

# Radiation Profiles

# Radiation Profile

- ❖ A radiation profile is the dose rate at specified distances from the product.
- ❖ A radiation profile may be submitted in the form of an isodose profile or an isodistance profile
  - Isodistance profiles are preferred
  - Isodose profiles are good for calculating likely doses (e.g., generally licensed devices)

# Radiation Profile (cont.)

## ❖ For Sources:

- With maximum allowable quantity of nuclide.
- On contact and at 5, 30, and 100 cm.
- In beam and at sides if applicable.

## ❖ For Devices:

- Typically rely on ANSI/HPS N43.8-2008 for all devices.
- Lecture on Prototype Testing should be consulted for information on ANSI/HPS N43.8-2008 classifications.

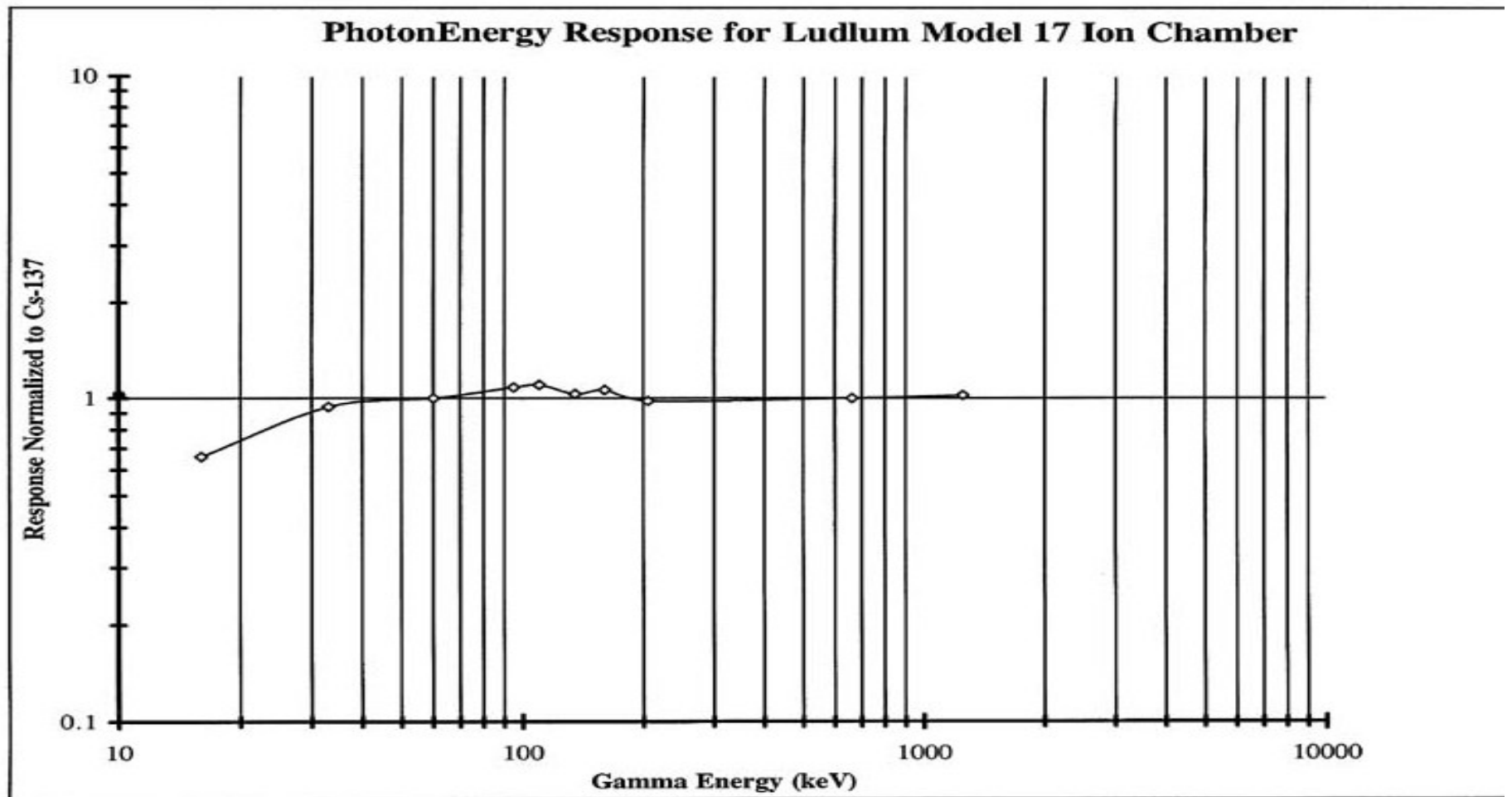
# Radiation Profile (cont.)

