# PUBLIC SUBMISSION

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Security and Continued Use of Cesium-137 Chloride Sources and Notice of Public Meeting

**Comment On:** NRC-2008-0419-0014
Security and Continued Use of Cesium-137 Chloride Sources: Granting Extension of Comment Period

**Document:** NRC-2008-0419-DRAFT-0069
Comment on FR Doc # E8-22688

## Submitter Information

7/31/08
73 FR 44780
(71)

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**Organization:** Americas Blood Centers



## Comment

Americas Blood Centers provides the attached comments for you consideration related
to Cesium Chloride and blood irradiators. Thank you for the opportunity to comment
and to participate in the workshop.

## Attachments

**NRC-2008-0419-DRAFT-0069.1:** Comment on FR Doc # E8-22688
**NRC-2008-0419-DRAFT-0069.2:** Comment on FR Doc # E8-22688

SUNSI Review Complete
Template=ADM-013

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Add=J. Jankovich (JPS2)

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15 OCTOBER 2008

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Number NRC-2008-0419: Request for Comments on the Security and Continued Use of Cesium-137 Chloride Sources and Notice of Public Meeting

Dear Docket Officer:

On 31 July 2008 the US Nuclear Regulatory Commission published a notice in the Federal Register (Volume 73, Number 148), entitled "Request for Comments on the Security and Continued Use of Cesium- 137 Chloride Sources and Notice of Public Meeting." Subsequently, an extension, until 15 October 2008, to the comment period was granted (Volume 73, Number 188). America's Blood Centers (ABC) would like to take this opportunity to provide our comments.

For your information, ABC member centers supply about half of the United States of America's blood and blood components for transfusion. The centers irradiate approximately 500,000 blood components a year destined to transfusion into patients (immunosuppressed, blood related donor, etc.) to prevent Graft-versus-Host-Disease, a usually fatal condition.

ABC commends the NRC (Nuclear Regulatory Commission) for their efforts to gather input on the major issues associated with the use of certain forms of Cesium Chloride (CsCl). Soliciting information on the impact of major issues prior to undertaking rulemaking activities is important to ensure the continued availability of critical life-saving radiation modalities and to understand the potential economic impact of changes that are being considered.

ABC participated in the public workshop providing an abbreviated PowerPoint presentation of a survey conducted of our 75 US members. That presentation in its entirety is attached to these comments. We provide the following additional comments for your consideration:

**Issue 1.1: Feasibility of the use of other forms of Cs-137:** It was made clear at the public workshop that CsCl is critical to the medical research community as well as the radiation calibrator industry. Should a different form of Cs-137 become available, current Cs-137 irradiators would have to be retrofitted, if possible, to accept the alternative forms. Currently, ABC member centers have 65 Cs-137 irradiators with an average of 12 years remaining of useful life valued at $50,145 on average.

**Issue 1.2: Feasibility of the use of isotopes other than Cs-137:** There are two Co-60 blood irradiators in operation among ABC member centers. Co-60 irradiators are not favored by blood centers because they require significant and expensive facility modifications due to the heavy weight load of the instrument. In addition, processing time is double that of Cs-137 and X-Ray irradiators (average cycle time of 11 min for Co-60 compared to 6 and 5 respectively).

**Issue No 2 – Use of Alternative Technologies:** X-Ray irradiators are currently available and are satisfactory for irradiation of blood components. There are currently 13 X-Ray irradiators in use among ABC member centers. Unfortunately the acquisition cost of X-Ray is on average 139% higher than that of Cs-137 irradiators. The operational cost (average of $20,375/year) is double that of CsCl irradiators (average of $9,230/year). Additionally, the anticipated life expectancy of X-Ray irradiators is less than one-half that of Cs-137 irradiators (10 years compared to 25 years based on manufacturer's claims) (Table 1).

Table 1. Blood component irradiators in operation among members of ABC, including number and types, purchase price, operating costs and remaining useful life.

| Type | Number of Devices | Average Year Purchase | Average Purchase Price | Average Operating Costs | Average Anticipated Life Span | Average Years of Life Remaining |
|---|---|---|---|---|---|---|
| n | 80 | 68 | 47 | 56 | 68 | 68 |
| Cs-137 | 65 | 1996 | $107,272 | $ 9,230 | 25 | 12 |
| X-Ray | 13 | 2005 | $149,747 | $20,375 | 10 | 7 |
| Co-60 | 2 | 1993 | N/A | $ 6,500 | 25 | 10 |

Our survey data, based on a total of 80 devices, did not show significant differences between Cs-137 and X-Ray blood irradiators in terms of capacity and reliability. (Table 2)

Table 2. Comparison of operational characteristics of blood irradiators in ABC member centers.

| Type | Number of Devices | OVERALL AVERAGE | | | | |
|---|---|---|---|---|---|---|
| | | Cycle Time (min) | Maximum # of RBCs[1]/run | Maximum # of AphPLTs[2]/run | Maximum # of RandPLT[3]/ run | Reliability # of Days inoperable |
| n | 80 | 68 | 68 | 68 | 46 | 68 |
| Cs-137 | 65 | 6 | 3 | 3 | 10 | 15 |
| X-Ray | 13 | 5 | 2 | 3 | 10 | 5 |
| Co-60 | 2 | 11 | 2 | 2 | 15 | 3 |

