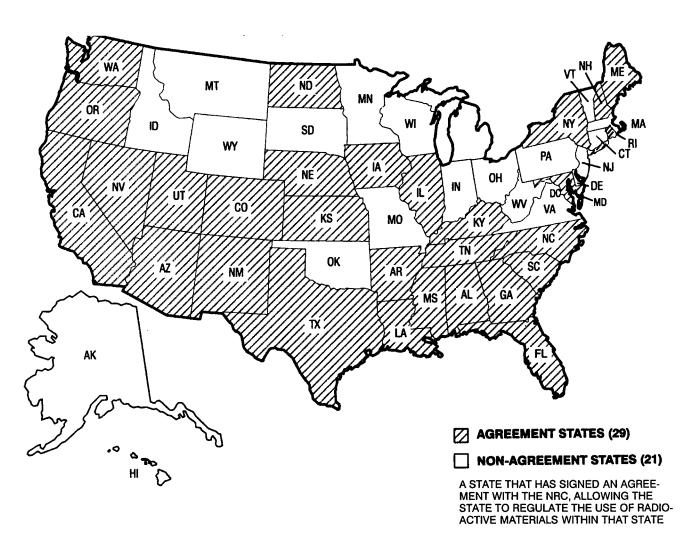
## APPENDIX A

## **AGREEMENT STATES**



A current listing of Agreement States and related contact information can be obtained either via the NRC Inernet homepage or by mail from the Office of State Programs.

Internet: http://www.hsrd.ornl.gov/nrc/home.html

mail: U.S. Nuclear Regulatory Commission

ATTN: Office of State Programs

Mail Stop: O-3-D-23 Washington, DC 20555-0001

# APPENDIX B SAMPLE AGENDA FOR A RADIATION SAFETY COMMITTEE MEETING

The sample RSC agenda below should be used as a guideline for developing an agendum that meets the needs of the licensed program.

- 1 OLD BUSINESS
- 1.1 Approval of previous RSC minutes
- 1.2 Update on status of action items from last meeting
- 2 NEW BUSINESS
- 2.1 Regulatory Issues:
  - Review of inspection results and status of corrective actions
  - Reports of followup enforcement actions
  - Discussion of license amendment or renewal
  - Proposed or final rules
- 2.2 Incident and Event Reports:
  - Misadministrations and recordable events
  - Other incidents or reportable events
- 2.3 Review of Doses and ALARA Program
- 2.4 Review of Applications for New Uses, Visiting Authorized Users, and Use Facilities
- 2.5 Review of Radiation Safety Program:
  - Patient therapy procedures requiring confinement
  - Radiation safety training schedule
  - Results of required periodic radiation surveys
  - Radioactive material waste storage program
  - Results of periodic quality control tests on measurement, detection and imaging equipment, and spot-checks and calibration tests on the cobalt-60 teletherapy or linear accelerator units
  - Resource needs
- 2.6 Review of Audits and Consultant Reports

# APPENDIX C SAMPLE MINUTES OF A RADIATION SAFETY COMMITTEE MEETING

The sample RSC minutes should be used as a guideline to develop minutes based upon discussions at the previous RSC meeting. The minutes should be comprehensive, easy to understand, reviewed by the RSO and RSC chairperson, and distributed in a timely manner to all members.

	Meeting Date:	
RSC Members Present		
Chair:	(name)	177.
RSO:	(name)	···
Management:	(name)	
Radiation Therapy:	(name)	
Teletherapy:	(name)	
Nuclear Medicine:	(name)	
Nursing:	(name)	
Research:	(name)	
Laboratory:	(name)	

- 1 OLD BUSINESS:
- 1.1 Previous minutes approved
- 1.2 The recent problem of timely return of personnel monitoring devices to the "film-badge" company was discussed. As a followup action, the radiation safety staff will place a collection container in a centralized location of each use area and will send a memorandum to each affected department, to be signed by the RSC chairperson, which stresses the importance of timely return.
- 2 NEW BUSINESS:
- 2.1 Regulatory Issues:
  - It has been approximately 2 years since the last inspection was conducted by the regulatory agency; therefore, the facility is due for an unannounced inspection.
  - The license is due for renewal in approximately 5 months and the renewal package should be submitted by 30 days prior to the expiration date.
- 2.2 Incident and Event Reports:
  - An event that almost qualified as a recordable event was described. An individual operating under the supervision of an authorized user did not verify a patient's identity before preparing

the patient for a diagnostic scan. The technologist caught the error and eventually the correct patient was found. The root cause was determined to be that the training program for individuals working under the supervision of authorized users, e.g., residents, was too narrowly focused. The committee unanimously agreed that the authorized user and RSO would conduct additional training with all individuals under the supervision of authorized users.

## 2.3 Doses and ALARA Program:

- Radiation exposure report from RSO: No monitored workers exceeded the in-house investigational level. The highest whole-body exposure was 60 mrem (nuclear pharmacist) and the highest extremity exposure was 150 mrem (brachytherapy).
- The committee discussed the need to identify a "long-term" brachytherapy source storage area to store sealed sources no longer used for therapy procedures (radium-226). This will reduce radiation exposure levels to therapy personnel while working in the current small, overcrowded source storage room. Mr. Anderson (executive management representative) will work with facilities management to identify proposed storage areas for approval by the RSC at the next regularly scheduled meeting, if possible.

## 2.4 Applications for New Uses, Visiting Authorized Users, and Use Facilities:

• The committee discussed the qualifications of two individuals who want to be authorized users. One user (Dr. Smith) was unanimously approved for diagnostic use on the basis of a review of documented training and experience criteria. The committee voted (5-2) to require the second physician (Dr. Jones) to obtain more experience with high-dose-rate afterloaders before being approved. Dr. Smith's name will be submitted to the regulatory agency to be added to the license as an authorized user; however, authorized user responsibilities will not be designated until the license amendment is received.

### 2.5 Radiation Safety Program:

- The committee followed up on the discussion from the last meeting regarding the possibility of using the teletherapy machine to irradiate blood. The RSO looked into the regulatory requirements and worked with the teletherapy physicist to calculate doses based on the proposed new use factors (report attached). The RSO reported that since the facility's radioactive materials license only authorized the use of the teletherapy machine on humans, the hospital will need to request an amendment to the radioactive materials license to be able to irradiate blood and blood products. The committee voted (6-1) to submit an amendment request to the regulatory agency.
- One cesium-137 brachytherapy implant procedure was performed on the 5th floor since the last RSC meeting. The procedure went smoothly except that, during day two, the RSO discovered that the evening shift nurse had not received the necessary radiation safety training regarding care of the therapy patient. At that time, the RSO provided a 30-minute hands-on training session that included the use of dummy sources to simulate the sealed sources in use. After discussions with the nursing supervisor the next day, it was apparent that the newly hired nurse had not attended the most recent radiation safety training session as scheduled and will attend the next one. The RSC chairperson instructed the RSO to determine the root cause of this lack of training and report those findings at the next meeting.
- The five-year full calibration of the cobalt-60 teletherapy unit was completed last week by the service contractor. A full report is expected within the next 30 days and will be discussed with the

## Appendix C - Sample Minutes of a Radiation Safety Committee Meeting

RSC at the next regularly scheduled meeting. Findings requiring more immediate attention will be coordinated with the RSC chairperson.

## 2.6 Audits and Consultant Reports:

Nothing to report.

## APPENDIX D NRC'S REQUIRED PROCEDURES FOR MEDICAL PROGRAMS

The NRC requires the following procedures in 10 CFR Part 35 and Regulatory Guide 10.8, Rev. 2. Licensees should develop and maintain procedures to describe their individual program, and should periodically review these procedures to identify modifications necessary to reflect the current program. This list is not all inclusive and licensees may need to implement additional procedures to reflect the licensed program.

- receiving and opening packages
- securing byproduct material
- inventory record of byproduct material
- using byproduct material safely
- emergency/spill procedures
- periodic radiation surveys
- periodic checks of survey instruments and other safety equipment
- decay in storage
- disposal of byproduct material
- training personnel who frequent areas where byproduct material is used or stored
- personal dosimeters and/or bioassays
- licensees authorized for radiopharmaceutical therapy
  - special safety instructions
  - special safety precautions
- licensees authorized for brachytherapy
  - special safety instructions
  - special safety precautions
- quality management program procedures, if applicable

## APPENDIX E SUGGESTED TRAINING PROGRAM FOR MEDICAL LICENSEES

All personnel who may come in contact with or enter an area that contains radioactive material should be instructed in the proper ways to use or handle radioactive material. This training should be completed before an individual assumes responsibility in a restricted area, and should be repeated annually as a refresher.

## General information to be presented:

Definition of radiation

Radiation types and sources of radiation

Potential hazards or risks

Radiation signs, symbols, and labels

Radioactive materials used at the facility

Locations where radioactive materials are used or stored

ALARA program

Protective measures to keep personal exposure low (time, distance, shielding)

Each worker's obligation to report unsafe conditions

Who to contact in the event of a spill or accident

How to respond to an emergency or accident

Specific procedures required by the radioactive materials license

Existence and location of license

Existence and role of regulatory agencies

Workers' rights (10 CFR Part 19 requirements)

Who to contact if there are questions

Specific information for authorized users and supervised individuals handling radioactive materials:

Radiation safety program requirements (e.g., radiation surveys, bioassays, waste handling)

Specific license requirements

Assigned or delegated duties

Quality Management Plan (if applicable)

Use of radiation survey equipment

Additional information that may need to be conveyed to specific groups:

## Housekeeping:

How to recognize, handle, and avoid radioactive trash

Procedures for entering restricted areas

Procedures for handling materials in patient care rooms

#### Maintenance:

Procedures for entering restricted areas

Description of "work permit" requirements

## Management of Radioactive Material Safety Programs at Medical Facilities

## Security:

Procedures for entering restricted areas
After-hours package receipt

Emergency callout procedures

## Nursing:

Quality Management Program (if applicable)
Restricting areas to visitors
Recognition and identification of brachytherapy sources
Special precautions for handling patients
Use of portable shields

Other personnel such as animal caretakers, incinerator operators, and waste processors should receive training appropriate to their responsibilities.

## APPENDIX F NRC'S NOTIFICATION AND REPORTING REQUIREMENTS

Licensees should ensure that the RSO at their facility is aware of and understands the regulatory reporting and notification requirements specified below. Additionally, licensees should be aware that once an incident has been reported as required, regulatory agencies will continue to collect information until all regulatory and health and safety issues have been fully addressed. In other words, the information flow between the licensee and regulatory agency does not stop once the incident has been reported. In most cases, there will be a need for the regulatory agency to gain additional information or clarification of earlier information. This may be necessary to ensure that the magnitude of the incident has been determined, appropriate corrective action by the licensee has or will be taken to reduce the likelihood or prevent recurrence, the root cause has been determined so that generic issues that may affect other licensees can be identified and communicated, the appropriate regulatory action has been taken, or to make a determination regarding whether regulatory modifications are needed.

## Fires and Explosions - Catastrophic Incidents

10 CFR 30.50 (a) and (b)(4), "Records, Inspections, Tests, and Reports," requires licensees to report, as specified below, incidents involving radioactive materials and fires, explosions, etc., to the NRC Operations Center ((301) 816-5100) by telephone within the time limits specified below and to follow up within 30 days with a written report to the NRC Document Control Desk, Washington, DC 20555-0001, with a copy to the appropriate NRC regional office:

- 1. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events include fires, explosions, toxic gas releases, etc.).
- 2. Each licensee shall notify the NRC within 24 hours after the discovery of an unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when the quantity of the material involved is greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR Part 20 for the material; and the damage affects the integrity of the licensed material or its container.

## **Exposures**

10 CFR 20.2202, "Notification of Incidents," requires licensees to notify the NRC Operations Center ((301) 816-5100) by telephone and the administrator of the appropriate NRC regional office of any event involving radioactive material possessed by the licensee that may have caused or threatens to cause dose(s) to an individual as specified below. Notification should be:

- 1. Immediate for a total effective dose equivalent of 25 rem (0.25 Sv) or more; or an eye dose equivalent of 75 rem (0.75 Sv) or more; or a shallow-dose equivalent to the skin or extremities of 250 rad (2.5 Gy) or more; or the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake.
- 2. Within 24 hours of the discovery of the event for a total effective dose equivalent exceeding 5 rem (0.05 Sv); or an eye dose equivalent exceeding 15 rem (0.15 Sv); or a shallow-dose equivalent to the skin or extremities exceeding 50 rem (0.5 Sv); or the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake.

10 CFR 20.2203 (a)(1)(2), "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits," requires, in addition to notification required by 10 CFR 20.2202, that a licensee file a written report with the NRC Document Control Desk in Washington, D.C. with a copy to the appropriate NRC regional office within 30 days after learning of the occurrence of doses in excess of any of the following:

- 1. The occupational dose limits for adults in 10 CFR 20.1201; or
- 2. The occupational dose limits for a minor in 10 CFR 20.1207; or
- 3. The limits for an embryo/fetus of a declared pregnant woman in 10 CFR 20.1208; or
- 4. The limits for an individual member of the public in 10 CFR 20.1301; or
- 5. Any applicable limit in the license.

#### Levels of Radiation or Concentrations of Radioactive Material

10 CFR 20.2203(a)(3), requires that a licensee file a written report with the NRC Document Control Desk in Washington, D.C. with a copy to the appropriate NRC regional office within 30 days after learning of the occurrence of:

- 1. Levels of radiation or concentrations of radioactive material in a restricted area in excess of any applicable limit in a licensee's radioactive material license; or
- 2. Levels of radiation or concentrations of radioactive material in an unrestricted area in excess of 10 times the applicable limits in 10 CFR Part 20, whether or not it involves exposure of any individual in excess of the limits in 10 CFR 20.1301.

In addition to the requirements of 10 CFR 20.2203(a)(3), 10 CFR 30.50 requires licensees to report to the NRC Operations Center ((301) 816-5100) by telephone within the time limits specified below and to follow up within 30 days with a written report to the NRC Document Control Desk, Washington, DC 20555-0001, with a copy to the appropriate NRC regional office as follows:

- 1. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits.
- 2. Each licensee shall notify the NRC within 24 hours after the discovery of an unplanned contamination event that:
  - a. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area.
  - b. Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR Part 20 for the material; and has access to the area for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

#### Loss and Theft

10 CFR 20.2201, "Reports of Theft or Loss of Licensed Materials," requires that licensees notify the NRC Operations Center ((301) 816-5100) by telephone within the time limits specified below and shall within

30 days after making the telephone report, make a written report as described in 10 CFR 20.2201(b) to the administrator of their appropriate NRC regional office, as follows:

- 1. Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C of 10 CFR Part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas.
- 2. Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in Appendix C of 10 CFR Part 20 that is still missing at this time.
- 3. Subsequent to filing the written report, the licensee should report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

#### **Medical Misadministrations**

10 CFR 35.33, "Notifications, Reports and Records of Misadministrations," requires licensees to:

- 1. Notify the NRC Operations Center ((301) 816-5100) by telephone no later than the next calendar day after discovery of a misadministration.
- 2. Submit a written report of the investigation, supplying the information stipulated in the regulation, to the appropriate NRC regional office with 15 days after discovery of the misadministration.
- 3. Notify the referring physician and the patient (unless in the medical judgment of the referring physician such notification would be harmful to the patient) within 24 hours after discovery of the misadministration.
- 4. Furnish a written report to the patient within 15 days after discovery of the misadministration, if the patient was notified.
- 5. Retain a record of each misadministration for 5 years.

## **Contaminated Packages**

10 CFR 20.1906(d), "Procedures for receiving and opening packages," requires that the licensee immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the administrator of the appropriate NRC regional office listed in Appendix D to 10 CFR 20.1001 – 20.2401 when:

- 1. Removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i). In general, the licensee should provide notification if the removable external contamination exceeds 10<sup>-5</sup> μCi/cm<sup>2</sup> or 22 dpm/cm<sup>2</sup> for beta-gamma emitting radionuclides; all radionuclides with half-lives less than 10 days; natural uranium; natural thorium; uranium-235; uranium-238; thorium-232; thorium-228 and thorium-230 when contained in ores or physical concentrates and 10<sup>-6</sup> μCi/cm<sup>2</sup> or 2.2 dpm/cm<sup>2</sup>. For exclusive use shipments (Note: medical shipments are rarely exclusive use) by rail or highway only, the removable radioactive contamination should not exceed 10 times these levels; *or*
- 2. External radiation levels exceed the limits of 10 CFR 71.47. In general, the licensee should provide notification if the external radiation level exceeds 200 millirem per hour at any point on the external surface of the package and the transport index does not exceed 10. For exclusive use shipments, allowable levels are higher in accordance with 10 CFR 71.47(a).

## **Equipment/Device Failure**

10 CFR 21.21, "Notification of failure to comply or existence of a defect and its evaluation," requires that the licensees to notify the NRC Operations Center ((301) 816-5100) by telephone and within 30 days after making the telephone report, make a written report as described in 21.21(c)(4) to the NRC Document Control Desk, Washington, DC 20555-0001, with a copy to the appropriate NRC regional office if they suspect or identify an equipment defect or failure of the device to comply that could create a substantial safety hazard, were it to remain uncorrected. In addition to the requirements of 10 CFR 21.21, 10 CFR 30.50(b)(2) requires licensees to report, within 24 hours to the NRC Operations Center ((301) 816-5100) by telephone and to follow up within 30 days with a written report to the NRC Document Control Desk, Washington, DC 20555-0001, with a copy to the appropriate NRC regional office, any event in which equipment is disabled or fails to function as designed when the equipment is required by regulation or license condition to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident (such as loss of shielding in a device) or if the equipment is required to be available and operable when it is disabled or fails to function and no redundant equipment is available and operable to perform the required safety function (such as failure of an area radiation monitor with no survey meter backup).

In addition to the NRC notification and reporting requirements discussed above, the Center for Devices and Radiological Health of the Food and Drug Administration (FDA) also maintains a product problem reporting program that requires notification.

#### **Medical Treatment of Contaminated Individual**

10 CFR 30.50(b)(3) requires that each licensee notify the NRC Operations Center ((301) 816-5100) by telephone within 24 hours and follow up within 30 days with a written report to the NRC Document Control Desk, Washington, DC 20555-0001, with a copy to the appropriate NRC regional office, any event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

It should be noted that the NRC Operations Center facsimile number is (301) 816-5151 in the event that a licensee needs to send written information relevant to the event reported.

## APPENDIX G NRC'S REQUIRED RECORDS FOR MEDICAL PROGRAMS

The following NRC required records are found in 10 CFR Parts 20, 30 and 35 and Regulatory Guide 10.8, Rev. 2. Licensees should review their recordkeeping procedures to ensure that all required information is maintained.

- Radiation safety committee meeting minutes (35.22)
- Visiting authorized user (35.27)
- Ministerial changes (35.31)
- Misadministrations (35.2, 35.33)
- Recordable events (35.2, 35.32)
- Dose calibrator: accuracy, linearity, geometry and constancy (35.50)
- Survey instrument calibrations (35.51)
- Sealed source leak tests (35.59)
- Sealed source inventories (35.59)
- Radioactive gas clearance calculations (35.205)
- Measurement of radiopharmaceutical dosages (35.53)
- Molybdenum concentration (35.204)
- Brachytherapy patient surveys (35.404)
- Brachytherapy source use (accountability with each use) (35.406)
- Brachytherapy safety instructions and precautions (35.410, 35.415)
- Radiopharmaceutical therapy safety instructions and precautions (35.310, 35.315)
- Postradiopharmaceutical therapy survey of contiguous restricted and unrestricted areas (35.315)
- Bioassay results (35.315)
- Individual monitoring results (20.2106, 35.22)
- Calibration and quality control tests for teletherapy units (35.632, 35.634)
- Safety checks on teletherapy facilities (35.636, 35.641, 35.643)
- Surveys for contamination and ambient exposure rate (35.70)
- Sealed source storage surveys (35.59)

## Management of Radioactive Material Safety Programs at Medical Facilities

- Waste disposal, waste surveys (20.2108, 35.92)
- Radiation protection program (20.2102)
- Receipt, transfer, and disposal (30.51)

## APPENDIX H

# NRC'S SUGGESTED TRAINING AND EXPERIENCE CRITERIA FOR RSOS AT A LIMITED SPECIFIC MEDICAL LICENSEE (10 CFR 35.900)

The specified training and experience should have been obtained within seven years preceding the date of application or the individual should have had related continuing education and experience since the required training and experience were completed (10 CFR 35.972).

#### **BOARD CERTIFICATION**

- A) American Board of Health Physics in Comprehensive Health Physics
- B) American Board of Radiology
- C) American Board of Nuclear Medicine
- D) American Board of Science in Nuclear Medicine
- E) Board of Pharmaceutical Specialties in Nuclear Pharmacy
- F) Royal College of Physicians and Surgeons of Canada in Nuclear Medicine
- G) American Board of Medical Physics in Radiation Oncology Physics
- H) American Osteopathic Board of Nuclear Medicine
- American Osteopathic Board of Radiology

OR

#### TRAINING AND EXPERIENCE

- A) 200 hours of classroom and laboratory training that includes:
  - 1) Radiation physics and instrumentation
  - 2) Radiation protection
  - 3) Mathematics pertaining to the use and measurement of radioactivity
  - 4) Radiation biology
  - 5) Radiopharmaceutical chemistry AND
- B) One year of full-time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the RSO on an NRC or Agreement State license that authorizes the medical use of byproduct material

OR

## PREVIOUS AUTHORIZATION

A) Be an authorized user identified on the licensee's license.

# APPENDIX I NRC'S SUGGESTED COMBINATIONS OF TRAINING AND EXPERIENCE CRITERIA FOR RSOs AT A BROAD SCOPE MEDICAL LICENSEE (A, or B, or C, etc.)

