Dear Mr. Lesar:

The American Association of Physicists in Medicine[1] (AAPM) submits the following comments to the U.S. Nuclear Regulatory Commission (NRC) regarding the *Request for Comments on the Security and Continued Use of Cesium-137 Chloride Sources and Notice of Public Meeting*; NRC-2008-0419] [*See* 73 FR 44780 (July 31, 2008) and 73 FR 5580 (September 26, 2008).

The use of radioactive materials in medicine has resulted in significant health benefits to patients. Cesium Chloride (CsCl) irradiators are used in a number of applications in the contemporary process of care, from "back office" tasks such as sterilization and calibration activities to direct clinical care such as the reduction of potentially fatal graft vs. host reactions related to blood product administration. AAPM is concerned that the prohibition or elimination

[1] The American Association of Physicists in Medicine's (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,700 medical physicists.

of the use of CsCl irradiators could result in a decrease in the standard of care that exists in this country.

AAPM conducted a survey of its members and others in August 2008 to assess their experience with irradiators. The result of the survey likely reflects primarily hospital-based or university-based irradiators. However, for the information gathered, that should not affect the conclusions.

- Of the 363 respondents, 297 had irradiators, 84.6% of those used Cs-137 as the source, 9.3% used conventional x-ray units and 6% used medical linear accelerators (linacs).
- The Cs units represented the major vendors. Only 10% were purchased within the last two years, with 7% planning on replacing the units within the next 5 years.
- A quarter of the cesium units had had some malfunction but most were repaired in less than 7 days. Of the x-ray units, 35% had malfunctions, with 44% being repaired within 7 days.
- Only 40% used for blood irradiation, with about 25% material irradiations, 25% animal irradiations and 10 % other.
- Of the x-ray units, 50% were for blood irradiation, while 19% were for material irradiation and 32% for animals.
- Forty percent of the medical linacs were used predominantly for blood irradiation and 11% for animals.

This survey indicates that, while fairly reliable, conventional x-ray units and medical linacs account for a small minority of the irradiators in the field. They had slightly more downtime than cesium units. The cesium units have been reliable and their users, in general, have no plans to replace them. Forced removal of the cesium irradiators would result in a very large loss of resources, both radiation sources and funds, not only for blood banks but for research institutions as well.

There will be an impact on ongoing research and clinical trials involving use of CsCl irradiation if these sources are proscribed. Sponsors of such trials, whether for new drugs, medical devices or biological products would have to consider the impact of the change of the irradiation source on the protocol for the trial, and depending on the analysis of the impact of the different type of radiation, provide additional justification and submissions to the U. S. Food and Drug Administration to substantiate the validity and comparability of data obtained with the different source. If such validity cannot be demonstrated with appropriate data, such ongoing clinical trials might have to be significantly revised and extended.

AAPM believes that any decision to remove CsCl sources from use should be based on a true cost benefit analysis. AAPM believes that any analysis should include a risk matrix that demonstrates where radiation risk falls in relation to the risk from all other hazards.

We do know is that there is “real or true” risk of lives lost from lack of blood product irradiation or substitution of significantly more expensive or less reliable technology for this essential

clinical function.. While future technologies may diminish the need for these irradiators in research, careful consideration must be given to the impact that swift and comprehensive elimination of these valuable devices would have on significant medical research and the practice of medicine.

It is AAPM's belief that the additional protection level added to the already safe use of CsCl irradiators by a heightened security program,[2] coupled with proactive personnel engaged in the security of these devices, is an effective solution for the continuation of CsCl irradiator use as a vital component of high-end research and the practice of medicine.

We commend NRC management and staff for a well organized and very productive workshop which facilitated the exchange of information and encouraged a wide variety of views and inputs for further consideration by all involved. AAPM looks forward to reviewing the staff's "options paper" scheduled to be submitted to the Commission during November 2008 and, as such, respectfully request that the staff options paper be released immediately to the public upon issuance rather than adhering to the standard ten day holding period.

