

**U.S.NRC**

UNITED STATES NUCLEAR REGULATORY COMMISSION

*Protecting People and the Environment*



# MEDICAL INSPECTIONS

# Medical Inspections

## Purpose

- **To determine if licensed activities involving the medical use of byproduct material are being conducted in a manner that will protect the health and safety of workers, the general public, and patients.**
- **To determine if licensed programs are being conducted in accordance with U.S. Nuclear Regulatory Commission requirements.**

# References

- **NUREG-1556, Volume 9: Program-Specific Guidance About Medical Use Licenses**
- **Manual Chapter 2800, “Materials Inspection Program”**
- **Inspection Procedures: 87130, 87131, 87132, 87133, 87134**

# Basic Inspection Process

- **Preparation for all inspections (MC2800):**
  - **License review**
  - **Trip planning**
  - **Review Inspection and Enforcement History**
  - **Review event reports since last inspection**

# Basic Inspection Process

- **Review any notes in license file regarding areas of special emphasis**
- **Be familiar with the types of uses and the generic requirements applicable to the licensed program.**
- **Prepare: The time/effort for inspection preparation should be based upon the complexity and scope of licensed activities and on the experience level of the individual inspector.**

# Conduct of the Inspection

- **Meet with management: Entrance and Exit Meetings**
- **Follow up on previous items**
- **Obtain general overview of licensed activities**
  - **Organization**
  - **Scope of Program**

# Conduct of the Inspection

- **Observe facilities and licensed activities**
- **Perform confirmatory/independent measurements**
- **Inspect any special license conditions**

# **Eight Focus Elements of a Medical Inspection**

## **1 - Security and control of licensed material**

- Nuclear Medicine - packages, unit doses, Hot Lab locked when unattended**
- Brachytherapy – sources locked in hot lab and/or sealed source storage safe**
- HDR, gamma knife, teletherapy - room access**



# Eight Focus Elements of a Medical Inspection

## 2 - Shielding of licensed materials

- L-blocks, syringe shields, etc.
- Lead “safes” for brachytherapy sources
- Room shielding (HDR, teletherapy, gamma knife suites)
- Unit shielding (HDR, teletherapy, gamma knife units)
- Portable shielding (bedside shields)
- Source carriers

# Eight Focus Elements of a Medical Inspection

## 3 - Comprehensive safety measures

- **package integrity**
- **fire safety**
- **ventilation**
- **protection from elements**
- **special interlocks (shared rooms)**

# Eight Focus Elements of a Medical Inspection

## 4 - Radiation dosimetry program

- **Whole-body dosimeters**
- **Ring dosimeters**
- **Direct-reading dosimeters - nurses**

# **Eight Focus Elements of a Medical Inspection**

## **5 - Radiation instrumentation and surveys**

- **Nuc Med, Brachy: portable survey instruments**
- **Nuc Med: swipe counting equipment**
- **Brachy, Gamma Knife: room monitors**

# **Eight Focus Elements of a Medical Inspection**

## **6 - Radiation safety training & practices**

- Initial training**
- Annual re-fresher training**
- Dry runs on emergency procedures**
- Empowered to implement the radiation safety program.**

# **Eight Focus Elements of a Medical Inspection**

## **7 - Management Oversight**

- Representatives attend RSC meetings**
- Provide financial support for the program**
- Conduct audits/reviews of the program (at least annually)**
- RSO has sufficient authority to halt unsafe activities**
- Interview authorized users, RSC members, facility management representatives**

# Eight Focus Elements of a Medical Inspection

**(8) - New or emerging technologies (extra bonus focus element)**

**Examples: Seeds Used for Localization of Non-Palpable Lesions, Leksell Gamma Knife® Perfexion™, NeoVista Epi-Rad90 TM Epiretinal Ophthalmic System**

- **Review radiation safety practices for these uses**
- **Ensure that the licensee has been approved for such uses.**

# Neo Vista Epi-Rad90



The Epi-Rad system  
handpiece. The surgeon  
lowers a small strand of  
Strontium-90 into the tip after  
insertion into the eye. The brief exposure  
damages diseased cells preferentially.



# Leksell Gamma Knife® Perfexion™



# Unsealed Byproduct Material

## 10 CFR 35.100-200

- **Commonly known as Diagnostic Studies**
- **Radioactive material use that does not require a written directive**

# Unsealed Byproduct Material

## 10 CFR 35.100-200

### Hazard Analysis

- **Main Radionuclides**
  - **Technetium-99m (“work horse”) (Tc-99m)**
  - **Thallium-201 (Tl-201)**
  - **Flourine-18 (F-18)**
  - **Indium-111 (In-111)**
  - **Iodine-123 (I-123)**
  - **Xenon-133 (Xe-133)**

# Unsealed Byproduct Material

## 10 CFR 35.100-200

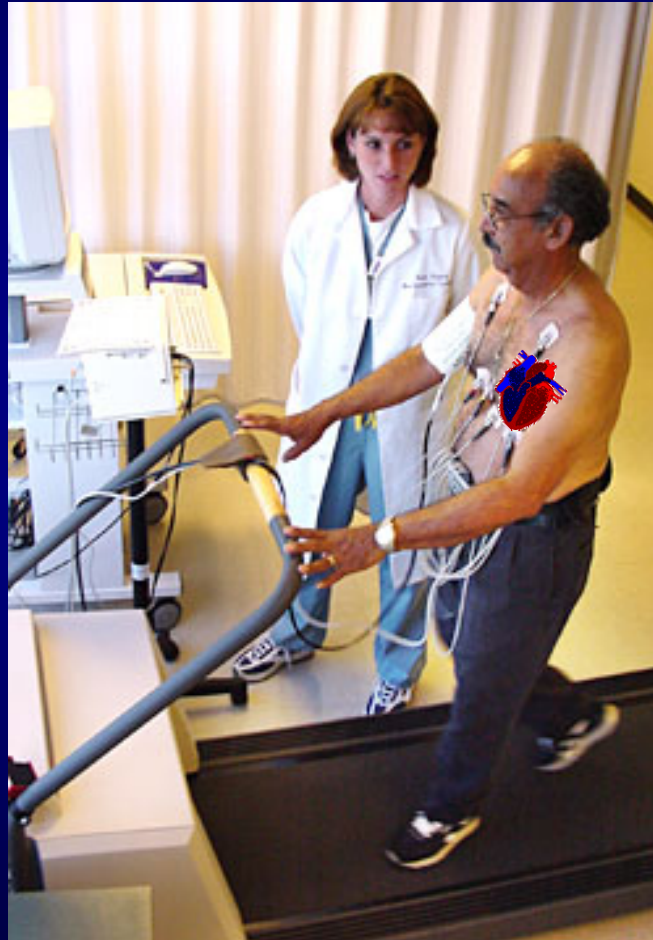
- **Relative Hazard - Low**
  - **Radionuclides have short half-lives (few hours to few days)**
  - **The material is typically handled in unit dosage quantities (~100 microcuries for I-123 to 20-30 millicurie range for Tc-99m)**
  - **Unit dosage administrations are not likely to exceed dose thresholds for “medical event” as defined in 10 CFR Part 35 (i.e., 5 rem EDE, 50 rem to organ/tissue or 50 rem SDE to skin)**

# Unsealed Byproduct Material

## 10 CFR 35.100-200

- **The hazards to workers are minimal, provided shielding is used (syringe and vial shields)**
- **Spill clean up typically results in minimal doses**
- **Loss of a unit dosage quantity is not likely to pose a significant radiological hazard to members of the public given the short half-life (provided that the syringe/container is adequately shielded).**