F(	DRMAL EDUCATION AND CERTIFICATION		EXPERIENCE
A.	Bachelor's degree in health physics or radiological health AND	A.	Four years of applied health physics experience in a program with radiation safety problems similar to those in the program to be managed
В.	Bachelor's degree in a physical science or a biological science with a physical science minor, and one year of graduate work in health physics AND	B.	Same as A
C.	Master's degree in health physics or radiological health AND	C.	Three years of applied health physics experience in a program with radiation safety to be managed
D.	Doctorate degree in health physics or experience radiological health AND	D.	Two years of applied health physics in a program with radiation safety problems similar to those in the program to be managed
E.	Comprehensive certification by the American Board of Health Physics AND	E.	Same as D
F.	Certification by the American Board of Radiology in Medical Nuclear Physics AND	F.	Same as D
G.	Certification by the American Board of Science in Nuclear Medicine in Radiation Protection AND	G.	Same as D
Н.	Certification by the American Board of Medical Physics in Medical Health Physics	H.	Same as D

## APPENDIX J SUGGESTED CHECKLIST FOR REVIEWING ADEQUATE TRAINING AND EXPERIENCE FOR AN RSO AT A BROAD SCOPE PROGRAM

NA	ME OF PROPOSED RSO:		
ED	UCATION: (DEGREE AND MAJOR)		
CERTIFICATION: (SPECIALTY BOARD, CATEGORY, MONTH AND YEAR CERTIFIED			
_			
	TES AND LOCATION OF ALL PRACTICAL EXPERIENCE OBTAINED TO MEET THE PERIENCE REQUIREMENTS DESCRIBED BELOW:		
TR	AINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES:		
	Radiation Physics and Instrumentation		
	Radiation Protection		
	Mathematics pertaining to the use and measurement of radioactivity		
	Radiation Biology		
	Radiopharmaceutical Chemistry		
EX	PERIENCE USING RADIOISOTOPES:		
	Isotopes		
	mCi used at one time		
	Location of use		
	Clock hours		
	Types of use		
EX	PERIENCE SUPERVISING USE OF RADIOISOTOPES:		
	Isotope		
	Maximum activity		
	Location		
	Clock hours		
	Types of use		

H.	EX	PERIENCE IMPLEMENTING A RADIATION SAFETY PROGRAM:			
		Performed safety evaluations of facilities and equipment of proposed uses.			
		Evaluated qualifications of authorized users and individuals working under the supervision of authorized users for proposed uses.			
		Conducted a laboratory audit program.			
		Research and development labs			
		<ul> <li>Medical labs – nuclear medicine, oncology, etc.</li> </ul>			
		Maintained personnel monitoring program for determining external exposure.			
		<ul> <li>Selected appropriate devices</li> </ul>			
		<ul> <li>Monitored exposure records</li> </ul>			
		<ul> <li>Established exposure investigational levels</li> </ul>			
		Maintained a bioassay program for determining internal exposure.			
		- Determined method: in vivo and in vitro			
		<ul> <li>Established action levels</li> </ul>			
		<ul> <li>Emergency and followup actions</li> </ul>			
		Calculated internal and external radiation doses.			
		Monitored and maintained absolute and other special filter system associated with the use, storage, or disposal of radioactive material.			
		Evaluated, selected, designed, and supervised maintenance of process control and confinement systems, such as glove boxes and hoods.			
		Performed shielding evaluations, including determination of type and amount needed.			
		Calculated radioactive decay, buildup, and secular and transient equilibrium.			
		Evaluated, selected, maintained, and effectively used respiratory protective equipment.			
		Maintained a contamination control program.			
		- Ambient radiation surveys			
		<ul> <li>Contamination surveys</li> </ul>			
		<ul> <li>Air sampling program</li> </ul>			
		<ul> <li>Sealed source leak testing</li> </ul>			
		<ul> <li>Sample analysis</li> </ul>			
		Conducted investigations.			
		- Overexposures			
		<ul> <li>Accidents, spills, losses, thefts</li> </ul>			
		<ul> <li>Unauthorized receipts, uses, transfers, disposals</li> </ul>			
	r	- Misadministrations			
		Conducted radiation protection training for facility personnel.			
		<ul> <li>Authorized users and lab workers</li> </ul>			
		- Animal caretakers			
		- Nursing staff			
		- Incinerator operators			
		- Ancillary staff (custodial staff, etc.)			
		- Security			
		<ul> <li>Waste processors/handlers</li> </ul>			

# Appendix J – Suggested Checklist for Reviewing Adequate Training and Experience for an RSO at a Broad Scope Program

$\Box$ .	Developed radiation safety manuals.
	Selected instrumentation associated with the measurement of radiation.
	- Survey instruments (gm, ion-chamber, scintillation)
	<ul> <li>Counting equipment</li> </ul>
	<ul> <li>Special equipment (dose calibrator, direct reading dosimeter, air sampler)</li> </ul>
	Performed instrument calibrations.
	Coordinated material inventory and accountability program.
	<ul> <li>Monitored receipt, use, decay, transfer, and disposal</li> </ul>
	Coordinated radioactive waste disposal program.
	- Effluent monitoring
	- Collection
	<ul> <li>Treatment (decay-in-storage, incineration, and compaction)</li> </ul>
	- Packaging
	– Disposal
	Prepared radioactive packages for transportation.
	Developed and maintained a facility emergency plan for responding to release of radioactive materials.
	Determined need for financial assurance for decommissioning.
	Developed and maintained decommissioning financial assurance funding plan.
AP	POINTMENTS:
AW	ARDS, SCIENTIFIC PRESENTATIONS AND PUBLICATIONS:

## APPENDIX K SUGGESTED RADIATION SAFETY EQUIPMENT FOR MEDICAL FACILITIES

Below is a list of the types of equipment needed to support a radiation safety program for a medical facility. This information may be helpful to plan for the startup of a new program or for changing the scope of an existing program.

## **Radiation Safety Office**

- Radiation survey measurement and detection instruments appropriate for the types and quantities of radioactive materials possessed
- Extra personnel dosimetry devices
- Reference sources for quality control tests on gamma counters, gamma cameras, etc.
- Filter paper for independent contamination surveys
- Department of Transportation labels for packages containing radioactive material
- Decontamination kit
- Locked cabinet to secure keys for long-term source or radioactive waste storage areas, or any equipment which is out of service and poses a hazard

#### In Vitro Studies

- Gamma well counter
- Beta counter or monitor
- Drum for collecting vials of waste
- Dedicated sink for disposing of liquid wastes

## Sealed Sources for Diagnosis (Bone Mineral Analysis)

- Availability of radiation survey instrument
- Shielded shipping container for source exchange (typically supplied by manufacturer)

## Imaging, Localization and Radiopharmaceutical Therapy

- Dose calibrator
- Check source(s) for dose calibrator
- Radiation survey instrument
- Radiation measurement instrument
- Instrument check source(s)
- Thyroid uptake probe and phantom
- Gamma camera flood source
- Wipe test counter
- Syringe and vial shields
- Fume hood
- Shielding blocks

- Drum to collect waste
- Dedicated sink for disposal of liquid wastes

## **Brachytherapy**

- Radiation measurement and survey instruments
- Instrument check source
- Source handling tools, e.g., long-handled forceps, magnifying leaded glass
- Source storage safe and shielding blocks
- Shielded transporter
- Portable bedside shields
- Appropriate radiation posting materials

## Teletherapy

- Area radiation monitor with backup power
- Appropriate radiation posting materials for treatment room
- Continuous patient viewing and intercom system
- Door interlocks
- Dosimetry system
- Radiation measurement and survey instruments
- Instrument check source
- Shielded treatment room

#### Remote Afterloaders

High-Dose Rate Afterloading (HDR)

Pulsed-Dose Rate Afterloading (PDR)

Medium-Dose Rate Afterloading (MDR)

Low-Dose Rate Afterloading (LDR)

- Emergency source recovery equipment (HDR, PDR, MDR)
- Surgical equipment for intervention (HDR, PDR, MDR)
- Portable shields (LDR)
- Radiation measurement and survey instrument
- Area radiation monitor with backup power supply (HDR, PDR, MDR)
- Instrument check source
- Door interlocks (HDR, PDR, MDR)
- Continuous patient viewing and intercom system (HDR, PDR, MDR)
- Shielded treatment room (HDR, PDR)
- Appropriate radiation posting materials for treatment room

## APPENDIX L SAMPLE AUDIT OUTLINE FOR MEDICAL PROGRAMS

The following outline can be used as a guide in designing a method to conduct an audit. This outline is intended as a general guide and should not be considered all inclusive because many programs have unique requirements. Where appropriate, the applicable section of the regulations is noted. Where "L/C" is noted, the reference will typically be found in a license condition or an attachment to a license or its application. Agreement State licensees should refer to the equivalent regulations and license conditions.

## 1. Review Background Information

- Review the license, original license application, subsequent amendments, and applicable regulations to identify the scope of the licensed program and determine whether modifications to the license or program are needed to reflect all areas of use and users.
- Determine the authority designated to RSO and RSC by executive management, and interrelationships and lines of authority between these three members of the management triangle.

## 2. Organization—The Management Triangle

- Radiation safety officer (35.21)
- Radiation safety committee (35.22)
- Executive management (35.11, 35.12)

## 3. Scope of Program

- Isotopes, chemical forms, quantities, and authorized uses (L/C, 35.100-35.600)
- Location and number of clinical or research laboratories (L/C), and frequency of use of material
- Number of authorized users (L/C)
- Determination if there have been visiting authorized users (35.27)
- Number of radiation safety support staff
- Radiation safety program changes (35.31)
- Review of RSC minutes to identify records of program changes, conduct of formal audits or program reviews, and corrective actions taken

## 4. Audit/Inspection History

- Findings identified during previous audits or inspections addressed or corrected or both
- Response to findings documented
- Determination if corrective actions were adequate to prevent recurrence of violation or safety problem

## 5. Training, Retraining, and Instructions to Workers

- Instructions to workers (19.12)
- Instructions to workers on radiation safety program relative to their use, and the licensee's quality management program, when required (35.25)

- Training/retraining program (L/C)
- Supervision of individuals (35.25)
- Records maintained

## 6. Personnel Monitoring Program

- ALARA program implemented (35.20)
- Determination if film or TLD supplier is NAVLAP approved (20.1501)
- Reports reviewed by RSO and RSC at required frequency (L/C, 35.21, 35.22)
- Dosimeters exchanged at the required frequency (L/C)
- External exposures account for contributions from airborne radioactive materials (20.1203)
- Adequate evaluations to determine that workers not monitored for external doses were unlikely to receive in one year external doses over 10% of the limits in 20.1201(a) (20.1501, 20.1502)
- Internal and external doses summed (20.1202)
- Dose to embryo/fetus (20.1208, 20.1502, 20.2106)

## 7. Facilities and Equipment

- Facilities accurately described in license application
- Adequate areas for storage and use of radioactive material (RAM) (security/control) (20.1801,1802)
- Dose calibrator quality control (35.50) (If errors in calibration are found, determine whether recordable events or misadministrations occurred as a result.)
- Quality control tests performed on mobile gamma imaging cameras (35.80)
- Appropriate/calibrated survey instruments used (35.120, 220, 320, 420, 520, 35.620)
- Syringes/vials containing RAM properly labeled and shielded (35.60, 35.61)
- Adequate shielding to reduce exposures ALARA, including portable shielding used in rooms of patients undergoing sealed source therapy procedures
- Radioactive material handling equipment such as long—handled tongs, lead pigs, portable carriers for safe transportation and storage
- Restricted areas properly identified and necessary precautions taken
- Unrestricted areas adjacent to restricted areas (20.1302)

## 8. Radiation Surveys, Source Inventory, and Leak Tests

- Radiation level and contamination surveys performed as required (35.70, 35.404)
- Source inventory, leak tests, and surveys of sealed source storage areas performed as required (35.59, 35.406)
- Trigger levels for radiation surveys established (L/C, 35.70)
- Survey techniques detect trigger levels 0.1 mR/hr, 2000 dpm (35.21, 35.70)
- Records maintained (L/C, 35.59, 35.70, 35.404, 35.406)
- Patients released from confinement surveyed after therapy procedures (L/C, 35.75)

## 9. Receipt and Transfer of Radioactive Material

- Package receipt (20.1906)
- Transfer(s) between licensees performed in accordance with requirements

- Records of surveys and receipt/transfer maintained
- 10. Radioactive Effluents, Waste Management and Disposal
  - Waste held for decay-in-storage and subsequent disposal (35.92, L/C)
  - Licensed material released into sanitary sewerage (20.1501, 20.2003)
  - Waste storage area(s) (20.1801, 20.1902, 20.1904, 20.2103, 20.2108)

#### 11. Misadministrations and Recordable Events

Review records of recordable events or misadministrations (defined in 35.2) to determine if root cause was properly identified and appropriate corrective action taken to prevent recurrence. Review the quality management program to determine if modifications are needed to prevent recurrence. In addition, review a sample of administration records, as required by the QM rule, to identify recordable events or misadministrations not previously identified.

## 12. Radiological Protection Procedures

- Procedures developed and maintained for the safe use of RAM (L/C: App. I of RG 10.8 or equivalent L/C)
- Individuals' understanding of current policy/procedures adequate for general use of RAM and in emergencies

## 13. Notification and Reports

- Notifications to workers: reports to individuals (annual reports to individuals monitored to show compliance with Part 20, copies of reports to NRC per 20.2202-2206)
- Notifications to NRC:
  - theft or loss (20.2201)
  - incidents involving high doses/releases (20.2202)
  - reports of overexposures, high levels (20.2203)
  - misadministrations (35.33)
  - change in authorized users, RSO or teletherapy physicist or change in their name, or change in licensee's mailing address (35.14)
- Notifications to patients or referring physicians or both (35.33)

### 14. Posting and Labeling

- NRC-3 "Notice to Workers" posted (19.11)
- Parts 19, 20, and 21, and license posted or a notice posted indicating where documents can be examined (19.11, 21.6)
- Other posting and labeling (20.1902, 20.1904)

## 15. Transportation (10 CFR 71.5(a) and 49 CFR 170-189)

- Waste classified and characterized
- Shipments (49 CFR 173.200–204, 173.403, 173.415, 173.416, 173.436, 173.438, 173.440)
- If return shipments of radiopharmacy doses are made, licensee assumes responsibility of all shipper requirements or arrangements made between licensee and radiopharmacy ensures performance of shipper responsibilities.

## 16. Independent Measurements

Independent measurements should be taken by the auditor to verify measurements recorded and ensure adherence to the ALARA principle.

## 17. Radiopharmaceutical Therapy

- Safety instruction provided to all personnel caring for the patient to include control of patient, visitors, contamination and waste; and notification of RSO in case of emergency (35.310)
- Safety precautions implemented (35.315, L/C)
- Area dose rate surveys and patient room contamination surveys performed (35.315)
- Release of patients containing radiopharmaceuticals meets 35.75 (5 mR/hr @ 1 meter, less than 30 mCi)
- Records maintained (35.310, 35.315, 35.32, 20.2103, 20.2107, L/C)

## 18. Brachytherapy

- Safety instruction provided to all personnel caring for the patient to include size/appearance of sources, safe handling/ shielding of dislodged sources, control of patient and visitors, and notification of RSO in case of emergency (35.410)
- Safety precautions implemented (35.415, L/C)
- Surveys demonstrate that activities involving brachytherapy comply with 20.1301 (35.415, 20.1302)
- Patients surveyed immediately after implanting the sources (35.406)
- Patients surveyed with a survey instrument that meets 35.420 (35.404) immediately after removing the last temporary implant source
- Inventory of brachytherapy sources (35.59, 35.406)
- Brachytherapy sources leak tested (35.59)
- Written operating and emergency procedures used for HDR remote afterloaders, staff trained on the procedures, procedures followed (L/C)
- Records maintained

## 19. Teletherapy

- Teletherapy physicist qualifications (35.961)
- Safety precautions (35.615)
- Dosimetry equipment (35.632)
- Calibrations (35.632)
- Spot checks (35.634)
- Five—year inspections (35.647)
- Records maintained

## 20. Bulletins, Information Notices and Generic Letters or Other Communications

- Bulletins, information notices, generic letters, etc. received
- Appropriate action taken in response to bulletins, information notices, generic letters, etc.

## 21. Special License Conditions or Issues

The auditor should be knowledgeable of license conditions unique to the facility and ensure that appropriate action is taken to maintain compliance.

## APPLENDIX M GLOSSARY

Agreement State: A State which has entered into a formal agreement with the NRC to regulate the safe use of byproduct material in that State. Agreement States also regulate the safe use of other sources of radiation. These include such devices as X-ray units including dental, computerized tomography (CT) scanners, fluoroscopy units, linear accelerators, non-byproduct material in sealed sources (e.g., radium-226) and radiopharmaceuticals (e.g., thallium-201).

ALARA: This acronym for "as low as is reasonably achievable" means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest. Medical licensees are required by NRC and most States to implement an ALARA program. Typically, licensees establish "investigational" levels for occupational exposures which are far below the regulatory dose limits and which, when exceeded, prompt investigative activities by the RSO and/or RSC to identify the root cause and determine whether future exposures can be reduced, if practical.

Allegation: An assertion made by an employee of the licensee or by a member of the public regarding management of a licensed program, use of licensed material, incident response, etc. that should be investigated by the RSO and/or RSC and reported to and discussed with the RSC.

Ancillary Personnel: Licensee personnel that, as part of their assigned duties, work in or around restricted areas where radioactive material is received, used, or stored; and as a result of their duty may receive minimal radiation exposure.

Audit: A periodic examination of the radiation safety program including, but not limited to, a review of operating procedures, the ALARA program, consultant or regulatory agency inspection reports, radiation safety committee meeting minutes, the adequacy of the radiation safety training program for facility personnel and supervision of these individuals, and records maintained to document activities related to the possession, use, storage, transfer, and disposal of licensed material. Audits may either be informal or formal; however, NRC requires that the conduct of the annual review be documented in a written report and discussed with members of the radiation safety committee.

Authorized User: A physician, dentist, or podiatrist who is identified as an authorized user on an NRC or Agreement State license that authorizes the medical use of byproduct material. It should be noted that Part 35 authorizes dentists and podiatrists for the *external* administration of byproduct material only. Additionally, NRC broad scope licensees have authority to authorize individuals who meet Part 35 training and experience criteria to use byproduct material, and often refer to these individuals as authorized users.

**Bioassay:** The quantitative and qualitative determination of radioactive materials as well as the location of deposition in the human body by direct (*in vivo*) measurement or by indirect (*in vitro*) measurement.

**Board Certified**: An individual who has been certified by a professional board recognized by a regulatory agency to meet the required training and experience criteria described for authorized individuals, i.e., RSO, authorized physician user, and a medical or health physicist.

**Brachytherapy:** A method of radiation therapy in which sealed sources are used to deliver a radiation dose by topical, intracavitary, interstitial, or intraluminal application. This includes the use of

strontium-90 eye applicators, manual afterloading, and high-, pulse-, medium-, and low-dose-rate remote afterloading patient procedures.

Brachytherapy Source: An individual sealed source or manufacturer-assembled source train that is not designed to be disassembled by the user. Sealed sources are either temporarily or permanently implanted in the patient.

Broad Scope: Broad scope licenses issued by NRC pursuant to 10 CFR Part 33, which provides for three categories of licenses. Broad scope licenses authorize possession of a wide variety of radioactive material to facilities with considerable prior experience in the use of radioactive material; a good regulatory performance record; a need for operational flexibility; and an administrative structure, organization, and procedures adequate to ensure safe operations. Unlike other licensees, broad scope programs licensed by NRC have authority to authorize users of licensed material.

Byproduct Material: Any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

Calibration: The determination of the relationship between the value of some parameter measured by an instrument and the true value of the quantity being measured to ascertain necessary correction factors. Adjustments made to fix, check or correct the graduations of the measuring instrument within a tolerance range.

Code of Federal Regulations (CFR): A codification of the general and permanent rules published in the *Federal Register* by the Federal Government. The code is divided into 50 titles, each title is divided into chapters, each chapter is divided into parts, each part into subparts and sections. Medical use licensees are primarily bound by 10 CFR Parts 19, 20, 21, 30, 33, and 35.

Contamination: The deposition of radioactive material in any place where it is not desired, particularly where its presence may be harmful, or the amount of radioactive material in a restricted area exceeds trigger or regulatory limits. The potential harm may be in the actual spread of radioactive material or resulting radiation exposure levels.

**Decommissioning:** To remove (as a facility) safely from service and reduce residual radioactivity in a facility that previously contained radioactive material to a level that permits release of the property for unrestricted use.

**Decontamination**: The process of removing radioactive material contamination, whether in response to a spill or accident, or as part of the decommissioning process.

**Decay-in-Storage (DIS):** Storing radioactive waste in an authorized area for a required minimum time (typically 10 half-lives) and until the radiation levels at the surface of the storage container, absent interposed shielding, is equal to or less than background levels of radiation.

Declared Pregnant Worker: An occupational worker who voluntarily notifies her employer (licensee) in writing of her pregnancy and the estimated date of conception.

**Dosage:** 10 CFR Part 35 uses the term to indicate quantities of radioactivity that are measured with the base unit of curie (Ci), such as radiopharmaceutical patient dosages administered for diagnostic or therapeutic procedures.

**Dose:** A general term denoting the quantity of radiation or energy absorbed per unit mass. 10 CFR Part 35 uses the term "dose" to indicate quantities of radiation absorbed dose or dose equivalent that are measured with the base unit radiobiological equivalent man (rem) or radiation absorbed dose (rad).

**Dose Calibrator:** An ionization chamber specifically designed for the measurement of dosages of radioactive material. Typically, the amount of radioactivity in a capsule or a syringe containing a radiopharmaceutical is measured in a dose calibrator prior to administration.

**Dosimetrist:** An individual who is trained to calculate parameters and design treatment plans based on a prescribed dose for patients undergoing therapeutic procedures utilizing sealed sources or linear accelerators.

**Dosimetry:** Monitoring equipment used to measure the radiation dose delivered to either an individual or a physical area being monitored. Monitoring equipment (dosimetry) for personnel includes devices such as pocket dosimeters, film badges, and thermoluminescence dosimeters.

Exclusive Use: This term applies to transportation of radioactive material. The sole use of a conveyance by a single consignor and for which all initial, immediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. (Note: medical packages are rarely exclusive use.)

**Executive Management:** The highest level of management in the facility. Typically, the chief executive officer, president, or administrator. This level of management may be represented by an executive manager who has authority to delegate resources to, and is responsible for, the radiation safety program.

Exposure: A measure of X- or gamma-radiation at a certain point, based on its ability to produce ionization in air. The unit of exposure is the roentgen (R). Sometimes used to refer to radiation absorbed dose (rad).

Financial Assurance: The posting of financial surety which essentially guarantees the availability of funds in the event that decommissioning is necessary.

Gamma Stereotactic Surgery: A patient therapy procedure utilizing several cobalt-60 beams focused by collimators on a finite target within the brain. Several diagnostic tests are performed to precisely identify the target location and prescribed delivered dose prior to treatment.

Generator Eluate: The amount of radioactive material withdrawn or eluted from the radioactive material generator. Many medical licensees utilize molybdenum-99/technetium-99m pertechnetate generators. In this generator, the Mo-99 is absorbed on an alumina column, as the Mo-99 decays to Tc-99m, and the newly formed Tc-99m may be eluted off the alumina column with saline. Tc-99m is widely used in diagnostic patient procedures. See the related definition, "molybdenum breakthrough."

Half-Life (T1/2): That amount of time required for the activity of a radionuclide to decay to one-half of its original activity. The half-life of technetium-99m, used routinely in nuclear medicine, is approximately 6 hours.

Institutional Review Board: Any board, committee, or other group formally designated by an institution to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects in accord with and for the purposes expressed in the Federal Policy for the Protection of Human Subjects (refer to 20 CFR Part 56).

Intake: Radioactive material taken into the body by absorption, ingestion, or inhalation.

Isotope: Any of two or more forms of an element having the same atomic number but different atomic weights (e.g., uranium-238 and uranium-239).

Leak Test: A test to identify possible leakage of radioactive material from a sealed source (e.g., cesium-137 sources used for therapy).

License: A document issued by a regulatory agency to authorize a facility for the possession, use, storage, and/or transfer, or distribution of licensed material.

Licensee: The entity to whom the license is issued. For medical licensees, this could be executive management of a medical institution, chief executive officer of a corporation, owner of a facility, or private physician.

Limited Specific Medical License: A specific (versus a general) license issued to a physician, group of physicians, medical institution (including facilities such as clinics, hospitals or medical centers), or corporation such as those operating a mobile nuclear medicine service, to authorize the possession and medical use of a predetermined maximum quantity or types of radioactive material. As compared to broad scope specific licenses, limited specific licenses have less flexibility in management of the radiation safety programs, and require prior approval by the appropriate regulatory agency for certain types of modifications to the licensed program. The term of the license is typically 5 years.