A point-by-point response to the questions asked in the Federal Register Notice is attached.

Thank you for the opportunity to comment. Feel free to contact me or Lynne Fairobent, Manager of Legislative and Regulatory Affairs at 301-209-3364 or via e-mail: lynne@aapm.org if you have questions.

Sincerely,

Gerald A. White, Jr., FAAPM

Attachment

[2] The heightened security program which includes the recently mandated increased controls and security requirements, personnel security requirements, and the proposed enhancements to the irradiators themselves.

AAPM Comments on CsCl Questions
October 15, 2008

FR Doc E8-17545[Federal Register: July 31, 2008 (Volume 73, Number 148)]
[Notices]
[Page 44780-44783]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr31jy08-81]

Note text in bold or italics is from the Federal Register notice.

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

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

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

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

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

As stated during the September 29th NRC workshop, the manufacturers indicated that in theory it is possible to develop a non-dispersible form of cesium that could replace the use of cesium chloride (CsCl). They indicated that although they believe it can be done, that it will take at least 6-9 months more to confirm the belief. However questions remain as to whether or not the specific activity could be sufficient to be equal to the existing forms. In addition, if possible to maintain the specific activity, can it be in the same physical size as the existing CsCl sources. The manufacturers also indicated that it would take between three and five years to determine if alternative forms are actually feasible.

Since the only source of CsCl in the world is Mayak, Russia issues related to US and Russian agreements would need to be understood in order to determine if the Mayak facility would be agreeable to changing their product lines to manufacture the alternative for once developed.

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

As mentioned in Q.1.1-1, the manufacturers indicated that it would take between three and five years to develop an alternative source and then the additional time for approval by the US Food and Drug Administration (FDA) and NRC source registry program and the time to bring the product to market. Based on the discussion at the NRC workshop, it appears that between 8 – 10 years minimum is needed to develop an alternative form of CsCl, if it can be demonstrated to be effective.

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

If the density loading is not equivalent to the existing CsCl sources, the irradiation times would be longer. If due to the density loadings needing to be equivalent, the physical size of the sources is different there would need to be modifications of the device.

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

As discussed in Q.1.1-1. The manufacturers indicated it could take between 8 and 10 years to confirm the belief that alternative forms could be developed, test the sources, get FDA/NRC approval, manufacture them and bring them to market.

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

It was indicated during the workshop that currently the community only has the scientific results and a basis for an alternative form, however the new technology for alternative forms does not yet exist. After the scientific basis is developed, an engineering study would also need to be conducted prior to any decision on change occurring. In addition, there would need to be a US/Russian agreement to assist in the change or addition of a new product line at the Mayak facility.

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

There is not a simple yes or no answer to this question. If a new product line could be established at the Mayak facility, and if it could be demonstrated that the alternative form is equivalent, and that the devices could be modified to accept the new sources then perhaps other entities would engage in the marketing of alternative forms of CsCl.

During the workshop a representative from Oak Ridge National Laboratory (ORNL) stated that ORNL has no plans to be the world's supplier of Cs but they are interested in developing new

source forms and evaluating forms developed by others providing that is what the Department of Energy directs them to do.

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

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

For a few applications (e.g., large animal studies), Co-60 could possibly be used. However, there was significant agreement by the attendees at the workshop that it could not be used for much, if any of the small animal research. Additionally it would be difficult to switch to Co-60 for instrument calibration and personnel dosimetry.

It was also indicated that it would not be a simple process to develop an irradiator using Co-60 as a substitute for the CsCl irradiators for blood. This is due in part due to the added weight and footprint requirement for the irradiator. Many of the CsCl irradiators used in blood banks and hospitals are not located on the ground floor of the facility and the weight of the Co-60 irradiator due to the additional shielding required would , in many cases necessitate relocation of the device or reinforcement of the floor support structure

Q1.2-2. Can the shielding challenges for Co-60 be addressed by switching from lead shields to more effective tungsten or depleted uranium shielding?