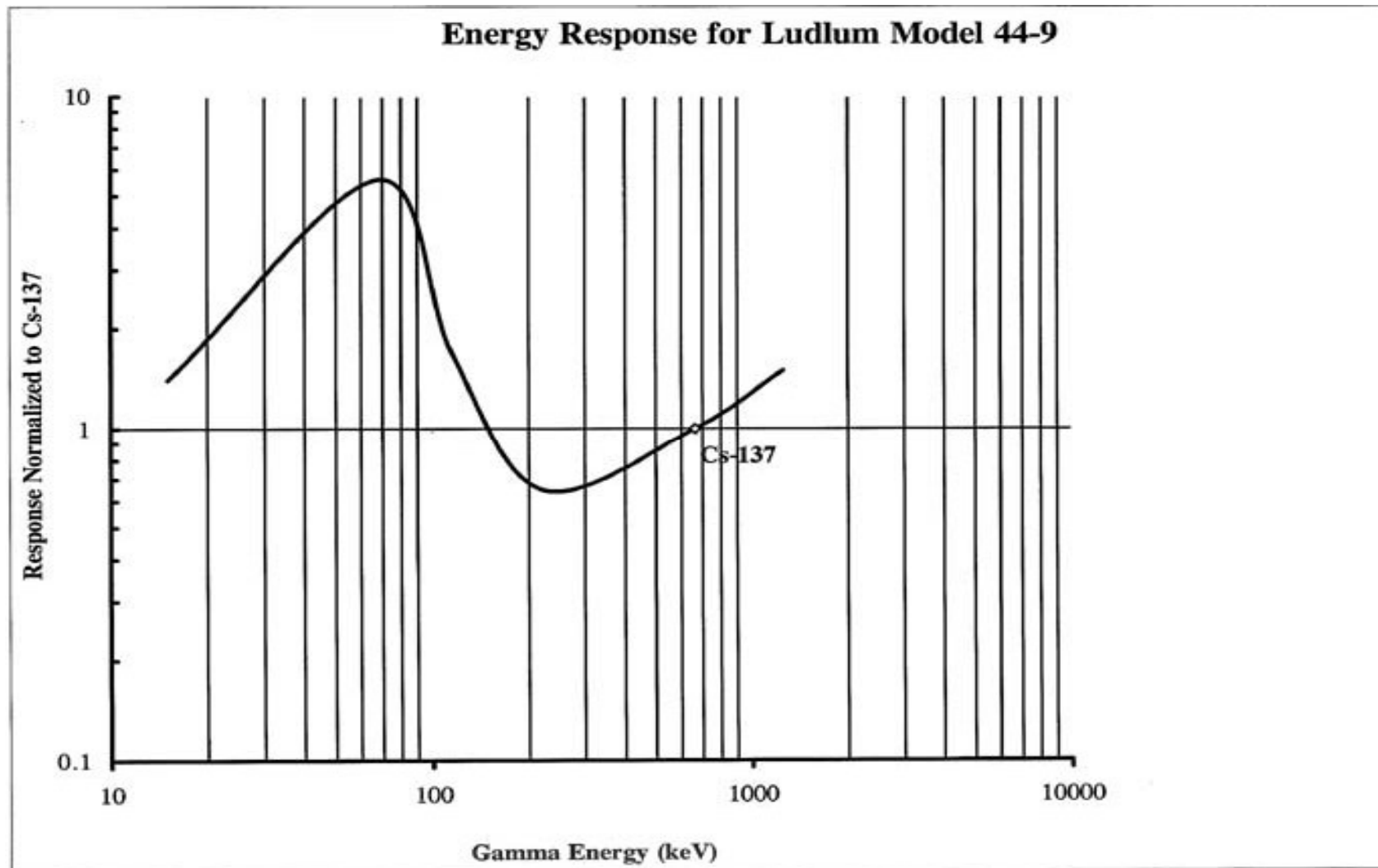
- ❖ Dose and Dose Rates:
  - Note radionuclide emission types
  - Note emission energies
  - Delivered depth dose differences?  
(7 vs 300 vs 1000 mg/cm<sup>2</sup>)

