

### **The Report of the ACMUI Subcommittee on <sup>137</sup>CsCl Irradiators**

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### **Purpose of the Subcommittee**

- The National Research Council's report made several assumptions that seemed questionable to the ACMUI.
- This subcommittee investigated the concerns raised by the ACMUI

### **Concerns Addressed**

- The need for <sup>137</sup>CsCl irradiators
- Viable alternatives
- Current Security

### **The Need for the Irradiators Blood Products**

- The original report assumed that approximately 10% of the blood used in the US was irradiated.
- Discussions with hematologists and oncologists indicated that for these practices, the value ranged between 15% and 40%.
- The patients involved have depressed immune systems and need the irradiated blood.
- The lower number probably comes from a higher fraction of trauma cases, where irradiation is irrelevant.

### **The Need for the Irradiators Animal Irradiation**

- Research on stem cells and other systemic therapies increasingly requires whole-body irradiation of the animals (usually mice) before infusion.
- This research is growing and may soon lead to treatments for currently untreatable conditions.

### **The Need for the Irradiators Summary**

- Without irradiators available, hematology and oncology patients would suffer potential death from the lack of irradiated blood.
- Without irradiators available, much of the stem-cell and systemic drug research would not be able to proceed.

### **Alternatives to <sup>137</sup>CsCl Irradiators**

- The alternatives are conventional x-ray units or linear accelerators.
- Both have been and are used for blood, animal and material irradiation.

### **Conventional X-ray Units Blood Irradiation**

- For blood irradiation, only one unit is FDA approved.
- The National Research Council listed the price as \$180,000, with \$10,000/y for the service contract.
- The current price is \$250,000 with \$33,000/y for the service contract.
- A replacement tube is extra, as is calibration and quality management.

### **Conventional X-ray Units Blood Irradiation**

- Throughput is lower for the x-ray unit.
- With 48,000 blood-product units / x-ray tube, a 50-unit per day operation would replace the tube every 3.7 years, adding to the cost of running the unit.

### **Conventional X-ray Units Animal Irradiation**

- About 10 x-ray units are available.
- Few provide beams of 200 kV or higher, which limits their use with animals due to lack of penetration.
- Most prices range from \$146k - \$250k, plus the service contracts of about 10% per year.
- One low energy, short distance, small field size units markets for \$43k - \$87k.

### **Conventional X-ray Units Animal Irradiation**

Issues with the x-ray units for animal irradiators, other than price, include:

- The different Relative Biological Effectiveness (RBE) compared with <sup>137</sup>Cs – possibly a factor of 2 for the lower energy units.
- The dose rates, which can have an effect on the biological effectiveness as well as make anesthesia more difficult.
- Penetration may require irradiating animals from several directions.

### **Medical Linear Accelerators**

- If the radiotherapy department's accelerator is used, time available for blood or animal irradiation become a problem.
- If not using a radiotherapy department's accelerator, price becomes a problem, at \$1.5M to start.

### Security

Since the National Research Council report raising the concerns about the security of these units, several things have changed.

- The security of the users has been enhanced through the required background checks and fingerprinting.
- The security of the facility has been enhanced following directives of the Nuclear Regulatory Commission (sometimes at great costs to the facility.)
- The security of the units are being enhanced through a program of the DOE and DHS.

### Security

- Following these three security enhancements, the units present little hazard for unauthorized source removal or disruption.
- The lack of such security was a major factor in the original report.

### Summary

- Irradiation facilities are essential for irradiation of blood and in research.
- Forced replacement of  $^{137}\text{CsCl}$ -based units would force many facilities to stop irradiations because of the large expense, since most of the facilities are non-profit and have few resources for funding a new x-ray unit or maintaining the unit.
- If not leading to the termination of the irradiations, the replacement would place a large financial burden on facilities which usually have little funding.

### Summary

- While x-ray units have been used for blood, animal and material irradiation, the difference in the RBE complicates simple replacement of the  $^{137}\text{Cs}$ .
- Finally, with the enhanced security programs for the  $^{137}\text{CsCl}$  units, replacement is unnecessary.