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

Encouraging more widespread dispersion of depleted uranium into the commercial production cycle would create yet another potential source of terrorist activity. While innocuous from a radiological safety standpoint, the public perception on any incident involving misuse of depleted uranium would lead to many of the problems that the CsCl initiative is intended to avoid.

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

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

As indicated in the Federal Register, it is during transportation that most radioactive material is most vulnerable. Therefore, the cost/benefit and risk analysis that would be required in substituting Co-60 for CsCl must consider the increased s number of shipments of material due to the need for replacing Co-60 sources more frequently plus need to consider the shipments of

CsCl sources being replaced. It is important to note that there are few if any transportation casks available and no disposal option.

Issue No. 2--Use of Alternatives Technologies

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

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

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

Yes there are commercially available x-ray generators used for blood, specimen and animal irradiation. Based on a recent survey conducted by the American Association of Physicists in Medicine (AAPM) of the 363 respondents, 297 had irradiators, 84.6% of those used Cs-137 as the source, 9.3% used conventional x-ray units and 6% used medical linear accelerators (linacs). Of the x-ray units, 35% had malfunctions, with 44% being repaired within 7 days.

The only non CsCl alternative for a free-standing self-contained blood and research component irradiator is an x-ray generating device. To our knowledge, there is only one available on the market now, it is branded as the RayCell and distributed by Nordion of Canada. Nordion acquired the license to distribute this device from RadSource in 2003 and is the sole distributor. So, the current RayCell is the same device as the preceding RadSource. It costs about $200,000, plus taxes and shipping fee. There are two x-ray tubes per machine, and they are stated to have 2,000 hours of service each (maximum), which equals 120,000 minutes each. It takes 4-5 min to warm up the machine from a cold start (the machine must not be used continuously) and another 5-6 minutes to accomplish the irradiation, so 10 minutes per cycle, or 24,000 cycles per two new x-ray tubes.

Replacement x-ray tubes (or “bulbs”) costs $20,000 per tube. In addition, there are yearly preventive maintenance costs, and the cost of recommended twice yearly dosimetry assessments. Compare this to CsCl, where there are no costs for upkeep of the device other than the yearly preventive maintenance and dosimetry ($6000/yr).

For the X-ray system, there is also the requirement for a source of running cooled water and drain, or closed circuit chiller, since chilled water must run at 10-20 liters per minute to cool the x-ray tubes during the 10 minutes of operation of each cycle of radiation.

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

The cost of alternative technologies should include not only the cost of replacement, calibration and maintenance, but also the cost of down-time for critical-use equipment, such as blood irradiators. A quantifiable cost for alternative blood sterilization during equipment down-time should be possible, as well as a human cost for patients who need blood. It is easily demonstrable that CsCl sources utilized in blood irradiators have a much more reliable performance record than machine-produced technologies, and both the costs of continuity of operation or failure should be considered financially and in possible impact on human life. The life cycle replacement approximately 8-10 years for x-ray irradiators versus 30 yr for Cs irradiators.

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

Currently the only alternatives to CsCl are Co-60 and X-ray. The current x-ray systems have a poor performance/up-time history. Improvement in x-ray device reliability may be possible.

There is no expected improvement of the x-ray system over the Cs system in either dose delivery or economic viability. There is no other isotope delivery device currently under consideration. Additional discussions with X-ray generator and source manufacturers may provide additional information on this topic.

Q2-4. Regarding the availability of alternative technologies, (a) what is the timeframe of future availability of each alternative, and

As indicated during the workshop, 3-5 years to verify feasibility, 1- 2 years for engineering studies, 3-5 years to bring to market.

Q2-4. (b) what is the cost for each of the alternative technologies (capital costs, operation costs, cost to users)?

It is premature to discuss cost. However, in any cost analysis the total life cycle cost must be analyzed. Some parameters to be considered are the cost of the replacement irradiator, cost for maintenance of the new irradiator, cost for source removal, cost for transportation (including design and approval of new transportation casks), cost of disposal (providing a disposal options can be identified) and the cost for demolition and construction for new facilities if necessary.

