



# **Extremity Monitoring Policy Meeting Rockville, MD**

January 16, 2003

# Purpose

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- Open a dialogue between the NRC and the regulated community on an adequacy standard for extremity monitoring
- Present an overview of nuclear pharmacy practice
- Review the issues that led to our request for today's meeting
- Present some information that we believe should be considered in policy making

# Overview of Nuclear Pharmacy Practice

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- Activities that involve potential exposure;
  - Receipt and check-in of RAM
  - Eluting Tc-99m from Mo-99/Tc-99m generator
  - Mo-99 assays
  - Preparing Tc-99m radiopharmaceuticals from “cold” kits
  - Quality Control testing of products
  - Dispensing of Tc-99m in multidose vials & unit dose syringes

# Overview of Nuclear Pharmacy Practice

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- Activities that involve potential exposure (cont'd)
  - Dispensing of Tl-201, In-111, Ga-67, I-123, Sr-89, Y-90, etc.
  - Preparation of I-131 capsules and solutions
  - Labeling of blood elements with Tc-99m or In-111
  - Packaging for transport
  - Segregating residual materials for decay in storage

# Issues leading to today's meeting

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- CORAR & industry support NRC changes to 10 CFR 20.1201(c) ...a less restrictive, risk-based approach
- A change in inspection approach to routine extremity exposure without communication to the regulated community
- NRC Region differences as well as Agreement State differences in approach
- SDE to the fingertips versus the SDE recorded by the extremity monitoring device, calculational methods, and the lack of a clear, consistent approach

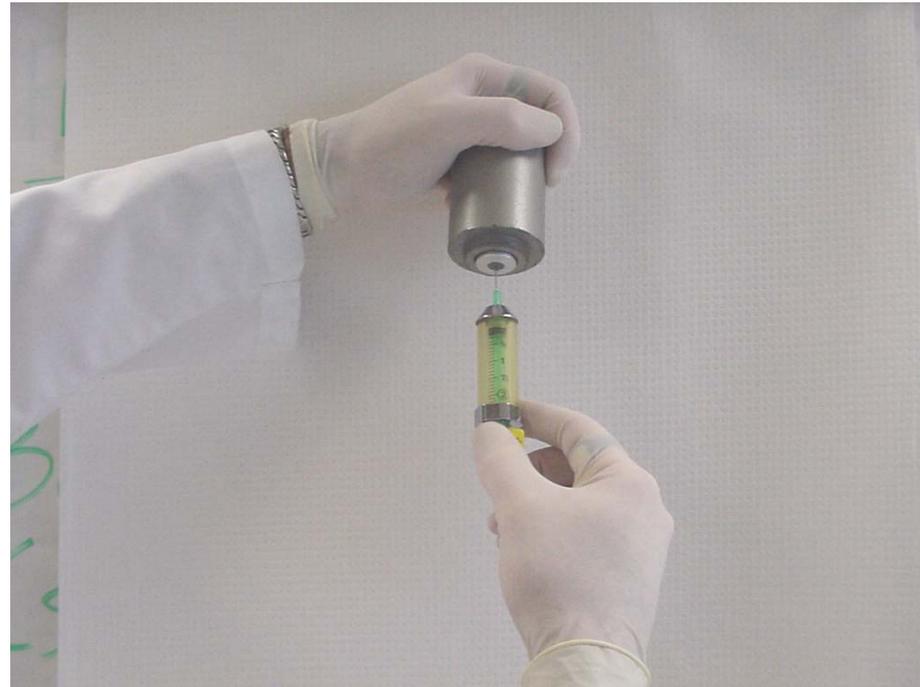
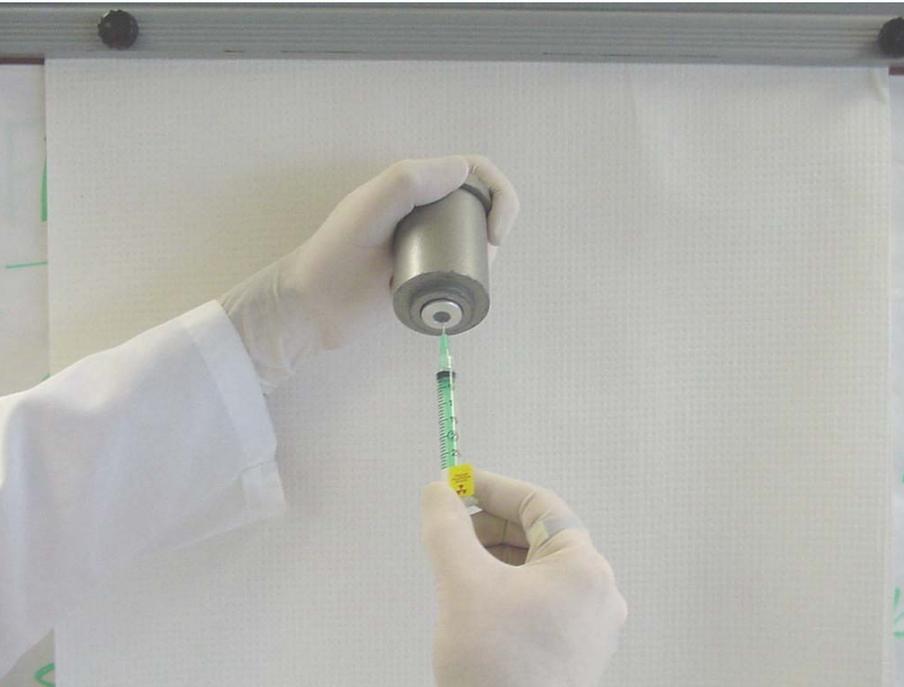
# Historical – Extremity Monitoring