1. RBC = Red Blood Cells
2. AphPLTS = Apheresis Platelets, collected by automated methods
3. RandPLT = random platelets

**Issue No. 3 – Possible Phase-Out of CsCl Sources:** Blood centers and hospitals can use alternative irradiators, primarily X-Ray based. However, the replacement of CsCl irradiators currently in use will have significant operational and economic impact in addition to security and cost concerns about their disposal. Seven irradiators were decommissioned by ABC member centers in recent years with cost ranging from $17,300 to $30,000. Two member centers obtained grants from the Department of Energy that covered all decommissioning costs. More critical than the cost however, is the difficulty in transporting and disposing of the Cs-137. Special containers are required as well as security escorts. In addition, available disposal sites currently do not exist in the U.S. Transport and disposal issues must be addressed before any action is taken to decommission all Cs-137 irradiators.

Once the issue of transport and disposal has been addressed, then the economic impact of replacement of the irradiators by US Blood Centers may be considered. ABC Member centers currently have 65 Cs-137 irradiators that have an average remaining value of $50,145, a total of over $3,259,425. This is in addition to the disposal costs. Conversion to X-Ray technology is costly as shown above, both in terms of capital, facility renovations (i.e. water cooling) and operating costs. Unfortunately, blood centers are reimbursed by hospitals that have difficulties recovering costs from Medicare, Medicaid and third party payers. Reimbursement fees lag technology enhancements in the blood bank industry by at least 5 years. Reimbursement has never covered the total cost to recruit blood donors, collect the blood, test the donation, and prepare components for transfusion into patients. Therefore, a mandatory conversion from Cs-137 to X-Ray can only occur if subsidized. In addition, reimbursement by CMS and third party payers needs to recognize the increased operational costs and shorter life span of the X-Ray blood irradiators. The total costs estimates to phase out Cs-137 in ABC centers is over $21 MILLION as detailed in the Table 3.

Table 3. Estimated cost of replacement of the 65 CsCl irradiators in operation among ABC member centers.

| | Average / Device | Total for 65 Cs-137 Devices |
|---|---|---|
| **Remaining Value in Cs-137** | **$54,491** | **$3,541,915** |
| **Decommissioning cost** | **$17,300** | **$803,205** |
| **Purchase Cost of X-Ray *excluding* facility modifications & installation costs** | **$149,747** | **$9,733,555** |
| **Additional Operating Costs/Yr (*assuming 10 yr anticipated life expectancy)** | **$11,145** | **$7,244,250*** |
| **Total** | **$227,740** | **$21,322,925** |

**Issue No. 4 – Additional Requirements for Enhanced Security of CsCl Sources**: ABC member centers have implemented all increased control requirements recommended by the NRC (FRN 72128 and Section 652 of Energy Policy Act of 2005). We would encourage the NRC to assess the added security provided by these increased controls before issuing any additional requirements. Assessments should always be made after each initiative to determine the initiative's effectiveness. Unfortunately, for security reasons, the NRC is not able to present the complete risk picture to the owners of these devices. ABC encourages additional educational efforts by the NRC directed to the owners of Cs-137 devices to reinforce the importance of the recommended security measures..

**Issue No. 5 – Role of Risk Analysis in the Future CsCl Requirements:** It is imperative that the NRC take into consideration the potential impact of any future rulemaking on owners of CsCl devices. The public workshop clearly indicated that simple elimination of CsCl irradiators without an appropriate alternative would be disastrous for the medical research community. Years of research could be lost. Another critical area is radiation calibration, affecting over 1 million calibrators in use in many sectors, including in the nuclear power industry, disaster and emergency preparedness, and the Department of Defense. In our specific case, a requirement for replacement of CsCl irradiators by the not-for-profit blood banking community would constitute an unfunded mandate that exceeds $35 MILLION dollars.

In conclusion, ABC believes that the best course of action for the NRC is funding of the research and development of alternative forms of CsCl that do not carry the inherent risks of the current soluble salt form. In addition, funds should be made available to the current manufacturer of CsCl to retool its factory to produce this new form of Cs-137. Furthermore, blood centers and hospitals will need economic assistance to retrofit existing devices or to replace them with new X-Ray or modified Cs-137 devices. In the interim, emphasis should be placed on the recently recommended control measures to assure the security of irradiators currently in use.

Thank you for the opportunity to comment.