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

Discontinuation of the further use of CsCl sources with activity levels in IAEA Category 1 and 2 was recommended for consideration by the Radiation Source Protection and Security Task Force and by the NAS, referenced above.

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

In considering Issue No. 3, possible phase-out of CsCl sources, there are four main issues that should be considered and discussed:

Issue 3.1: Potential rulemaking issues and justification for regulatory change; Issue 3.2: Transportation and storage issues associated with removal of CsCl sources from licensee facilities; Issue 3.3: Consideration of government incentives and voluntary actions by industry and manufacturers; and Issue 3.4: Impact of U.S. changes to regulating CsCl on the international community. Each of these issues are presented below.

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

Q3.1-1. (a) What would be the medical consequences if CsCl was to be banned for medical (e.g., blood) irradiators?

CsCl blood irradiators could be changed out as a dose delivering system, but current available off the shelf devices will not perform the function as efficiently. The medical community has stated that CsCl blood irradiation to eradicate graft-host transfusion virus is 100% effective, the virus is 100% fatal within 1-2 weeks of a human being exposed to it, and there is no available effective alternative at this time. While not the current standard of care, there is a trend in many large medical institutions to irradiate every unit of blood to be transfused. Blood irradiation alternatives to CsCl systems will require additional equipment – not just a one-to-one replacement of existing equipment.
In addition, there is a possible negative impact on patient care and biomedical research if alternative technologies cannot exactly replace CsCl systems in terms of exposure uniformity or timeliness of delivery of needed rapid processing of product when urgently needed.

Q3.1-1. (b) What would be the impact to existing and future biomedical research using these devices?

Biomedical research is highly dependent on the CsCl irradiator. Past research has been based on irradiation of cells and animals using Cs. Changing the beam quality will make inter-comparison of future research results with those published in the literature very difficult.

Additionally, such a change may have a significant impact on funding of future biomedical research since the proposed research may not have a sound scientific basis if key assumptions are being made based on results obtained from Cs irradiations.

Q3.1-1. (c) Can alternative technologies be used for medical applications and/or biomedical research (research on animals and tissue?)

There will be an impact on ongoing research and clinical trials involving use of CsCl irradiation if these sources are proscribed. Sponsors of such trials, whether for new drugs, medical devices or biological products would have to consider the impact of the change of the irradiation source on the protocol for the trial, and depending on the analysis of the impact of the different type of radiation, provide additional justification and submissions to the FDA to substantiate the validity and comparability of data obtained with the different source. If such validity cannot be demonstrated with appropriate data, such ongoing clinical trials might have to be significantly revised and extended.

Irradiation of cells, blood, animals, pathogens or other materials is an essential component of many research projects performed at the National Institutes of Health (NIH) and at grantee institutions. This is particularly true for immunologists. The CsCl irradiators have proven to be the "gold standard" in providing effective, reliable, dependable and very experimentally reproducible means of irradiation. They utilize a single primary photopeak of sufficient abundance, desired energy and a long half-life. Dose rates only change with isotope decay so the dose for experimental use is extremely stable and predictable over time.

Although Cesium sources have been considered the best, there are X-ray devices. These are not as widely used. If one makes an assumption that for the user, safety can be roughly the same, the major problem of changing technologies is related to cost for most researchers. X-ray sources are not as stable over time as the sealed sources and the tubes must be periodically replaced. This increases the potential for more variability and more lost experiments. It can be minimized with modern dependable and accurate dose monitoring devices but overall, it likely translates to additional maintenance and operational costs. These are minimal, however, in comparison to the replacement expense of the current sealed sources used by research institutes and their researchers (e.g., NIH and its grantees). There are three major expenses; the new equipment, safe transit and disposal of the old radioactive source, and since often these have been built into the buildings they may require partial demolition and reconstruction to remove the old source. At a time when budgets are flat causing major cuts to the NIH supplies, services and equipment operating budgets there is no way that the NIH can afford to replace the cesium sources located at NIH or in the grantee institutions on a more than an end of useful life basis without special funding from Congress or the Department of Homeland Security (DHS).