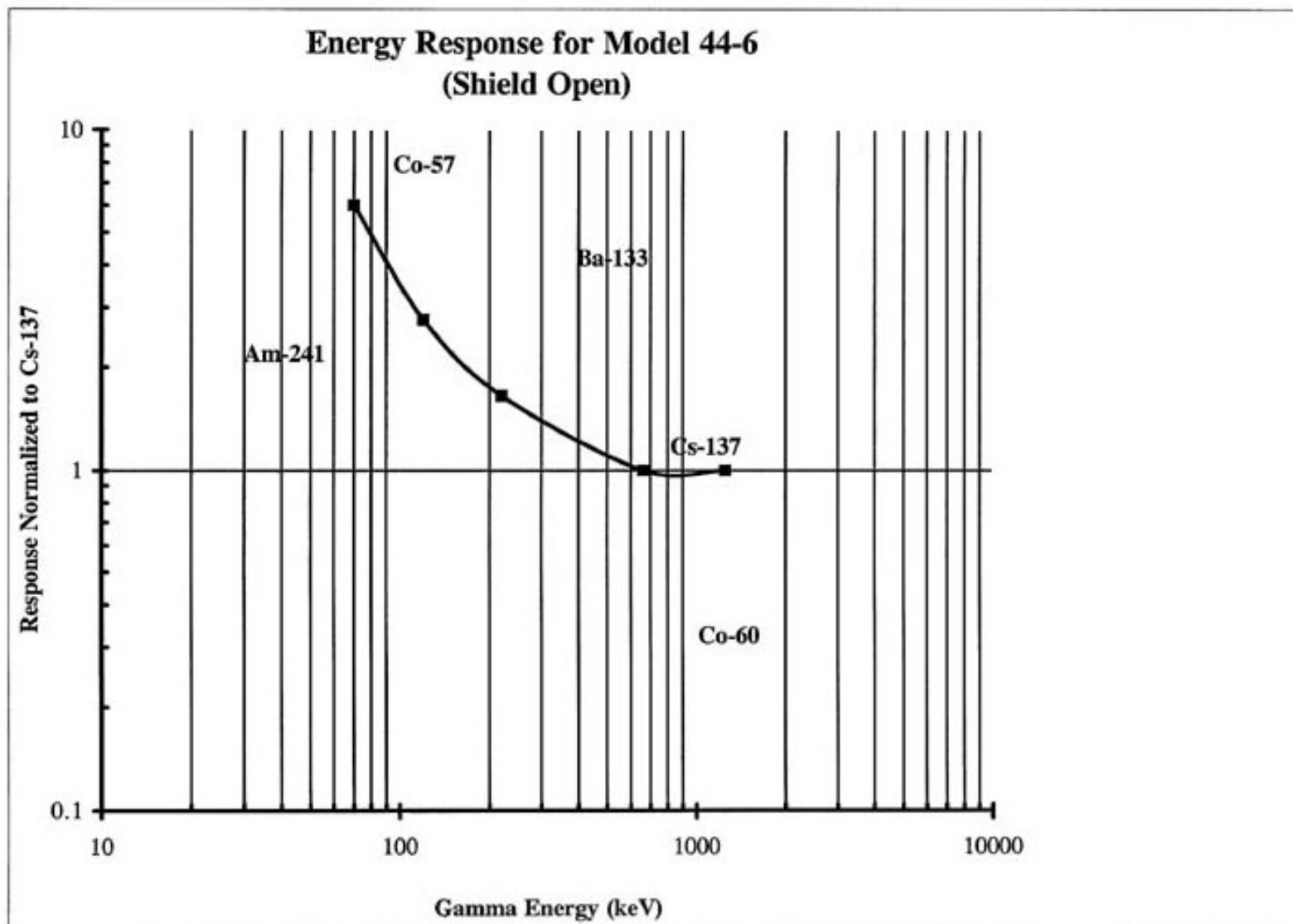
# Radiation Profile (cont.)