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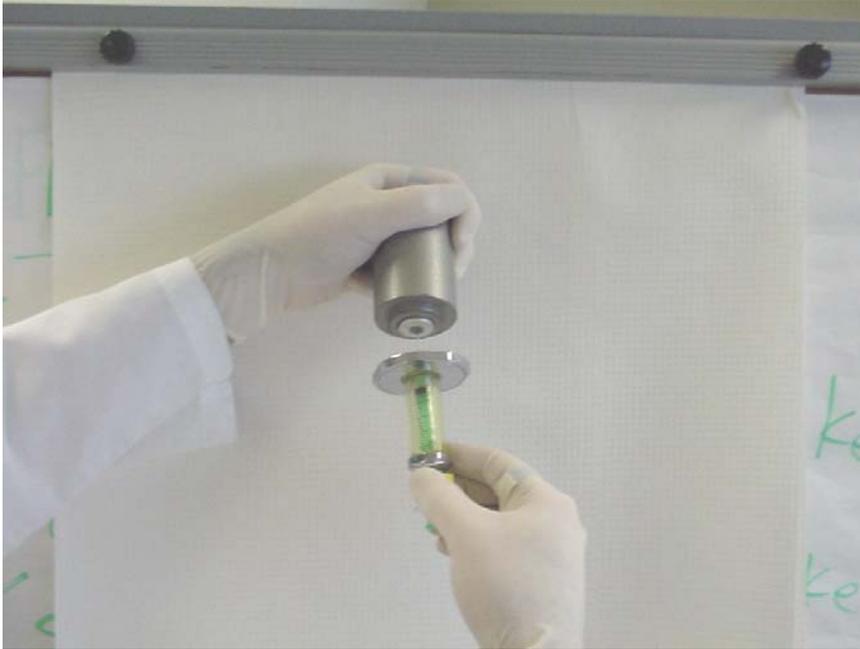
# Evolution of shielding

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# Current State – Shielding

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# Current State – Extremity Monitoring

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# Needle Recapping Issue

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# Items to consider

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- Absence of observed effects in nuclear pharmacy dispensing and other licensee's activities.
  - FR 67, No 66 p. 16301, 2002: “....current skin dose limit, at which no clinically significant effects have ever been reported.”
- >30 years experience without effects including many years of wrist dosimeters, no syringe shields and a 75 rem annual limit

# Items to consider

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- NRC Statement No. 9, Issued March 30, 2001
  - “Specifically, it is recommended that: For skin, limitation of occupational radiation exposure from external sources be based on ensuring that irradiation from any source would not be expected to result in breakdown of skin barrier function with the consequent possibility of infection.”