Q3.1-2. (a) What would be the consequences if CsCl was to be banned for irradiators that are used for industrial and calibration purposes?

AAPM agrees with the comments made by the US Department of Agriculture (USDA), the commercial power industry and the Department of defense (DoD) made at the September 29th workshop.

Q3.1-2. (b) What is the impact on existing American National Standards Institute (ANSI) standards and licensee conditions that require the use of Cs-137 for calibration purposes?

AAPM agrees with the comments made by the National Institute of Standards and Technology (NIST) made at the September 29th workshop.

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

There would be the cost to dispose of the CsCl source, if disposal was an option. This would include the cost of packaging (including the cost to procure and/or rent the shipping cask) and transportation. In addition, there is the cost of purchasing an x-ray unit (about $200,000, not counting taxes and shipping fee). Replacement tubes cost approximately $20,000 per tube. In addition, there are yearly preventive maintenance costs, and the cost of recommended twice yearly dosimetry assessments and staff training for new systems. In addition, some facilities would need electrical wiring and plumbing for cooling systems that are not required for the CsCl irradiator. Lifecycle replacement of approximately 8-10 years for x-ray irradiators verses 30 years for Cs irradiators, thus the operating cost are almost twice just from equipment longevity.

In changing from a Cs source to a Co-60 source, there will be the cost for additional shielding if an existing facility can be modified, the cost of a new facility and the shielding needed, source removal, and decontamination of the existing facility, if applicable.

Included in all options is the cost for FDA approval and the cost to bring a new product to market including the research and development cost, engineering studies and scientific research to demonstrate product acceptability.

Aside from the immeasurable cost of delay or discontinuation of certain research, the direct cost for removal and replacement of existing irradiators with another tool would be substantial. For research irradiators, the existing machines are largely the “cabinet” type, and the researchers have, over many years, designed, built and commissioned various applicators and jigs to support their experiments in the radiation environment. These would all have to be replaced, and all the dosimetry would have to be repeated requiring a great deal of effort, and considerable expense. The transition and production of these would delay experiments in progress or proposed, and could jeopardize the success of those experiments. Spectral differences between Cs-137 and polychromatic x-ray sources would introduce an additional, perhaps uncontrolled, variable into research efforts.

This is in addition to the considerable costs already born by institutions in the last few years for a complete overhaul of the security of these devices, including new security hardware, extensive training, and increase in man-hours developing and maintaining a compliant security program.

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

See the answer to Q3.1-3 above.

Q3.1-5. (a) Should the NRC discontinue all new licensing and importation of these sources and devices?

No. Before a decision is made to discontinue all new licensing and importation of CsCl sources and devices using CsCl sources a detailed cost/benefit, generic risk analysis should be conducted.

Q3.1-5. (b) What is the regulatory basis?

AAPM believes that any additional changes to the regulatory process should be done through rulemaking and not through issuance of orders.

Q3.1-5. (c) Who (NRC, DHS, or jointly) should conduct the risk analysis?

A generic risk analysis should be conducted by the NRC with input from its federal partners and the stakeholder community. Once the generic risk analysis is conducted, there should be no need for a specific licensee to conduct any further risk analysis for the use of the sources.

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

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

Costs associated with decommissioning CsCl sources based solely on national security concerns should be borne by the nation as a whole. It is critical that the review and approval of transportation casks be expedited by the NRC and Department of Transportation (DOT) as applicable.

Q3.2-2. (a) How could the current CsCl sources be disposed given that CsCl is defined as a ``Greater Than Class C'' source and currently has no disposal mechanism in the U.S.?

Without legislative changes, there does not appear to be a disposal option available. It was indicated during the September 29th workshop that the Department of Energy (DOE) plans to issue a Notice of Intent for an environmental impact statement on GTCC in 2009 and that the

earliest a disposal option could be available is 5 – 10 years after the issuance of a Record of Decision.