- ❖ Measurement instruments
  - What kind of instrument is used?
  - Is it appropriate for radiation type?
  - Are correction factors needed?

# Relative Response Curves

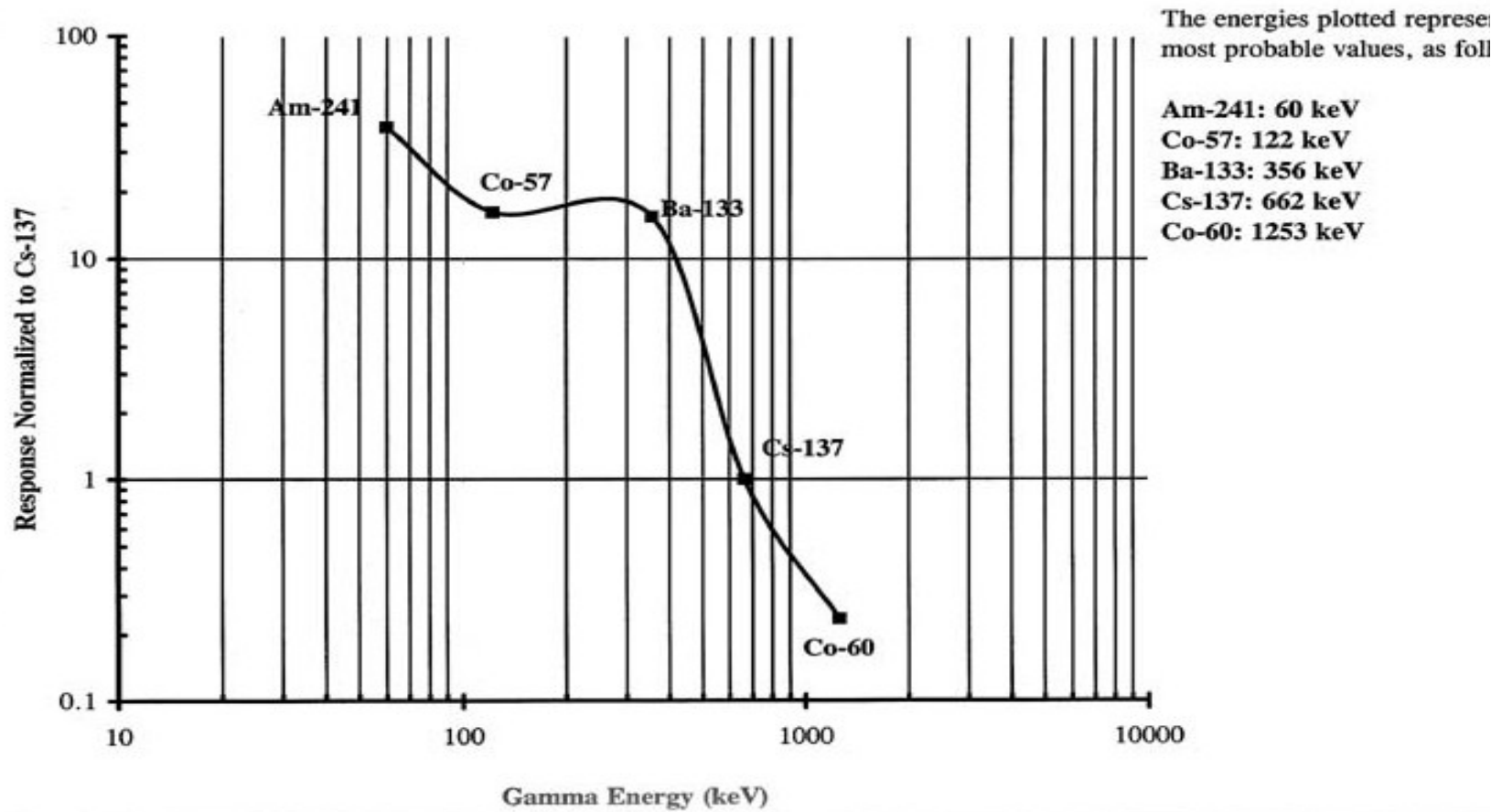






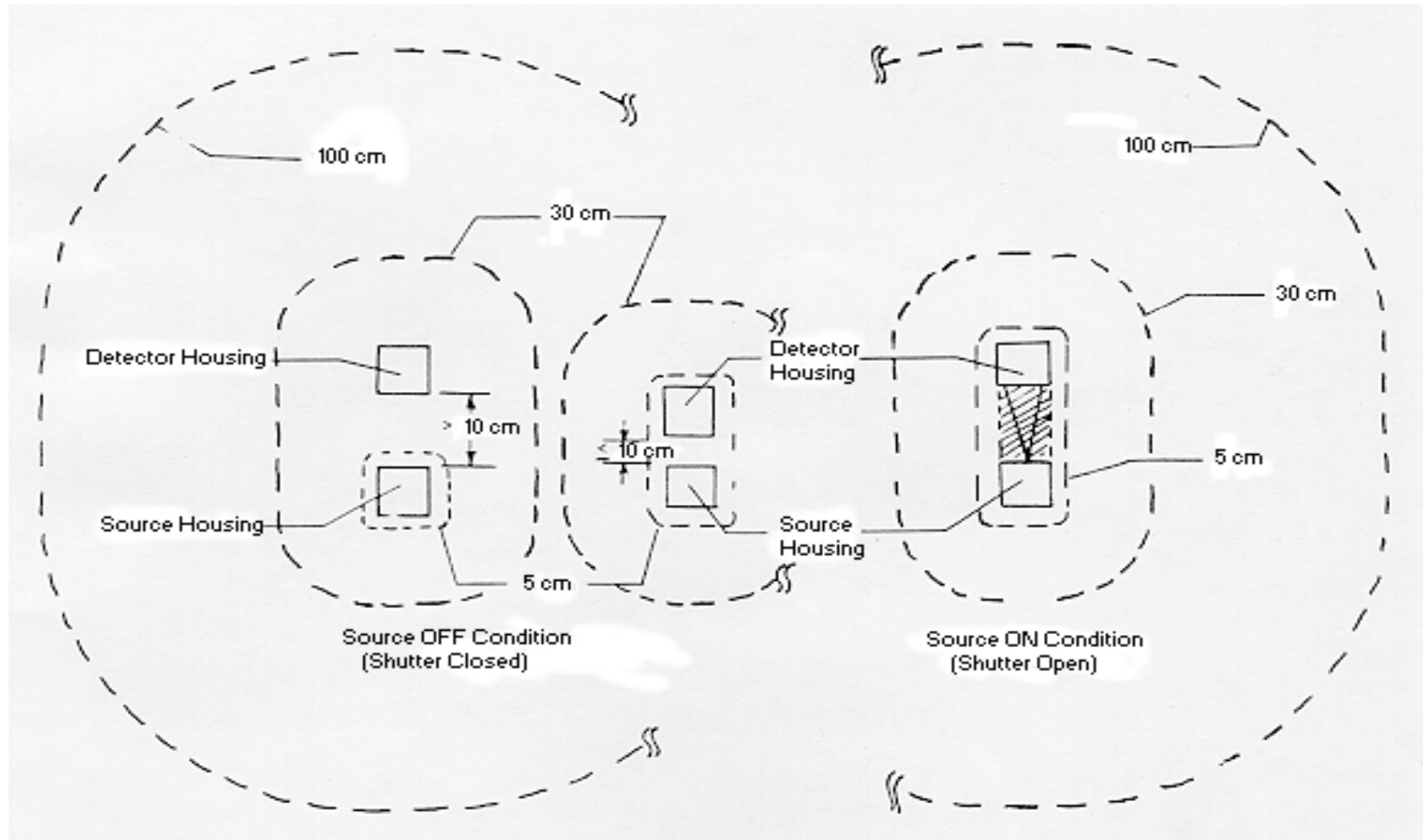


### Energy Response for Model 44-21



# Radiation Profile (cont.)

## Isodistance contours from ANSI/HPS N43.8-2008



# Maximum Radiation Dose Rate

- ❖ Sources?
- ❖ Specifically Licensed Devices?
- ❖ Generally Licensed Devices?
- ❖ Exempt Products?