Yours truly,

Celso Bianco, MD
Executive Vice President

# Blood Irradiators in ABC Member Centers


**Celso Bianco, MD**
**Executive Vice President**

**Ruth Sylvester, LtCol, USAF (Ret)**
**Director, Regulatory Services**

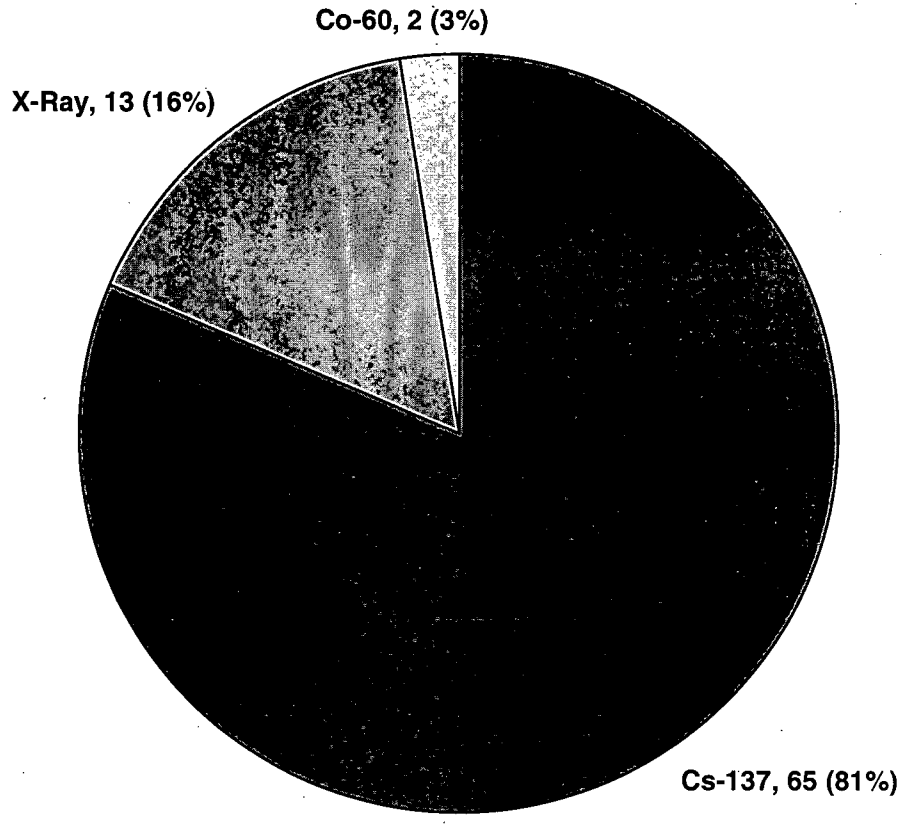

America's Blood® Centers
It's About *Life.*

# About America's Blood Centers

- ABC was founded in 1962 as the federation of the not-for-profit, community-based blood centers
- Today, ABC represents all of Canadian & 77 US community blood centers
- All blood provided comes from Volunteer Donors
- ABC Members provide half the US blood supply (more than 9 million donations) and 100% of Canada's blood supply
- Collections by Members vary from 10,000 to 844,000 units per year
- ABC members serve over 3,300 hospitals