Limits: The maximum internal or external radiation dose, or releasable concentration allowed by the regulations.

Management Triangle: A concept used throughout this report to emphasize the importance of a team approach for managing the radiation safety program at licensed medical facilities. The primary triangle elements comprise licensee executive management, the radiation safety committee, and the radiation safety officer. The triangle is augmented by authorized users, health and medical physicists, pharmacists, technologists (including dosimetrists), nurses, ancillary workers, and consultants or contractors who provide services to augment the program.

Medical Institution: A facility at which three or more medical disciplines are practiced by more than one physician. The disciplines are not limited to those utilizing radioactive material and could include such specialties as diagnostic radiology, pathology, and physical therapy. NRC requires medical institutions to establish an RSC.

Medical Non-Institution: A facility at which one or two medical disciplines are practiced by one or more physicians, and the facility is not sited within a medical institution. Medical non-institutions are not required to have an RSC. Note that a single physician is not considered by NRC to be a "medical institution" regardless of the number of medical disciplines practiced at the licensed facility.

Medical Use: The intentional internal or external administration of radioactive material, or radiation therefrom, to humans in the practice of medicine for either diagnostic or therapeutic purposes.

Member of the Public: Any individual, except an individual who is performing assigned duties for the licensee, who might be exposed to sources of radiation at the licensed facility, or receives radiation as a patient.

Ministerial Change: An administrative change made to the radiation safety program, that is not particularly important to safety and is made by authorized facility personnel in conformance with 10 CFR 35.31.

Misadministration: An error in the delivery of the prescribed dose (radiation from a sealed source) or dosage (radiopharmaceutical) that exceeds the acceptable range of error and, therefore, is reportable to the regulatory agency. See 10 CFR 35.2 for specific NRC definitions.

Mobile Services: Nuclear medicine or radiation therapy procedures provided by a licensee who may be authorized to perform the procedure on board a mobile service vehicle and/or inside an equipped client facility authorized as a radioactive materials use location on the license issued to the mobile service. Today, there are various emerging mobile health care scenarios, and regulatory agencies may need to redefine "mobile services" and related requirements.

Molybdenum Concentration (Breakthrough): A test to check the integrity of the molybdenum alumina column in a molybdenum-99/technetium-99m pertechnetate generator. An assay is performed of the molybdenum contained in the volume of technetium-99m withdrawn from the generator. Molybdenum-99 contributes to patient dosimetry with no clinical benefit; therefore, 10 CFR 35.204 limits the concentration of patient dosages to: 0.15 microcurie of Mo-99 per 1.0 millicurie of Tc-99m.

Multidose: A vial containing more than one dosage of a pharmaceutical versus a unit dosage which is a single pharmaceutical dosage.

Nuclear Medicine: A medical specialty involving the administration of radiopharmaceuticals to patients for the diagnosis and treatment of disease.

Occupational Dose: The radiation dose received by a worker in a restricted area or who as part of his/her assigned duties is exposed to radiation. It does not include dose received from background radiation, as a patient from medical procedures, from voluntary participation in medical research programs, or as a member of the public.

Occupational Worker: An individual, who as part of his/her assigned duties, works in a restricted area and may handle radioactive material or receive radiation exposure. Occupational workers, either by formal training or inservice, have received the necessary training to work safely in restricted areas.

Output: The radiation exposure or dose rate, or quantity of radiation, related in a known manner to radiation rates emitted from a teletherapy unit for a specified set of exposure conditions.

Overexposure: A radiation exposure to an individual which exceeds a predetermined limit, or above that intended or expected.

Patient Release Criteria: Regulatory criteria for the release of patients from confinement (the licensee's control) who have undergone radiopharmaceutical diagnosis, therapy, or brachytherapy procedures. The criteria may describe a radiation exposure rate measured at a specified distance from the patient and/or an amount of residual radioactivity.

**Permanent Implants**: Brachytherapy sealed sources permanently implanted in the patient for the treatment of tumors.

Physicist (Radiation): An individual authorized on the license to perform calibrations and quality control tests on teletherapy and/or remote afterloading units. Physicists often perform dose calculations or develop patient treatment plans at the direction of the authorized physician user.

**Public Dose:** The radiation dose received by a member of the public from sources of radiation. Public dose does not include occupational dose, dose received from background radiation, dose received as a patient from medical procedures, or from voluntary participation in medical research programs.

Quality Management Program: A program required by NRC for some medical licensees and designed by each licensee to meet the objectives of the requirements described in 10 CFR 35.32. The objective of the requirement is to ensure that patients receive the dose or dosage of radiation as prescribed by the

authorized physician user. Guidance on how to meet the rule objectives is provided in NRC Regulatory Guide 8.33, "Quality Management Program."

Radiation: Energy emitted as electromagnetic waves, as gamma- or X-rays, or as energetic particles, i.e., neutrons, alpha, beta and positron particles.

Radiation Safety Staff: Licensee staff designated to support the radiation safety officer in the conduct of the day-to-day operations of the radiation safety program. Staff may include health physicists, radiation specialists, technologists, or equally trained individuals.

Radiation Oncology (Therapy): The medical specialty involving the internal or external administration of sealed sources of radiation to patients for therapeutic purposes. Sealed sources may be implanted on either a temporary or permanent basis and use manual or remote afterloading procedures. Sealed sources contained in cobalt-60 teletherapy devices and gamma stereotactic surgery devices, and the radiation emitted by a linear accelerator, are used to deliver an external beam of radiation to the patient.

Radioactive: Capable of giving off radiation, in the form of particles or rays, by the spontaneous disintegration of atomic nuclei.

Radioactive Drug Research Committee: A committee established by the licensee, and approved by the FDA, to review proposed research studies intended to obtain basic information regarding metabolism of a radioactively labeled drug, or regarding human physiology, pathology, or biochemistry, but not intended for immediate diagnostic or therapeutic purposes, e.g., to carry out clinical trials. (See related definition of Institutional Review Board.)

Radiation Surveys: Physical surveys conducted with a radiation instrument used to measure radiation levels to ensure that limits are not exceeded.

Radiopharmaceutical: A pharmaceutical that is used in its native radiochemical form or labeled with a radioactive tracer to conduct a patient diagnostic study or therapy procedure. Some radiopharmaceuticals may be used for diagnostic and therapeutic purposes by varying the amount of radioactivity administered to the patient.

Recordable Event: An NRC term used to identify those events that exceed a recordkeeping threshold, but do not meet the definitions of misadministration. Recordable events warrant prompt, corrective action by the licensee to deter recurrence and a record should be maintained for future inspections by NRC.

Rem: A dosage of any ionizing radiation that will produce a biological effect approximately equal to that produced by one roentgen of X-ray or gamma-ray radiation. Millirem (mrem) is one/one-thousandth of a rem.

Remote Afterloader Devices: A therapy device where the insertion and removal of radiation sealed sources during a patient therapy procedure is remotely activated and controlled, thereby allowing the radiation exposure to workers and members of the public to be reduced by returning the radiation sources to the shielded, or non-radiation position whenever necessary.

**Restricted Area:** An area to which access is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation or radioactive materials.

Sealed Source: Any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Specific License: A license issued to named persons or an organization based upon an application filed pursuant to either 10 CFR Parts 33 (broad scope) or 35 (limited) that authorizes the possession and use of licensed material for medical use. Most medical use licenses are of limited scope.

Survey (Radiation Survey): To detect the presence of or measure the amount of radioactivity, or measure radiation exposure rate, in a designated area. Units are typically recorded in counts or disintegrations per minute or millirems per hour.

Survey Instrument: A calibrated radiation detection or measurement instrument used to conduct a physical survey of radiation levels.

Supervised Individual: An individual who, as part of his/her assigned duties, is responsible for the safe handling of radioactive material or other sources of radiation and is supervised by an individual authorized to use the licensed material.

Teletherapy: Treatment of a patient with an external beam of radiation, e.g., from a cobalt-60 sealed source housed in a shielded device.

Transport Index: The number placed on the label of a package containing radioactive material to designate the degree of control or security to be exercised by the carrier during transportation. It is determined by the radiation levels measured at a predetermined distance from the surface of the package. (Index is determined by the Department of Transportation.)

Trigger Level: A predetermined level set by the licensee to initiate prompt investigation to determine the cause of an elevated radiation level, a high dosimeter reading, or radioactive contamination in an area.

Visiting Authorized User: An authorized user who is not identified as an authorized user on the license where the user intends to use licensed material. NRC and Agreement States have various requirements for authorized users who temporarily perform services at a licensed facility in the absence of or in addition to authorized users listed on the license. (Note: This authorization, allowed by 10 CFR 35.27, is currently under review as part of the NRC's final radiopharmacy rule which is scheduled to become effective in January 1995.)

X-Rays: A band of electromagnetic radiation, with wavelengths between gamma rays and ultraviolet radiation, produced by the bombardment of a heavy metal by a stream of electrons moving at great velocity in a vacuum tube.

	<b>APPENDIX</b>	$\mathbf{N}$	
SAMPLE NRC LICENSE FOR	<b>A LIMITED</b>	SPECIFIC MEDICAL	PROGRAM

		(a) (a) (a) (a) (a) (a)			
NRC FORM 374	II S MUCI FAR REGU	LATORY COMMISSION	PAGEOFPAGES		
(10-89)			Amendment No. 01		
	MATERIA	LS LICENSE			
Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.					
Licensee		In accordance	e with the letter dated		
1. Sample Medical Limited Specif License	ic	March 16, 19			
2.321 Main Street Anytown, Pennsylvania 18904		4. Expiration date	January 31, 1998		
		5. Docket or Reference No.	030-54321		
6. Byproduct, source, and/or special nuclear material	7. Chemical and form	1,	8. Maximum amount that licensee may possess at any one time under this license		
A. Any byproduct material identified in 10 CFR 35.100		opharmaceutical ed in 10 CFR	A. As needed		
B. Any byproduct material identified in 10 CFR 35.200	B. Any radio identifie	opharmaceutical ed in 10 CFR scept generators	B. As needed		
C. Any byproduct material identified in 10 CFR 35.300	C. Any radio	pharmaceutical d in 10 CFR	C. As needed		
D. Any byproduct material identified in 10 CFR 35.400	D. Any brach	ytherapy source d in 10 CFR	D. 2 curies		
E. Any byproduct material identified in 10 CFR 35.500	E. Any diagn	ostic source d in 10 CFR	E. As needed		
F. Any byproduct material	F. Prepackag	ed kits	F. As needed		
identified in 10 CFR 31.11 G. Cesium-137	G. Sealed so (Amersham 77302)	urce /Tech Ops Model	G. 165 millicuries		
H. Americium-241	H. Sealed so	urces   Model AMC.21)	H. 3 millicuries per source and 6 millicuries total		
I. Uranium depleted in isotope U-235	I. Metal	Ploder Anc.21)	I. 500 kilograms		
9. Authorized use					
A. Any uptake, dilution, and of B. Any imaging and localization C. Any radiopharmaceutical the D. Any brachytherapy procedure E. Medical use of sealed sour registered pursuant to 10 to 1	on procedure a erapy procedur e approved in ces included i	pproved in 10 CF e approved in 10 10 CFR 35.400	FR 35.200 CFR 35.300		

15	Form 374A	U.S. NUCLEAR REGU	LATORY COMMISSION		PAGE	2	OF	4	PAGES
(5-84)	J			License number	27 EA	221	 ∩1		
		MATERIALS LICENSE		Docket or Reference	3/-34	321-	01	·	
		SUPPLEMENTARY SHEET		Bocket of Reference	030-5	4321			
					Amend	ment	No.	01	
).	Authoriz	ed use (continued)							
F.	In vitro	studies							
G.	Non-huma	n use. For use in a Ame	rsham Calibrati	on Device Mod	lel 773	for	cal	ibrat	ion
н	and chec	king of licensee's surve n anatomical marker	y instruments						
Ï.	Shieldin	g in a linear accelerato	r						
		-	COUNTITIONS						
			CONDITIONS						
10.	Licensed Street,	material may be used on Anytown, Pennsylvania.	ly at the licen	see's facilit	y loca	ted	at 3	21 Ma	in
11.	The Radi	ation Safety Officer for	this license i	s Jane Smith,	M.D.				
12.	Licensed supervis	MATERIALS LICENSE SUPPLEMENTARY SHEET  ed use (continued) studies n use. For use in a Ame king of licensee's surve n anatomical marker g in a linear accelerato  material may be used on Anytown, Pennsylvania.  ation Safety Officer for material listed in Item ion of, the following in horized Users	6 above is onl dividuals for t	y authorized he materials	for us	e by es i	, or ndica	unde ted:	r the
	<u>Aut</u>	horized Users	<u>Materia</u>	1 and Use					
	Jan	e Smith, M.D.	300.100	<u>o</u> studies 137	300; 3	5.500	)		
	Joh	n Doe, M.D.	§35.400 Deplete	d uranium					
13.	the posse	ion to the possession linession of licensed mater and 30.35(d), 40.36(b), and sioning.	ial to quantiti	es below the	minimu	n lin	nit s	peci	fied
14.	the posse limits sp	ion to the possession linession of licensed mater opecified in 10 CFR 30.72 plan for responding to	ial at a single which require	location to consideration	quanti of the	ties	belo	w the	rict
15.	for suci	led sources and detector leakage and/or contamina n other intervals as are erred to in 10 CFR 32.210	ation at intervented by the	als not to ex ne certificat	ceed so	ix mo	nths	ora	
	alpi	withstanding Paragraph A na particles shall be tes to exceed three months.							
	has	the absence of a certific been made within six morector cell received from	iths prior to t	he transfer,	a seal	ed so	urce	or	est

- 9. Authorized use (continued)
- F. <u>In vitro</u> studies
- Non-human use. For use in a Amersham Calibration Device Model 773 for calibration G. and checking of licensee's survey instruments
- Н. Use as an anatomical marker
- Shielding in a linear accelerator Ι.

#### CONDITIONS

- Licensed material may be used only at the licensee's facility located at 321 Main 10. Street, Anytown, Pennsylvania.
- The Radiation Safety Officer for this license is Jane Smith, M.D.
- 12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

<u>Authorized Users</u>	<u>Material and Use</u>					
Jane Smith, M.D.	§35.100; 35.200; 35.300; 35.500 <u>In vitro</u> studies Cesium-137 Americium 241					
John Doe, M.D.	§35.400 Depleted uranium					

- In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.
- In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material at a single location to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.
- 15. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
  - В. Notwithstanding Paragraph A of this condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
  - С. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

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	<i>3</i>		Amen	dmen	t No.	01	

- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
  - (i) they contain only hydrogen-3; or
  - (ii) they contain only a radioactive gas; or
  - (iii) the half-life of the isotope is 30 days or less; or
  - (iv) they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material; or
  - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
- 16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
- 17. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
- 18. The licensee shall conduct a physical inventory every three months to account for all sealed sources and devices containing licensed material received and possessed pursuant to 10 CFR 35.59, 35.400, and 35.500 and every six months for all other sealed sources and devices.

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		030-34321
		Amendment No. 01
10	The Birman is subbruied to the survey by	
19.	The licensee is authorized to transport licens provisions of 10 CFR Part 71, "Packaging and T	ed material in accordance with the
,	provisions of to circ rate /1, rackaging and i	ransportation of Radioactive material.
20.	Except as specifically provided otherwise in t	his license, the licensee shall conduc
	its program in accordance with the statements,	representations, and procedures
	contained in the documents, including any encl	osures, listed below, except for minor
	changes in the medical use radiation safety pro The U.S. Nuclear Regulatory Commission's regula	ocedures as provided in 10 CFR 35.31.
	statements, representations, and procedures in	
	correspondence are more restrictive than the re	
	·	•
	A. Application dated June 10, 1992	
	B. Letter dated November 18, 1992 C. Letter dated March 16, 1993	
	c. Letter dated ridicii 10, 1333	
		,
	For the	U.S. Nuclear Regulatory Commission
ate	Ву	
u . c	ByNuc1	ear Materials Safety Branch
	Regi	on I
	King	of Prussia, Pennsylvania 19406

APPENDIX	$\mathbf{CO}$
SAMPLE NRC LICENSE FOR A BROAI	SCOPE MEDICAL PROGRAM

NRC FORM 374			2005 1 05 7 20055				
(10-89)	J.S. NUCLEAR REGU	LATORY COMMISSION					
		S LICENSE	Amendment No. 01				
Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.							
Licensee							
<sup>1.</sup> Sample Medical Broad Scope Lic	cense	January 1, 3. License number	ce with the letter dated 1994, 37-12345-01 is amended in y to read as follows:				
2. 123 Main Street Anytown, Pennsylvania 18904		4. Expiration date	November 30, 1998				
		5. Docket or Reference No.	030-12345				
6. Byproduct, source, and/or special nuclear material	7. Chemical and form		8. Maximum amount that licensee may possess at any one time under this license				
A. Any byproduct material between atomic numbers 3 and 83 with half lives less than or equal to 120 days.	A. Any		A. Not to exceed 300 millicuries per isotope, 20 curies total				
B. Any byproduct material between atomic numbers 3 and 83 with half lives	B. Any		B. See Condition 12				
greater than 120 days. C. Phosphorus-32	C. Any		C. 2 curies				
D. Sulfur-35	D. Any		D. 1 curie				
E. Iodine-125	E. Any		E. 5 curies F. 2 curies				
F. Iodine-131	F. Any		G. 1 curies				
G. Xenon-133 H. Any byproduct material	G. Any H. Sealed so	urces	H. Not to exceed 100				
between atomic numbers 3			millicuries per source, 5 curies total				
and 83 I. Cesium-137	I. Sealed so	urce	I. 165 millicuries				
1. CC3   UIII	(Amersham 77302)	/Tech Ops Mode					
J. Iridium-192	J. Sealed so Mallinckr	urces (Byk odt Model CI L	J. 2 sources not to exceed 10 curies each				
K. Uranium depleted in the isotope U-235	BV) K. Metal		K. 500 kilograms				
9. Authorized use							
AI. Medical diagnosis, therapy Food and Drug Administrat defined in 10 CFR 30.4, in instruction, and <u>in</u> vitro	ion (FDA) requ ncluding anima	lirements. Kes	accordance with any applicable earch and development as trument calibration, student				

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			Amei	ndmer	nt No	. 01	

- 9. Authorized use (continued)
- J. One source to be used in a Nucletron Corporation MicroSelectron High Dose Rate Remote Afterloading Brachytherapy Device for interstitial, intercavitary, or bronchial therapy. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.
- K. Shielding in a linear accelerator.

#### CONDITIONS

- Licensed material may be used only at the licensee's facility located at 123 Main Street, Anytown, Pennsylvania.
- 11. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, David James, M.D., Chairperson.
  - B. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.
  - C. Physicians, dentists, or podiatrists designated in writing to use licensed material in or on humans shall meet the training criteria established in 10 CFR 35, Subpart J, and shall be designated by the licensee's Radiation Safety Committee. Exceptions may be made on a case-by-case basis in accordance with the procedures described in the application dated March 31, 1992.
  - D. The Radiation Safety Officer for this license is Joyce Smith, M.S.
  - E. The Medical Physicist for this license is Roger Williams, M.S. [Required for HDR]
- 12. A. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column I. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.
  - B. Notwithstanding paragraph A of this condition and 10 CFR 33.100, Schedule A, Column I, the applicable quantities for the following radionuclides are reduced to:

Carbon-14 10 curies
Krypton-85 10 curies
Iodine-129 10 millicuries

Any byproduct material other than alpha-emitting byproduct material not listed in 10 CFR 33.100, Schedule A 10 millicuries

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- In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material at a single location to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.

  Notwithstanding the requirements of 10 CFR 35.49(a) and (b), 35.100, 35.200, 35.300, 35.400, and 35.500, the licensee may use, for any medical use, any byproduct material or reagent kit. The licensee shall possess and use byproduct material for medical use in accordance with the prescriptive and performance criteria in the other sections of 10 CFR Part 35. This does not relieve the licensee from complying with applicable FDA, Federal, and State requirements.

  The licensee shall possess and use byproduct material for human research in accordance with the prescriptive and performance criteria in all sections of 10 CFR Part 35 except Sections 35.49(a) and (b), 35.100, 35.200, and 35.300.

  A. Access to the treatment room housing each high dose rate remote afterloading brachytherapy unit shall be controlled by a door at each entrance.

  B. Each entrance to the treatment room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source and the source "on-off" control is reset at the control panel.

  C. Electrical interlocks on each entrance door to the treatment room shall be tested for proper operation at least once each day of use.

  D. In the event of malfunction of the door interlock, the unit shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

  Prior to initiation of a treatment program, and subsequent to each source exchange for each high dose rate remote afterloading brachytherapy unit, a radiatio

- - B. All areas adjacent to the treatment room with the source in the exposed position. The survey shall clearly establish that:
    (1) Radiation doses to occupationally exposed individuals do not exceed the limits specified in 10 CFR 20.1201(a), 20.1207, and 20.1208.

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- (2) Radiation doses to individual members of the public do not exceed the limits specified in 10 CFR 20.1301(a).
- 18. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such service:
  - A. Installation and replacement of the sealed sources contained in each high dose rate remote afterloading brachytherapy unit.
  - B. Maintenance or repair operations on any high dose rate remote afterloading brachytherapy unit and associated equipment involving work on the source safe, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.
- 19. In lieu of the source inventory described in 10 CFR 35.406, the licensee shall:
  - A. Promptly determine that all sources have returned to the safe shielded position at the conclusion of each high dose remote brachytherapy procedure.
  - B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.
  - C. Make a record of the survey including survey instrument used, dose rate, time, date, and name of the individual making the survey.
  - D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).
- 20. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).
- 21. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months, or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
  - B. Notwithstanding paragraph A of this condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.

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١.	NRC Form 374A	U.S. NUCLEAR REGULATORY COMMISSION		PAGE	5	OF	7	PAGES
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- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
  - (1) they contain only hydrogen-3; or
  - (2) they contain only a radioactive gas; or
  - (3) the half-life of the isotope is 30 days or less; or
  - (4) they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material; or
  - (5) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with NRC regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by NRC or an Agreement State to perform such services.
- Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

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23.	th	e licensee shall not acquire licensed materia e source or device has been registered with N uivalent regulations of an Agreement State.	l in a sealed source or device unless RC pursuant to 10 CFR 32.210 or
24.	se: pui	e licensee shall conduct a physical inventory aled sources and devices containing licensed or suant to 10 CFR 35.59, 35.400, and 35.500, and aled sources and devices.	every three months to account for all material received and possessed nd every six months for all other
25.	det	intenance, repair, cleaning, replacement, and tector cells shall be performed only by the de ecifically authorized by NRC or an Agreement	disposal of foils contained in evice manufacturer or other persons State to perform such services.
26.	Α.	Detector cells containing a titanium tritide shall only be used in conjunction with a promechanism which prevents the foil temperature the certificate of registration referred to	operly operating temperature control res from exceeding that specified in
	В.	When in use, detector cells containing a til tritide foil shall be vented to the outside.	tanium tritide foil or a scandium
27.	Exp adm	erimental animals, or the products from experinistered licensed materials shall not be use	rimental animals, that have been
28.	The les	licensee is authorized to hold radioactive m s than 120 days for decay-in-storage before d	naterial with a physical half-life of lisposal in ordinary trash, provided:
	Α.	Waste to be disposed of in this manner shall half-lives.	be held for decay a minimum of 10
-	В.	Before disposal as ordinary trash, the waste surface with the appropriate survey instrume and with no interposed shielding to determin distinguished from background. All radiatio obliterated.	shall be surveyed at the container int set on its most sensitive scale e that its radioactivity cannot be n labels shall be removed or
	С.	A record of each such disposal permitted und retained for three years. The record must i on which the byproduct material was placed i of, the survey instrument used, the backgrou at the surface of each waste container, and performed the disposal.	nclude the date of disposal, the date n storage, the radionuclides disposed nd dose rate, the dose rate measured
29.	rep	ioactive waste generated shall be stored in a resentations, and procedures included with th ensee's letter dated May 12, 1993.	ccordance with the statements, e waste storage plan described in the
30.	The pro	licensee is authorized to transport licensed visions of 10 CFR Part 71, "Packaging and Tra	material in accordance with the nsportation of Radioactive Material."