# Cardiac Stress Test



# Xenon Ventilation Study



# Tc-99m - Shielding

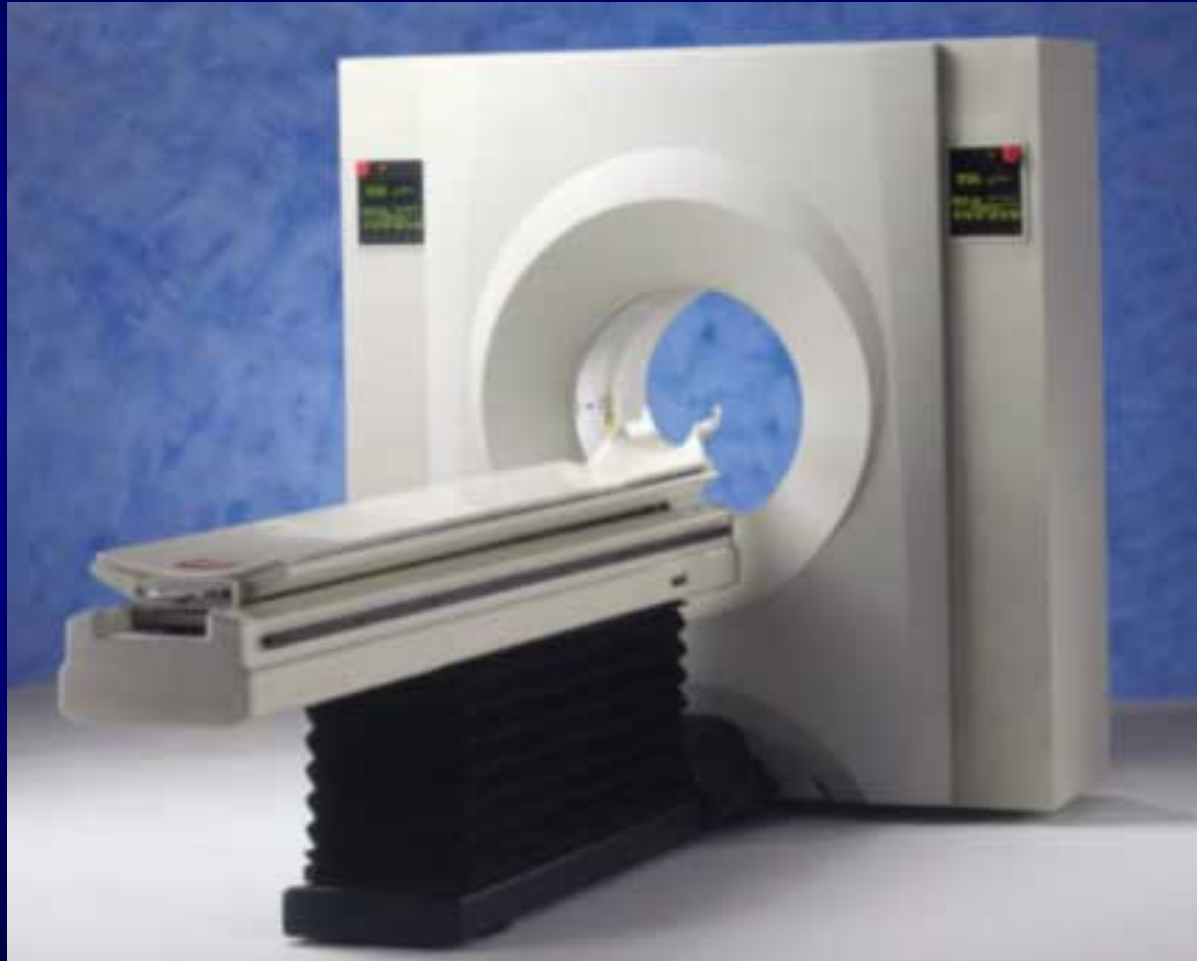




# Positron Emission Tomography (PET) - Shielding



# PET Scanning Unit



# Unsealed Byproduct Material

## 10 CFR 35.100-200

- **Increased hazard: Some radionuclides can be dispensed in large quantities (Tc-99m, about 200 millicuries and F-18, about 5-10 curies).**
  - **If Tc-99m is mis-handled, it could result in doses that exceed the dose thresholds for a medical event if enough radioactivity is administered**
  - **Workers must handle large quantity of material with shields (with lids, if applicable!)**

# Unsealed Byproduct Material

## 10 CFR 35.100-200

- **Spills of bulk quantities could have higher dose consequences to workers, but are still not likely to be significant**
- **Losses of large quantities could result in significant radiological hazards to members of the public**

# Unsealed Byproduct Material

## 10 CFR 35.100-200

- **Increased Hazard: Use of Mo-99/Tc-99m generators**
  - **Contain 1-20 curies**
  - **Can result in unnecessary worker doses (extremities) if not properly shielded, used, and stored.**
  - **Elutions contain significant quantities of Tc-99m (1 or more curies!)**
  - **Significant doses from dropped/spilled elution vials; usually secure the area and wait 24 hours to clean up (~4 half lives = 1/16th of activity).**
  - **Tests on eluted material to ensure that there is no significant Mo-99 breakthrough**

# Isotope Generators



# Unsealed Byproduct Material

## 10 CFR 35.100-200

- **What to observe during a diagnostic nuclear medicine inspection using unit dosages:**
  - **Use of syringe shields to minimize occupational dose**
  - **Use of monitoring devices and protective clothing**
  - **Package receipt and return surveys**
  - **Verification of patient ID before dosage administration**

# Unsealed Byproduct Material

## 10 CFR 35.100-200

- **Proper control of materials (e.g., material in locked hot lab when unattended, waste in locked storage, radioactive waste only in designated receptacles, return packages handled only by properly identified pharmacy staff)**
- **Sufficient number of appropriate, calibrated radiation survey & detection instruments (e.g., batteries work, respond appropriately to radiation as compared to inspector's instrument, calibrated at the required frequency by authorized persons)**



# Unsealed Byproduct Material

## 10 CFR 35.100-200

- **Proper technique to minimize likelihood of spills and staff knowledgeable of proper spill response**
- **Surveys are conducted in accordance with 10 CFR 20.1501 and 10 CFR 35.70 (as applicable)**

# Unsealed Byproduct Material

## 10 CFR 35.100-200

- ensure that the RSO exercises proper oversight of the program and has the authority to do so (i.e., management support); and
- ensure that the program is reviewed at least once each year for content and implementation

# Unsealed Byproduct Material

## 10 CFR 35.100-200

- **Dose calibrator calibration in accordance with nationally recognized standards or the manufacturer's instructions (e.g. daily constancy, quarterly linearity over the range of activities used, annual accuracy over the range of energies administered, and initial geometrical variance for all configurations used).**

# Unsealed Byproduct Material

## 10 CFR 30.300

- **Written Directive Required**
- **Large quantities of radioactive material used**
- **Fewer administrations than 10 CFR 35.100 and 200 activities**

# Unsealed Byproduct Material

## 10 CFR 30.300

- **Written directive:**
- **A document(s) that must be generated prior to an administration if an authorized user wants administer iodine-131 greater than 30 microcuries or any therapeutic dose of unsealed byproduct material.**

# Unsealed Byproduct Material

## 10 CFR 35.300

### Hazard Analysis

- **Some Radionuclides**
  - **Iodine-131 (I-131) (thyroid diseases)**
  - **Phosphorus-32 (P-32) (rare use, for bone marrow, and cavity cysts/tumors)**
  - **Strontium-89 (Sr-89) (bone pain)**
  - **Samarium-153 (Sm-153) (bone pain)**
  
- **Relative Hazard - High**

# Unsealed Byproduct Material

## 10 CFR 35.300

- **Radionuclide half-lives of days to weeks; and are intended to deliver high doses/dose rates with a high specific activity. Single dosages can include hundreds of millicuries.**
- **The dose thresholds for “medical event” can be easily exceeded due to errors.**
- **Spill clean up could result in significantly higher doses, especially from intakes of volatile materials.**
- **Loss of a unit dosage quantity can pose a radiological hazard to members of the public.**

# Unsealed Byproduct Material

## 10 CFR 35.300

- **Inspection guidance for therapeutic nuclear medicine is the same as diagnostic activities, plus:**
  - **Selected written directives contain the required information (patient name, nuclide, form, amount, AU sign and dated)**
  - **Staff understands the procedures for administering radiopharmaceuticals requiring a written directive (verifying patient identification, verifying that the dosage is administered in accordance with the written directive)**



# Thyroid Ablation



# Unsealed Byproduct Material

## 10 CFR 35.300

- **Patients are released under 10 CFR 35.75 (calculations and methodologies)**
- **Staff who care for patients hospitalized under 10 CFR 35.75 are properly trained (e.g., patient and visitor control, contamination control, waste control, medical emergency/death response).**
- **Patients hospitalized under 10 CFR 35.75 are provided with private facilities**
- **Waste generated by patients hospitalized under 10 CFR 35.75 is handled as radwaste**

# Unsealed Byproduct Material

## 10 CFR 35.300

- **Licensee assessment of internal dose:**
  - **Bioassays are performed at the appropriate frequency**
  - **Bioassay results are compared to established and appropriate administrative action levels.**
  - **Action plans are available and implemented if administrative action levels are exceeded.**

# Unsealed Byproduct Material

## 10 CFR 35.300

- **Proper radioactive waste storage:**
  - **Packaged, labeled, and contained**
  - **Licensee maintains radioactive waste inventory.**
  - **Secure storage area.**

# Manual Brachytherapy

## 10 CFR 35.400

- **Sealed sources using high activity to treat cancer**
- **Complicated Treatment Planning – take your time inspecting**

# Manual Brachytherapy

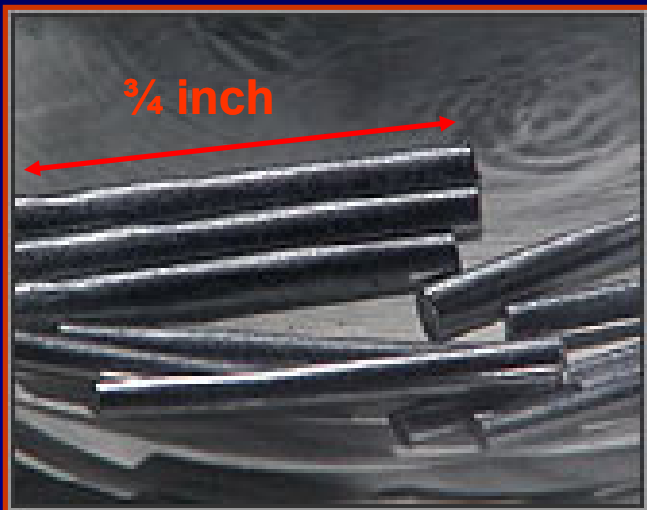
## 10 CFR 35.400

### Hazard Analysis

#### ➤ Modalities:

- **Manually Afterloaded Brachytherapy**
  - **Cesium-137 (Cs-137) “tube” sources**
  - **Iridium-192 (Ir-192) seeds in nylon ribbon**
  - **Paladium-103 (Pd-103) seeds**
  - **Iodine-125 (I-125) seeds**
- **Remotely Afterloaded Brachytherapy (10 CFR 35.600)**
  - **Ir-192 (HDR)**