1                   **Advisory Committee on the Medical Uses of Isotopes's**  
 2                   **Report on <sup>137</sup>CsCl Irradiators**

3  
 4                   **Summary**

5  
 6 After studying the issues, the Advisory Committee on the Medical Uses of Isotopes  
 7 (ACMUI) came to the following conclusions:

- 8       1. Irradiators are necessary for medical practice and medical research.  
 9       2. It is not clear from the available data that x-ray sources are biologically equivalent  
 10      to <sup>137</sup>CsCl irradiators.  
 11      3. Alternatives to the <sup>137</sup>CsCl irradiators currently in operation present greatly  
 12      increased expense to programs that need the functionality and operational  
 13      reliability of the irradiators.  
 14      4. The recommendation of the National Research Council (NRC) of the National  
 15      Academies to eliminate the use of irradiators that employ <sup>137</sup>CsCl was based on  
 16      the situation at the time of their study. Since that time, security of medical  
 17      irradiators units has been substantially strengthened in three ways:  
 18          a. Increased security of persons with access. The December 2005 NRC  
 19          orders increased the security requirements for all persons having  
 20          unescorted access to <sup>137</sup>CsCl irradiators, including background checks,  
 21          personal reference checks, and fingerprinting checks against the FBI  
 22          fingerprint database.  
 23          b. Increased security of the facilities housing the units, including high-  
 24          security locks on facility door, multiple doors with locks for access,  
 25          motion sensors, video cameras monitored by facility security, preplanning  
 26          with local law enforcement, database encryption, and secured facility  
 27          schematics, and drawings.  
 28          c. Increased security of the units themselves, including locks on source  
 29          access panels and entry points.

30      Given these changes, we found that the National Research Council concerns do  
 31      not currently apply as previously stated, and have been superseded by increased  
 32      safeguards as required by the Nuclear Regulatory Commission and state  
 33      regulatory authorities. Well-secured <sup>137</sup>CsCl irradiators present little security  
 34      hazard.

35  
 36                   **Practicality of Alternatives to <sup>137</sup>CsCl Self-Shielded Irradiators\***

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 38                   **Blood and Blood-Product Irradiation**

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 40      Based on our survey of the literature and other publicly available information sources, the  
 41      only medical x-ray irradiator that the U.S. Food and Drug Administration (FDA) has  
 42      cleared to irradiate blood and blood products to prevent graft-versus-host disease is the

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\* Content taken from manuscript submitted to *Health Physics* June 17, 2008: Dodd, B and Vetter, R. "Replacement of <sup>137</sup>Cs Irradiators with X-Ray Irradiators"

1 Raycell (Best Theratronics 2008) originally manufactured and sold by Rad Source (Rad  
2 Source 2007a) as the unit model RS 3000. Other manufacturers may also be developing  
3 plans for new irradiators.

4 The first question regarding practicality of an x-ray machine to irradiate blood or  
5 blood products is whether there are any technical issues. Although the photon energy of  
6 x-ray machines is lower than those of  $^{137}\text{Cs}$ , Janatpour et al. (2005) demonstrated that x-  
7 ray machines can deliver the necessary 25 Gy dose with sufficient uniformity and  
8 stability to meet FDA guidelines. The typical x-ray irradiator generates a filtered energy  
9 spectrum with a peak energy of approximately 160 kVp, compared to the monoenergetic  
10 662 keV gamma rays from  $^{137}\text{Cs}$ . While a radiation weighting factor of 1 is applied to  
11 both gamma rays and x rays for radiation protection purposes (NCRP 1993), the  
12 biological effectiveness of low energy photons is approximately twice that of 662 keV  
13  $^{137}\text{Cs}$  gamma rays (ICRU 1986). Consequently, a dose of 25 Gy delivered by an x-ray  
14 irradiator will not produce the same biological effect as 25 Gy from  $^{137}\text{Cs}$  gamma rays.  
15 The significance of this difference in radiation effectiveness relevant to transfusion  
16 medicine and immunological research is unknown.