- The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with NRC pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
- 24. The licensee shall conduct a physical inventory every three months to account for all sealed sources and devices containing licensed material received and possessed pursuant to 10 CFR 35.59, 35.400, and 35.500, and every six months for all other sealed sources and devices.
- Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by NRC or an Agreement State to perform such services.
- 26. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.
  - B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
- Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
- The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash, provided:
  - Waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
  - Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
  - C. A record of each such disposal permitted under this license condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed of, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
- Radioactive waste generated shall be stored in accordance with the statements, representations, and procedures included with the waste storage plan described in the licensee's letter dated May 12, 1993.
- 30. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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			Amendment No. 01
31.	Exce cond prod for CFR the corn	ept as specifically provided for otherwise duct its program in accordance with the statedures contained in the documents, including in the U.S. Nuclear Regulatory Commissistatements, representations, and procedure respondence are more restrictive than the respondence are more restrictive than the respondence are more at the statements of the statements	in this license, the licensee shall atements, representations, and ing any enclosures, listed below, except a safety procedures as provided in 10 ssion's regulations shall govern unless in the licensee's application and regulations.
	A. B. C. D.	Application dated March 31, 1992 Letter dated May 12, 1993 Letter dated September 7, 1993 Letter dated January 1, 1994	
		4.4 	
		For the l	J.S. Nuclear Regulatory Commission
		, 5. ••	· ·
Date		By	ar Materials Safety Branch
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### APPENDIX P NRC ENFORCEMENT PROGRAM

The Commission developed an enforcement program and Enforcement Policy to support the NRC's overall safety mission in protecting the public and the environment. Consistent with that purpose, enforcement action should be used as a deterrent to emphasize the importance of compliance with regulatory requirements, and to encourage prompt identification and prompt, comprehensive correction of violations.

Violations are identified through inspections and investigations. All violations are subject to civil enforcement action and may also be subject to criminal prosecution. After an apparent violation is identified, it is assessed in accordance with the Commission's Enforcement Policy. The Policy is published as NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions." Because it is a policy statement and not a regulation, the Commission may deviate from this statement of policy and procedure as appropriate under the circumstances of a particular case.

There are three primary enforcement sanctions available: Notices of Violation, civil penalties, and orders. A Notice of Violation (NOV) summarizes the results of an inspection, identifies a requirement and how it was violated, and formalizes a violation pursuant to 10 CFR 2.201. A civil penalty is a monetary fine issued under the authority of section 234 of the Atomic Energy Act. That section provides for penalties of up to \$100,000 per violation per day; however, that amount has been adjusted by the Debt Collection Improvement Act of 1996 to be \$110,000. NOVs and civil penalties are issued based on violations. Orders may be issued for violations, or in the absence of a violation, because of a public health or safety issue.

The Commission's order issuing authority is broad and extends to any area of licensed activity that affects the public health and safety. Orders modify, suspend, or revoke licenses or require specific actions by licensees or individuals. As a result of a rulemaking in 1991, the Commission's regulations now provide for issuance of orders to individuals who are not themselves licensed.

The first step in the enforcement process is assessing the severity of the violation. Severity Levels range from Severity Level I, for the most significant violations, to Severity Level IV, for those of more than minor concern. Minor violations are not subject to formal enforcement action. Severity levels may be increased for cases involving a group of violations with the same root cause, repetitive violations, or willful violations.

A predecisional enforcement conference is normally conducted with a licensee before making an enforcement decision, if escalated enforcement action (i.e., Severity Level I, II, or III violations, civil penalties or orders) appears to be warranted and if either the NRC concludes that it is necessary or the licensee requests the conference. If the NRC concludes that a conference is not necessary, it will normally provide a licensee with an opportunity to respond to the apparent violations before making an enforcement decision. The purpose of the conference is to obtain information that will assist the NRC in determining the appropriate enforcement action, such as the following information: (1) a common understanding of facts, root causes and missed opportunities associated with the apparent violations, (2) a common understanding of the corrective action taken or planned, and (3) a common understanding of the significance of issues and the need for lasting comprehensive corrective action. The decision to hold a conference does not mean that the agency has determined that a violation has occurred or that enforcement action will be taken. In accordance with the Enforcement Policy, conferences are normally opened to the public. However, the Commission will close conferences under certain circumstances.

Civil penalties are considered for Severity Level III violations. However, civil penalties are normally assessed for Severity Level I and II violations, and for knowing and conscious violations of the reporting requirements of Section 206 of the Energy Reorganization Act.

The NRC imposes different levels for civil penalties based on a combination of the type of licensed activity, the type of licensee, the severity level of the violation, and the following information: (1) whether the licensee has had any previous escalated enforcement action (regardless of the activity area) during the past 2 years or past 2 inspections, whichever is longer; (2) whether the licensee should be given credit for actions related to identification; (3) whether the licensee's corrective actions are prompt and comprehensive; and (4) whether, in view of all the circumstances, the matter in question requires the exercise of discretion. Although each of these decisional points may have several associated considerations for any given case, the outcome of the assessment process for each violation or problem, absent the exercise of discretion, is limited to one of the following three results: no civil penalty, a base civil penalty, or a base civil penalty escalated by 100%.

In order to provide greater assurances for safety, the Commission strongly encourages licensees to monitor, supervise, and audit their activities in an effort to identify problems and violations before they are either discovered by an NRC inspection or lead to an unfortunate incident. Thus, civil penalties may be mitigated for violations identified by a licensee, and increased for violations identified by the NRC.

Similarly, upon discovery of a violation, licensees are encouraged to take prompt to restore safety and compliance with the regulation, license condition, or other requirement. Corrective actions are expected to be lasting actions that will not only prevent recurrence of the specific violation, but also be sufficiently comprehensive to prevent similar violations. Civil penalties are mitigated or escalated based on the promptness and extensiveness of the corrective action.

If a civil penalty is to be proposed, a written Notice of Violation and Proposed Imposition of Civil Penalty is issued. The licensee has 30 days to respond in writing, by either paying the penalty or contesting it. The NRC considers the response, and, if the penalty is contested, may either mitigate the penalty or impose it by order.

If the civil penalty is to be imposed by order, the order is published in the *Federal Register*. Thereafter, the licensee may pay the civil penalty or request a hearing.

In addition to civil penalties, orders may be used to modify, suspend, or revoke licenses. Orders that modify a license may require additional corrective actions, such as removing specified individuals from licensed activities or requiring additional controls or outside audits. The NRC issues a press release announcing a proposed civil penalty or order.

In addition, the Commission has a rule concerning deliberate wrongdoing by unlicensed individuals. The "Deliberate Misconduct Rule" applies to an employee of a licensee, a contractor, or subcontractor, who knowingly provides components or any other goods or services that relate to licensed activities. This rule prohibits (1) engaging in deliberate misconduct that causes, or but for detection would have caused, a licensee to be in violation of any NRC requirement, or (2) deliberately submitting to NRC, a licensee or contractor, or subcontractor, information known to be incomplete or inaccurate in some respect material to the NRC. Deliberate misconduct is either (1) an intentional act or omission that the person knows would cause a violation or (2) a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee or contractor, regardless of whether the person knew a resulting violation of NRC requirements would occur. An order issued under the deliberate misconduct rule may order the wrongdoer to remain out of licensed activities for a specified period, or to notify the NRC before resuming involvement in licensed activities.

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The NRC relies on individuals who perform duties involving NRC licensed activities to not only perform the duties properly but to record and report information accurately to NRC upon request or when required. The Commission requires that all information required to be recorded or communicated to the Commission be complete and accurate in all material respects. This requirement applies to both oral and written information, and omitted information that causes an affirmative statement to be materially incomplete or inaccurate. Also, under the deliberate misconduct rule described previously, actions are taken against individuals who deliberately submit information known to be incomplete or inaccurate.

In accordance with 10 CFR 30.7 and related regulations, it is a violation of Commission requirements to discriminate against an individual with respect to the terms, conditions, and/or privileges of employment because the person engaged in protected activity. According to Section 211 of the Energy Reorganization Act, protected activities include, but are not limited to the following activities: notifying an employer of an alleged violation; refusing to participate in any activity made unlawful by the Energy Reorganization Act or the Atomic Energy Act; testifying before Congress or any Federal or State proceeding; commencing or causing to be commenced a proceeding under the Energy Reorganization Act; and testifying or assisting in any such proceeding.

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# APPENDIX R LITERATURE ABSTRACTS PREPARED BY BROOKHAVEN NATIONAL LABORATORY

# MANAGEMENT OF RADIATION SAFETY PROGRAMS AT LICENSED MEDICAL FACILITIES\*

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1. LICENSING CRITERIA FOR NUCLEAR MEDICINE. WESTERMAN, B.R. (University of Arizona, Tucson, USA). Seminars in Nuclear Medicine, Vol. 3, July 1986, pp. 171-178.

The use of radioactive materials in medicine is one of the most highly regulated areas the physician has to deal with. There are three basic types of licenses for use of radioactive material defined in the Code of Federal Regulations (CFR), chapter 10, part 35. These are the general license, which is mainly applicable to small volume in vitro work; the specific license, which is used in most medical facilities; and the broad license, which is suited for larger research-oriented practices. Licensing requires proof of competence of the user and of adequate provision for protection of public health. Materials used in medicine are grouped for convenience into three diagnostic categories and two therapeutic categories. A sixth group, for sealed implants, is not generally applicable in nuclear medicine. Training and experience of users may be documented in a number of ways, including board certification in nuclear medicine. Therapeutic applications require additional proof of direct personal experience. The radiation safety officer is a pivotal individual in the licensing procedure, being directly responsible for carrying out the highly detailed requirements for protection of personnel and patients. A radiation safety program based on the as low as reasonably achievable (ALARA) concept requires personal monitoring, inventory control, detection and control of contamination, and strict adherence to licensing rules. Training of personnel and proper maintenance of equipment and facilities are also vital parts of the licensing process. The requirements of licensing and for renewal are clearly spelled out by the various regulatory agencies and require meticulous record keeping with documentation that all prescribed procedures have been followed and duly recorded.

2. A LOCAL AREA NETWORK FOR CONTROLLING THE ORDERING AND PURCHASING OF RADIOACTIVE MATERIAL. WEBER, P.J.; CASTRONOVO, F.P., JR. (Brigham & Woman's Hospital, Boston, MA, USA), Health Physics, Vol. 61, No. 4, October 1991, pp. 547-52.

Efficient control over the purchase and receipt of radioactive material is a necessary part of any radiation safety program. The authors describe a novel computerized method for monitoring the flow

of radioactive material within a large broad-licensed medical research complex. The local area network (LAN) described interfaces the radiation safety office with radionuclide receiving, the authorized user, grants and contracts, special accounts and purchasing. Task-specific software enables the authorized user to place an order and allows the monitoring of possession/ordering limits, personnel, date of order, and time of receipt via the screen. The resultant database is easily annexed for specific information. The system is user-friendly and adaptable to any set of circumstances.

3. DATABASE MANAGEMENT SYSTEM FOR A RADIATION SAFETY PROGRAM. MC KETTY, M.H.; ROACH, D.M. (Howard University, Washington, DC, USA), Health Physics, Vol. 60, No. 3, March 1991, pp. 453-456.

A database management system (DBMS) has been developed that simplifies the retrieval of data concerning radioisotope use at a university and hospital. The system customizes software that is commercially available to perform several functions. Reports can be developed concerning receipt of radioactive materials, radioactive waste disposal, and research proposals submitted by investigators. Reports can be prepared that utilize the software's ability to perform numerical calculations. The main advantage of the DBMS is that it allows the easy retrieval of information that is used in the day-to-day operation of a radiation safety office; it also provides easy access and manipulation of data for the preparation of reports, budget proposals, and justifications for purchases.

4. RADIOCONTAMINATION IN MEDICAL CENTERS FROM DIAGNOSTIC NUCLEAR MEDICINE PROCEDURES. WIATROWSKI, W.A.; COOKE, E.P.; KOPP, D.T.; JORDAN, D.W. (Audie L. Murphy Memorial Veterans Hospital, San Antonio, TX, USA), Health Physics, Vol. 47, No. 2, August 1984, pp. 297-298.

The extent to which patients, dosed with diagnostic quantities of radiopharmaceuticals, contaminate facilities in a medical center was studied. Two 1-month studies were conducted independently in two large government hospitals. Both hospitals have large, well equipped nuclear medicine facilities as well as comprehensive radiation safety programs. Some contamination was observed in conjunction with

diagnostic procedures, however, the contaminating activity was very low. Although it is unclear whether the observed frequency of contamination in this study is typical of other hospitals, the study suggests that for comparable nuclear medicine workloads, radiocontamination from diagnostically dosed nuclear medicine patients does not present a major problem for the hospital health physicist.

5. UPDATE ON RADIATION SAFETY IN A NUCLEAR MEDICINE DEPARTMENT. GANDSMAN, E.; NORTH, D.; TYSON, I. (Miriam Hospital, Providence, RI, USA), Health Physics Vol. 46, No. 6, June 1984, pp. 1293-1295.

The results of a Nuclear Medicine Department Radiation Safety Program are reviewed following substantial changes in the department's work load due to the advent of nuclear cardiology. It is important to emphasize that a good radiation safety program can be implemented by applying a combination of very simple measures of radiation protection; shielding, distance and time. By enforcing these principles with care and persistence, it has been possible to decrease the radiation dose to technologists in spite of the concurrent increase in work load and the total administered activity. Technologist dose equivalents have been maintained below the suggested 0.5 rem/yr (5 mSv) ALARA guideline.

6. SIX YEAR EXPERIENCE OF NUCLEAR MEDICINE RADIATION SAFETY PROGRAM: TECHNIQUES, PITFALLS IN THE USE OF PERSONNEL FILM BADGE RECORDS IN EVALUATING RADIATION SAFETY PROGRAMS. STANTON, R.; GEORGE, D.; MOORE, M. (Cooper Hospital, University Medical Center, Camden, NJ, USA), Thirty-first Annual Meeting of the Health Physics Society, Pittsburgh, PA, June 29-July 3, 1986. Health Physics, Vol. 50 (Suppl. 1), 1986, p. S51.

During the six year period from 1977 through 1982, the radiation safety officer at Cooper Hospital instituted several new procedures to lower the occupational radiation exposures to the nuclear medicine imaging technicians. Among these were the regular use of syringe shields, the discontinuing of lead salvage from Tc99m generators, discontinuing the use of Tc99m generators and the substitution of unit dose Tc99m from an outside radiopharmacy. The impact of those dose reduction techniques were

evaluated by reviewing the commercial whole body film badge and TLD ring badge records of all Correlations between the radioisotope workers. implementation of these new procedures and personnel exposure will be discussed. preparation of this data indicated many pitfalls in the use of badge records to evaluate safety procedures. For example, simple averaged badge readings hide the complications of personnel turnover, individual variability of techniques, and job duty variations which carry different radiation hazards. Whole body film badge location, dealt with extensively in the literature for radiographic workers, has not been evaluated for radioisotope workers. This presentation is part of an ongoing program to evaluate and upgrade the radiation safety program in our institution.

7. PERSONNEL DOSE ASSIGNMENT PRACTICES. FIX, J.J. (Battelle Pacific Northwest Laboratory, Richland, WA, USA), PNL-SA-22241; CONF-9304128-1; NTIS Accession Number DE93013285, April 1993, Presented at the Department of Energy (DOE) Radiation Protection Conference, Las Vegas, NV, USA, April 13-15, 1993, 8 p.

Implementation of DOE N 5480.6 Radiological Control Manual Article 511(3) requirements to minimize the assignment of personnel dosimeters should be done only under a broader context ensuring that capabilities are in place to monitor and record personnel exposure both for compliance and for potential litigation. As noted in NCRP Report No. 114, personnel dosimetry programs are conducted to meet four major objectives: radiation safety program control and evaluation; regulatory compliance; epidemiological research; and litigation. A change to Article 511(3) is proposed that would require that minimizing the assignment of personnel dosimeters take place only following full evaluation of overall capabilities (e.g., access control, area dosimetry, etc.) to meet the NCRP objectives.

8. FORMS FOR DOCUMENTING RADIATION SAFETY PROGRAMS - FINAL REPORT. WEED, R.; DONOVAN, L. (Medical Center, Scott Air Force Base, IL, USA), USAFMCS/TR-88/001, NTIS Accession Number AD-A193 180/7, January 1988, 78 p.

The Department of Radiology, U.S. Air Force Scott Medical Center, created and compiled this booklet of

forms in Ouality Assurance/Risk document Management and ALARA (as low as reasonably Medicine/Radiology achievable) for Nuclear Departments. A health physicist manages, evaluates, trial tests, and currently uses forms such as these. They can be altered or easily redesigned as the needs of radiation surveillance programs change. These Documental Forms for Ionizing Radiation (Formless Forms) should be useful for facilities that devise their own Nuclear Medicine/Radiology Quality Assurance-Risk Management and ALARA Programs.

9. ROLE OF PERSONAL AIR SAMPLING IN RADIATION SAFETY PROGRAMS AND RESULTS OF A LABORATORY EVALUATION OF PERSONAL AIR-SAMPLING EQUIPMENT - FINAL TECHNICAL REPORT. RITTER, P.D.; HUNTSMAN, B.L.; NOVICK, V.J.; ALVAREZ, J.L.; RICH, B.L. (EG&G Idaho, Inc., Idaho Falls, ID, USA), EGG-2352, NUREG/CR-4033, December 1984, 79 p.

Recommended applications for personal air sampling in NRC licensee radiation protection programs are presented. The performance tests show that personal air samplers are available which can provide a reliable, convenient means for breathing-zone sampling of workers in practically any work environment which might be encountered in the licensee industries. The research literature emphasized that estimates of an individual's exposure may be greatly underestimated if based on general area air samples, as is common practice in current licensee programs, due to the unpredictable variability of airborne-activity concentrations in the worksite. A conclusion which may be drawn from the literature and from experimental results is that in most situations, personal air sampling (or more generally, true breathing-zone sampling) is the only means to reliably estimate the airborne activity to which a worker has been exposed (MPC.h). concerning the applicability of air-sampling measurements for estimating intake, uptake, and internal dose was also reviewed.

10. SAFE HANDLING OF TISSUE CONTAINING RADIOACTIVE SUBSTANCES. WARREN, S. (New England Deaconess Hospital, Boston, MA, USA), CONF-751143-1; COO-3017-23; 1975, 6 p.

Patients recently treated with radioactive isotopes may present problems or even hazards during physical examination, surgery, or autopsy, especially following the use of exp 131 I and exp 198 Au. Exp 32 P is rarely a significant hazard. Contamination of victims of radiation accidents may be a problem initially, but they are usually promptly decontaminated. Guidance of the hospital's radiation safety officer is helpful, particularly with regard to handling of contaminated persons or materials. Long-lived isotopes, such as radium or thorotrast, are usually present in too low a concentration to be dangerous.

- 11. RADIATION SAFETY PROGRAM AT THE NATIONAL INSTITUTES OF HEALTH. HOLCOMB, W.F.; ZOON, R.A.; AUSTIN, J.H.; AUGUSTINE, R.J. (U.S. Environmental Protection Agency, Washington, DC, USA), Nuclear Safety, Vol. 25, No. 5, September-October 1984, pp. 676-688.
- A large variety of radionuclides and radiation-producing machines are used in biomedical research and medical diagnostic applications at the National Institute of Health (NIH), Maryland. The NIH radiation safety branch administers a comprehensive radiation safety program covering some 2,000 radionuclide laboratories and over 4,500 users of radiation sources under licenses issued by the Nuclear Regulatory Commission (NRC). Radiation exposure monitoring, laboratory inspections, waste management, training, and environmental monitoring are part of the program. The safety efforts have maintained personnel radiation exposures well below NRC regulatory radiation limits.
- 12. NURSING PERSONNEL TAKING CARE OF BRACHYTHERAPY PATIENTS: TO BE OR NOT TO BE CLASSIFIED AS RADIATION WORKERS? DATTA, R.; DATTA, S. (Department of Radiology, Louisiana State University Medical Center, Shreveport, LA, USA), Health Physics, Vol. 57, No. 1, 1989, pp. 199-201.

The purpose of this study is to review the radiation doses received by these personnel in a medium-size medical center under a good radiation safety program and to look into the rationale for providing personal monitors.

13. RESULTS OF A SURVEY REGARDING THE NECESSARY QUALIFICATIONS OF CAMPUS RADIATION SAFETY OFFICERS.

WEGST, W.F. JR. (UCLA, Los Angeles, CA, USA), Health Physics, Vol. 39, No. 2, 1980, pp. 348-351.

The results of an opinion survey on the necessary qualification for a Campus Radiation Safety Officer (Type A, Broad License) has shown fairly clearly that a Masters of Science degree with some experience is the preferred level of training. ABHP Certification is not considered to be of overriding importance and the Certification process itself is thought to be in need of revision. Since the NRC is currently developing both Regulatory Guide 10.5 (on Broad License performance specifications), and a guide on RSO qualifications (for all types of RSOs), the results of this survey should be of interest to those discussions. In addition, the survey results may be of interest to both educators and members of the American Board of Health Physics.

14. ANALYSIS OF RADIATION EXPOSURE SITUATION AT THE INSTITUTE OF NUCLEAR MEDICINE & ALLIED SCIENCES, DELHI. SHARMA, K.L.; JOHN, R.; RAY, N.K. (Inst. Nucl. Med. All. Sci., Delhi, India), Indian Journal of Radiology, Vol. 32, No. 3, 1978, pp. 204-206.

The paper presents the experiences of INMAS over a period of 18 years and analyses the radiation exposure situation to the various categories of staff. The groups potentially subjected to higher levels of radiation exposure are categorized. The isotope consumption pattern and the protection problems associated with the staff to the use of newer generator-produced radiopharmaceuticals have been discussed. The organizational aspect of a radiation safety program including methods for radioactive waste disposal shows that by the institution of appropriate health physics procedures it is possible to carry on the activities without any one exceeding one-third of the maximum permissible exposure.

**15. THE RADIATION SAFETY OFFICER.** HUERTA, L.K., Applied Radiology and Nuclear Medicine, Vol. 5, No. 5, 1976, pp. 71-72 and p. 108.