# Low Dose Rate Source



## <sup>137</sup>Cs Tube Sources

- Compatible with most vaginal and cervical applicators
- Outer shell permanently marked with serial number and isotope
- Easily stored in most shielded safes and containers

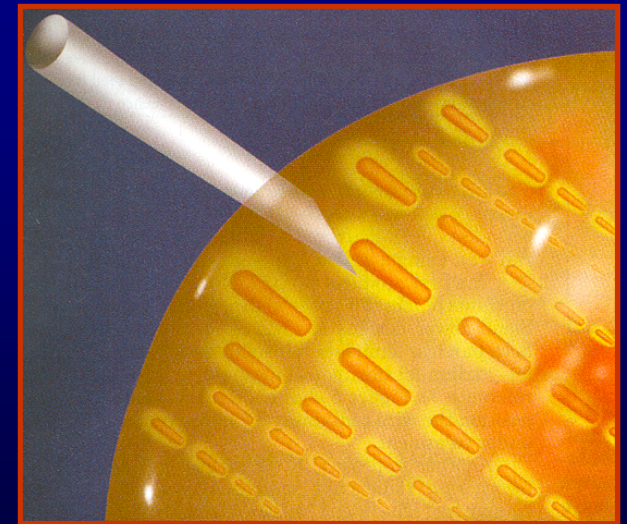
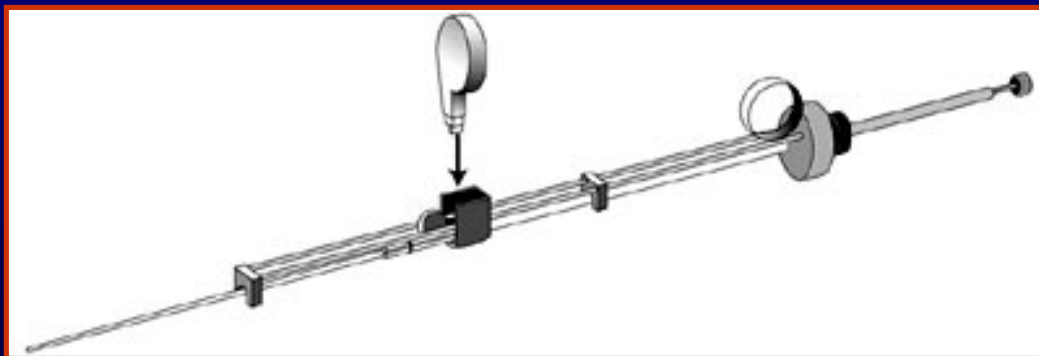
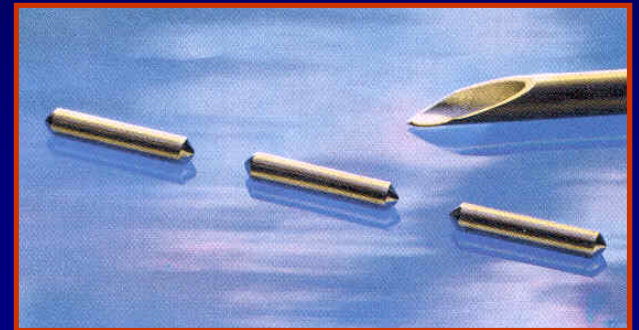
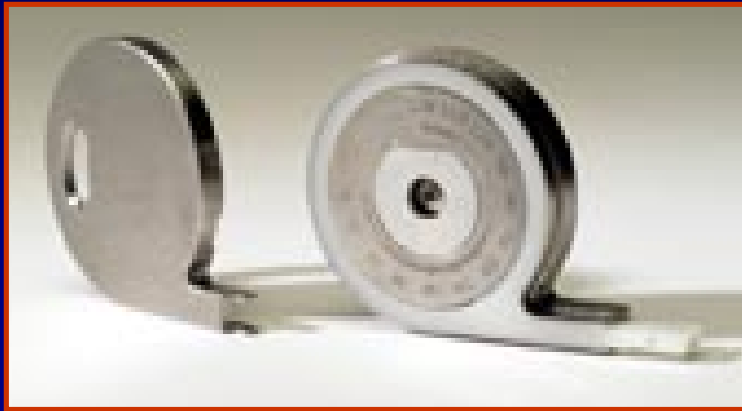
SPECIFICATIONS		Capsule wall thickness	0.92 mm
Active length	15.6 mm	Initial calibration accuracy	± 2.0%
Active diameter	0.8 mm	Linear activity uniformity	2.0% dev.
Total length	20.3 mm	Maximum Non-Removable contamination	<5x10 <sup>-9</sup> Ci
Total diameter	2.65 mm		

# Applicators

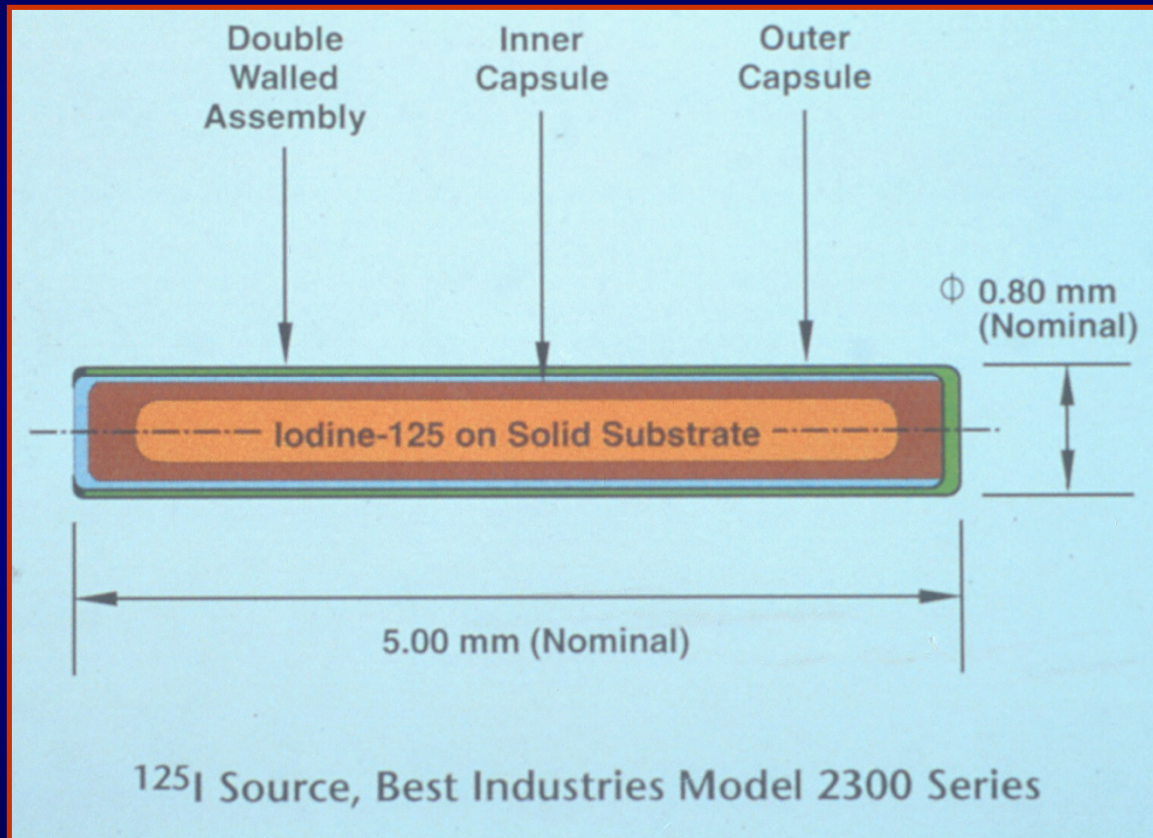




# Seeds



# I-125 Seed



**Small seeds  
can be  
crushed or  
broken**

# Needles



Yellow Hub  
18 Gauge  
MTP-1820-C

Blue Hub  
17 Gauge  
MTP-1720-C

The "sharpest" and  
"smoothest"  
Mick TP Needle  
available today!