Q3.2-2. (b) If disposal was made available by DOE, what would be the cost of disposal?
It is premature to know the answer to this question. See Q.3.2-2(a).

Q3.2-3. (a) Where could the decommissioned sources be stored?

If a decision as made to remove the CsCl sources prior to disposal being an option, the sources would need to be stored at a DOE site. Existing facilities do not have the space for long term storage of the CsCl sources if they can no longer be used.

Q3.2-3. (b) What disposition options are needed in the United States?

See the response to Q.3.2-2(a). In addition, the US needs to ensure that reentry of disused sources for return to manufacturers is allowed because if the potential for returning sources to manufacturers is not allowed this could result in stockpiling of the sources in less secure facilities in the U.S. or abroad.

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

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

Yes, after the decision is substantiated by a detailed cost/benefit risk analysis that includes demonstration that patient care and research are not negatively impacted, the Federal government should provide the necessary financial support for conversion to alternative sources where the change is necessitated by national security needs. However, any decision should be substantiated by a detailed cost/benefit risk analysis that includes demonstration that patient care and research are not negatively impacted.

If, after reviewing of all available resources, a ban of new licenses for CsCl is determined to be the best path forward, NRC should consider grandfathering CsCl irradiators currently in use for patient care and research. Additionally, NRC should explore federal compensation / financial incentives if licensees are forced to transition to alternatives.

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

At this time there are no incentives to shift from CsCl irradiators. If by feasible incentives, one means monetary, that is not the sole determining factor.

There will be an impact on ongoing research and clinical trials involving use of CsCl irradiation if these sources are proscribed. Sponsors of such trials, whether for new drugs, medical devices or biological products would have to consider the impact of the change of the irradiation source

on the protocol for the trial, and depending on the analysis of the impact of the different type of radiation, provide additional justification and submissions to the FDA to substantiate the validity and comparability of data obtained with the different source. If such validity cannot be demonstrated with appropriate data, such ongoing clinical trials might have to be significantly revised and extended.

Q3.3-2. (b) Manufacturers?

Additional discussions should continue with the manufacturers to determine if there are feasible incentives to shift users away from CsCl sources.

Q3.3-3. (a) What incentives should the Federal government provide to licensees to decommission their existing sources or devices because the devices still have use value?

Development of a government-facilitated disposal pathway is essential to help financially subsidize the safe transit and disposal of the sources at the end of their useful life. In many instances, the building may have to undergo some demolition to remove the old sources. Any incentives should be a direct re-imbursement and not a tax benefit. Life cycle costs should be assessed for all alternatives including the depreciation of the sources.

Financial help in all aspects of disposal and replacement is critical. In both clinical facilities and research applications, there are several major expenses; procurement of the new equipment, removal, packaging, safe transit and disposal of the old radioactive source, decommissioning of the old device and room and since often these have been built into the buildings they may require partial demolition and reconstruction to remove the old source. New sources and x-ray equipment may have significant facility modification costs associated with this type of change. Consideration should be given to whether or not the Centers for Medicare and Medicaid Services could increase the reimbursement rate if done on newer technology.

It is necessary have significant financial incentives for the replacement of the old sources where greater security risks are perceived or if the government wants the phase out to proceed faster.

Q3.3-3. (b) For licensees that are defined as ``not-for-profit'' (e.g., hospitals), what type of incentives could be made available to change technologies?

The types of incentives are not that different for not-for-profit institutions than for for-profit facilities. Not-for-profit institutions generally do not have excess funding for unplanned expenses or for replacement capital equipment. Any Homeland Security related mandated change for these facilities will be a major financial burden which may result in the not-for-profit organization being required to cease operations.

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

In summary, future units may be able to meet research requirements, but at this point it is clear that we must move slowly and carefully, consideration must be given to the cost benefit ratio of our actions. Even if money was available to procure the newer units which do not utilize CsCl, it is unclear if these units would be able to meet the current requirements of clinical or research programs.