Within the last 15 years, the radiation safety officer has become a new addition to the staff of hospitals and research facilities. During this period, the position has expanded, yet it still is not rigidly defined. Across the country, vast differences were encountered concerning duties and background of

radiation safety officers. Qualifications and outside department control of radiation safety officers are emphasized in this article.

**16. HEALTH PHYSICS SERVICES IN HOSPITALS.** STEPHENSON, S.K., Annals of Occupational Hygiene, Vol. 6, No. 3, 1963, pp. 167-174.

The protection of hospital workers in contact with radiation sources is described. The extent of hospital worker radiation exposure is discussed, together with the history of exposure monitoring in British hospitals. The organization of a radiological safety program for British hospitals is described, along with protective services offered to hospital workers by the Manchester Regional Hospital Board. Hospital protection programs such as those associated with diagnostic radiology, X-ray therapy, nursing services for radiology patients, routine handling of unsealed radioisotope sources, and staff education on radiation safety procedures are considered. Exposure routes also are noted.

17. RADIATION SAFETY FOR LABORATORY TECHNICIANS. KELSEY, C.A. (University of New Mexico Medical Cente., Albuquerque, NM, USA), Allied Health Professions Monographs, Gardner, A.F. (Ed.), Published by Warren H. Green, Inc., June 1983, ISBN 0-87527-319-X, 42 p.

This booklet includes the following required knowledge for persons working with radioisotopes: the nature and characteristics of radiation and radioactivity, radiation detection, possible hazards of radiation including hazards to the fetus, safety practices which can reduce radiation exposure to workers and the environment, what to do if something goes wrong, and current regulations and license provisions.

18. RADIATION SAFETY IN NUCLEAR MEDICINE: A PRACTICAL GUIDE -- FINAL REPORT. SODD, V.J. (Bureau of Radiological Health, Rockville, MD, USA). FDA/BRH-82/31; DHHS/PUB/FDA-82-8180; NTIS Accession Number PB82-159963, November 1981, 144 p.

This publication brings together, in concise form, information regarding the many recommendations and requirements for safe operation of a nuclear medicine laboratory. The need for such a compendium was

perceived by the staff of the Nuclear Medicine Laboratory. This need arises from several sources. Many individuals enter the field with little training in the handling of radioactive materials; for example, a physician trained in cardiology, oncology, or neurology. The increasing development of portable has allowed movement instrumentation radiopharmaceuticals from the confines of the nuclear medicine lab to coronary and intensive care facilities where personnel may lack adequate knowledge of safe handling procedures. A health physicist, trained to account for all radioactive material placed under his control, may have difficulty adapting to the accepted practice of releasing a patient who has been administered millicurie quantities of radioactivity, with little or no control over subsequent disposal of excreta. Further differences exist between handling practices for radioactive materials in the scientific laboratory and in the medical facility. This guide tries where possible to clarify some of these issues.

19. MONITORING OCCUPATIONAL RADIATION EXPOSURE IN MEDICINE. PARKS, R.E.; VIAMONTE, M. JR., Industrial Medicine and Surgery, Vol. 31, No. 7, July 1962, pp. 284-286.

The monitoring of occupational radiation exposure is reviewed. In discussing radiation safety the personnel of the medical facility can be divided into those assigned to work with or around radiation sources and those who are considered not controlled because their exposure is not monitored due to its occasional or accidental nature. The controlled worker is permitted a higher radiation environment because it is presumed the exposure will be carefully watched. maximum permissible dose for a radiation worker is 0.1 rem per week. When previous occupational exposure of a worker is not definitely known it is assumed he has met the maximum and is therefore allowed a maximum of 5 rems per year. Where intense forms of radiation are used or stored a background monitor of some sort is needed. A radiation worker needs a personal monitoring device to show the amount of radiation personally received. The pocket dosimeter is one such device. This is a small ionization chamber which records the amount of ionizing radiation reaching its chamber. If the intensity of the radiation is high or the instrument has reached its maximum, the pocket dosimeter may not be very accurate. False low or high gauging may result from pocket dosimeters. The chief advantage is that the readings are readily available. The film badge is probably the only practical personal monitoring device in use now. It is compact and easy to wear and will measure a wide range of exposure intensity. It can be used practically for a long period of time and is not easily tampered with. The accuracy of the film and the difficulties of development are disadvantages. The badge provides the employer with the information necessary for protection from occupational injury liability. The authors conclude that the film badge is the only practical means of monitoring ionizing radiation exposure in occupational situations at this time.

20. APPLIED RADIATION BIOLOGY AND PROTECTION. GRANIER, R.; GAMBINI, D.-J. (Hospital Laennec, Paris, France), published by Ellis Horwood, London (United Kingdom), ISBN 0-13-039991-4, 1990 (Translated from the French by Roy Lisker), 355 p.

This book grew out of a series of courses in radiobiology and radiation protection which were given to students in schools for radiology technicians, radiation safety officers and to medical students. Topics covered include the sources of ionizing radiation and their interactions with matter; the detection and measurement of ionizing radiation; dosimetry; the biological effects of ionizing radiation; the effects of ionizing radiation on the human body; natural radioexposure; medical radio-exposure; industrial radioexposure of electronuclear origin; radioexposure due to experimental nuclear explosions; radiation protection; and accidents with external and/or internal radio-exposure.

21. TRAINING IN RADIOLOGICAL PROTECTION AT THE INSTITUTE OF NAVAL MEDICINE. POWELL, P.E.; ROBB, D.J. (Institute of Naval Medicine, Defense Radiological Protection Services, Gosport, United Kingdom), Conference on Occupational Radiation Protection, Guernsey, United Kingdom, April 29-May 3, 1991, Published by British Nuclear Energy Society, London (United Kingdom), CONF-910429--, ISBN: 0 7277 1623 9, pp. 179-184, 358 p.

The Training Division at the Institute of Naval Medicine, Alverstoke, UK, provides courses in radiological protection for government and military personnel who are radiation protection supervisors, radiation safety officers, members of naval emergency

monitoring teams, and senior medical officers. The course programs provide formal lectures, practical exercises and tabletop exercises. The compliance of the Ministry of Defense with the Ionizing Radiations Regulations 1985 and the implementation of Ministry of Defense instructions for radiological protection rely to a large extent on its radiation protection supervisor's understanding of the training he receives. Quality assurance techniques are therefore applied to the training.

22. RADIATION PROTECTION FOR NURSES-REGULATIONS AND GUIDELINES. JANKOWSKI, C.B. (Radiation Safety Office, Brigham and Women's Hospital, Boston, MA, USA), Journal of Nursing Administration, Vol. 22, No. 2, February 1992, pp. 30-34.

Rules and regulations of federal agencies and state radiation protection programs provide the bases for hospital policy regarding radiation safety for nurses. Nursing administrators should work with the radiation safety officer at their institutions to ensure that radiation exposures to staff nurses will be as low as reasonably achievable and that special consideration will be given to pregnant nurses. Nurses' fears about their exposure to radiation can be greatly reduced through education.

23. RADIATION PROTECTION TRAINING FOR PERSONNEL EMPLOYED IN MEDICAL FACILITIES -- TECHNICAL REPORT. MC ELROY, N. L.; BRODSKY, A. (Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC, USA), NUREG-1134, May 1985, 61 p.

This report provides information useful for planning and conducting radiation safety training in medical facilities to keep exposures as low as reasonably achievable, and to meet other regulatory, safety and loss prevention requirements in today's hospitals. A brief discussion of the elements and basic considerations of radiation safety training programs is followed by a short bibliography of selected references and sample lecture (or session) outlines for various job categories. This information is intended for use by a professional who is thoroughly acquainted with the science and practice of radiation protection as well as the specific procedures and circumstances of the particular hospital's operations.

Topics can be added or subtracted, amplified or condensed as appropriate.

24. GETTING THROUGH THE MAZE OF FEDERAL AND STATE RADIATION REGULATIONS. MARSHALL, C.H., 73rd Scientific Assembly and Annual Meeting of the Radiological Society of North America, Chicago, IL, November 29, 1987, CONF-871175, 229 p.

This course is designed to help radiologists, physicists, technologists, and administrators understand the complex system of federal and state radiation safety regulations that have an impact on the practice of radiology, nuclear medicine, and radiation therapy, and biomedical research. Emphasis is placed on the practical impact of these regulations and on strategies to meet individual and institutional responsibilities. Topics to be covered include the relative roles of the NRC, FDS, DOT, EPA, OSHA, and state and local agencies; the obligations of manufactures, institutions, and individuals; and licensing, documentation, and reporting requirements JCAH standards will also be mentioned. The role and responsibilities of the Radiation Safety Officer and of institutional radiation safety, radioactive drug, and human research committees are discussed.

25. TRANSPORTATION ISSUES IN NUCLEAR MEDICINE AND THE RELEASE OF RADIOACTIVITY INTO THE ENVIRONMENT. WESTERMAN, B.R. (University of Arizona, Tucson, AZ, USA), Seminars in Nuclear Medicine, Volume 3, July 1986, pp. 191-197.

Large volumes of radioactive materials are shipped daily over the nation's highways, by air, and by other transportation modes for a variety of purposes. These shipments include those intended for nuclear medicine applications. Shipments are governed by the Federal Department of Transportation, the Nuclear Regulatory Commission, and, for international shipments, the International Atomic Energy Agency. Knowledge of the regulations of these agencies is essential for maintenance of a viable radiation safety program. The use of radioactive materials is invariably accompanied by the potential for release of radioactivity into the environment. This potential is addressed in the recommendations and regulations of several voluntary and governmental agencies. Recently, new concepts have been introduced into these recommendations and regulations that use the concepts of annual limit of intake, committed effective dose equivalent, and derived air concentrations. These concepts improve the applicability of present standards for the release of radioactive materials into the environment and for the protection of individuals from these materials.

26. USE OF A RADIATION THERAPY TREATMENT PLANNING COMPUTER IN A HOSPITAL HEALTH PHYSICS PROGRAM. ADDISON, S.J.; KATHREN, R.L.; HIGBY, D.P.; MCKINNEY, M.A. (Western Colorado Radiologic Associates, P.C., St. Mary's Hospital and Medical Center, Grand Junction, CO, USA), 17th Midyear Topical Meeting of the Health Physics Society, Pasco, WA, USA, CONF-840202, Computer Applications in Health Physics, February 5, 1984, pp. 7031-7033.

An onsite treatment planning computer has become state of the art in the care of radiation therapy patients, but in most installations the computer is used for therapy planning a diminutive amount of the day. At St. Mary's Hospital, arrangements have been negotiated for part time use of the treatment planning computer for health physics purposes. Computerized Medical Systems, Inc. (CMS) produces the Modulex radiotherapy planning system which is programmed in MUMPS, a user oriented language specially adapted for handling text string information. St. Mary's Hospital's CMS computer has currently been programmed to assist in data collection and write-up of diagnostic x-ray surveys, meter calibrations, and wipe/leak tests. The computer is setup to provide timely reminders of tests and surveys, and billing for consultation work. Programs are currently being developed for radionuclide inventories. Use of a therapy planning computer for health physics purposes can enhance the radiation safety program and provide additional grounds for the acquisition of such a computer system.

27. QUALITY ASSURANCE IN NUCLEAR MEDICINE: A COMPUTERIZED APPROACH. HOORY, S.; LEVY, L.M.; SCHIFF, R.; MOSKOWITZ, G.; BANDYOPADHYAY, D. (Long Island Jewish-Hillside Medical Center, New Hyde Park, NY, USA), Health Physics, Vol. 47, No. 3, September 1984, pp. 468-471.

The presence of an adequate quality assurance (QA) program is important in the operation of a nuclear medicine laboratory. Such a program is a requirement for obtaining a radiopharmaceutical

license and is essential for maintaining a radiation safety program. With recent advancements in the field of nuclear medicine, the development of new radiopharmaceuticals, the increasing use of generators, the quality assurance program has become a complex and tedious task. Recently, a computerized system for maintaining QA in the nuclear medicine laboratory has been implemented at Long Island Jewish-Hillside Medical Center. It is designed as an extension of the computerized system for control and management of radionuclide inventory. The system is described.

28. REVIEW OF A THALLIUM-201 CONTAMINATION INCIDENT. LEDNIK, J.L. (Venice Hospital, FL, USA), Journal of Nuclear Medicine Technology, Vol. 9, No. 3, September 1981, pp. 156-158.

During a thallium cardiac stress study, the needle and syringe disengaged resulting in a minor radioactive spill. Decontamination of patient, administering technologist, and surrounding area was performed according to the nuclear medicine policy manual. There was a reading of approximately 5 mr/hr at 6 cm above the floor. All surfaces were surveyed 4 days after clean-up and levels did not exceed 0.1 mr/hr (background). The radiation safety committee and hospital safety committee reviewed the incident to determine if alternative administration devices were needed to insure radiation safety.

29. PANEL III: RADIATION PROTECTION AND INSTRUMENTATION (A REPORT OF THE PANEL DISCUSSION). DAS, K.R.; GOPALAKRISHNAN, A.K. (Eds.), Radiation Protection: Proceedings of a National Seminar on Radiation Protection including Development of Radiological Physics in Bombay, India, December 21-24, 1976, Bhabha Atomic Research Centre, Bombay, India, 1980, CONF-761279, pp. 317-323. The topics and problems related to radiological protection in the medical institutions in India were discussed by the panel. They included: (1) problems involved in the use of open isotopes in the hospitals with respect to their procurement, handling and disposal, (2) dosimeters and other equipment essential in the physics department of the hospitals, (3) the services rendered for the safety of radiation sources and radiological personnel by the Division of Radiological Protection (DRP) of the Bhabha Atomic Research Centre, Bombay, to the medical institutions,

(4) development in India of the dosimeters and radiation related instruments required in medicine, (5) the role of the radiation safety officer and the medical physicist in implementing the countrywide radiation protection program of the DRP in medical institutions, and (6) use of cobalt-60 and cesium-137 sources in preference to radium sources. The report of the discussion is presented.

30. TRAINING IN RADIATION PROTECTION AND RADIOLOGICAL PHYSICS IN INDIA. VENKATARAMAN, G. (Bhabha Atomic Research Centre, Div. of Radiological Protection, Bombay, India), Radiation Protection: Proceedings of a National Seminar on Radiation Protection Including Development of Radiological Physics in Bombay, India, December 21-24, 1976, K.R. Das and A.K. Gopalakrishnan (Eds.), Bhabha Atomic Research Centre, Bombay, India, 1980, CONF-761279, pp. 21-25.

With rapid increase in the number of facilities of diagnostic radiology and radiotherapy, it became necessary to have operators who handled radiation sources trained in radiation safety aspects. immediate need was met by running short term courses on the safety aspects in the medical uses of The courses were conducted by the Division of Radiation Protection (DRP) of the Bhabha Atomic Research Centre, Bombay. The DRP also started a similar course for personnel working in the field of industrial radiology. These courses however are of introductory nature. For successful implementation of a countrywide radiation safety program, medical physicists are required. The DRP in collaboration with WHO started in 1962 a one-year postgraduate course in hospital physics and radiological physics. The course is recognized by the Bombay University. Contents of the syllabus and teaching staff are described. Present requirements of medical physicists in the country are discussed.

31. REFLECTIONS ON CANCER TREATMENT AND THE FEDERAL AGENCY REGULATIONS. SAENGER, E.L.; KEREIAKES, J.G. (University of Cincinnati, Cincinnati, OH), Radiology, Vol. 137, No. 3, December 1980, pp. 865-866.

Medical licenses issued by the Nuclear Regulatory Commission contain the restriction that patients who are being treated with <sup>131</sup>I should not be discharged from the hospital if the body burden is greater than

30 mCi (1110 MBq). It is argued that there are no sound data supporting the theory that a patient receiving more than 30 mCi (1110 MBq) of <sup>131</sup>I is dangerous to others. This limitation may result in the use of lower, less effective doses of <sup>131</sup>I, so that expensive, unnecessary hospitalization can be avoided. The need for adequate radiation safety programs that will advise patients and their families of the necessary precautions following therapy with <sup>131</sup>I is discussed.

32. COLLECTION AND DISPOSAL OF LOW LEVEL WASTE AT AN EDUCATIONAL INSTITUTION. ANDREWS, D.L.; GILCHRIST, J.R.; BERK, H.W. (University of Virginia, Charlottesville, VA, USA). Watson, J.E. (Ed.), Low-Level Radioactive Waste Management, May 1979, 12th Health Physics Society Midyear Topical Symposium, Williamsburg, VA, February 12, 1979, pp. 101-106.

Low level radioactive wastes are generated by a number of different laboratories and departments at the University of Virginia. Radioactive materials are utilized in a variety of research applications including medical and basic sciences, as well as for diagnostic and therapeutic uses at the University Hospital. Radioisotopes are purchased from commercial sources and are produced locally for use in research and medical diagnosis and treatment by the University of Virginia Reactor. In 1974, the University Radiation Safety Committee adopted rules for discharging radioisotopes to the environment which are more restrictive than the Nuclear Regulatory Commission regulations. The committee's philosophy is that no radioactive substances should be discharged to the environment which can be reasonably avoided, including those used in medical diagnosis and therapy. This policy has caused a significant increase in the accumulation of low-level radioactive wastes. The volume of low-level wastes at the University has increased from about 1.5 M<sup>3</sup> in 1969 to over 68 M<sup>3</sup> in 1977. Disposal costs have increased proportionately. Currently the University employs a full-time technician to collect and package radioactive wastes under the supervision of the health physics staff of the Radiation Safety Office. In 1976, the Radioactive Waste Management Facility (RWMF) was completed. This facility houses the Radiation Safety Office staff and has modern facilities for collecting and packaging all types of radioactive wastes. The facility is being used to limit the total cost of radioactive waste disposal, while fulfilling the objectives of the Radiation Safety Committee. Methods used to limit waste disposal volumes and costs are compaction, storage and decay of short half-life isotopes, solidification of liquid wastes, and education and training of radioactive material users throughout the University in reducing waste volume.

33. WORKING SAFELY AROUND IMPLANTED RADIATION SOURCES. BREEDING, M.A.; WOLLIN, M., Nursing, Vol. 5, No. 5, May 1976, pp. 58-63.

The article is concerned with patients in whom applicators containing cesium have been vaginally or cervically implanted. In working with such patients, radiation exposure to the attendant can be minimized in several ways: working as far as possible from the radiation source; using a lead shield between patient and attendant; reducing time spent near the patient as much as possible. Film badges and pocket dosimeters indicate levels of radiation to which workers are exposed; more than 400 mrem/month requires investigation by a Radiation Safety Officer. Pregnant attendants should not be assigned to care for patients with sealed radiation sources. Special precautions involving visitors and room assignments are discussed. Various aspects of caring for the patients are detailed. Six informative tables have information about the following: general guide to total time a person may spend with a patient containing a cesium radiation source; equipment for insertion of two types of sources and for removal; general precautions; notes for inserting Fletcher after-loaders, cesium molds and removing cesium.

34. PRINCIPLES AND PRACTICES FOR KEEPING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS AS LOW AS REASONABLY ACHIEVABLE. (Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, DC, USA), NUREG-0267 (Draft), October 1977, 54 p.

Some of the major considerations in establishing management policies, staff, facilities and equipment, and operational procedures to promote radiation safety in medical or hospital care programs using radioactive materials licensed by the U.S. Nuclear Regulatory Commission (NRC) are presented. It is a compendium of good practices for establishing adequate radiation safety programs in medical institutions. The information presented is intended to

aid the NRC licensee in fulfilling the philosophy of maintaining radiation exposures of employees, patients, visitors, and the public as low as reasonably achievable (ALARA). Each subsection of this report is designed to include the major radiation safety considerations of interest to the specific type of activity.

35. RADIOACTIVE TREATMENT AT SIX CANCER CENTERS HALTED. (ONCOLOGY SERVICES CORP.'S AFTERLOADER TREATMENT SUSPENDED DUE TO SAFETY CONCERNS). (U.S. Nuclear Regulatory Commission, Washington, DC, USA), Cancer Weekly, Vol. 6, No. 1, February 1, 1993, p. 6.

FULL TEXT: Few of the patients treated at six Pennsylvania cancer centers were affected by the U.S. Nuclear Regulatory Commission's (NRC) decision to halt a specific treatment the facilities offered, an The NRC ordered the Oncology official said. Services corporation satellite offices to stop inserting radioactive material into patients suffering from cancerous tumors. The NRC said it was not indicting the method of treatment, which is widely used, but instead was concerned about safety measures undertaken by Oncology Services. The order came three months after radioactive material was left inside two patients treated at Oncology Services offices in Indiana County and Pittsburgh. NRC licenses were suspended at the Exton Cancer Center in suburban Philadelphia, the Greater Harrisburg Cancer Center, Greater Pittsburgh Cancer Center, Life Care Cancer Center in Stoneboro, Mahoning Valley Cancer in Lehighton and the Indiana Regional Cancer Center. Ray Caravan, vice president for Harrisburg-based Oncology Services, said most patients are treated with external-beam radiation therapy. Only about 5 percent of the firm's patients -- usually the more seriously ill -- receive the internal treatment, known as high-dose afterloading. A catheter is used to position the radioactive material near a tumor in an attempt to kill the cancerous cells. In the Indiana case, an 82-year-old woman died of multiple organ failure five days after a sliver of iridium-192 broke away from a wire and remained lodged in her body. It fell out the day before she died when the catheter become dislodged. About 90 people were inadvertently exposed to radiation because of the mistake, the NRC said. Indiana County Coroner Thomas Streams said he is waiting for a final autopsy report before he rules on whether the accident

contributed to the patient's death. In the Pittsburgh case, the iridium broke off just inside the patient's body. A technician spotted it an placed it in a lead box, resulting in a fairly small exposure. The NRC said it visited the Indiana officer after the November 16, 1992, incident and conducted surprise inspections of Oncology Services facilities in Exton and Lehighton. "Key personnel at several satellite facilities do not know the requirements of the NRC license, do not have access to the pertinent license documents, and have not been adequately trained in either the pertinent regulatory requirements or the procedures and instrumentation to be employed to protect themselves and others from radiation exposure," the NRC said in a statement. Oncology services can request a hearing on the indefinite suspensions within 20 days. If it doesn't contest the allegations, it can remedy them and petition the NRC to reinstate the licenses. Caravan had not been officially notified of the license suspensions and sad he would defer comment until he reviews the NRC's findings. Oncology Services operates 24 cancer treatment centers in nine states. The government singled out the six centers because they were under the supervision of the same radiation safety officer, were covered by the same NRC license, and all used the high-dose afterloader for treatment, NRC spokesman Karl Abraham said. At the Lehighton center, the NRC said the medical director admitted he had not read the terms and conditions of the license. At the Exton facility, emergency procedures were not posted at the console of the afterloader, as required. The NRC also reprimanded Oncology Services for not alerting its other facilities about the problems in Pittsburgh and Indiana. Officials at the satellite offices read about the problems in the newspaper instead of in a corporate memo, the NRC said.

**36. DESIGN FOR RADIATION SAFETY.** THON, W.J., Air Conditioning, Heating and Ventilating, Vol. 61, October 1964, pp. 87-93.