# Wires



Continuous Wire

Single-Leg Hairpin

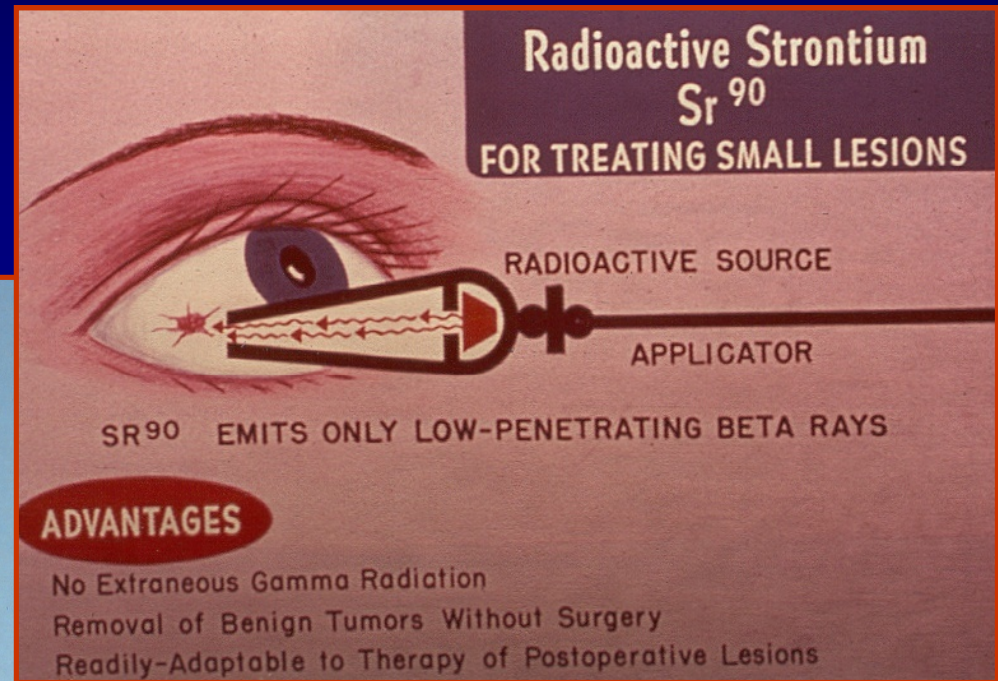
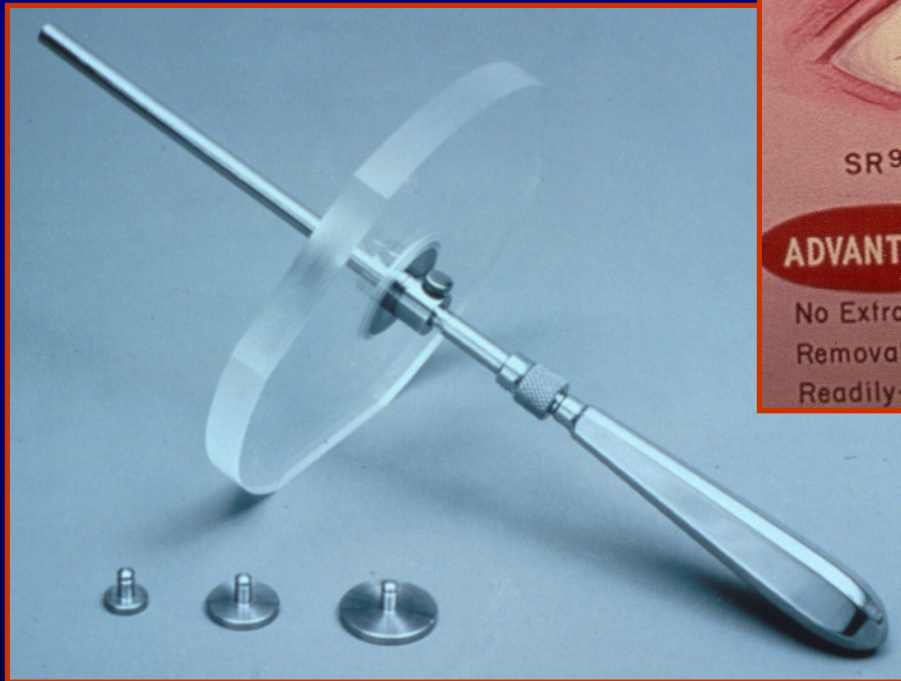
Double-Leg Hairpin

## 192 Iridium Wires

- Uniform quality with reliable calibration
- Usable throughout entire active life
- Individually packaged in lead shielded containers
- Compatible with *all* currently used interstitial implant accessories

**Not commonly used in current treatment programs**

# Strontium-90 Beta Eye Applicator



# Strontium-90 Beta Eye Applicator

**Verify licensee possesses and uses a certificate of calibration, or data from manufacturer-supplied source identification plate**

**Certificates of calibration supplied by manufacturer/vendor or calibration laboratory with established traceability to the NIST for performing Sr-90 ophthalmic applicator calibrations**

# Strontium-90 Beta Eye Applicator

**Certificate of calibration or source identification plate, must match, by source serial number, the source for which its data are being used.**

**Determine if source output (dose rate) is being properly corrected for source decay (T1/2 is 29.1 years).**

# Strontium-90 Beta Eye Applicator

**Sample records of exposure times to verify that the calculated administered doses correspond to the prescribed doses.**

**Verify leak tests at intervals not exceeding 6 months or other approved intervals**

**Survey source storage area**



# Sr-90 Eye Applicator Typical Storage Boxes



# Sr-90 Eye Applicator in Storage Box



# Sr-90 Eye Applicator



(reversed for legibility)

# Manual Brachytherapy

## 10 CFR 35.400

- **Hazards - High.**
  - **Half-lives of days to years; intended to deliver relatively high doses in a short time with a small source. Single sources can range from microcuries (Pd-103 & I-125) to curies (Ir-192 HDR).**
  - **Medical events (10 CFR 35.2) can occur if the sources are mispositioned and/or applied for too long or short of a time**

# Manual Brachytherapy

## 10 CFR 35.400

- **The hazards to workers are dependent on the source/device.**
  - **For single sources, workers must use forceps during handling. Sources should only be handled behind shielding.**
  - **For HDR devices, the hazards to workers are greatly reduced, provided that the devices function properly and they are used as designed.**

# Manual Brachytherapy

## 10 CFR 35.400

- **Key concerns with individual sources is control:**
  - **small size, especially Pd and I seeds**
  - **dose rates vary - most individual seeds are <1 millirem/hour at one meter, but some sources generate a few millirem per hour at one meter - in comparison, a new HDR source can generate more than 5 R/hr at one meter**

# Manual Brachytherapy

## 10 CFR 35.400

- **Inspection guidance for sealed source implant therapy:**
  - **Selected written directives contain the required information**

# Manual Brachytherapy

## 10 CFR 35.400

- **Staff understands the procedures for administering sealed source implant therapy**
  - **verifying patient identification**
  - **verifying that the administration is in accordance with the treatment plan/written directive (e.g., for cesium-137 implants, how do the staff verify the loading sequence of sources?)**



# Manual Brachytherapy

## 10 CFR 35.400

- **checking both manual and computer-generated dose calculations**
- **verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units (e.g., HDR)**
- **Patients are released in accordance with 10 CFR 35.75 and that associated calculations and methodologies are reasonable (e.g., permanent implants)**

# Manual Brachytherapy

## 10 CFR 35.400

- **Patient care staff who attend to patients hospitalized in accordance with 10 CFR 35.75 are properly trained (e.g., size and appearance of sources, safe handling and shielding of sources, patient and visitor control, and medical emergency/death response) (Review responses to such emergencies)**
- **Verify source inventory for individual sources and the radiation levels in and adjacent to the source storage room**
- **Verify access control to source storage room**
- **Verify that sources are calibrated**

# Manual Brachytherapy

## 10 CFR 35.400

- **Survey instruments:**
  - **Should be adequate for the types of radiation involved**
  - **Should be operational (i.e., it passes the battery check and it responds appropriately to radiation (compared to inspector's instrument))**
  - **Should be calibrated as required**

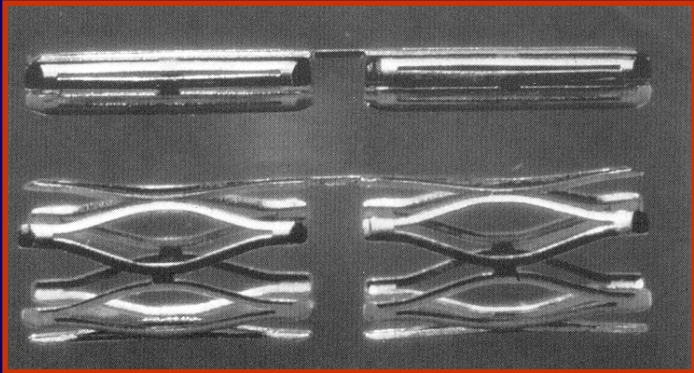
# Manual Brachytherapy

## 10 CFR 35.400

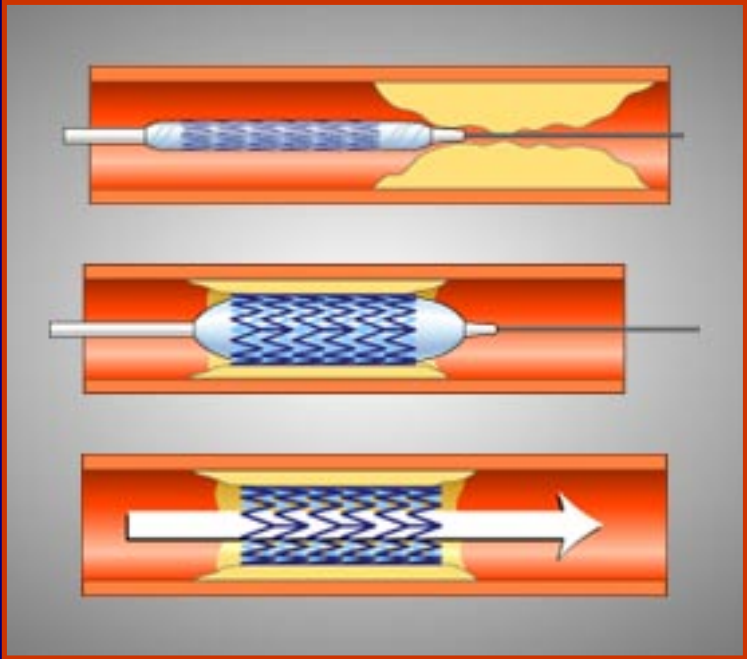
- **Waste disposal:**
  - **Sources are transferred to an authorized person**
  - **Source exchanges are conducted by authorized persons**
  - **Sources are properly prepared for shipment**