# Sep 2008 ABC Member Irradiator Survey

- 68 of 77 Responded
- 88.3 % of membership
- 93.6 % of member collections



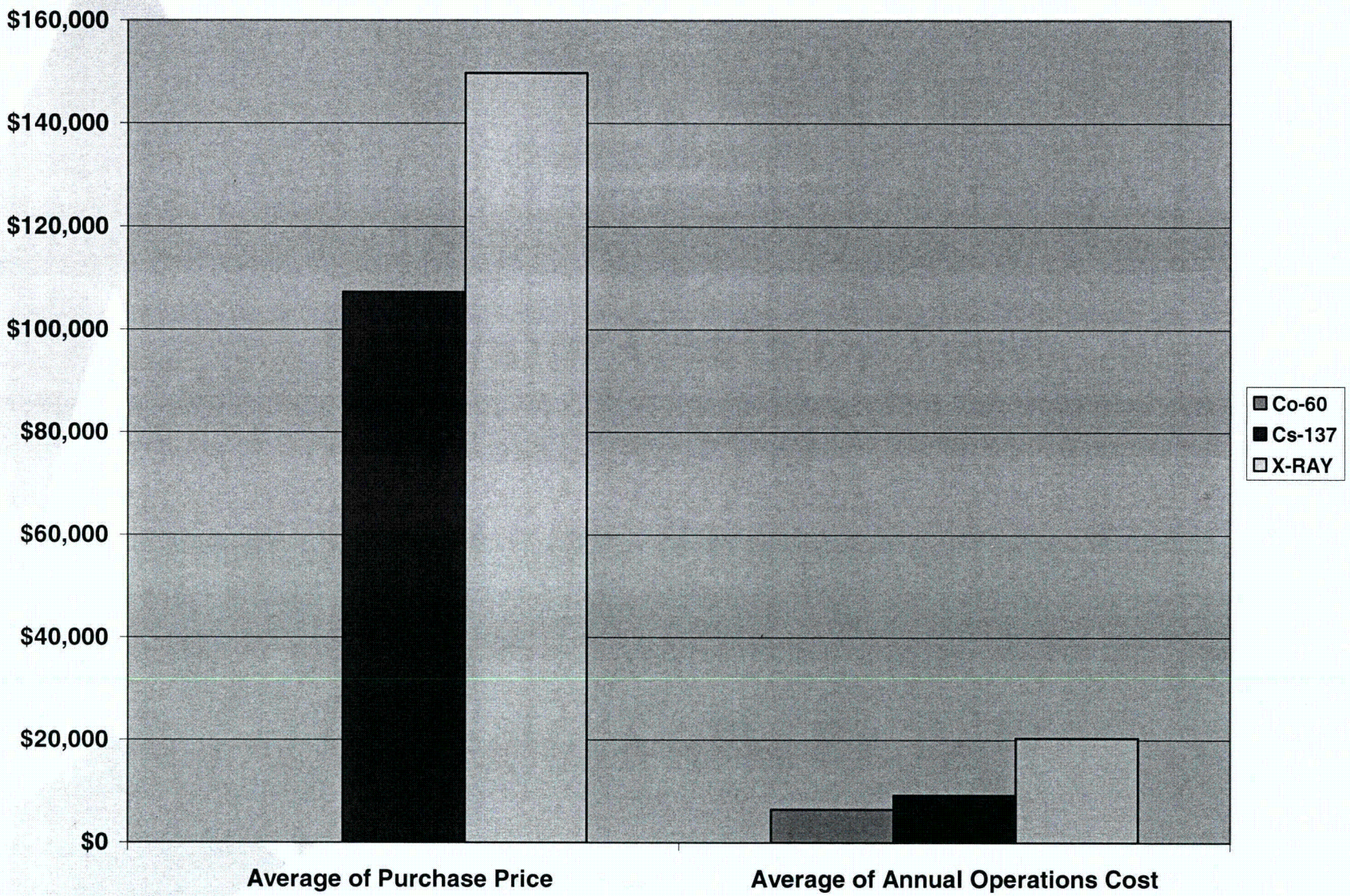

**Total 80 Irradiators**

# Snapshot of ABC Member Irradiators

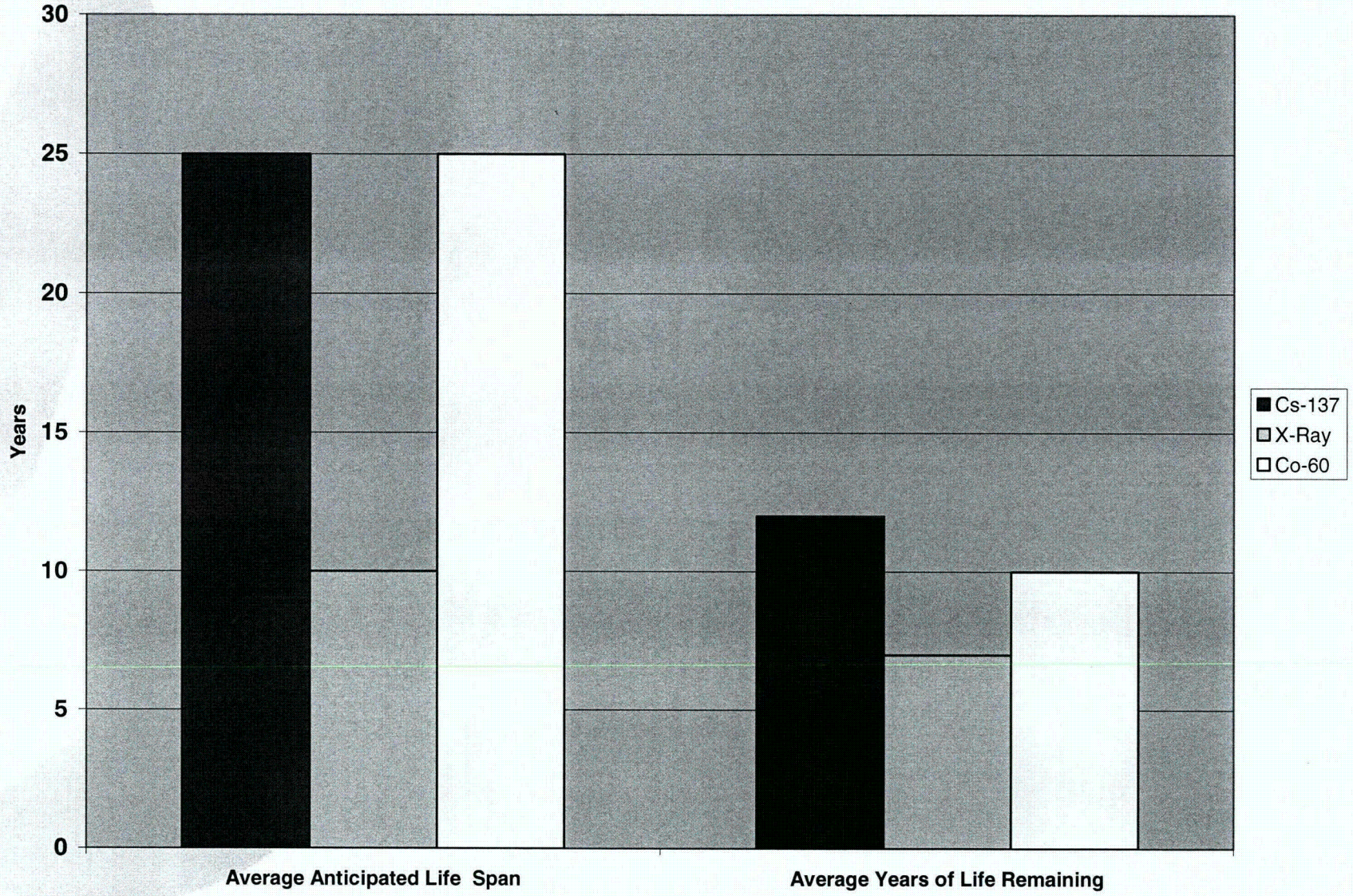
- 10 Do ***NOT*** irradiate in-house
- 58 irradiate >531,000 components annually
- Own 80 irradiators
- Irradiate for 1,461 facilities
- Provide backup irradiation capabilities to 188 facilities