The most important principle in radiation safety is that each step must be planned in advance and detailed procedures for each work area prepared before an accident occurs. Proper design of ventilation, vacuum, alarm, and other systems can ensure that sealing off a work area is automatic; however even where this is possible, matters of personal judgment will always be involved. Constant emphasis on the harmful effects of radiation to those working with radioactive materials can sometimes

lead to an unintended neglect of the dangers of the more common industrial materials used in such work. Thus a safety procedure itself, in its psychological effect, may be a hazard; assurance, for example, of having eliminated the risk of radioactive contamination by use of stable isotopes in a laboratory test might diminish alertness to possible chemical toxicity of the now "safe" materials. Special precautions are required by the special hazards involved, but treatment of the problem remains within the pattern established by the overall radiation safety program. Each regulation and responsibility can be deduced from the general principles of containment, hazards of containment, hazards evaluation, and zoning, with reasonable qualifications based on the need to achieve maximum safety with a minimum of restrictions in a special situation.

**37. PRINCIPLES OF RADIATION SAFETY AND PROTECTION.** HASSEY, K.M. (Department of Radiation Therapy, Beth Israel Hospital, Boston, MA, USA), Seminars in Oncology Nursing, Vol. 3, No. 1, 1987, pp. 23-29.

Radiation is part of our natural environment. While major sources of radiation exposure come from medical tests, x-rays, and consumer products in our home, such as television, natural gas, and tobacco, occupational exposure to radiation is a major issue for It has been shown that the average nurses. occupational exposure per year for nurses who routinely care for patients with radioactive implants is comparable to annual exposure from background radiation of about 100 to 120 mrem. The issues and concerns of radiation exposure consistently raise the question: how can one adequately care for patients with radioactive implants and provide for radiation safety and protection at the same time? The principles of radiation safety and protection are reviewed under the following headings: physics of radioactive isotopes; modes of radioactive decay (alpha particle decay, beta particle decay, gamma radiation); mechanism of radiation injury; units of radiation protection; standards for radiation safety and protection; principles of time, distance, and shielding; guidelines for radiation protection; and radiation safety with personnel monitoring devices. Radiation safety and protection require basic knowledge of the physical properties of the radioisotopes and application of the principles of time, distance, and shielding. Close collaboration among the radiation safety officer, the radiation therapist, and the nursing

staff must be established and maintained. The radiation therapist alerts the nursing staff regarding potential patients whose implants require a higher volume of radioisotopes. Nursing staff collaborates with the radiation safety officer in development of radiation safety policies and procedures, maintaining knowledge of safety and protection, and orienting new staff to the care of implant patients.

38. THE MINERS' CANARY. Chalk River Committee on Scientific Freedom and Responsibility (American Association for the Advancement of Science, Washington, DC, USA), Bulletin of the Atomic Scientists, Vol. 38, No. 2, 1982, pp. 16-22.

The ramifications of advising the public of harmful uses of technology (whistle blowing) by scientists and engineers is discussed. One case involved the readmission of a cancer patient to the hospital with four iridium seeds in her abdomen which should have been removed previously. The radiation safety officer notified the Nuclear Regulatory Commission of the incident, and was subsequently fired by the hospital. Reinstatement was obtained after over 2 years of litigation. Many professional groups are now offering support and protective mechanisms for members involved in ethical conflicts with industry.

39. PROTECTION IS BETTER THAN CURIE. Nurses Action Group, London, England Nursing Mirror, Vol. 152, No. 8, 1981, pp. 26-30.

Radiation safety guidelines for nurses and other personnel working in radiology units are discussed. "Designated workers" exposed to greater than 30% of the max permissible exposure level (MPEL: 5 rem/yr; max 3 rem in any 4 mo), need film badges, appropriate protective clothing, and badges with of the film correlations Pocket radiation thermoluminescent dosimeters. alarms should be supplied to persons regularly exposed to high doses, and film badges to nondesignated workers (exposed to less than 30% of the MPEL) if they request them. Chromosome counts should be performed after radiation emergencies and in workers whose film badges show overexposure. The medical records of designated workers should be updated annually, transferred when the worker changes jobs, and kept for 30 yr after the worker leaves the designated employment. It should be possible for overexposed workers to change jobs without a loss of pay or seniority. All personnel should be familiar with safe work practices and their duties in an emergency. Safety rules should be displayed in all relevant languages. Accurate records must be kept both of the use of sealed and unsealed sources and of the results and dates of maintenance and testing of all equipment. These and other records should be made available to a representative of the radiation safety committee. Staff members must not exceed time and distance limits permitted in the care of patients having radioactive implants or being treated with radioisotopes, and these duties must be rotated. When any radioactive substance is used, it may only be used for a certain time before the dose approaches the MPEL. These limits should be put in writing and should be known by all staff members. Multidisciplinary cooperation in observing these safety guidelines is imperative.

40. SPECIFIC PROBLEMS. PROBLEMS IN HANDLING RADIUM ACCIDENTS AND EMERGENCIES. FIELDS, T. In: Radiation Accidents and Emergencies in Medicine, Research, and Industry, L.H. Lanzl, J.H. Pingel, and J.H. Rust (Eds.), published by Charles C. Thomas, Springfield, Illinois, 1965, pp. 380-84.

Handling of radium accidents and emergencies was reviewed. Those at greatest risk due to the use of radium in medicine were those involved in dermatology, radiology, and hospital work. Standard methods for radium storage, testing for leaks, record keeping, surveying, decontaminating, and monitoring of personnel were described. Maximum permissible dose levels and concentration levels for radium and its daughter products were used as reference points to determine whether a radiation emergency exists. Radium sources are available in various shapes and designs including a hollow tube (needle type) with the radium sealed within the tube, a sheathed needle the tip of which unscrews, tubes, or plaques. The most difficult problem for contamination prevention is created by the plaques which have a surface layer of radium-226 and are used chiefly in the treatment of superficial skin lesions. It was recommended that records in a storage area for radium contain the date the source was ordered and the date issued; the patient, hospital, department, or physician who ordered the material; the type of radium or radon used: the signature of the person who received the material; and the date of expected return. Protection surveys were recommended at all installations where handling or storage of radium or radon occurs. It was also recommended that all radium sources be tested for leaks, and that each installation have a radiation safety officer with authority to carry out and enforce the directives of a radiation safety committee. Several types of radiation accidents and the appropriate responses were considered.

41. RADIATION PROTECTION PROGRAMS IN NUCLEAR MEDICINE. ST. GERMAIN, J. Seminars in Nuclear Medicine, Vol. 16, No. 3, July 1986, pp. 198-202.

The reduction of dose administered, optimization of clinical information, and protection of the patient, radiation worker, and the environment are considered in relation to the use of radiation in medical In institutions with programs using treatment. radioactive materials, there is a requirement for licensing of the user, and for a set of guidelines or a manual in which the minimum working rules are specified. The development of policy in radiation protection usually is the function of an institutional committee on radiation. For the patients, the medical benefits may be approached through standard actuarial methods. Optimization of clinical information must be considered and can be influenced by the choice of imaging device employed. Special policy problems need to be considered when volunteers are used to establish normal test results and the range of normal Nuclear medicine investigations in pregnant or lactating women are of special concern, because of possible transmission of radioactive material across the placenta and resultant fetal uptake. Studies in children require that administered activity be corrected so that the activity per kilogram of body weight is comparable with an adult examination. Policy for radiation workers includes regulations which define the role of the institution in radiation protection, the education regarding radiation protection that must be provided, and applicable permissible dose limits. A radiation safety committee is required to specifically review all aspects of the program including the expected and typical doses received by personnel and recommend improvements to reduce these doses.

**42. CONTROL OF RADIATION HAZARDS. ROLE OF THE HEALTH PHYSICIST.** HUGHES, L., Journal of Occupational Medicine, Vol. 11, No. 1, January 1969, pp. 30-32.

The role of the health physicist in the control of radiation hazards at the University of California, Berkeley campus is discussed. The health physicist administers the radiation safety program on campus and is a member of the Radiation Safety Subcommittee. Each proposed use of radioactive substances must first be cleared with the health physicist and at least one other member of the subcommittee. The physicist also coordinates the legal, medical, and social aspects of radiation use and maintains liaisons with department chairmen and state and federal government officials.

43. NEW ADVENTURES IN BIOMEDICAL ENGINEERING: RADIATION SAFETY PROGRAM MANAGEMENT. DICKEY, D.M. (Washington Hospital Center, Washington DC, USA), Biomedical Instrumentation & Technology, Vol. 25, No. 5, January 1969, pp. 380-384.

The author discusses the appropriate regulations for and outlines the duties and responsibilities of the RSO (radiation safety officer), and discusses the similarities between radiation safety program management and BME/CE program management. Radiation safety and health physics represent a technical field that can be incorporated into and/or managed by a technically competent BME/CE program.

44. GUIDELINES FOR AN EFFECTIVE RADIATION SAFETY PROGRAM IN A HUMAN IMMUNODEFICIENCY VIRUS (HIV) LABORATORY. STINSON, M.C.; KURITZKES, D.R.; MASSE, F.X. (Radiation Protection Office, MIT, Cambridge, MA, USA), Health Physics, Vol. 58, No. 4, April 1990, pp. 503-505.

Guidelines have been provided for the establishment of an effective radiation safety program in a human immunodeficiency virus (HIV) laboratory. These guidelines are general and based on constraints of work within a biosafety level III laboratory. With proper modification, these guidelines may be extended to other laboratories working with potentially infectious radioactive materials and the resulting wastes.

45. THE IMPACT OF THE PROBABILITY OF CAUSATION ON THE RADIATION PROTECTION PROGRAM. MEINHOLD, C.B. (Radiological Sciences Division, Brookhaven National

Laboratory, Upton, NY, USA), Health Physics, Vol. 55, No. 2, August 1988, pp. 375-377.

Although the probability of causation approach is the only scientific basis on which a given cancer can be judged to be causally related to a given exposure, the impact of this concept on the radiation safety program could be counter-productive. As health physicists, the practices and the concepts one employs have been developed to protect the worker. Effective dose equivalent and committed dose equivalent are protective concepts but useless for probability of causation analysis. Perhaps extensive records will be the only way that good radiation protection and probability of causation analysis can coexist.

46. RADIATION SAFETY PROGRAM FOR A HIGH DOSE RATE REMOTE AFTERLOADER. STANTON, R.; NUNNO, M.; LIN, A.; HOLST, R.; MOORE, M. (Radiation Oncology, Cooper Hospital/University Medical Center, Camden, NJ, USA), Health Physics, Vol. 64 (Suppl. 6), 1993, p. S36.

Nuclear Regulatory Commission (NRC) requirements for brachytherapy include quality management (QM) procedures to document (if not prevent) patient misadministrations and unnecessary personnel exposures (10 CFR 35 1/27/92). Our institution developed a program aimed at maximizing radiation safety while simultaneously fulfilling NRC QM requirements. We particularly wanted to involve all therapy personnel in this process, both in its design In addition, a recent and its implementation. treatment misadministration due to High Dose Rate (HDR) brachytherapy machine source failure (11/92) caused the NRC to mandate increased safety surveillance of HDR patient treatments. notification of this November incident, immediately expanded our procedures including patient monitoring and record forms. participating personnel were involved in the development of our procedures to optimize the patient treatments and to maximize staff input. We instituted pre- and post-procedure patient radiation surveys, the location of shielded source holders in the treatment room, and the provision of long tweezers for source handling. These procedures and their documentary forms have helped improve our program and have been justified by our initial clinical experience. Part of our preparation included the development of scenarios of machine failure and patient rescue. By

interviewing physicians to determine techniques for source retrieval, a range of expected exposures for emergency personnel was developed. Estimates of exposures include the following: simple source retrieval, (source still enclosed in catheter) -- 36 mR; bronchoscopic source retrieval -- 1 R; surgical source retrieval -- 2.3 R.

47. COMPUTER-ASSISTED MANAGEMENT OF LIQUID RADIOACTIVE WASTE AT THE UNIVERSITY OF CALIFORNIA SAN DIEGO. HAMANO, D.M.; HELM, K.S.; PAPIN, P.J. (Physics Department, San Diego State University, San Diego, CA, USA), Health Physics, Vol. 64, No. 2, 1993, pp. 192-194.

Commercially available software has been obtained and internal software applications have been developed to implement a tracking system for liquid radioactive wastes. This system utilizes a number of data bases that maintain sampling, waste pickup and disposition information based on various parameters. Computerization has allowed access to summary information and inventory totals that are necessary for radioactive materials license compliance. Comparative reports, which are used to show trends and track historical information, can also be generated.

**48. QUALITY ASSURANCE WITHIN A DOE LABORATORY.** PALMER, J.R.; MYERS, D.S. (Lawrence Livermore National Laboratory, Livermore, CA, USA), Thirty-sixth Annual Meeting of the Health Physics Society, Washington, DC, USA, July 21-26, 1991, Health Physics, Vol. 60 (Suppl. 2), 1991, p. S71.

The Department of Energy (DOE) recently established a 10-point program to bring its facilities up to current environmental and safety standards. Three of these points are (1) to bring DOE into full compliance with environmental, safety and health (ES&H) laws; (2) to open communications with local establish governments and the public on ES&H issues at DOE facilities; and (3) to revitalize the aging DOE physical plant. One of the first efforts in this program was to initiate a series of Tiger Team appraisals. These appraisals are designed to provide a baseline assessment of DOE facilities from which plans could be designed and progress measured. A common finding of the Tiger Team visits was that inadequate attention had been paid to quality Assurance programs that assure achievement of ES&H objectives. The result of the corrective actions required to remedy this finding has placed increased focus on the Quality Assurance systems that we use to control our work. The expanded Quality Assurance program has required significant modification to some elements of the radiation safety program, in particular the counting laboratory and the bioassay program.

**49. A SERVICE ORIENTED RADIATION SAFETY PROGRAM.** CUTLER, N. (Medical Branch, University of Texas, Galveston, TX, USA), 27th Annual Meeting of the Health Physics Society, Las Vegas, NV, USA, June 27-July 1, 1982, Health Physics, Vol. 43, No. 1, 1982, p. 151.

There has been much discussion recently about public relations for the nuclear industry and the concern of health physicists for better public information. Discussed here will be a different type of public relations problem for health physicists -- specifically, the relations within a University/Medical complex between the health physicist in his role as a regulator and those actually being regulated. Resentment is often generated in such a situation. But when the radiation safety office can instead be thought of as service oriented and has a program that is designed to be beneficial to those it interacts with, this resentment can be very satisfactorily dissipated. Outlined here will be the types of extra services, assistance, and new programs that were offered to elicit the better understanding and cooperation between the radiation safety office and the radioactive material users. In addition to the programs that had a direct effect, new programs having an indirect effect will also be discussed. These programs all led ultimately to better compliance on the part of the radioactive material users with local, state, and NRC regulations.

**50. USE OF COMPUTERS IN RADIATION SAFETY PROGRAMS FOR ACCOUNTABILITY AND CONTROL PURPOSES.** EUBIG, C.; TRUEBLOOD, J.; and YOUNG, M., Health Physics, Vol. 33, No. 6, 1977, pp. 677-678.

Computer facilities ranging from a large computer based in a university computer center to an office minicomputer/calculator should be available to university or medical center radiation safety offices responsible for broad radioactive material licenses. Computerized inventory records were found by us to be essential for the maintenance of an up-to-date

inventory of possession and turnover of radioactive In addition to satisfying some of the materials. requirements of regulatory agencies for records keeping, these inventory records were also found useful for some safety decision making, and for organizing and carry out routine activities such as The possibilities of involvement of computers in the radiation safety office activities are examined. The use of the computer by personnel with minimal training is considered an important objective. A comparison of the advantages, disadvantages, and limitations of both large and small computers is made. Our experience is based on the use of a CDC 6400 computer located at the University of Arizona Computer Center with a terminal at the Health Sciences as well as minicomputer/calculators equipped with a number of input and output devices available to the Medical Physics Office of the Medical College of Georgia.

**51.** A GAMMACELL SAFETY PROGRAM. MILLER, K. L.; CHRISTENSEN, R. C. Health Physics, Vol. 32, No. 1, January 1977, p. 40

The use of self-contained irradiation facilities (e.g., Gammacells) for irradiation of small laboratory samples is becoming increasingly popular. Although these irradiation sources are self shielded and generally considered foolproof, a formal program of use must be adopted to insure continued safe use. The authors present a discussion of program requirements in the hope that it may provide help to those considering licensing and installation of a self-contained irradiator.

**52.** THE EMERGING ROLE OF THE CAMPUS RADIATION-SAFETY OFFICER. ZIEMER, P.L., Nuclear Safety, Vol. 13, No. 6, November-December 1972, p. 482

University radiation-safety officers (RSOs) from throughout the United States and Canada met at Purdue University in September 1971 to examine their role on the campus and how this role is changing. The conference focused primarily on administrative aspects of campus radiation safety programs, but also included discussions of practical health-physics problems common to the campuses. A wide diversity was seen in the organizational structures and responsibilities of the many universities represented. The campus RSO participates in health-physics administrative, teaching, and research. Finding the

proper balance of these functions in an organizationally sound framework will permit him to fill his role in meeting the growing health physics needs of his campus in the future.

53. RADIOLOGICAL ASSESSMENT PROGRAM FOR A BROAD SCOPE BY-PRODUCT MATERIALS LICENSEE. COLLOPY P. (Environmental Health and Safety, Carnegie Mellon University, Pittsburgh, PA, USA), Health Physics, Vol. 60, No. 4, 1991, pp. 593-596.

A multilevel assessment program can be integrated into normal operational requirements and used to identify and correct operational errors. Assessments are made during routine surveys by field technicians, monthly by the Radiation Safety Officer, and biennially by an independent radiological expert. These systematic assessments can prevent the occurrence of significant program problems and result in a decreased number of Nuclear Regulatory Commission citations.

54. RADIATION ALARMS AND ACCESS CONTROL SYSTEMS. RECOMMENDATIONS OF THE NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS (NCRP, Bethesda, MD, USA), NCRP Report 88, 1986, 62 p.

In facilities where radioactive materials are handled, or where radiation-producing equipment is used, the building, the equipment, and the associated safety procedures should be designed and developed together to provide a safe work environment. The specific combination of requirements for a given facility is defined by the operational radiation safety program. It should be emphasized that this report describes a range of alarm and access control systems that can and do provide an acceptable level of safety at many types of facilities. Depending on circumstances, the solutions offered here may not be appropriate for certain facilities because they are too restrictive, not restrictive enough, or do not cover all circumstances. Thus, this document is offered as a starting point providing ideas that professional health physicists can adapt to meet the needs of a particular situation. Under no circumstances should this report be interpreted in 'cookbook' fashion, with literal adherence to every recommendation demanded, nor should it be expected to provide adequate protection in every case without consideration of local conditions. It is also worth noting that the weakest link in any system of personnel protection is not the hardware but the people themselves. The single leading cause of accidents is the failure of personnel to follow established procedures. Thus, the simplification of procedures, regular training, and replacement of administrative control with hardware that does not unduly impede the normal operation of the facility will go a long way toward reducing the potential for accidents.

55. UNIVERSITY/HOSPITAL FETAL DOSE POLICY EXPERIENCES. WILSON, B.M.; VINSON, W.R.; DEFOREST, W.W.; WASHBURN, D.B. (University of North Carolina, Chapel Hill, NC, USA), 24th Midyear Topical Meeting of the Health Physics Society, Raleigh, NC, January 20-25, 1991, Implementation of Current NCRP and ICRP Guidance and Revised 10 CFR Part 20: Proceedings, Jorgensen, D.B.; Seagondollar, L.W.; Watson, J.E. Jr. (Eds.), CONF-910137--, NTIS accession number DE91016184, 1991, pp. 242-247, 257 p.

Since at least 1981, an informal policy has existed at the authors' research university and teaching hospital institution to interview, inform and assure appropriate personnel monitoring for pregnant radiation workers. Events, such as popular and technical publications (NCRP 87) and the maturation of NRC's proposed changes in 10 CFR 20 (NRC 88), brought increased attention to the subject of fetal radiation dose. The need for a formal approach to the subject became evident. By 1987, a concerted effort to promulgate a formal policy was launched. A draft policy statement was presented to each institutional radiation safety committee for review and action. There was immediate strong interest. A thorough, multilevel review, comment and redraft process developed. Well tested policy statements were then approved in 1988.

56. DEVELOPMENT AND DESIGN OF A COMPUTER-ASSISTED INFORMATION MANAGEMENT SYSTEM FOR RADIATION SAFETY MANAGEMENT AT THE UNIVERSITY OF WASHINGTON. RICHES, C.G.; RIORDAN, F.J.; ROBB, D.; GRIEB, C.; PENCE, G.; O'BRIEN, M.J.; KATHREN, R.L.; HIGBY, D.P.; MCKINNEY, M.A. (Environmental Health and Safety, Radiation Safety Office, University of Washington, Seattle, WA, USA), 17th Midyear Topical Meeting of the Health Physics Society, Pasco,

WA, February 5, 1984, Computer Applications in Health Physics, CONF-840202-, 1984, pp. 3039-3048.

The Radiation Safety Office (RSO) at the University of Washington (UW) found that it needed a computerized information system to help manage the campus radiation safety program and to help provide the records necessary to show compliance with regulations and license requirements. The John L. Locke Computer Center at the UW had just developed the GLAMOR system to aid information entry and query for their computer when the RSO turned to them for assistance. The module that was developed provided a mechanism for controlling and monitoring radioactive materials on campus. This became one part of a multi-faceted system that registers users, employees, sealed sources and radiation-producing machines. The system is designed to be interactive, for immediate information recall, and powerful enough to provide routine and special reports on compliance status. The RSO information system is designed to be flexible and can easily incorporate additional features. Some future features include an interactive SNM control program, an interface to the information system currently being developed for the occupational safety and health program and an interface to the database provided by the commercial film badge service used by the University. Development of this program lead the RSO to appreciate the usefulness of having health physics professionals on the staff who were also knowledgeable about computers and who could develop programs and reports necessary to their activities.

57. CRC HANDBOOK OF MANAGEMENT OF RADIATION PROTECTION PROGRAMS. MILLER, K.L.; WEIDER, W.A., CRC Press, Boca Raton, FL, USA, 1985, 536 p.

This volume details the organization and management of radiation safety programs, including both preventive and emergency response measures. Included are guidelines and checklists for managing radioactive waste processing programs, dealing with litigation, and responding to public or news media concerns. The last sections list state, federal, and international requirements for transportation of radioactive materials.

58. OPERATIONAL RADIATION SAFETY - TRAINING. Published by the National Council on

Radiation Protection and Measurements, Bethesda, MD, USA. NCRP Report No. 71, 1983.

This report was written to supplement NCRP Report No. 59, Operational Radiation Safety Program, which sets forth the basic elements of a radiation safety program. Effective radiation safety programs should include training for workers exposed to either radioactive material or other radiation sources and this report seeks to provide guidance for the development of training in organizations with employees who are exposed to radiation in the course of their work. The guidance provided is intended to cover the basic elements of needed training and thus should be useful to the entire range of radiation users from small single source operations to relatively complex radiation operations.

**59. OPERATIONAL** RADIATION SAFETY PROGRAM. Published by the National Council on Radiation Protection and Measurements, Washington, DC, USA. NCRP Report No. 59, 1978.