# Stents Using Beta Radiation

Before Expansion



After Expansion



# Manual Brachytherapy

## 10 CFR 35.400

- Evaluate how the staff would respond to emergency situations (e.g., patient medical emergency during treatment, source retraction failure, treatment interruption)
- Review previous response to emergencies
- Determine if the RSC is involved with sealed source implant therapy (e.g., events, audits)

# Sealed Sources for Diagnosis

## 10 CFR 35.500

- **Not common in today's medical institutions**
- **Replaced by X-ray units capable of similar measurements**

# Sealed Sources for Diagnosis

## 10 CFR 35.500



Gd-153 for  
bone mineral density  
study (osteoporosis)

I-125 for a  
“quick x-ray”





# Photon Emitting Units

## 10 CFR 35.600

- **Consists of:**
  - **Remote Afterloader Units (HDR's)**
  - **Gamma Stereotactic Radiosurgery units (Gamma Knife)**
  - **Teletherapy Units**

# Photon Emitting Units

## 10 CFR 35.600

- **For HDR:**
  - **Review device safety checks, including response to failed checks (e.g., interlock failure, emergency stop failure, radiation monitor failure)**
  - **Review previous response to failed operability checks**
  - **Verify that device maintenance and service is conducted by authorized persons**

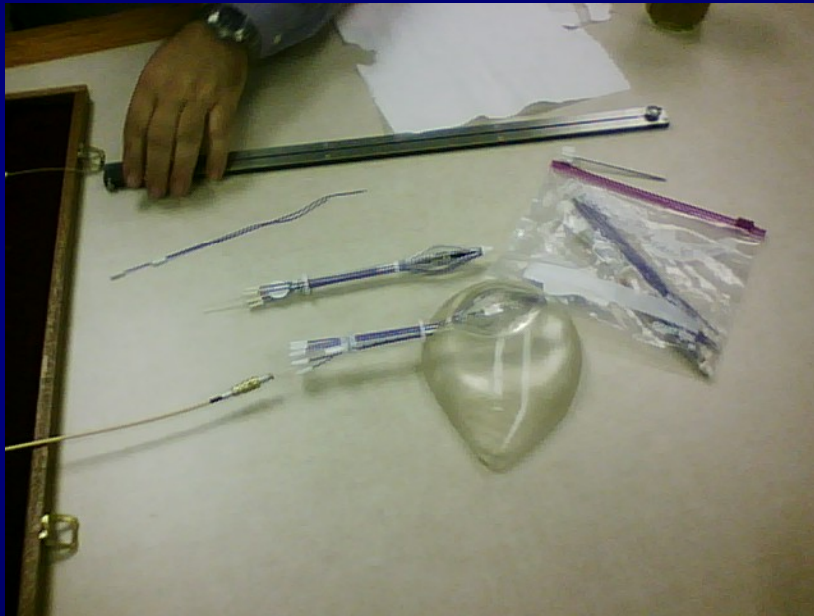
# High Dose Remote Afterloading (HDR)



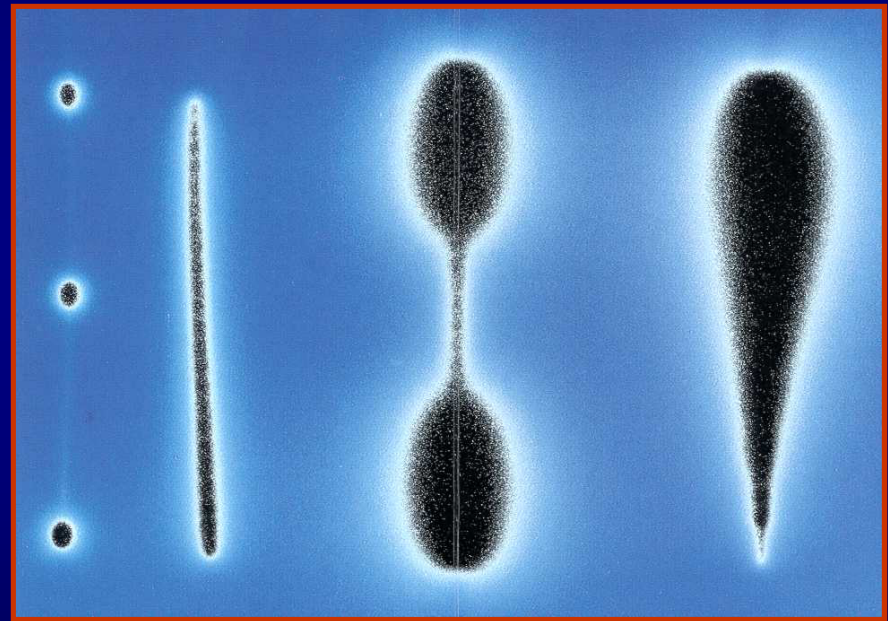
**Source travels from unit,  
through catheter  
(plastic guide tube)  
into patient**