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

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

It is difficult for the US to control what the rest of the world decided to do regarding the use of this material. The only manufacturer of the CsCl is in Mayak, Russia. For any change to the process and chemical form of the CsCl, the US would need an agreement with Russia to cause the Mayak facility to change its process stream.

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

Any consideration by the US to ban the use of CsCl should not be done in isolation. Consideration on the impact of the ban on other countries should also consider the fact that many countries do not have adequate electrical capacity for the alternatives being considered and may not have adequate water supplies for cooling an x-ray irradiator. In some cases CsCl irradiators are the only devices available for providing medical care in developing countries.

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

The role of the IAEA should be in standard setting, recovery and return of sources in developing countries, assay of recovered sources and education of the potential threat.

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

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

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

[Note: The current requirements for increased security of certain high-risk radioactive sources in the U.S. are: (a) Compensatory Measures for panoramic irradiators; (b) Additional Security Measures for manufacturers and distributors; (c) Increased Controls for licensees with

Category 1 and 2 devices and sources; (d) Fingerprinting for access to radioactive material (see http://www.nrc.gov/security/byproduct/orders.html).]

AAPM does not believe that NRC or the Agreement States need to require more stringent security measures than those currently mandated for Category 1 and 2 sources. The NRC and Agreement States along with the users of CsCl irradiators have worked hard to assure that these devices are secured. NRC and the Agreement states implemented increased controls and security orders and amendments beginning in December 2005 increasing the security requirements for CsCl irradiators. These orders or amendments require the owners to:

- Allow access only to approved personnel who have undergone a thorough FBI background check, fingerprinting, work history review, psychological review, and local law enforcement background check;
- Provide redundant reinforced doors, locks, heavy walls, computer-coded key-card access, and continuous video monitoring of the halls, entry, and workspace occupied by the irradiator units;
- Development of documented procedures to ensure that authorized users support the institution's system to prevent unauthorized access and protect access information, drawings, schematics, maps, and facility floor plans from unauthorized use; and
- Coordination with local law enforcement agencies for rapid response if there is an attempt of unauthorized access to the irradiators.

The NRC with its federal partners, the Department of Homeland Security and the Department of Energy/National Nuclear Security Administration have conducted research and have found a method to further enhance the security of the sources from removal from the device. The enhancement would significantly delay the removal of sources from the device allowing law enforcement additional time to intercept and prevent the theft. The upgrades to the devices are currently being conducted throughout the United States and it is anticipated that this activity will be completed for all irradiators by 2010. Although the cost for the upgrades is being born by the federal government, there is still an impact for the licensee on downtime for the installation. It is important to note that these upgrades are voluntary on the licensee.

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

No. AAPM does not believe there has been any justification for the inclusion of more stringent security measures for lower than Category 2 CsCl sources. In fact, there was not a cost/benefit analysis to justify the inclusion of increased security measures for Category 1 and 2 sources since these were implemented by orders and not through rulemaking.

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

If, by this question, NRC is asking over and above those currently implemented for Category 1 and 2 sources, it is difficult to say without a true cost/benefit analysis to justify the measures.

For smaller medical institutions the cost could be prohibitive and result in access to care being impacted for patients especially in rural communities.

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

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

Q5.1. (a) How should the NRC determine the economic and social disruptions/impacts to the public, licensees, and the environment?

A generic risk analysis should be conducted by the NRC with input from its federal partners and the stakeholder community. Once the generic risk analysis is conducted, there should be no need for a specific licensee to conduct any further risk analysis for the use of the sources.

(b) How should these factors be measured in decision making?

Life Cycle cost to include:
Source removal/packaging/cost of rental cask
Transportation
Storage
Disposal
Recovery of increased controls cost
Security
Impact on practice of medicine
Need to look at the risk over consolidating decommissioning source vs. continued use
Consideration of impact in grant process for research
Manpower and training of personnel
Remaining value of existing technology