17 Regarding costs, the NRC study (2008) quoted about \$180,000 for a new x-ray  
18 irradiator and an annual service agreement cost of just over \$10,000. However, the actual  
19 cost of the x-ray system has increased. In May 2008 this manufacturer quoted a purchase  
20 price of \$250,000 and \$66,000 for a 3-year maintenance contract including a routine  
21 service call and one set of replacement parts as needed. While the purchase price might  
22 be about the same as a  $^{137}\text{Cs}$  irradiator, the annual maintenance cost with a service  
23 agreement may be much greater unless the owner has engineering capabilities to provide  
24 service and maintenance in-house. Also, the service contract does not include physics  
25 services. Depending on the number of set-ups, calibration costs may exceed \$10,000 per  
26 year if outside physics services are required. In addition, there would be a one-time cost  
27 of installing a 240 volt line to the room for most of the x-ray units replacing a cesium  
28 irradiator.

29 Based on repair history of clinical x-ray machines, a user of an x-ray irradiator  
30 may experience a higher failure rate and require more service and down-time than a  
31  $^{137}\text{CsCl}$  irradiator. Since maintenance of an irradiated blood supply is important,  
32 purchasers of x-ray blood irradiators find it necessary to purchase an annual maintenance  
33 agreement. However, outside service can result in a facility being unable to perform life-  
34 saving irradiations for a time. For example, one owner experienced a service response  
35 and re-calibration time of two weeks. Both the upper and lower power supplies had to be  
36 replaced after a few years of operation. Therefore, blood banks and hospitals may need  
37 to plan for an alternative means of irradiation or an alternative supply of irradiated blood  
38 components to meet critical demand. Without  $^{137}\text{CsCl}$  as an alternative, the facility may  
39 have to purchase two units to assure a continuous supply of irradiated blood.

40 Another factor to evaluate for practicality is the throughput of an x-ray irradiator.  
41 Two units of blood can be irradiated at one time with the Raycell, and irradiation time is  
42 about 5 min. This is sufficient for two blood centers contacted, which do about 30-100  
43 units per month, and it is adequate for a clinic doing about 20 units per day. However, a  
44 significant workload like that at a large academic medical center with a throughput of 50-  
45 60 units per day may exceed the capabilities of a single x-ray unit. While it may seem  
46 that the exposure rate with the x-ray would keep up with the demand, the blood

1 irradiation is not continually as with an assembly line. Rather, units are irradiated as  
2 needed based on the clinical demand, in irregular intervals. Thus, the duration required  
3 for the irradiation becomes an important limiting factor. One potential buyer stated that  
4 about 48,000 blood products could be irradiated within the x-ray tubes' 2000-h warranty  
5 period (Blood Bank Talk 2007). For a site processing 50 units per day and assuming that  
6 procedures requiring irradiated blood happen mostly during normal work days, that  
7 would imply the need for a new tube each 3.7 years, adding considerably to the cost of  
8 the operation.

9 Since  $^{137}\text{Cs}$  has a half-life of 30 years, it is not financially practical to replace  
10 those units that were installed within the last 15 years. Ease of use is comparable  
11 between the  $^{137}\text{CsCl}$  irradiator and the x-ray irradiator.

12 One issue that has not been investigated is whether all the operating cesium  
13 irradiators could afford to replace the units, or whether some facilities will cease  
14 operation, depriving patients of irradiated blood and researchers a source of radiation.  
15

### 16 **Biomedical and Small Animal Irradiators**

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18 Ten x-ray irradiators are commercially available for cell, tissues and small animals, eight  
19 from three U.S. manufacturers and two irradiators from outside the U.S. A few will be  
20 discussed as being representative of the issues.

21 The **RS 2000** (Rad Source 2007b) has been sold by Rad Source since 1999, with  
22 about 15-20 units placed in Europe and Asia and 50-60 placed in the USA. Several users  
23 contacted seem satisfied with the device. The purchase price is little over \$100,000, and  
24 a service agreement is around \$10,000 per year. Apparently reliability has been good;  
25 however, owners should expect to refurbish or replace the power supply about every 4-5  
26 years.