# Maximum Radiation Dose Rate Standards

- ❖ Sources? -- none
  - desired dose rates depend on use
  
- ❖ Generally Licensed Devices? – none
  - 5 mrem/hr (50  $\mu$ Sv/hr) at 12 in. (30 cm) is an industry goal
  
- ❖ Exempt Products? – no limit
  - distances are specified as 5 and 25 cm in 10 CFR 32

# Maximum Radiation Dose Rate Standards

- ❖ Specifically Licensed Devices? -
  - Limit radiography - 10 CFR 34.20 & 34.21 (for transportation purposes)
  - 5 mrem/hr (50  $\mu$ Sv/hr) at 12 in. (30 cm) is an industry goal
  - No ALARA requirements - but it is suggested at the vendor level...use in accordance with 10 CFR 20
  - Dose to the patient should be provided as a reference point in approving and licensing the product

# Maximum Radiation Dose

- ❖ Sources - 10 CFR Part 20
  - Occupational dose limits under normal conditions of use [e.g. 5 rem (0.05 Sv)/yr to workers deep dose]
- ❖ Specifically Licensed Devices - 10 CFR Part 20
  - Occupational dose limits under normal conditions of use [e.g. 5 rem (0.05 Sv)/yr deep dose to workers]

# Maximum Radiation Dose (cont.)

- ❖ Generally Licensed Devices - 10 CFR 32.51
  - 10% of occupational limits under normal conditions of use [e.g. 500 mrem (5 mSv)/yr deep dose]
  - 15 rem (0.15 Sv) accident conditions [deep dose].
  
- ❖ Exempt Products - 10 CFR 32.22(a)(2)(vi), (xiii), and (xiv), and 10 CFR 32.26(b)(6), (13), and (14)

# Applicable Regulations

## Regulations

- 10 CFR 32.22(a)(2)(vi), (xiii), and (xiv)
- 10 CFR 32.26(b)(6), (13), and (14)
- 10 CFR 32.51(a)(2)(ii) &(iii)
- 10 CFR 34.20 & 34.21

## Applicability

- 10 CFR 30.19 exemption
- 10 CFR 30.20 exemption
- General Licensed Devices
- Radiography



# Evaluating Dose Rates

- ❖ The maximum radiation dose rates, when it contains the maximum allowable quantity of each nuclide, or combination of nuclides.
- ❖ On and Off position (if applicable), at surface of the product, at 5, 30, and 100 cm (2, 12, and 39 in.) from the product.
- ❖ Dose rates when material is present in the measuring area.

# Evaluating Dose Rates (cont.)

- ❖ Dose rate during transient conditions and other likely conditions (e.g., calibration).
- ❖ Dose rates and doses to patients should be reported.
- ❖ Measured radiation levels are preferable, can scale to maximum activity, but calculated levels also are acceptable.

## Evaluating Dose Rates (cont.)

- ❖ For measured radiation levels, conditions under which the measurements were taken and the equipment used - including type, window thickness, and sensitivity -- are acceptable.
- ❖ If calculated levels are submitted, the reviewer needs to verify the calculations were performed in accordance with acceptable methods or standards.
- ❖ Are the radiation levels reasonable -- inverse-square law for gamma-emitters, not for beta-emitters, higher levels farther due to scatter.

# Evaluating Dose Rates (cont.)

- ❖ Is the applicant taking credit for external shielding or barriers or guards, if so, dose rates at, and at distances from, each barrier or guard need to be reported
- ❖ ALARA and Industry Standards.

# Evaluating “Likely” Doses

- ❖ Consider all likely activities and normal conditions of use:
  - Receipt
  - Installation
  - Use and environment
  - Multiple Units
  - Servicing
  - Testing/Calibrating
  - Transport (10 CFR 71)
  - Storage

# Evaluating “Likely” Doses (cont.)

- ❖ “Likely” accident conditions
  - Possible to occur in the life of an individual item or system or can be reasonably expected to occur in the life of a large number of items
  
- ❖ Consider likely accident conditions:
  - Loss of Shielding
  - Loss of Containment
  - Fire and Explosion
  - Impact