| Type | Number of Devices | Average Year Purchase | Average Purchase Price | Average Operating Costs | Average Anticipated Life Span | Average Years of Life Remaining |
|---|---|---|---|---|---|---|
| n | 80 | 68 | 47 | 56 | 68 | 68 |
| Cs-137 | 65 | 1996 | $107,272 | $ 9,230 | 25 | 12 |
| X-Ray | 13 | 2005 | $149,747 | $20,375 | 10 | 7 |
| Co-60 | 2 | 1993 | N/A | $ 6,500 | 25 | 10 |

# Irradiator Costs by Type



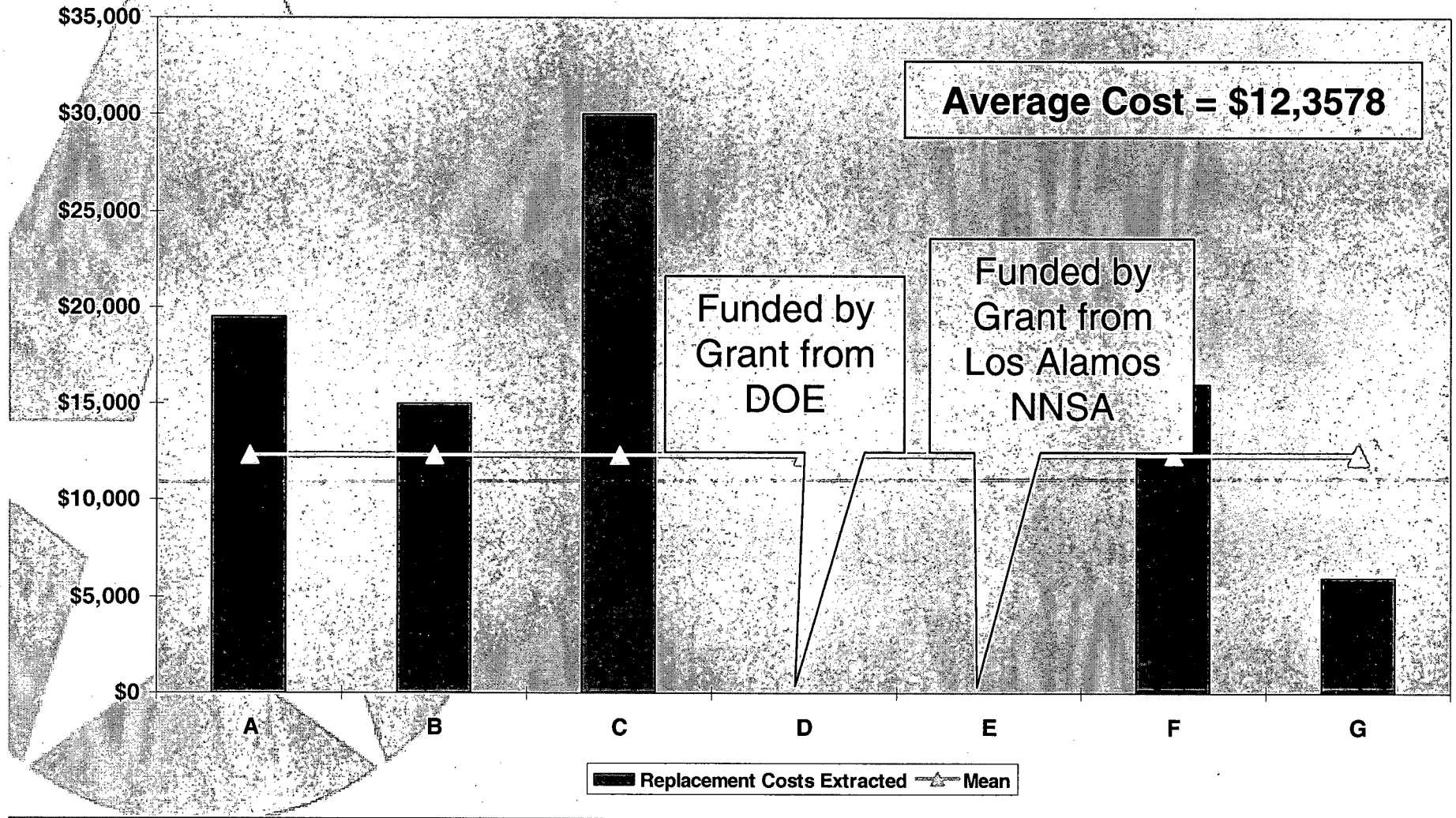