For many years the National Council on Radiation Protection and Measurements and its predecessors have provided extensive recommendations dealing with the many aspects of radiation protection. The objective of this report is to describe the elements of an operational radiation safety program incorporating many of these recommendations. An effective radiation safety program can do much to reduce exposures to a level as low as practicable within the NCRP recommended dose limits and to minimize the potential for accidental exposures.

**60. ORGANIZATION OF A SMALL-SCALE RADIATION SAFETY PROGRAM.** TOLAN, J.H. (University of Missouri, Rolla, MO, USA), 3rd Health Physics Society Midyear Topical Symposium, Los Angeles, CA, USA, January 29, 1969, Health Physics Operational Monitoring, Vol. 1 (Training of Professional Health Physicist), 1972, pp. 321-327, published by Gordon and Breach, Science Publishers, Inc., New York, CONF-690103--P1.

Steps in the training of a professional health physicist who has completed his academic education are discussed. A list of suggestions for a young health physicist considering a position is presented. The list includes determining the level of research expenditures for the past few years; determining growth of the graduate student body; and determining

the size of the radiation safety program. A list of suggestions for managing the program is given for a radiation safety officer who has just accepted a position.

61. RADIATION SAFETY IN A UNIVERSITY. PRINCE, J.R. (Oregon State University, Corvallis, OR, USA), Health Physics, Vol. 9, March 1963, pp. 347-349.

A survey of the administrative structure of radiation safety programs and regulations of many colleges and universities showed that universities vary considerably in the organizational structure of their radiation protection programs. The need is stressed for the technical evaluation of each program using ionizing radiation and the establishment of an effective control program.

**62. NUCLEAR PHARMACIST AS A RADIATION SAFETY OFFICER.** LIPRIE, S.F. (Lake Charles, LA, USA), Journal of Pharmacy Practice, Vol. 2, October 1989, pp. 276-279.

The responsibilities of the radiation safety officer in the hospital and the role of the nuclear pharmacist in this position are described. The duties of monitoring for environmental safety and personnel radiation exposure, monitoring of incoming and outgoing radioactive shipments and verification that all record-keeping activities, possession of quantities and uses of radioactive material are in keeping with the facility's radioactive material license are discussed.

63. PARENTERAL RADIOPHARMA-CEUTICALS. VIRGONA, A.J. Bulletin of the Parenteral Drug Association, Vol. 25, May-June 1971, pp. 126-131.

Problems associated with the manufacture of parenteral radiopharmaceuticals are discussed. Parenteral radiopharmaceuticals must be manufactured under the same stringent conditions used to manufacture nonradioactive parenteral pharmaceuticals. Complicating factors include the radioactivity, which must be handled remotely in appropriately shielded facilities to minimize radiation exposure; the half-life, which compounds the shielding and remote handling problems; and the precise scheduling and special distribution requirements for these perishable items. The duties of the radiation safety officer are outlined.

**64. RADIATION SAFETY IN BIOLOGICAL RESEARCH LABORATORIES.** GALANEK, M.S. Occupational Medicine: State of the Art Reviews, Vol. 6, No. 2, April 1991, pp. 255-269.

A report was provided that outlined a detailed approach to radiation safety in the highly technical biological research setting. The following topics were highlighted: administrative controls, worker training, laboratory surveillance, engineering controls and environmental monitoring, worker exposure monitoring, emergency procedures, and low level radioactive waste disposal techniques for biological Administrative controls and radioactive waste. mentioned included licensing, radiation safety officer, radiation safety liaison, and administrative procedures. Radiation worker training as discussed included units of radioactivity and radiation exposure, radioactive decay and half life, radiation detection and analytical instruments, licensed measurement, radioisotopes, safe handling and dose reduction techniques, distance from a radioactive source, appropriate shielding, maximum exposure limits, the as low as reasonably achievable concept, biological effect and risks from occupational exposures, bioassay and in-vivo measurement, and radiation and contamination surveys. Low level radioactive waste disposal was discussed for dry solids, liquids, liquid scintillation vials, animal carcasses and tissues, and mixed waste. Monitoring of worker exposure was discussed as it relates to external and internal exposures. Emergency procedures were considered for contamination and personnel injury and contamination of personnel and facilities with no injury.

65. LIFE-TABLE FACTORS FOR USE IN ESTIMATING THE CANCER RISK OF RADIATION EXPOSURE TO WORKERS. MAILLIE, H.D., Health Physics, Vol. 44, No. 4, April 1983, pp. 317-327.

Life table factors for calculating hazards to groups of individuals exposed to radiation are reviewed. Data for the 1976 U.S. population, taken from the 1977 publication of the U.S. life tables, is employed. The exponential mortality is extended to an age range of 15 to 100 years. Values of latency and plateau periods for leukemia, bone, and other cancers are presented. Equations for determining absolute and relative risk of radiation induced cancer are developed. Life table integrals for absolute and

relative risk are calculated for radiation induced leukemia, bone cancer, and other cancers, using data for the 1976 U.S. population and various values for latency and plateau periods. Results are presented in tabular form. Sample calculations are presented using these integrals for either the relative or absolute risk method. The author concludes that the tables presented should permit a radiation safety officer to estimate the number of radiation induced cancer mortalities from whole body exposures.

# 66. HOSPITAL EMERGENCY DEPARTMENT MANAGEMENT OF RADIATION ACCIDENTS. RICKS, R.C. (Medical and Health Sciences Division, Oak Ridge Associated Universities, Oak Ridge, TN, USA). Published by Oak Ridge Associated Universities, Oak Ridge, TN, USA, 44 p.

This training package, which includes one book and one videotape, covers the basic principles of medical and nursing care for radiation accident victims in the hospital emergency department. The package suggests way of adapting your emergency response plans for radiation accident management. Emphasis is placed on caring for the patient contaminated with radioactive material, including organization of the radiological emergency response team, facility and staff preparation, patient reception and triage, medical and decontamination procedures, contamination control, radiological monitoring, bioassay sampling, patient transfer and post-emergency activities. The important of health physics support and sources of assistance are also covered. Basic information about radiation, radiobiology, radiological monitoring equipment, and principles of radiation protection are discussed. The book is designed to complement a 25minute videotape entitled "Hospital Emergency Department Response to Radiation Accidents," which depicts a case study of emergency department response to both injured and uninjured contaminated Either the text or the videotape can, however, be used independently. These materials were developed by REAC/TS, the Radiation Emergency Accident Center/Training Site, which is part of the Medical and Health Sciences Division of Oak Ridge Associated Universities, Oak Ridge, Tennessee. Partial funding for development was provided by the Federal Emergency Management In addition, these Agency, Washington, D.C. materials have been reviewed by the Federal Radiological Preparedness Coordinating Committee, Training and Exercises Subcommittee.

67. PREHOSPITAL MANAGEMENT OF RADIATION ACCIDENTS. RICKS, R.C. (Medical and Health Sciences Division, Oak Ridge Associated Universities, Oak Ridge, TN, USA). Published by Oak Ridge Associated Universities, Oak Ridge, TN, USA, 36 p.

This training package, which includes one book and one videotape, covers the basic principles used in rescue and emergency medical care of radiation accident victims. Procedures described in the text apply to the management of peacetime radiation accidents in industry, research, transportation, and Emphasis is placed on recognizing hospitals. potential radiation hazards, protecting personnel, rescuing and giving emergency medical care to accident victims, transporting victims to hospitals, and post-emergency activities. Basic information about radiation, radioactivity, radiological monitoring equipment, and principles of radiation protection are also discussed. The book is designed to complement a 25-minute videotape entitled "Prehospital Response to Radiation Accidents," which presents several case studies that recommend procedures to be followed. Either the text or the videotape can, however, be used independently. These materials were developed by REAC/TS, the Radiation Emergency Accident Center/Training Site, which is part of the Medical and Health Sciences Division of Oak Ridge Associated Universities, Oak Ridge, Tennessee. Partial funding for development was provided by the Federal Emergency Management Agency, Washington, D.C. In addition, these materials have been reviewed by the Federal Radiological Preparedness Coordinating Committee, Training and Exercises Subcommittee.

## **68. THE UNIVERSITY RSO.** GRANLUND, R.W. (228 Accelerator Building, University Park, PA, USA). 18th Annual Meeting of Health Physics Society, Miami Beach, FL, June 17-21, 1973, p. 323.

Most university radiation safety programs have been unique because of the wide variety of health physics activities compared to the relatively small size of the program. The scope of such programs has been further enlarged the increased regulation of x-ray, laser, and microwave generators and the new OSHA regulations. The university RSO (radiation safety officer) can also expect that public concern about low-level radiation and the consequent regulatory changes will require more careful regulation of discharges and increased environmental monitoring.

The expansion of the radiation safety program and the larger staffs will require that the university RSO devote a larger fraction of his time to administrative duties. The establishment of additional safety programs in the various areas of industrial hygiene at universities may lead to significant changes in the organization and operation of the radiation safety program.

69. THE HOSPITAL RADIATION SAFETY OFFICER. VAN ROOSENBEEK, E. (Physics Department, The University of Texas, M.D. Anderson Hospital and Tumor Institute, Houston, TX, USA). 18th Annual Meeting of Health Physics Society, Miami Beach, FL, June 17-21, 1973, p. 323.

The University of Texas M.D. Anderson Hospital is a large cancer research and treatment hospital. The Radiation Safety Section is composed of the Radiation Safety Officer, Assistant Radiation Safety Officer, and two technicians, all full-time. In addition to the services at M.D. Anderson Hospital, the section serves the University of Texas at Houston complex: Medical School, Dental School, Dental Science Institute, School of Public Health, and the Associated teaching hospital and affiliated therapy hospitals. Radiation therapy equipment consists of a 28 MeV accelerator, 2 betatrons, 8 cobalt machines, 4-250 kvp machines, and about 3,000 milligrams of radium and cesium. Diagnostic equipment includes 35 x-ray rooms and 48 more x-ray rooms are under construction. contrast, the Radiation Safety Section a decade ago consisted of the Radiation Safety Officer, about 50% of the time and one technician 60% of the time. The facilities of that time consisted of 2 betatrons, 2 cobalt units, one cesium unit, 2-250 x-ray units and radium. There were 12 x-ray rooms. The impact of federal and state regulations and registration and publicity given to patient exposures by national organizations such as the Health Physics Society and federal agencies has forced a more detailed evaluation of diagnostic x-ray equipment and changes in procedures.

70. WORKSHOP ON THE CHANGING RESPONSIBILITIES OF THE GOVERNMENTAL RADIATION SAFETY OFFICER. PORTER, B.J. (Louisiana Division of Radiation Control, Baton Rouge, LA, USA). 18th Annual Meeting of Health Physics Society, Miami Beach, FL, June 17-21, 1973, pp. 323-324.

The Governmental Radiation Safety Officer is most usually assumed to be a person associated with a regulatory function. This discussion will be limited to those persons associated with a Governmental Regulatory Program. The diminishing availability of financial support forces proper political motivation. The increased awareness of the public and its concern for the environment requires development of effective means of communicating with the general public. Scientific jargon must be reduced to a level which is palatable to the non-scientific orientated citizen. In communicating with the public and motivating the political entities involved, the Governmental Radiation Safety Officer must retain his scientific integrity. With these responsibilities, personal restraint must be applied in dealing with politically popular but relative low hazard potential subjects. The lack of national strategy and priority for radiation coupled with dual responsibilities and in many areas a void of definition of federal agency responsibility result in wasted, illdirected independent actions on the part of many This has a direct effect on what agencies. responsibilities the Governmental Radiation Safety Officer must assume. It is mandatory that individuals responsible for program direction assume the obligation of directing consolidation and/or improved communication between the following programs: AEC, BRII, EPA, FDA, DOT, DOL, OSHA, DCPA, OEP, and HSMHA. The primary responsibility that must be retained is effective control of the use of radiation so that no person is needlessly exposed while permitting the largest scope of practical utilization.

71. ACTIVITIES OF THE RADIATION SAFETY COMMITTEE IN A LARGE MEDICAL CENTER. BLACKWELL, L.H. AND TANNER, R.L. (University of Tennessee, Memphis, TN, USA). 18th Annual Meeting of Health Physics Society, Miami Beach, FL, June 17-21, 1973, p. 332.

The organizational structure of the Radiation Safety Committee at the University of Tennessee Medical Center -- City of Memphis Hospital (which acts in an advisory, policy-formulating role to assist the RSO) will be described. A commentary on the way in which it has functioned, both successfully and otherwise, for the past 8 years will be presented. Some areas of interest to be included are: designation of membership and chairman, budget considerations, relationship to RSO, extension of services to outside enterprises, licensing of individual users, and

formulation of policy on patient dose reduction. Suggestions will be made for improvement of the committee's activity, including statements recognizing its responsibilities and limitations.

72. INTERPRETATION OF BIOASSAY MEASUREMENTS. LESSARD, E.T.; XIA. Y.; SKRABLE, K.W.; CHABOT, G.E.; FRENCH, C.S. (Brookhaven National Laboratory, Upton, NY, USA), NUREG/CR-4884, BNL-NUREG-52063, July 1987, 814 p.

This is a comprehensive manual describing how to computer intakes from both in-vivo and in-vitro bioassay measurements. To date, interpretations of intake have been inconsistent, particularly in the early phases after an accidental intake. This manual is aimed at completely describing a consistent approach and instructing others on how to compute intakes and committed organ dose equivalents. Tables for the interpretation of bioassay results are compiled for several hundred radionuclides. Measurements which employ whole-body counter, a thyroid counter, a lung counter, or measurements on excreta can be converted into estimates of intake based on the tables presented in the appendices. The values in the tables were determined by using lung, gastrointestinal tract, and systemic retention models published by the International Commission on Radiological Protection In a few cases, pseudo-retention (ICRP 79). functions, organ retention functions, and excretion functions were used to generate the tabulated values. The biological and radiological input parameters are included in an appendix, and a description of the mathematical approach that was used to derive the tabulated data is included in the methods section. Calculations for various particles sizes are addressed along with methods to interpret multiple or continuous exposures. Examples of use are based on actual bioassay measurements following accidental intakes, including tritium, Mn-54, Co-60, Sr-90, Nb-95, radioiodines, Cs-137, Ce-141, Ce-144, U-233, U-Nat, and Am-241.

73. GUIDE TO NRC REPORTING AND RECORDKEEPING REQUIREMENTS. COLLINS, M.; SHELTON, B. (Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, D.C., USA), NUREG-1460, November 1992, 190 p.

The compilation includes the first two sections the reporting and recordkeeping requirements applicable to U.S. Nuclear Regulatory Commission (NRC) licensees and applicants and to members of the public. It includes those requirements codified in Title 10 of the Code of Federal Regulation Chapter I, on December 31, 1991. It also includes, in a separate section, any of those requirements that were superseded or discontinued from January through December 1991. Finally, the appendix lists mailing and delivery addresses for NRC Headquarters and Regional Offices mentioned in the compilation.

74. RADIATION DOSE TO THE HANDS IN NUCLEAR MEDICINE. BATCHELOR, S.; PENFOLD, A.; ARIC, I.; HUGGINS, R. (Department of Medical Physics, St. Thomas' Hospital, London, UK), Nuclear Medicine Communications, Vol. 12, No. 5, 1991 pp. 439-444.

Study of the distribution of radiation dose across both hands during the dispensing and administration of radiopharmaceuticals is useful in the assessment of the extremity doses received by nuclear medicine personnel. Some staff in the UK have already been designated as classified radiation workers due to the radiation doses that their hands may receive. With possible forthcoming reductions in the dose limits, it is important that as much data as possible is available on such dosimetry. By measuring the dose at nine different locations on each hand, an optimal site (the base of the second digit) to represent a more accurate "mean hand dose" could be determined. The use of inserting different butterfly cannula into a vein, prior to radiopharmaceutical administration, was assessed in terms of the dose reduction effect to the member of staff performing the task. It was found that a long tubing cannula (300 mm) did not significantly reduce the radiation dose of the operator whereas shorter ones (95 mm) gave a very significant dose reduction.

75. THE ROLE OF NUCLEAR PHARMACY IN REDUCING RADIATION EXPOSURE. AHLUWALIA, B.; ALLEN, E.W.; BASMADIAN, G.; ICE, R. (Veterans Administration, Oklahoma Health Science Center, Oklahoma City, OK, USA), Health Physics, Vol. 40, No. 5, 1981, pp. 728-729.

The personnel working in a nuclear medicine imaging and therapeutic area are exposed to radiation during various phases of their work, including elution of isotope generators, dose preparation and calibration, administration of radioactive material and patient handling and imaging. Because of the larger amounts of radioactive material involved in elution of the generator and dose preparation, these two factors contribute the most to the exposure of personnel. In reviewing their procedures for maintaining occupational radiation exposure as low as reasonably achievable they have discovered that the utilization of a centralized nuclear pharmacy which distributes unit-doses of radioactive material substantially decreased the radiation exposure of the imaging personnel.

76. AIR AND SURFACE CONTAMINATION RESULTING FROM LUNG VENTILATION AEROSOL PROCEDURES. CRAWFORD, E.S.; QUAIN, B.C.; ZAKEN, A.M. (Department of Nuclear Medicine, State University of New York, Buffalo, NY, USA), Journal of Nuclear Medicine Technology, Vol. 20, No. 3, September 1992, pp. 151-154

The authors' investigation was conducted to compare the limit for worker dose from aerosols with measured air concentrations in the work area. They also wanted to determine the extent and causes of surface contamination from aerosol studies. Samples were collected during 35 aerosol studies at four different hospitals. The resulting data consisted of measured airborne aerosol concentrations and area wipe test counts for removable contamination. The patient's ability to cooperate was evaluated and recorded, as well as the aerosol equipment used in each case by each hospital. On average, air concentrations and floor and nasal contamination increased as the patient's ability to cooperate decreased. Contamination did not appear to be higher with any particular aerosol equipment. The patient's ability or inability to cooperate did not always correlate with the amount of contamination found. Patient practice and coaching appears to result in less contamination. The authors recommend that each clinic performing radioaerosol studies conduct an investigation similar to theirs to assess the extent of contamination in the clinic and to determine if any corrective actions are indicated.

77. TIME DEPENDENT RADIATION EXPOSURES SURROUNDING TECHNETIUM-99M MDP PATIENTS. CASTRONOVO, F.P., JR. (Brigham & Women's Hospital, Harvard Medical School, Boston, MA,

USA), Journal of Nuclear Medicine Technology, Vol. 19, No. 3, September 1991, pp. 182-184.

Radiation surveys of technetium-99m (<sup>99</sup>m/Tc) MDP bone scan patients were performed at 5 min, 4 hr, and 24 hr post administration. The measurement distances chosen were surface, 1 ft (30.5 cm) and 3 ft (100 cm) resulting in variable radiation exposures as a function of time and bony pathology. As expected the highest exposures were immediately after tracer administration. Thereafter, urinary excretion and biologic redistribution dominated, resulting in significantly lower exposures at 4 hr and 24 hr for the negative bone scan group. Patients with bony metastases retained more of the injected dose than those with negative scintigrams. This was reflected with the 4 hr and 24 hr surveys.

78. DOSIMETRIC CONSIDERATIONS WHILE ATTENDING HOSPITALIZED I-131 THERAPY PATIENTS. CASTRONOVO, F.P., JR.; BEH, R.A.; VEILLEUX, N.M. (Massachusetts General Hospital, Boston, MA, USA), Journal of Nuclear Medicine Technology, Vol. 10, No.3, September 1982, pp. 157-160

Radiation exposure to hospital personnel attending I-131 therapy patients was calculated relative to patient dose, distance, and time after administration. Routine or emergency contact with these patients would not exceed occupational maximum permissible doses for hands and whole body for attendance up to 30 min immediately after administration.

79. ABSORBED DOSES TO SKIN FROM RADIONUCLIDE SOURCES ON THE BODY SURFACE. FAW, R.E. (Nuclear Engineering Department, Kansas State University, Manhattan, KS, USA), Health Physics, Vol. 63, No. 4, 1992, pp. 443-448.

Beta-particle and electron doses are reported for radionuclides on the skin surface. Upper and lower bounds on doses are based on Monte Carlo calculations that include or exclude electron scattering in air, respectively. Upper bounds agree well with results of point-kernel calculations performed by others.

80. HUMAN BREAST MILK EXCRETION OF IODINE-131 FOLLOWING DIAGNOSTIC AND THERAPEUTIC ADMINISTRATION TO A

LACTATING PATIENT WITH GRAVES' DISEASE. DYDEK, G.J.; BLUE, P.W. (Nuclear Medicine Service, Fitzsimons Army Medical Center, Aurora, CO, USA), Journal of Nuclear Medicine, Vol. 29, No. 3, 1988, pp. 407-410.

Previous reports on the excretion of <sup>131</sup>I into human breast milk have recommended discontinuance of breast feeding from 1 to 12 days following diagnostic tracer doses of <sup>131</sup>I. Recent excretion models have calculated that breast feeding could safely resume 56 days following a 5 μCi (0.185 MBq) <sup>131</sup>I maternal tracer dose. We studied a postpartum patient with Graves' disease following first an uptake dose of 8.6 μCi (0.317 MBq) and then for 38 days following a 9.6 mCi (355 MBq) therapy dose of Na<sup>131</sup>I. We calculated from our data that although nursing could not be safely resumed for 46 days following the 8.6-µCi uptake dose, nursing could resume in this patient 8 days after a 100-nCi (3.7 KBq) dose. Extrapolating this data to impure <sup>123</sup>I (p, 2n or p, 5n) we feel that standard 100-µCi (3.7 MBq) doses of either <sup>123</sup>I preparation is not suitable is nursing is to be resumed.

81. RADIATION SAFETY AND HANDLING OF THERAPEUTIC RADIONUCLIDES. EARLY P.J. (NMA Medical Physical Services, Mallinckrodt, Inc., Cleveland, OH, USA), Nuclear Medicine and Biology, Vol. 14, No. 3, 1987, pp. 263-267.

The use of radionuclides in therapy, both as sealed sources and in the radiopharmaceutical form, is discussed from receipt of radiopharmaceuticals through their use, to their disposal. The licensing requirements for use of therapeutic radionuclides is presented. Discussions dealing with receipt, storage and administration of radiopharmaceuticals are treated in detail, as well as suggestions for personnel monitoring. Procedures involved in the event of emergency surgery and/or death are discussed. The misadministration rules of the Nuclear Regulatory Commission regarding therapies were presented.

82. WORKSHOP MANUAL FOR RADIONUCLIDE HANDLING AND RADIOPHARMACEUTICAL QUALITY ASSURANCE -- WORKSHOP MANUAL REPORT. Bureau of Radiological Health, Rockville, MD, FDA/BRH-82/103, July 1982, 64 p.

This manual is designed for use in the Radionuclide Handling and Radiopharmaceutical Quality Assurance

Workshop which aids nuclear medicine technologists and other nuclear medicine personnel in organizing and implementing quality assurance programs in their facility. The manual was developed collaboratively with the Universities of Colorado and Cincinnati Medical Centers and the Nuclear Medicine Laboratory, BRH, FDA. The six sections include material on generatroperation, yield, contaminants, and assay; calibrator testing procedure; radiopharmaceutical sterility, pyrogenicity, and purity; Xenon storing, handling, and disposal; and safety for patient and personnel: shielding, monitoring, decontamination, and good working habits.