# Items to consider

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- Skin of palms and fingers are less radiosensitive than other parts of skin, ICRP 41 states:  
“Different anatomical sites vary in decreasing order of responsiveness, as follows: (1) anterior aspect of neck, antecubital and popliteal areas, (2) anterior surfaces of extremities, chest, and abdomen, (3) face, not strongly pigmented, (4) back and posterior surfaces of extremities, (5) face, strongly pigmented, (6) nape of neck, (7) scalp, and (8) palms and soles (Katz, 1941; Rubin and Casarett, 1968)”

# Items to consider

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- ICRP 23 & 130 – Variations in epidermal thickness (micrometers)
  - Neck – 46-122
  - Back – 49-92
  - Arm – medial 37-52, lateral 41-71
  - Finger – 420-673
  - Palm – 500-650
  - Sole – 940-1377

# Items to consider

- Routine exposures are fractionated versus acute
  - From ICRP-41:

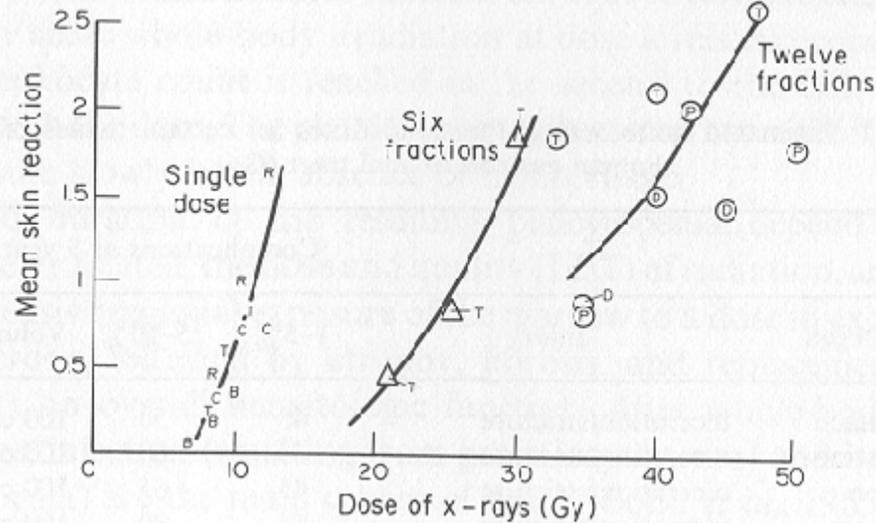


Fig. 9. Dose effect curves for human skin irradiated with x rays, obtained from the average reaction between 5 and 80 days after treatment. A score of 1 represents a faint erythema and a score of 2.5 necrosis. Each symbol represents a patient. (reproduced from Field *et al.*, 1976; UNSCEAR, 1982).

# Items to consider

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- Time – Speed is a key to ALARA
  - Process changes could increase overall time to dispense therefore increasing exposure.
  - Recapping devices tend to increase overall handling time
- Handling of sterile drugs
  - If sterility is compromised, higher exposure involved

# Items to consider

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- Calculational methods for 10 square centimeters
  - “The assigned shallow-dose equivalent must be averaged over the contiguous 10 square centimeters of skin receiving the highest exposure” - 10 CFR 20.120 (c)
  - “A dose as high as 500 rem (5.0 Sv) will be permitted to 1 square centimeter and will be recorded as 50 rem (0.5 Sv) when averaged over 10 square centimeters.” FR 67, No. 66 p. 16301, 2002.

# Conclusions

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- No risk-based reason to change from the current state of the art monitoring of routine occupational extremity exposure
- No risk-based reason to apply factors to state of the art measurements
- The new 10 CFR 20.1201 (c) provides an adequate method for calculating SDE for contamination or accidental exposures