# Irradiator Life



# Remaining Value in Cs-137 Irradiators

| Type | Number of Devices | Average Year Purchase | Average Purchase Price | Average Operating Costs | Average Anticipated Life Span | Average Years of Life Remaining |
|---|---|---|---|---|---|---|
| n | 80 | 68 | 47 | 56 | 68 | 68 |
| Cs-137 | 65 | 1996 | $107,272 | $ 9,230 | 25 | 12 |
| X- | Average Remaining Value Cs-137 Irradiators = $ 54,491 | | | | | |
| C | Total Remaining Value CS-137 Irradiators = $3,541,915 | | | | | |

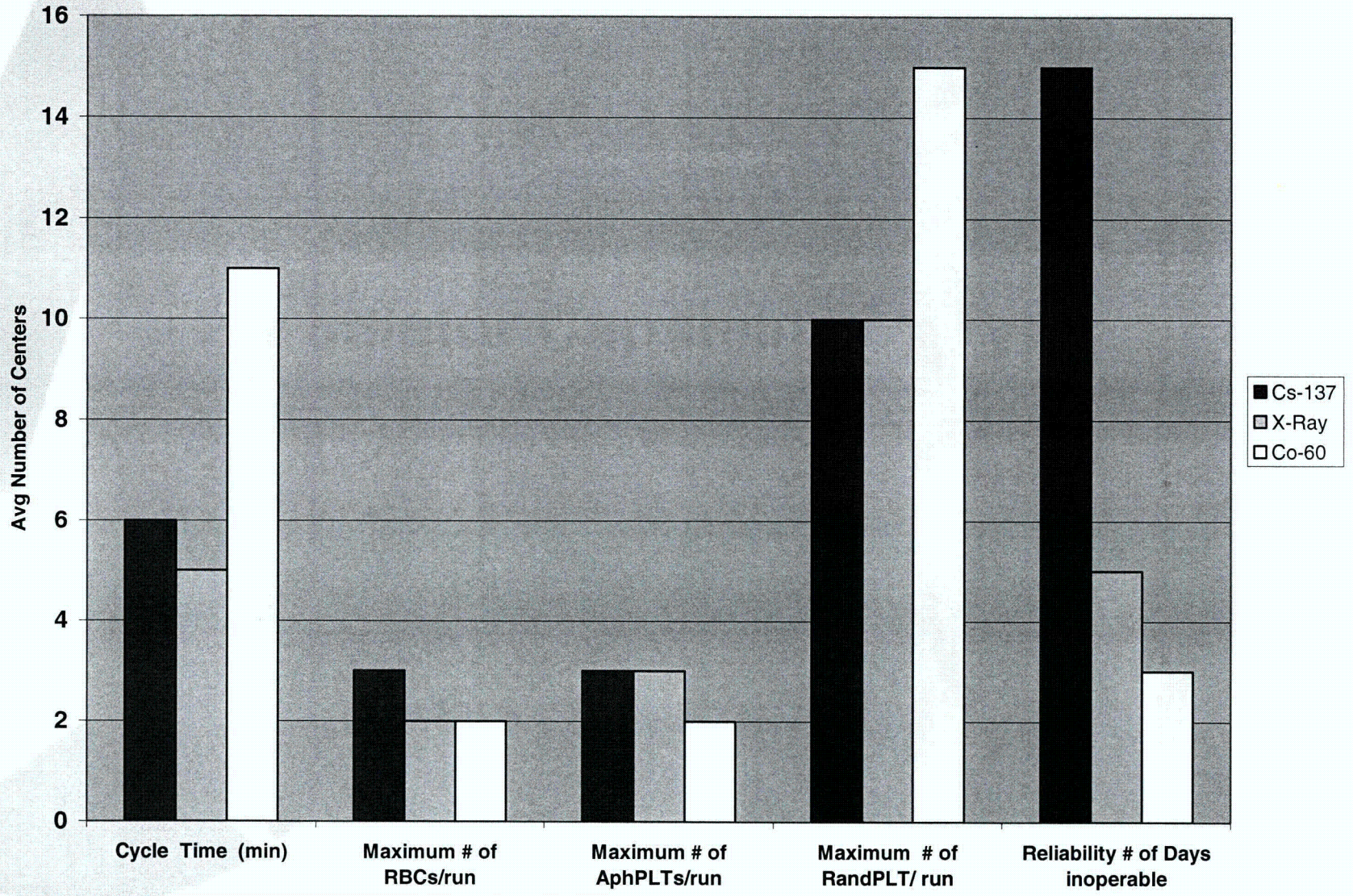
# Decommissioning Costs for Cs-137 Irradiators