27 The Rad Source RS 2400 (Rad Source 2007c), operating between 80 and 160 kV,  
28 delivers a higher dose rate using a new technology emitter. This 4-pi x-ray source may  
29 have the capability of eventually delivering about  $300 \text{ Gy min}^{-1}$ , but the two RS 2400s  
30 operated considerably lower than this. The International Atomic Energy Agency is  
31 testing one of these units for its sterile insect programs. The dose rate and irradiation  
32 volume of the RS 2400 are much larger than those for the RS 2000 and may allow five  
33 450-ml blood bags to be irradiated simultaneously at a dose rate about  $45 \text{ Gy min}^{-1}$ .  
34 However, the canister loading methodology may need some redesign before it would be  
35 practical for irradiation of blood. Rad Source expects to submit its application for FDA  
36 approval for irradiation of blood products with this device in 2008. The RS 2400 is  
37 expected to sell for about \$200,000 - 250,000 with an annual service contract of about  
38 \$20,000. To ensure a high degree of reliability and minimal down time, the service  
39 agreement will include a tube replacement every 2000 h.

40 **Faxitron** (2008) sells two irradiation systems, the RX-650 and the CP-160, with  
41 prices around \$43,000 and \$87,000 respectively. The Faxitron RX-650 operates at a peak  
42 energy of only 130 kVp. To achieve adequate uniformity of dose, Kennedy et al. (2004)  
43 had to irradiate the mice from several directions because of the attenuation of the lower  
44 energy radiation in the bodies of the mice. Woo and Nordal (2006) concluded that the  
45 Faxitron CP-160 could be useful for small animal research if radiation was delivered  
46 carefully to ensure accurate and uniform radiation dose. The authors stated that at a

1 distance of 33 cm the indicated beam diameter on the tray was 26 cm, whereas the part of  
2 the beam where the uniformity as within 10% was confined to a diameter of 16 cm.

3 **Precision X-Ray Inc.** (2005) sells four different biomedical and small animal x-  
4 ray irradiators with energies ranging from 160 kVp to 320 kVp. With 0.5 mm Cu and  
5 operating at 320 kV, the unit delivers a dose rate of 2 Gy/minute. The higher tube  
6 potential brings the RBE to the same value as the  $^{137}\text{Cs}$  gamma ray beam. The price runs  
7 around \$170,000, exclusive of the service contract.

8 **Kimtron** markets units similar to the Precision X-ray units, with four units  
9 operating between 160 kV and 450 kV. The prices appear comparable to similar units.

10 **Gilardoni**, an Italian company, sells the Radgil (Gilardoni 2000) with an energy  
11 of 200 kVp and a dose rate of about 1 Gy min<sup>-1</sup> at a cost of about 94,000 Euros  
12 (~\$146,000).

13 **Hitachi** (2008) manufactures the MBR-1520-3, which is a 150-kVp blood  
14 irradiator that can deliver doses from 15 to 35 Gy in 5-Gy increments. However, there is  
15 no indication of FDA approval for human use.

### 17 **AAPM Survey of Users**

18  
19 The American Association of Physicists in Medicine (AAPM) conducted a survey of its  
20 members in August to assess their experience with irradiators. The results of the survey  
21 would be skewed toward hospital-based or university-based irradiators; however, for the  
22 information gathered, that should not affect the conclusions. The survey, since it was  
23 targeted at medical physicists and some health physicists, represents only a small part of  
24 the irradiators in use. Of the 363 respondents, 297 had irradiators, 84.6% of those used  
25  $^{137}\text{Cs}$  as the source, 9.3% used conventional x-ray units and 6% used medical linear  
26 accelerators (linacs). The  $^{137}\text{CsCl}$  units represented the major vendors. Only 10% were  
27 purchased within the last two years, with 7% planning on replacing the units within the  
28 next 5 years.

29 A quarter of the  $^{137}\text{CsCl}$  units had had some malfunction but most were repaired  
30 in less than 7 days. Of the x-ray units, 35% had malfunctions, with 44% being repaired  
31 within 7 days.