# HDR Source

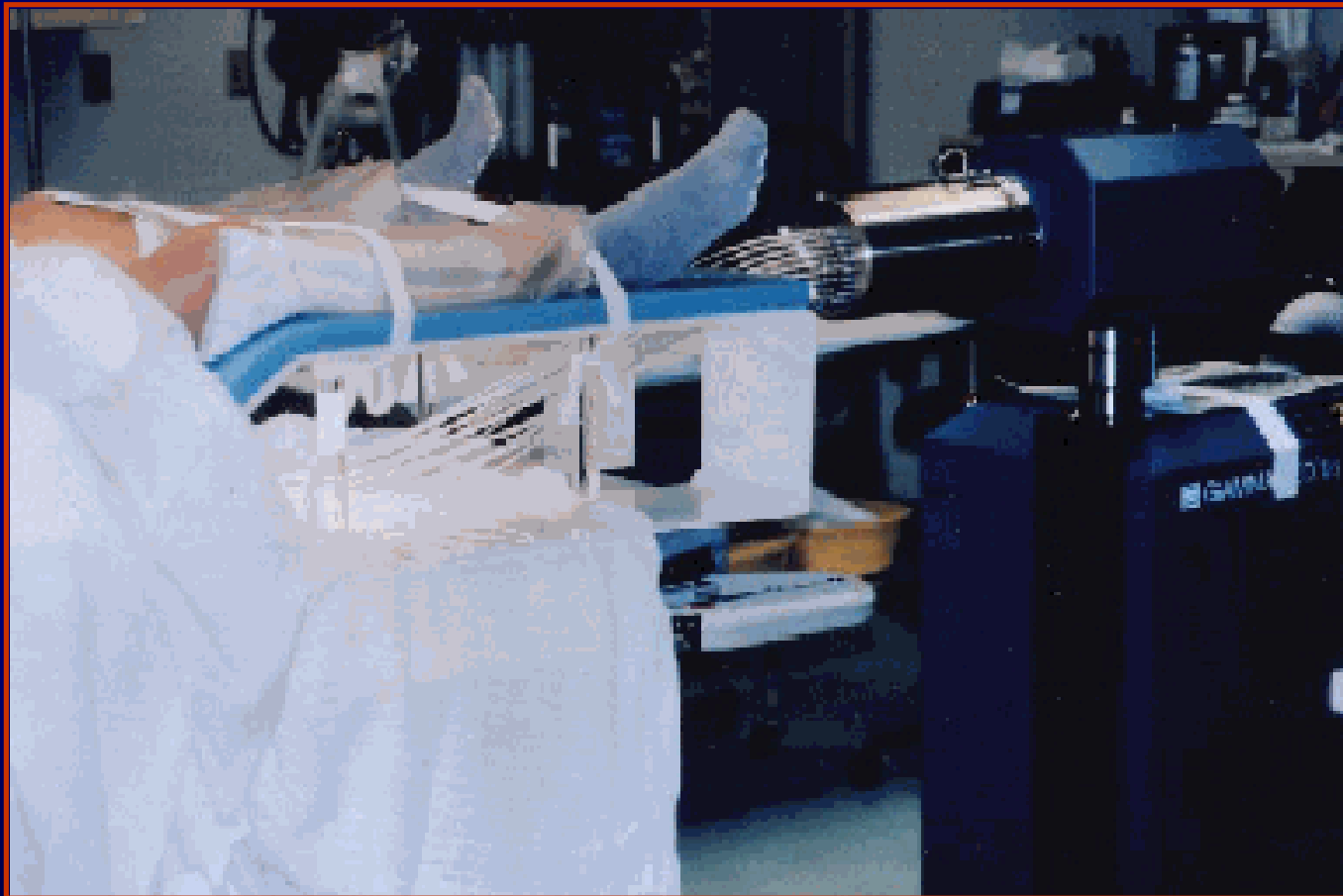
## Breast Applicator



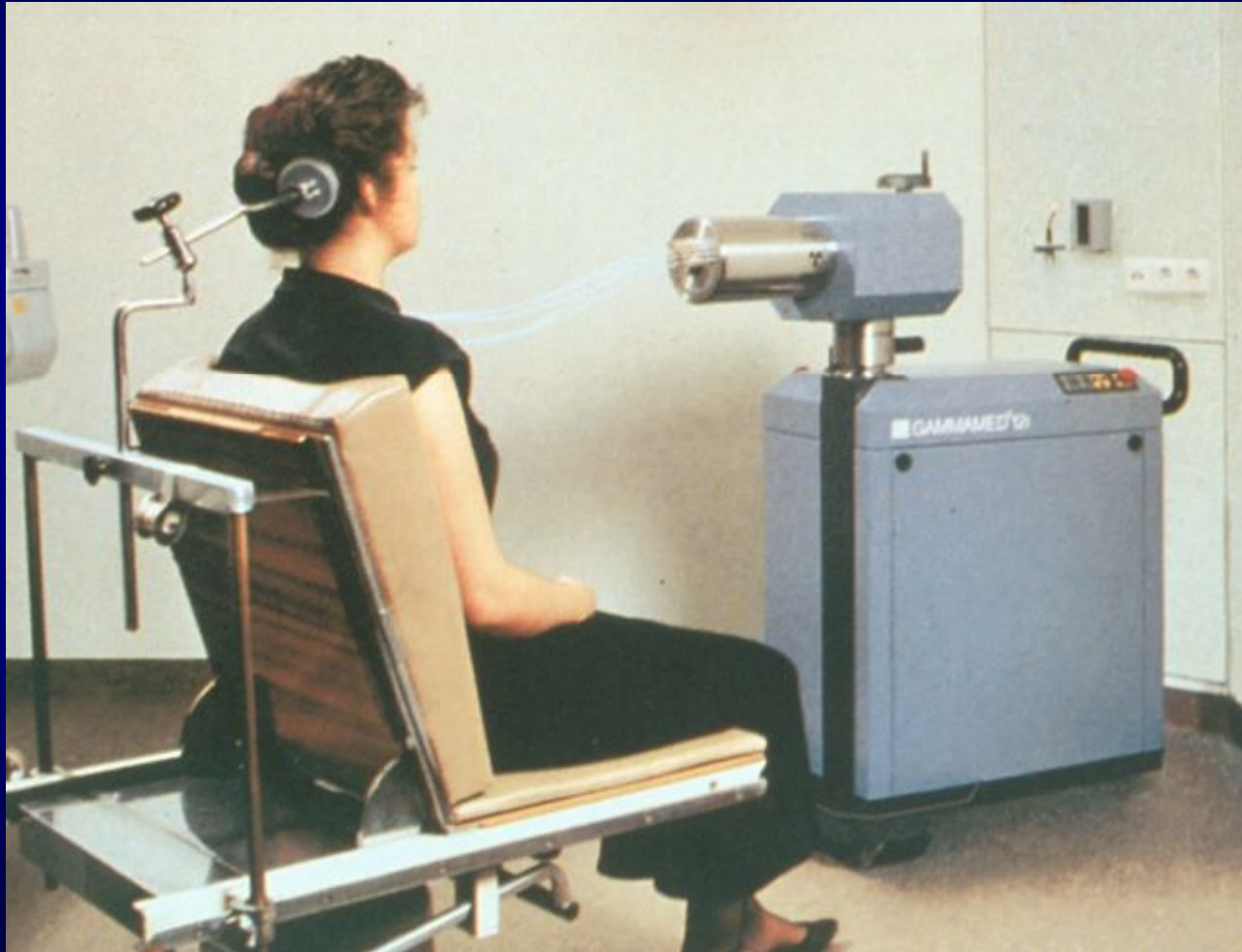
## Effect of Different Dwell Times



# Prostate HDR



# HDR Breast Treatment



# HDR Video Clip

- <http://www.cancercenter.com/video/treatments-technology/radiation-therapy/brachytherapy>

# High Dose Remote Afterloading (HDR)

- Patient release surveys
- Observe spot checks



# High Dose Remote Afterloading (HDR)

- **Written directives**
- **Associated procedures**
- **Review selected patient cases including, as applicable, simulation images, treatment planning records (e.g., is dose curves), and pre- and post-treatment HDR unit printouts to compare planned and implemented treatment actions**

# High Dose Remote Afterloading (HDR)

- **10 CFR 35.41: Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 10 CFR 35.600**

# High Dose Remote Afterloading (HDR)

- **Observe the licensee conduct or demonstrate how treatment planning and administration is conducted**
- **What is done to verify that the treatment is in accordance with the written directive/treatment plan before administration?**

# High Dose Remote Afterloading (HDR)

- **What is done to verify that the administered treatment was in accordance with the written directive/treatment plan?**

# Photon Emitting Units

## 10 CFR 35.600

### Hazard Analysis

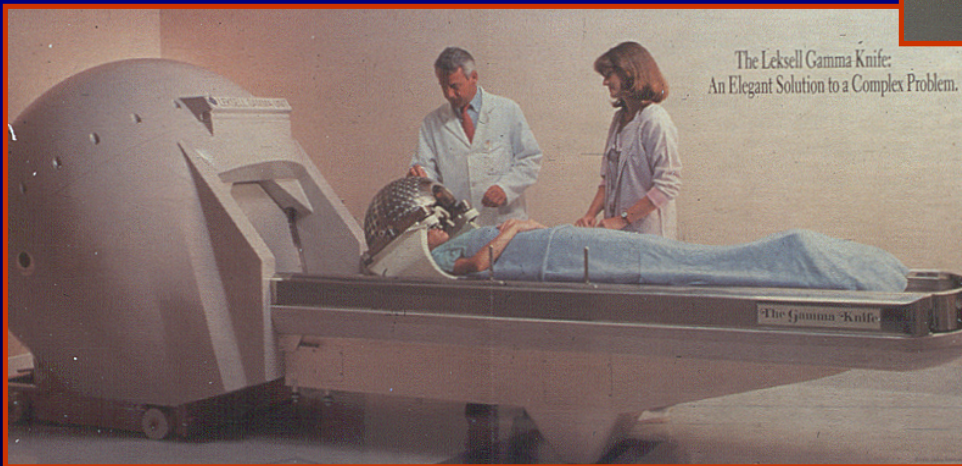
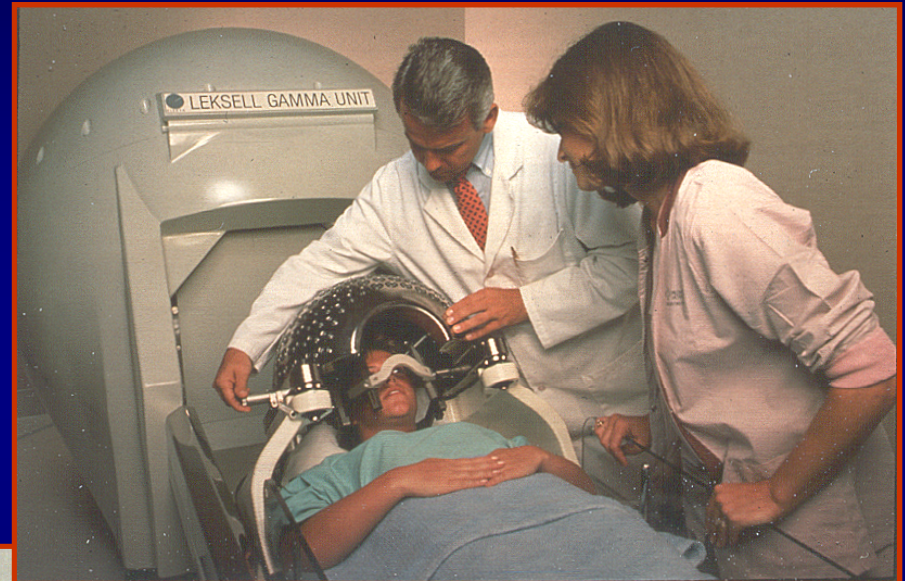
#### ➤ Modality

- **Gamma Stereotactic Radiosurgery (e.g. Gamma Knife)**
  - **~201 cobalt-60 sources in a hemispherical array, intersect to create a very high dose rate to a small volume, and the dose rate is significantly reduced outside of the small volume**

# Gamma Stereotactic Radiosurgery



**201 Co-60  
sources  
about  
33 Curies  
each**



The Leksell Gamma Knife:  
An Elegant Solution to a Complex Problem.

**Gamma  
Knife**



# Gamma Knife



# Gamma Knife





# Gamma Knife Head Set



# Gamma Knife Video

- [www.radonc.jhmi.edu/radiosurgery/gammaknife/Gamma\\_Knife\\_Surgery\\_dsl.mov](http://www.radonc.jhmi.edu/radiosurgery/gammaknife/Gamma_Knife_Surgery_dsl.mov)

# Gamma Knife



# Photon Emitting Units

## 10 CFR 35.600

- **Patient positioned on a couch and the treatment site is positioned in the small volume (i.e., the patient moves rather than the sources)**
- **Treatment parameters include coordinates (x,y,z), gamma angle (tilt of head), helmet size, and time**
- **Frame fixed to patient's head (screws into skull), and images (CT and MRI) are taken for treatment planning**

# Photon Emitting Units

## 10 CFR 35.600

### ➤ Hazards - Low

- The sources are fixed in device. Loss is not a credible concern
- The dose to workers is minimal because they are not exposed to unshielded sources. The typical ambient dose rate in the treatment room is  $<0.5$  mrem/hour, and there are no staff in the room during treatment
- There is no real potential for public dose

# Photon Emitting Units

## 10 CFR 35.600

- **The main concern is medical events. Previous medical events involved:**
  - **using wrong treatment plan**
  - **wrong treatment site (e.g., transposing coordinates)**
  - **not verifying treatment time**
- **There is a small margin for error with GSR (e.g., treatment time and patient position accuracy), so focus on verification of treatment time and patient position accuracy**

# Photon Emitting Units

## 10 CFR 35.600

- **Inspection guidance for gamma stereotactic radiosurgery:**
  - **Selected written directives contain the required information**
  - **Staff understands the procedures for administering gamma stereotactic radiosurgery**
    - **verifying patient identification**