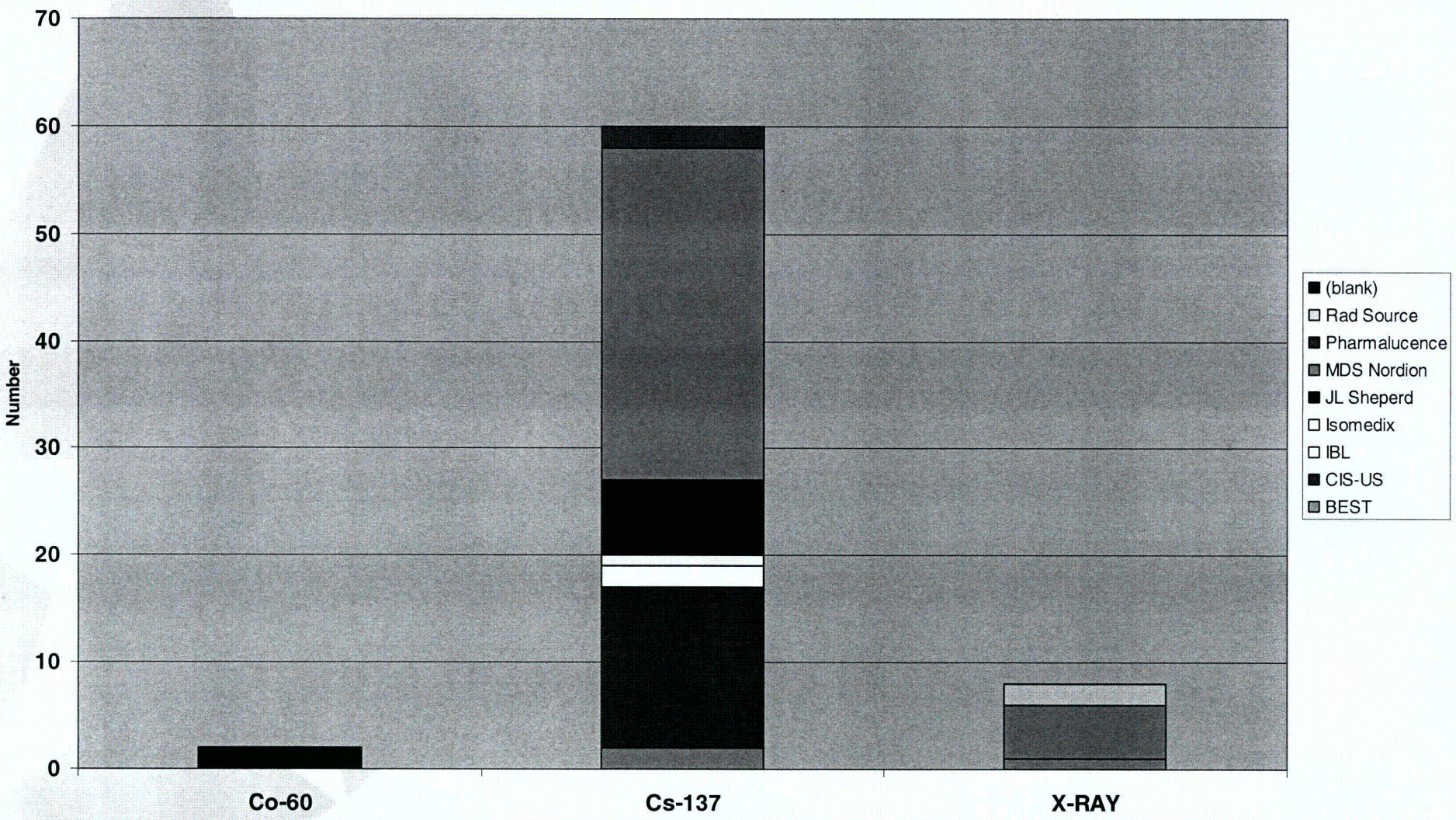
# ABC Member Irradiator Performance

| Type | Number of Devices | OVERALL AVERAGE | | | | |
|---|---|---|---|---|---|---|
| | | Cycle Time (min) | Maximum # of RBCs/run | Maximum # of AphPLTs/run | Maximum # of RandPLT/ run | Reliability # of Days inoperable |
| n | 80 | 68 | 68 | 68 | 46 | 68 |
| Cs-137 | 65 | 6 | 3 | 3 | 10 | 15 |
| X-Ray | 13 | 5 | 2 | 3 | 10 | 5 |
| Co-60 | 2 | 11 | 2 | 2 | 15 | 3 |