32 Only 40% of the cesium units were used for blood irradiation, with about 25%  
33 used for material irradiations and another 25% for animal irradiations. Of the x-ray units,  
34 half were for blood irradiation, while 19% were for material irradiation and 32% for  
35 animals. Forty percent of the medical linacs for the respondents were used  
36 predominantly for blood irradiation and 11% for animals.

37 This survey indicates that, while fairly reliable, conventional x-ray units and  
38 medical linacs account for a small minority of the irradiators in the field. They had  
39 slightly more downtime than  $^{137}\text{CsCl}$  units. The cesium units have also been reliable and  
40 their users, in general, have no plans to replace them. Forced removal of the cesium  
41 irradiators would result in a very large loss of resources, both radiation sources and funds,  
42 not only for blood banks but research institutions as well.

43

1 **Linear Accelerators**

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3 Medical linear accelerators (linacs) can and do provide irradiation for blood  
4 products and materials. While linacs can serve for animal irradiation, their use with mice  
5 presents some difficulties because of the build-up region in the dose that is on the order  
6 of the thickness of a mouse. Most facilities that use linacs for irradiation either are part  
7 of larger processing facilities (for example, medical product sterilization companies) or  
8 find time between patients (creating problems in scheduling and staffing) in a  
9 radiotherapy clinic because of the extremely large initial investment, about \$2,000,000  
10 for these units and the cost for maintenance of \$200,000 per year. Night time irradiations  
11 pose additional staffing issues. Because of the costs, linacs are not a viable replacement  
12 for <sup>137</sup>CsCl irradiators for the vast majority of facilities.

13  
14 **Alternative Radionuclides**

15  
16 At the time of writing, the only reasonable alternative radionuclide source for  
17 irradiators would be <sup>60</sup>Co. This radionuclide is used in large industrial irradiators, but is  
18 not currently available for blood or research irradiators. The use of <sup>60</sup>Co would require  
19 frequent source change due to the much shorter half-life compared with <sup>137</sup>Cs (5.27 years  
20 compared with 30 years), and higher initial source activities to extend the useful life of  
21 the sources. The <sup>60</sup>Co also requires thicker shielding because of the higher energy (1.2  
22 cm half-value layer in lead compared with 0.6 cm.) Since the half-value layer enters into  
23 shielding as an exponent, the difference in the thickness of shield required due to the  
24 differences in the values multiples rapidly. These two considerations would lead to high  
25 initial costs for a unit and frequent, repetitive costs for source replacement. Finally, there  
26 is no convincing evidence that the <sup>60</sup>Co sources of any form would pose less of a hazard  
27 than the <sup>137</sup>CsCl.

28  
29 **Further Considerations for Blood Irradiation**

30  
31 The subcommittee consulted 10 hematologists or oncologists and one clinical laboratory  
32 director. These included researchers at one of the nation's most prestigious blood  
33 disorder and hematologic cancer research centers having extensive use of <sup>137</sup>CsCl blood  
34 and small animal irradiators.

35 Most of the previous information, such as in the National Research Council  
36 report, focused use of irradiators at central blood banks.

37 Five of the 10 hematologists/oncologists reported that they regularly prescribe  
38 irradiated blood for transfusions. Of these, one said that up to 40% of all blood he  
39 prescribed was irradiated. The others estimated that 15% to 33% of all blood for  
40 transfusion was irradiated. They all mentioned that their patient population was the  
41 reason why they tended to prescribe more irradiated blood products than the nominal  
42 10% that often is used for planning. Patients who are post transplant are one such  
43 category, although none of these physicians had many patients in this subset. The more  
44 common reason was the use of certain chemotherapeutics that severely affect the host  
45 immune system.



1 Although no surveyed physicians were aware of difference between  $^{137}\text{Cs}$   
2 irradiated blood vs. x-ray, all ten (including one physician who doesn't presently  
3 routinely give irradiated blood transfusions) stated a regulation to eliminate or reduce the  
4 availability of irradiated blood products, or access to  $^{137}\text{CsCl}$  irradiators would represent  
5 a severe drawback in the hematology/oncology field of medical practice and research.  
6 One physician who prescribes irradiated blood 40% of the time said that hematologists  
7 and oncologist prescribe irradiated blood about 33% of the time and that figures which  
8 say that only around 10% of all transfused blood is irradiated are skewed by the trauma-  
9 related transfusions in hospital emergency rooms and for surgery-related transfusions.  
10 Oncologists might rely more on irradiated blood than other medical professionals.