# Photon Emitting Units

## 10 CFR 35.600

- **verifying that the administration is in accordance with the treatment plan/written directive (e.g., verifying that the coordinates, gamma angle, helmet size, and treatment time are accurate for each “shot”)**
- **checking both manual and computer-generated dose calculations**
- **verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units**



# Photon Emitting Units

## 10 CFR 35.600

### Things to Consider:

- Is GSR X, Y, and Z hardware labeled properly?
- Is fiducial box properly positioned on the stereotactic frame prior to imaging?
- Is fiducial box marked legibly

# Photon Emitting Units

## 10 CFR 35.600

- **Did licensee verify that configuration files were not corrupted by following service?**
- **Does licensee prevent equipment interference?**

# Photon Emitting Units

## 10 CFR 35.600

### 35.615 Safety precautions

**A licensee shall control access to the treatment room by a door at each entrance.**

# Photon Emitting Units

## 10 CFR 35.600

### 35.615 Safety precautions

**Use appropriate radiation monitors when entering the treatment room to assure that radiation levels have returned to ambient levels.**

**Use viewing and intercom systems to permit continuous observation of patient**  
**patient**

# Photon Emitting Units

## 10 CFR 35.600

### 35.615 Safety precautions

**For GSR, must have an authorized user and an authorized medical physicist to be physically present throughout all patient treatments.**

**Notify RSO and an authorized user as ASAP if patient has a medical emergency or dies.**

# Photon Emitting Units

## 10 CFR 35.600

### 35.615 Safety precautions

**Shall have applicable emergency response equipment available near each treatment room to respond to a source remaining in the unshielded position;**

# Photon Emitting Units

## 10 CFR 35.600

### 35.645 Spot-checks for GSR

**Must be done monthly; before the first use of the unit on a given day; and after each source installation.**

**Assure proper operation of –  
Treatment table retraction mechanism,  
using backup battery power or  
hydraulic backups with the unit off;**

# Photon Emitting Units

## 10 CFR 35.600

### 35.645 Spot-checks for GSR

- **Electrical interlocks at each room entrance;**
- **Source exposure indicator lights on the GSR unit, the control console, and in the facility;**
- **Viewing and intercom systems;**



# Photon Emitting Units

## 10 CFR 35.600

### 35.645 Spot-checks for GSR

- **Timer termination;**
- **Radiation monitors used to indicate room exposures; and**
- **Emergency off buttons.**

# Photon Emitting Units

## 10 CFR 35.600

- **Review licensee response to failed checks (e.g., interlock failure, emergency stop failure, radiation monitor failure)**
- **Review previous response to equipment malfunctions (potential medical event, overexposure )**
- **Review treatments that did not go according to plan (potential medical event, overexposure )**

# Photon Emitting Units

## 10 CFR 35.600

### Survey instruments:

- **Should be adequate for the type of radiation**
- **Should be operational**
- **Should be calibrated as required (annually)**

# Photon Emitting Units

## 10 CFR 35.600

### Servicing the unit:

- If the next source exchange is scheduled, discuss it with licensee and regional management for the opportunity to conduct a special inspection.
- Verify if the source exchange and device maintenance are conducted by authorized persons.

# Photon Emitting Units

## 10 CFR 35.600

- **Verify that the sources transferred to an authorized person**
- **Verify that sources properly prepared for shipment**

# Photon Emitting Units

## 10 CFR 35.600

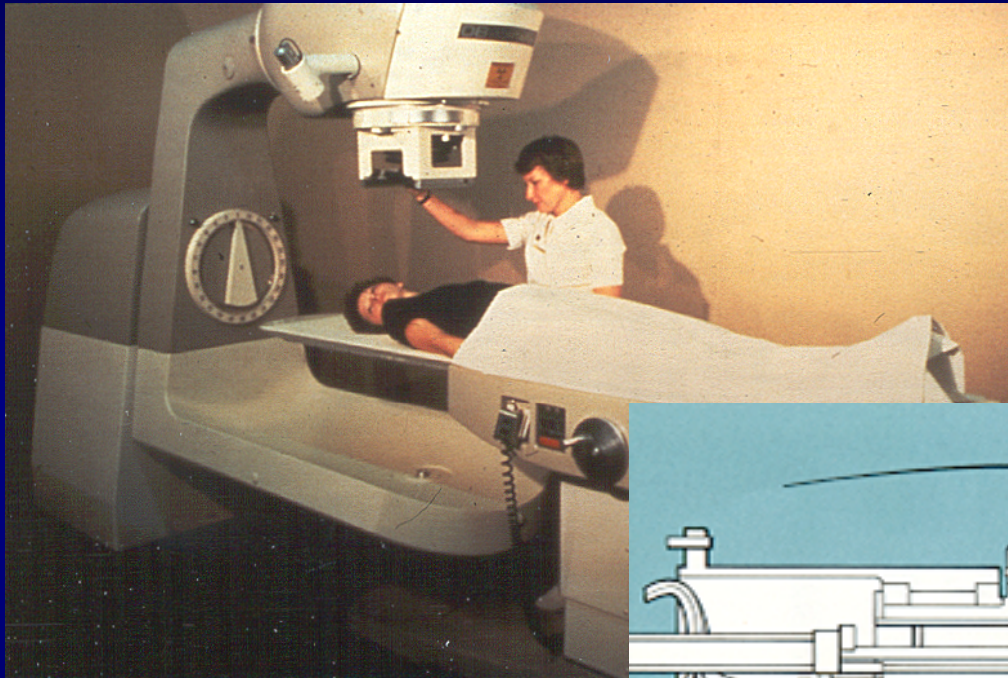
- Evaluate how the staff would respond to emergency situations (e.g., patient medical emergency during treatment, source shielding failure, treatment interruption)
- Review previous response to emergencies
- Verify that the sources are calibrated

# Teletherapy

## Teletherapy Modality (Few Remain)

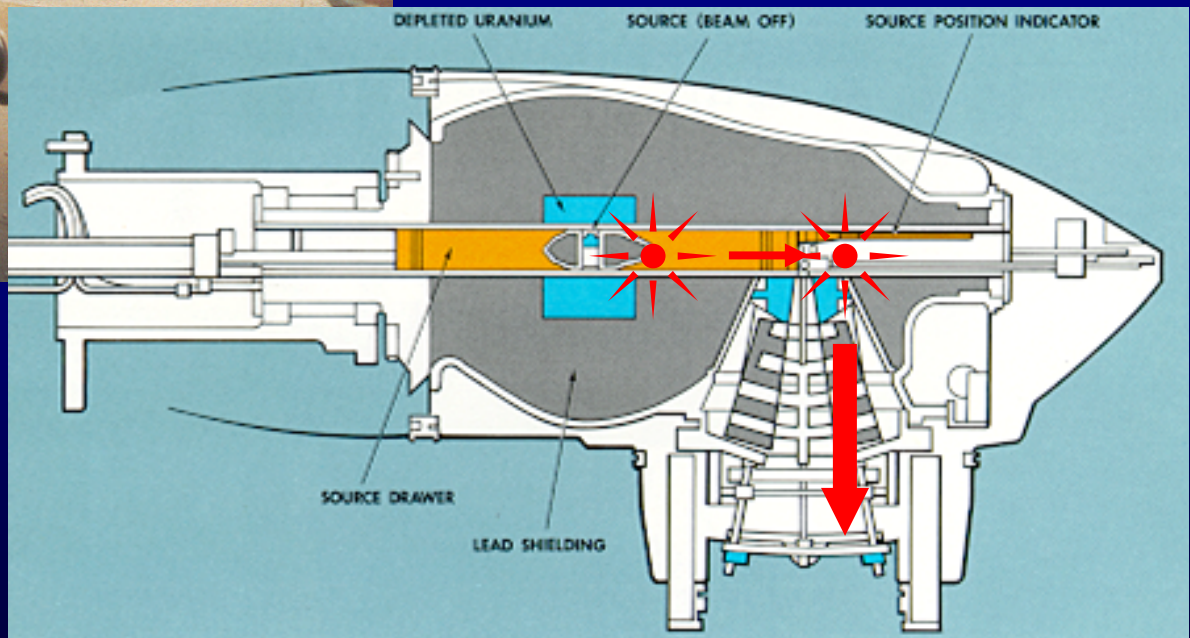
- **1 cobalt-60 source, typically 3,000 to 10,000 curies**
- **Patient positioned on table and source gantry rotates around patient. Can be either fixed position(s) or rotational treatment**