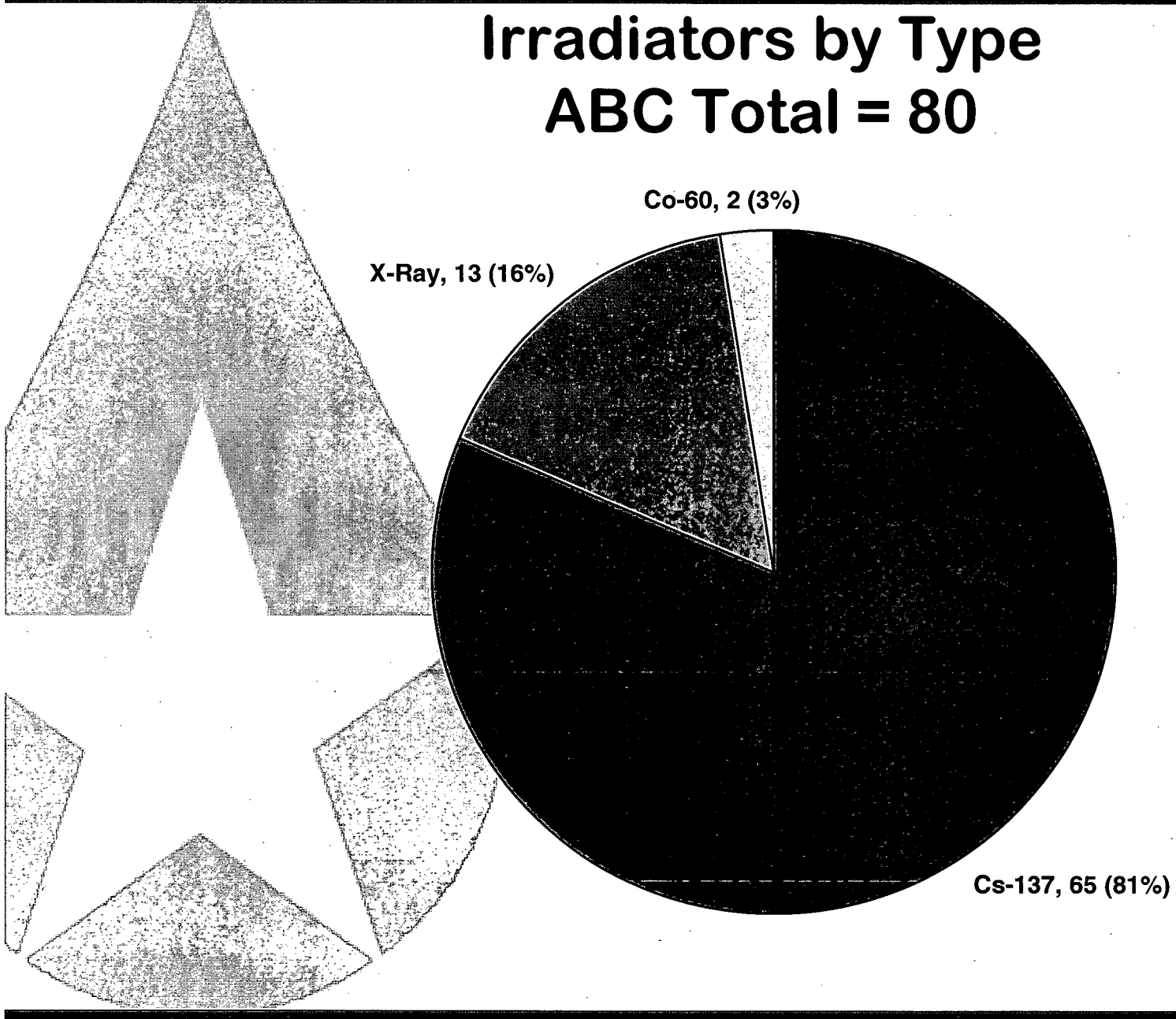
# Irradiator Capability by Type



# Irradiator Devices by Manufacturer



# Irradiators by Type
# ABC Total = 80



# Total Cost to Phase-out Cs-137 in ABC

| | Average / Device | Total for 65 Cs-137 Devices |
|---|---|---|
| Remaining Value in Cs-137 | $54,491 | $3,541,915 |
| Decommissioning cost | $12,357 | $803,205 |
| Purchase Cost of X-Ray | $149,747 | $9,733,555 |
| Additional Operating Costs/Yr (*assuming 10 yr anticipated life expectancy) | $11,145 | $7,244,250* |
| Total | $227,740 | $21,322,925 |

# Obstacles to Conversion of Irradiation Methodology

- Cost of the new X-Ray instrument
  - Acquisition, facility modifications, installation, calibration, validation, QC, maintenance, re-calibration, replacement parts
- Complexity of Decommissioning
  - Local and Federal regulatory requirements, police escorts, secrecy, disposal, cost
- Loss of use of current instrument
  - Justification for premature investment in a replacement
- Lack of Perception of Risk
  - ALL ABC Members have complied with recent increased control requirements required by NRC including physical location and control of access plus security clearance of personnel

# How Could the Conversion be Achieved? (or how to make it happen?)

- Education of users
- Precise assessment of availability of new instruments & comparison of effectiveness
- Facilitate decommissioning: regulatory process, handling and disposal
- Promote availability of new instruments; synchronize decommissioning with installation of replacement
- Funds for conversion (Grants?)
- Ordered conversion according to a timeline (completed in 10 years?)