11 One institution specializing in research on hematologic malignancies reported that  
12 four  $^{137}\text{CsCl}$  irradiators are used by 250 authorized users at a frequency of about 30 to 40  
13 times per day in support of about 20 research projects and eight active clinical trials.  
14 Although comparable x-ray systems could be obtained to replace the  $^{137}\text{CsCl}$  irradiators,  
15 four physician/PhD researchers indicated that the change would require more than a year  
16 to develop the radiation response relationships between the radionuclide-source and x-ray  
17 source irradiators, and that impacts on ongoing funded research would be enormous.

18 None of the physicians or the lab director had knowledge of the radiobiological  
19 differences between samples irradiated by x-rays or monoenergetic photons from  $^{137}\text{Cs}$   
20 sources. Four of six hematologists had experience with both irradiator systems. Three  
21 also had experience also with linac irradiated blood before their institutions obtained  
22 dedicated blood irradiators.

### 23 $^{137}\text{Cs}$ Cesium Chloride Irradiator Security

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25  
26 Prior to the publication of the National Research Council report the U.S. Nuclear  
27 Regulatory Commission (NRC) has disseminated orders to licensees for increased  
28 controls on sources of radioactive material in quantities of concern. The "Orders  
29 Imposing Increased Controls" issued in December 2005 contain requirements based on  
30 the International Atomic Energy Agency Code of Conduct. These measures were  
31 required to safeguard radioactive sources from theft or other unauthorized use. These  
32 requirements include:

- 33 1. Limit access to approved individuals who need to use radioactive materials in  
34 performing work activities.
- 35 2. Perform background and trustworthiness checks on all employees with access.
- 36 3. Escort all service providers who need to access the radioactive source.
- 37 4. Document the monitoring of sources with means for detecting source removal.
- 38 5. Increase source monitoring during source delivery or shipment.
- 39 6. Respond immediately to any attempted theft, sabotage, or diversion of sources.
- 40 7. Develop a plan for assistance from supporting authorities in the event of theft,  
41 sabotage, or diversion.
- 42 8. Provide means for transmitting information between personnel and components used  
43 to detect an intrusion.
- 44 9. Notify the NRC Operations Center of any attempted theft of radioactive material.
- 45 10. Document any attempt at theft or diversion of radioactive material.

- 1 11. Use trusted carriers with package tracking systems, who maintain constant control  
2 during transit, and who maintain communication for response or assistance.
- 3 12. Notify the NRC 90 days prior to certain shipments.

4 To review the changes resulting from the NRC orders for increased controls, a site  
5 visit for one of the members of this subcommittee was arranged to a major medical center  
6 with four <sup>137</sup>CsCl blood irradiators. The visit found that the licensee maintained access  
7 control to the irradiators by the means required in the Order, including:

- 8 1. Allowing access only to approved personnel who had undergone a thorough FBI  
9 background check, fingerprinting, work history review, psychological review, and  
10 local law enforcement background check.
- 11 2. Allowing access only to persons needing and trained to use the irradiators properly.
- 12 3. Providing redundant enforced doors, locks, heavy walls, computer-coded key-card  
13 access, and continuous video monitoring of the halls, entry, and workspace occupied  
14 by the irradiator units.
- 15 4. Presenting documented procedures to ensure that authorized users support the  
16 institutions system to prevent unauthorized access and protect access information,  
17 drawings, schematics, maps, and facility floor plans from unauthorized use.
- 18 5. Coordinating with local law enforcement agencies for rapid response to any  
19 attempted intrusion or theft of radioactive material.

20 In addition, we found the irradiator systems to be outfitted with additional  
21 padlocks and security measures for preventing unauthorized access to radioactive sources  
22 inside the irradiators. The irradiators weigh 4000 to 5000 pounds and do not have  
23 wheels.