# Teletherapy



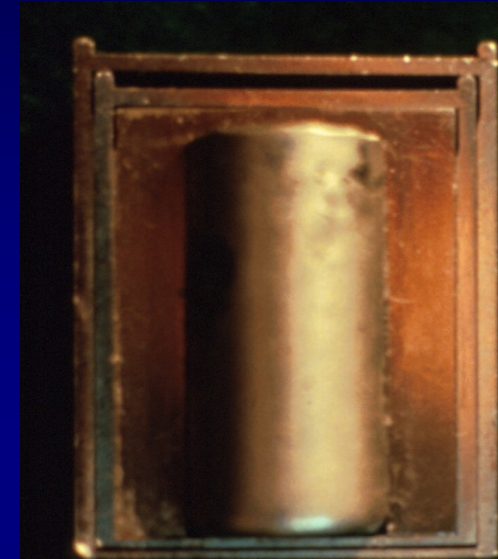
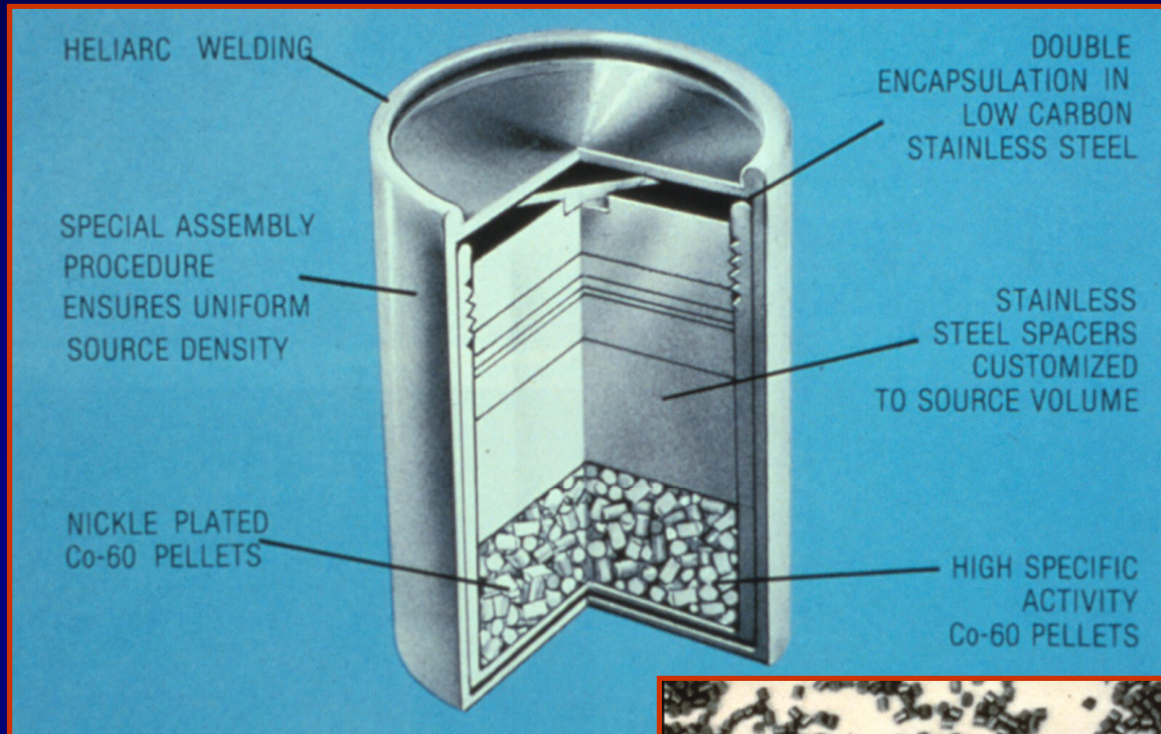
**Unit**

**Source Head**



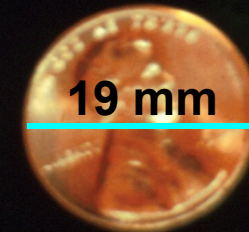
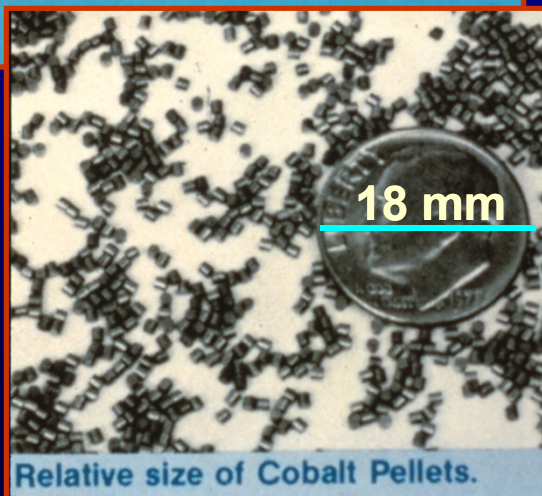


# Teletherapy Source

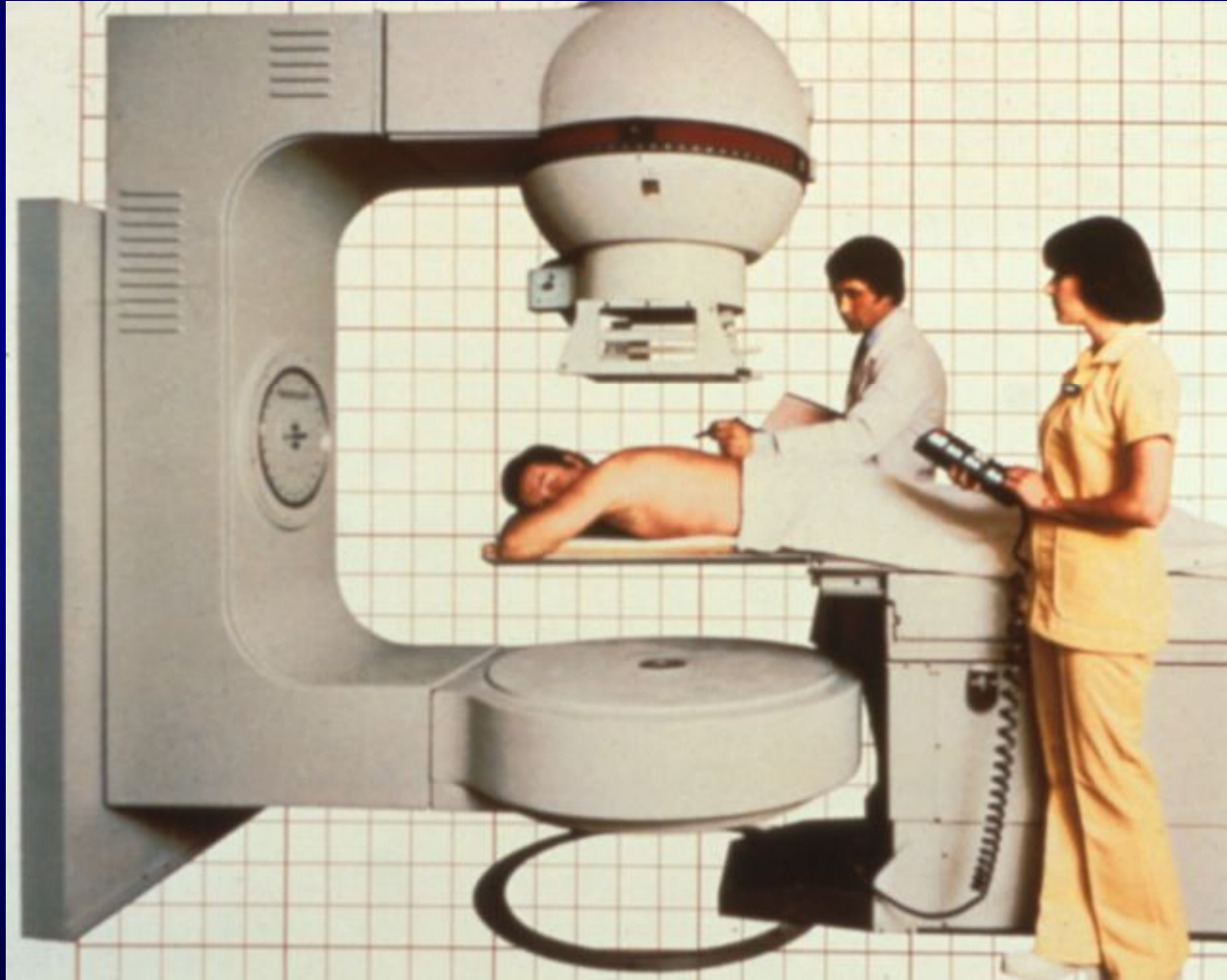


**Capsule**  
(~ 6,000 Ci)

**Cobalt-60 Pellets**



# Picker Teletherapy Unit



# Other Medical Uses

## 10 CFR 35.1000

- **Focus on the new therapeutic procedures/ modalities**
- **Follow the general inspection guidance provided for the most appropriate modality**
- **Take time to review the manufacturer's/distributor's operating and emergency procedures (or package insert for radiopharmaceuticals) - attempt to identify areas for potential human error or device malfunction**
- **Take time to learn**

# Plutonium Pacemaker



# Potential Pitfalls

## Medical Use Inspections

- **Avoid discussing your observations and conducting interviews with the workers during the preparation for, or delivery of medical treatment, if possible**
- **Use discretion when interviewing licensee staff in the presence of patients so that the discussions do not interfere with licensee staff administering patient care**

# Potential Pitfalls

## Medical Use Inspections

- **Do not interfere with patient care or a patient's privacy**
- **Obtain patient/physician permission before observing treatments and dose/dosage administrations**



# THE END

of the standard presentation

# Previously Identified Problems

- **Authorized user signs written directive**
- **Problem: AU not on the license**
- **What should you do?**



# Previously Identified Problems

- **During routine inventory audit, inspector found unknown source**
- **Licensee finally identified it as Ra-226**
- **What should you do?**

# Previously Identified Problems

## Medical Event:

- Licensee called in a medical event
- Three patients received burns to inner thigh due to brachytherapy source in inserted into patient
- What should you do?

# Previously Identified Problems

## Security Issue:

- Licensee left a Moly/Tc generator in an unsecured environment
- Next inspection, left a second Moly/Tc generator in an unsecured environment
- What should you do?

# Previously Identified Problems

- Licensee had a medical event involving a brachytherapy source
  - Authorized user claims all permanent seed implants were done appropriately and patients are doing well
  - NRC review of written directives show numerous seeds outside of implant area
  - What should you do?