24 In summary, we found highly increased security of <sup>137</sup>CsCl irradiators and  
25 increased controls over access by authorized personnel at the institution. It would be  
26 very difficult, even for personnel with access permission, to attempt theft, diversion, or  
27 misuse of the <sup>137</sup>CsCl irradiator systems. The institution had implemented all  
28 requirements to enhance the security of <sup>137</sup>CsCl irradiator systems in a manner typical of  
29 such irradiators.

30 In addition to the increased security enhancements required by the NRC, an  
31 initiative by the Department of Energy (DOE), the Department of Homeland Security  
32 (DHS), and the Domestic Nuclear Detection Office will harden <sup>137</sup>CsCl irradiators  
33 throughout the United States to delay unauthorized access to <sup>137</sup>Cs sources. This has  
34 been a cooperative effort for the past 18 months. The demonstration project was  
35 completed in March of 2008 and the pilot project is currently being conducted in nine  
36 facilities. DOE and DHS anticipate that this pilot program will be completed later this  
37 year.

38 The pilot project is the actual enhancement of the irradiators in the field. The  
39 manufacturer will install additional material and make minor changes to the exterior of  
40 the irradiator to make it more difficult to remove the source(s). There are nine facilities  
41 that have volunteered to participate. The pilot will have two of the manufacturers visit  
42 the facility and add the enhancements to the irradiators. The pilot will demonstrate the  
43 ease and ability of performing these tasks in a "real world" environment. The pilot will  
44 also validate the costs to perform the retrofit. It is estimated that the cost will be \$2,000  
45 to 4,000 for each device. The DHS and the DOE will pay the manufacturers for the

1 enhancements. It is expected that the pilot will be successful and the project will be open  
2 to all of the devices currently licensed in the United States.

### 4 **Alternative Forms for <sup>137</sup>Cesium Sources**

5  
6 The subcommittee considered whether this report should recommend to  
7 manufacturers of <sup>137</sup>CsCl irradiators that alternatives to the powder form of the source be  
8 pursued. However, as of this time, there is no convincing evidence that another form,  
9 particularly a solid form, would be safer. While a powder may be dispersed by a bomb, a  
10 solid poses a radiation hazard much greater than the dispersed powder. In addition, the  
11 manufacture of a solid source could pose a hazard to the workers making the sources.

### 13 **Conclusions**

- 14  
15 1. Cesium-137 irradiators are used in a number of important medical and research  
16 applications. As the population of the United States ages, the use of irradiated  
17 blood products will escalate, producing an increased demand for the availability  
18 of this technology for patient safety. The need for medical irradiators is  
19 unquestionable.
- 20 2. Some investigators are concerned about the ways that differences in radiation  
21 quality between <sup>137</sup>CsCl irradiators and x-ray systems would affect experimental  
22 results on blood samples, small animals, separated T-cells and stem cells, and  
23 other biological media.
- 24 3. Alternatives to <sup>137</sup>CsCl irradiators are expensive, and forcing the switch to x-ray  
25 sources would place an unnecessary and great financial burden on blood banks  
26 and research institutions.
- 27 4. The ACMUI subcommittee believes that the <sup>137</sup>Cesium Chloride Irradiator  
28 Security Enhancements and Increased Controls and Security Inspections have  
29 provided strong measures for ensuring the safety and integrity of <sup>137</sup>CsCl sources  
30 in medical irradiators, have reduced the vulnerability of these devices as material  
31 suitable for malicious intent, and should prove to be acceptable as an alternative  
32 to removal or prohibition of these devices.

### 34 **ACMUI <sup>137</sup>CsCl Irradiator Subcommittee**

35  
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41 Richard Vetter<sup>1</sup> (Lead of the X-ray Alternative Subgroup)  
42 James Welsh<sup>3</sup> (Lead of the Need Subgroup)  
43 <sup>1</sup>Member, X-ray Alternative Subgroup  
44 <sup>2</sup>Member, Security Subgroup  
45 <sup>3</sup>Member, Need Subgroup

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