**83. ALARA AND AN INTEGRATED APPROACH TO RADIATION PROTECTION.** HENDEE, W.R; EDWARDS, F.M., Seminars in Nuclear Medicine, Vol. 16, No. 2, April 1986, pp. 142-150.

Exposures of individuals to ionizing radiation have been restricted for many years by a number of guidelines and rules developed by various advisory and regulatory groups. Accompanying these restrictions has been an evolving principle that exposures to individuals and groups should be kept "as low as reasonably achievable" (ALARA), consistent with provision of the benefits of radiation use to society. Although the ALARA concept is a laudable goal in principle, its implementation in a clinical facility has not been a straightforward process. Problems of implementing ALARA have been confounded further by the efforts of regulatory agencies to incorporate the ALARA concept into regulations governing radiation exposures. facilitate the implementation of ALARA as a workable construct in a clinical facility, guidelines are needed for its application to both individual and collective exposures to radiation. The provision of such guidelines, including action and inaction levels for both individual and collective exposures, are presented here.

**84. RADIATION DOSIMETRY FROM BREAST MILK EXCRETION OF RADIOIODINE AND PERTECHNETATE.** HEDRICK, W.R; DI SIMONE, R.N.; KEEN, R.L., Journal of Nuclear Medicine, Vol. 27, No. 10, October 1986, pp. 1569-1571.

Measurements were made of the activity in samples of breast milk obtained from a patient with postpartum thyroiditis following administration of <sup>123</sup>I sodium

iodide and subsequently <sup>99m</sup>Tc pertechnetate 24 hr later. Both <sup>123</sup>I and <sup>99m</sup>Tc were found to be excreted exponentially with an effective half-life of 5.8 hr and 2.8 hr, respectively. Less than 10% of the activity was incorporated into breast-milk protein. After administration of <sup>123</sup>I sodium iodide breast feeding should be discontinued for 24-36 hr to reduce the absorbed dose to the child's thyroid.

85. EXCRETION OF RADIOIODINE IN BREAST MILK. HEDRICK, W.R; DISIMONE, R.N.; KEEN, R.L., Journal of Nuclear Medicine, Vol. 30, No. 1, January 1989, pp. 127-128.

No abstract available.

86. EXCRETION OF RADIOIODINE IN BREAST MILK - REPLY. BLUE, P.W.; DYDEK, G.J., (Fitzsimons Army Medical Center, Aurora, CO, USA), Journal of Nuclear Medicine, Vol. 30, No. 1, 1989, pp. 127-128.

No abstract available.

87. USE OF GENERATOR-PRODUCED RADIONUCLIDES IN NUCLEAR MEDICINE PROCEDURES: ANALYSIS OF PERSONNEL DOSES AND LABORATORY WORK PRACTICES. IYER, P.S.; DHOND, R.V. (Division of Radiological Protection, Bhabha Atomic Research Centre, Bombay, India), 10th Annual Conference of the Society of Nuclear Medicine, Madras, India, November 1978, Health Physics, Vol. 39, No. 3, September 1980, pp. 576-578.

A survey was conducted for evaluation of personnel doses and laboratory work practices in Indian institutions using 99mTc and 113mIn generators. Some of the information was obtained from replies to a questionnaire sent to these institutions and some from personnel dose records maintained by the Division of Radiological Protection, Bhabha Atomic Research Centre, Bombay. The results of this analysis are presented. The analysis suggests that, while a wide range of personnel doses is seen among the staff members working with generator produced radionuclides, there is a general trend toward increased doses in comparison with the doses of other personnel in nuclear medicine departments. Also, the doses received by personnel handling the generators were found to be higher than the doses prior to the installation of the generators.

88. RADIOIODINE VOLATILIZATION FROM REFORMULATED SODIUM IODIDE I-131 ORAL SOLUTION. LUCKETT, L.W.; STOTLER, R.E., Journal of Nuclear Medicine, Vol. 21, No. 5, May 1980, pp. 477-479.

By changing the pH and adding buffers, antioxidants, and stabilizers to a sodium iodide (I-131) oral solution, a reduced radioiodine volatilization was by a commercial supplier claimed This study compares the radiopharmaceuticals. from volatilized airborne radioactivity reformulated sodium iodide solution with that which became airborne from a previous formulation. Air samples were obtained from the fume hood's exhaust stack during initial venting, and from the breathing zones of physicians and technologists administering the solution to the patient. Analysis of the air samples indicates significant reduction in the airborne radioiodine following initial venting of the solution vial and during patient administration. Additionally, there has been a decline in the I-131 thyroid burdens for occupationally exposed personnel handling the reformulated sodium iodide solutions.

89. CONTAMINATION OF THE HOME ENVIRONMENT BY PATIENTS TREATED WITH IODINE-131: INITIAL RESULTS. JACOBSON, A.P.; PLATO, P.A.; TOEROEK, D. American Journal of Public Health, Vol. 68, No. 3, March 1978, pp. 225-230.

We have employed twin sodium iodide radiation detectors to analyze iodine-131 transfer from thyroid patients to their families. Unlike previous studies of this problem, we measured thyroid radioiodine activity directly and are able to detect as little as 92 pCi of iodine-131 in adult thyroids. As in previous studies, we have also measured direct radiation exposures of family members with wristband thermoluminescent dosimeters. Thus far, we have studied seven families with 17 persons. Eleven of these are children under age 16. Direct radiation exposure of family persons from proximity of these radioactive patients ranged from 0.17 to 126 mR per day (natural background radiation amounts to approximately 0.35 mR per day). The maximum activity of iodine-131 in family thyroids ranged from less than 92 pCi to as high as 110,000 pCi and resulted in thyroid dose equivalents of 4 to 1330 mrem. Based on recent estimates of thyroid cancer, the latter dose equivalent could possibly double the risk of thyroid malignancy in children over what is expected normally. Such a risk implies the addition of ten induced cases to the ten naturally occurring cases per million people per year.

90. LUNG VENTILATION STUDIES: SURFACE CONTAMINATION ASSOCIATED WITH TECHNETIUM-99M DTPA AEROSOL. MCGRAW, R.S.; CULVER, C.M.; JUNI, J.E.; SCHANE, E.C.; NAGLE, C.E. (Department of Nuclear Medicine, William Beaumont Hospital, Troy, MI, USA), Journal of Nuclear Medicine Technology, Vol. 20, No. 4, December 1992, pp. 228-230.

The authors' study was undertaken to determine amount of whether a measurable surface with contamination is associated routine technetium-99m DTPA aerosol ventilation studies. Three potential sources of contamination were evaluated: aerosol leakage related to the patients, aerosol leakage at the exhaust of the delivery system, and aerosol leakage related to operator error. A pre-defined protocol was used for setting up the apparatus and performing wipe tests. A GM survey was performed, and in all cases, no levels above background were detected. The results of the wipe tests, however, showed that 57% of patient studies had contamination underneath the exhaust of the device: 35% of the studies had floor contamination; and 39% of the studies contaminated the area adjacent to the patient.

91. USE OF RADIOLOGY IN U.S. GENERAL SHORT-TERM HOSPITALS: 1980-1990. METTLER, F.A., JR.; BRIGGS, J.E.; CARCHMAN, R.; ALTOBELLI, K.K.; HART, B.L.; KELSEY, C.A. (Department of Radiology, University of New Mexico, School of Medicine, Albuquerque, NM, USA), Radiology, Vol. 189, No. 2, November 1993, pp. 377-380.

Purpose: To determine changes in usage of radiologic services between 1980 and 1990. Materials and Methods: Complete data were obtained from 107 (42%) hospitals and incomplete data from eight (3%) (total survey response rate, 45%). Information was requested about the number of general radiologic examinations; specific modalities of computed tomography (CT), magnetic resonance (MR) imaging, nuclear medicine, and ultrasonography (US); and numbers of CT, MR imaging, and US machines. Results: The number of general radiologic

examinations in hospitals increased from approximately 126 million to 179 million (> 42%); for CT, from 3.6 million to 13.3 million; nuclear medicine, from 6.4 million to 7.4 million; and US, from 4.3 million to 11.8 million. MR imaging examinations performed during 1990 were estimated at 1.8 million. Conclusion: The number of radiologic examinations performed in U.S. hospitals increased by 30%-60% between 1980 and 1990, mainly due to increased usage of CT, MR imaging, and US.

**92. MEDICAL DOSES CLINICAL AND OCCUPATIONAL.** MILLER, K.L. (Milton S. Hershey Medical Center, USA), Radiation Protection Management, Vol. 7, No. 4, August 1990, pp. 30-37.

When comparing hospitals, wide variations are found in the level of radiation exposure administered for routine radiographic examinations. Regulatory agencies are taking steps to minimize these variations. In this paper typical exposures are presented for routine examinations in diagnostic radiology, dentistry and nuclear medicine. A brief review of the current recommendations regarding radiation and pregnancy is also given.

93. RADIATION DOSE RATES FROM ADULT PATIENTS UNDERGOING NUCLEAR MEDICINE INVESTIGATIONS. MOUNTFORD, P.J.; O'DOHERTY, M.J.; FORGE, N.I.; JEFFRIES, A.; COAKLEY, A.J. (Department of Nuclear Medicine, Kent and Canterbury Hospital, UK), Nuclear Medicine Communications, Vol. 12, No. 9, September 1991, pp. 767-777.

Adult patients undergoing nuclear medicine investigations may subsequently come into close contact with members of the public and hospital staff. In order to expand the available dosimetry and derive appropriate recommendations, dose rates were measured at 0.1, 0.5 and 1.0 m from 80 adult patients just before they left the nuclear medicine department after undergoing one of eight 99Tcm studies, an 1231 thyroid, an 111In leucocyte or a 201Tl cardiac scan. The maximum departure dose rates at these distances of 150, 30 and 7.3 microSv h-1 were greater than those found in similar published studies of adult and paediatric patients. To limit the dose to an infant to less than 1 mSv, an 111In leucocyte scan is the only investigation for which it may be necessary to restrict close contact between the infant and a radioactive parent, depending on the dose rate near the surface of the patient, the parent's habits and how fretful is the infant. It is unlikely that a ward nurse will receive a dose of 60 microSv in a working day if caring for just one radioactive adult patient, unless the patient is classified as totally helpless and has undergone a 99Tcm marrow, bone or brain scan. The data and revised calculations of effective exposure times based on a total close contact time of 9 h in every 24 h period should allow worst case estimates of radiation dose to be made and recommendations to be formulated for other circumstances, including any future legislative changes in dose limits or derived levels.

94. ESTIMATION OF CLOSE CONTACT DOSES TO YOUNG INFANTS FROM SURFACE DOSE RATES ON RADIOACTIVE ADULTS. MOUNTFORD, P.J. (Department of Nuclear Medicine, Kent and Canterbury Hospital, UK), Nuclear Medicine Communications, Vol. 8, No. 11, November 1987, pp. 857-863.

A general method is given to estimate the dose to an infant held in close contact to a radioactive parent. Calculated values of effective exposure times are given for various radiopharmaceuticals corresponding to a simplified sequence of periods of close contact. When multiplied by a measurement of the dose rate on the surface of an adult, these times can be used to give a quick upper estimate of a close contact dose. This allows a decision whether it is necessary to issue instructions for restricting the duration of close contact to an adult patient, before the patient leaves a nuclear medicine department. Estimates of close contact dose have been made from measurements of surface dose rate using these effective exposure times. Doses to infants from adults who have undergone diagnostic radiopharmaceutical procedures can be kept below 1 mSv without imposing restrictions in close contact. A close contact dose of 1 mSv will be exceeded by activities of 131-I iodide greater than 112 MBq.

95. GUIDELINES FOR RADIATION PROTECTION. MURPHY, P.H., Seminars in Nuclear Medicine, Vol. 16, No. 2, April 1986, pp. 131-141

Guidelines for radiation protection originate from numerous federal, state, and local agencies. Webster defines a guideline as a line by which one is guided, especially as an outline (as by a government) of

policy or conduct. Guidelines in radiation protection can be either mandatory or advisory. Regulations by federal, state, and local governments for the use of radioactive materials define operating practices. Adherence to these regulations is required by law and there are penalties for noncompliance. Regulations generally constitute the minimum requirements for good practice and are usually supplemented by less formal recommendations from regulatory agencies and advisory groups. The regulatory guides published by the Nuclear Regulatory Commission (NRC) and by radiation control groups of agreement states are intended to assist the user of radioactive material in maintaining compliance with regulations. guides recommend good practice but are not mandatory in that the user can propose alternatives to the regulatory agencies to meet the regulations. Many groups serve in an advisory capacity in formulating reports and recommendations for the safe use of radioactive material. The most prominent and influential among these are the National Council in Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP). Often the recommendations of these advisory groups evolve into either regulatory guidelines or regulations for the use of radioactive materials. At the present time, the backbone of the Nuclear Regulatory Commission's regulations relating to the medical use of radionuclides, "Standards for Protection Against Radiation" (10CFR20) and "Human Use of Byproduct Material" (10CFR35), are undergoing extensive review with major revisions anticipated within the very near future. proposed changes could have a significant impact on the practice of nuclear medicine. The changes will have some influence on radiation safety practice as it relates to the radiation worker, the patient, and the environment.

96. SKIN EXPOSURE TO I BLOCKS THYROID UPTAKE OF <sup>131</sup>I. MILLER, K.L.; WHITE, W.J.; LANG, C.M.; WEIDNER, W.A., Health Physics, Vol. 49, No. 5, November 1985, pp. 791-794.

Radioisotopes of I pose an important health risk to man in nuclear accidents associated with electric power generation due to their uptake by the thyroid glands. Topical application of tincture of I or povidone-iodine to the skin of rats has been found to be as effective as oral administration of potassium iodide in blocking thyroid uptake of parenterally administered <sup>131</sup>I. If the same effectiveness can be

demonstrated in humans, this may be an attractive alternative method of mass protection from radioisotopes of I following nuclear accidents.

97. EXPOSURE TO XENON 133 IN THE NUCLEAR MEDICINE LABORATORY. NISHIYAMA, H.; LUKES, S.J., Radiology, Vol. 143, No. 1, April 1982, pp. 243-247.

Exposure of nuclear medicine personnel to 133X was examined quantitatively at three area hospitals during ventilation-perfusion studies in which the technologists breathed through a specially made xenon-trapping apparatus. The accumulated mean xenon activity varied a great deal from hospital to hospital, ranging from 52 nCi (1.92 kBq) to over 5 microCi (185 kBq) during a typical 20-minute lung study. The observed difference largely depended on the xenon exhaust and trapping systems, which could make a 100-fold difference in exposure rates. The air flow and its exchange rate in the room were additional factors contributing to the different exposure rates. Although the patient continued to be a source of xenon contamination throughout the study, the xenon-trapping system, while operational, could exhaust substantial quantities of xenon. The exhaust duct system, on the other hand, left little contaminated air in the room, resulting in the least exposure to personnel.

98. SURVEY OF 99MTC CONTAMINATION OF LABORATORY PERSONNEL: ITS DEGREE AND ROUTES. NISHIYAMA, H.; LUKES, S.J.; FELLER, P.A.; VAN TUINEN, R.J.; WILLIAMS, C.C.; SAENGER, E.L., Radiology, Vol. 135, No. 2, May 1980, pp. 467-471.

Internal contamination of personnel preparing 99mTc labeled radiopharmaceuticals was confirmed by detection of radioactivity in urine. Observation of work habits, whole-body scanner studies, nose swabs, and wipe tests in the hot laboratory demonstrated that:
(a) contamination of the laboratory coat occurred during radiopharmaceutical preparation; (b) the degree of personnel contamination appeared to be higher among the short in stature; and (c) no gross evidence was found to indicate that internal contamination took place through an air-borne route. While the calculated internal radiation dose is minimal, even this could be avoided if particular precautionary practices are observed.

99. ASSESSMENT OF RADIATION DOSE TO INFANTS FROM BREAST MILK FOLLOWING THE ADMINISTRATION OF 99MTC PERTECHNETATE TO NURSING MOTHERS. OGUNLEYE, O.T. (University of Lagos, Nigeria), Health Physics, Vol. 45, No. 1, July 1983, pp. 149-151.

Results of measurements of <sup>99m</sup>Tc activity in the milk samples of nursing mothers who received <sup>99m</sup>Tc pertechnetate for thyroid scans are presented. The maximum concentration is found around 2 hours after injection. The total body dose to a 3-month-old infant feeding on the assayed milk varied with time from about 685 mrad to 0.5 mrad.

100. EVALUATION OF 133XE RADIATION EXPOSURE DOSIMETRY FOR WORKERS IN NUCLEAR MEDICINE LABORATORIES. PILTINGSRUD, H.V.; GELS, G.L. (University of Cincinnati Medical Center, OH, USA), Health Physics, Vol. 42, No. 6, June 1982, pp. 837-848.

Evaluation of past studies of 133Xe dosimetry and nuclear medicine laboratory air concentrations of <sup>133</sup>Xe indicates that significant levels of <sup>133</sup>Xe may exist in routine operational environments of a nuclear medicine laboratory. This leads to the question of whether present health physics radiation control methods are adequate to keep occupational personnel exposures within acceptable levels. It would appear that if personnel dosimeters (film and TLD badges) respond properly to the radiation of <sup>133</sup>Xe, normal health physics control procedures are probably adequate. If they do not respond adequately, personnel exposures may exceed recommended levels and special instrumentation or administrative procedures are called for. Therefore, the first step in studying potential problems in the subject area is to evaluate the response of a variety of personnel radiation dosimeters to <sup>133</sup>Xe. This paper describes the methods and materials used to expose personnel dosimeters to known amounts of 133Xe radiations in an exposure chamber constructed at the BRH Nuclear Medicine Laboratory. Also presented are calculated values for Dose Equivalents (D.E.) in a phantom from external radiation resulting from immersion in clouds having a constant concentration of <sup>133</sup>Xe but varying cloud radii. This implies the relative importance of the beta and the X + gamma radiation responses of the personnel dosimeters under various exposure conditions. Results of this study indicate that none of the dosimeter systems evaluated provide adequate performance for use as a primary indicator of the D.E. resulting from <sup>133</sup>Xe radiations for a worker in a nuclear medicine laboratory, and that personnel dosimetry considerations in <sup>133</sup>Xe-containing atmospheres are very dependent on the radii of the <sup>133</sup>Xe clouds.

101. PERFORMANCE OF A REFRIGERATED CHARCOAL TRAP FOR XENON-133. POWELL, M.; GRANDO, R.; ROBESON, W. (Department of Radiology, Park City Hospital, Bridgeport, CT, US), Medical Physics, Vol. 8, No. 6, November-December 1981, pp. 892-893.

The impulse response function of a charcoal trap to a bolus of xenon-133 was determined as a function of the total number of hours run both at room temperature and at 25° C. The peak of the response function for a new trap at room temperature reached a value of 360 MPC at 11 h. After 150 h of operation, the impulse response function was determined at -25° C reaching a value of only 35 MPC at 25 h. The exhaust concentration of a trap in a busy nuclear medicine department using 150 mCi of xenon per week was measured and found to be 1600 MPC. The trap was placed in the freezer and kept there while it continued in use. Over a period of 3 weeks, the concentration of xenon in the exhaust of the trap dropped to a value of 13 MPC, or less than 1% of its value at room temperature.

102. DOSE ESTIMATION TO THE INFANT FROM BREAST MILK FOLLOWING INTRAPERITONEAL ADMINISTRATION OF CHROMIC PHOSPHATE <sup>32</sup>P FOR THE TREATMENT OF EARLY OVARIAN CANCER. SHARMA, S.C.; OSBORNE, R.P.; JOSE, B.; CARLSON, J.A. JR. (University of Louisville, Louisville, KY, US), Health Physics, Vol. 47, No. 3, September 1984, pp. 452-454

The intraperitoneal (IP) administration of radioactive chromic phosphate <sup>32</sup>P has been used as an adjuvant to surgery in patients with early-stage ovarian cancer. Recently a 32-yr-old patient who was 2 weeks postpartum and breast-feeding, was treated with 15 mCi of <sup>32</sup>P intraperitoneally after a laparotomy for a cystadenocarcinoma of the ovary. The authors present dosimetry data on <sup>32</sup>P excretion in breast milk and discuss radiation protection and safety considerations for the newborn.

103. RADIATION EXPOSURE IN NUCLEAR CARDIOVASCULAR STUDIES. SYED, I.B.; FLOWERS, N.; GRANLICK, D.; SAMOLS, E. (V. A. Medical Center, Louisville, KY, USA), Health Physics, Vol. 42, No. 2, February 1982, pp. 159-163.

Nuclear cardiovascular studies are being introduced in almost every Nuclear Medicine Department. The number of studies performed per week is increasing very rapidly. The physical characteristics including the specific gamma ray constant for radionuclides used in cardiovascular studies are listed. The radiation dose estimates to different organs of a patient administered with <sup>201</sup>Tl and <sup>99</sup>mTc radiopharmaceuticals are shown. The radiation levels measured around patients administered with <sup>201</sup>Tl chloride, <sup>99</sup>mTc HSA (human serum albumin), and 99mTc-MDP (methylene diphosphonate) are within the permissible limits. Radiation doses to different organs from nuclear cardiovascular studies are less than those associated with fluoroscopy, particularly cardiac catheterization. However, the gonadal doses received from cardiac catheterization and angiocardiography are considerably lower than nuclear cardiovascular studies.

104. MONITORING RADIATION DOSE TO THE HANDS IN NUCLEAR MEDICINE: LOCATION OF DOSEMETERS. WILLIAMS, E.D.; LAIRD, E.E.; FORSTER, E. (Regional Medical Physics Department, Sunderland Unit, District General Hospital, UK), Nuclear Medicine Communications, Vol. 8, No. 7, July 1987, pp. 499-503.

The relatively high radiation dose which can be received by the hands of staff in nuclear medicine departments means that in many departments it is necessary to monitor such doses. A convenient method is to use a TLD sachet in a plastic strip around a finger. This study was done to determine whether a dosemeter worn at the base of the middle finger was adequate to monitor the dose to the surface of the whole hand. Dosemeters were worn at the finger tips, finger base and palm of both hands, on two people while preparing and dispensing radio-pharmaceuticals, and two others while giving injections using syringe shields. The pattern of distribution of radiation does to the hands was similar for all workers and for both types of work. A single, convenient site (base of middle finger) may therefore be used for monitoring radiation dose to the hand.

105. IS THE NUCLEAR MEDICINE SCAN PATIENT A SOURCE OF EXPOSURE? PENNOCK, R.E.; MILLER, K.L.; LEUTZELSCHWAB, J.E., Martin, T.G. and Price, K.W. (Eds.), Medical Health Physics, Proceedings of the Health Physics Society Fourteenth Mid-year Topical Symposium, Hyannis, MA, December 1980, pp. 5-15.

With additional emphasis being placed on the ALARA concept in Nuclear Medicine, we decided to reevaluate both the contamination and exposure potential from patients injected with radiopharmacueticals for diagnostic scans. The results of surveying, area monitoring, personnel monitoring, and computer analysis will be presented. Our surveys indicate the risk from such patients is minimal, with an average exposure of less than 10 mR for an individual in constant attendance close to the patient. A maximum population dose is projected to be less than 0.5 man-Rem per month from a typical Nuclear Medicine Department.

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NCRP Publications 7910 Woodmont Avenue Suite 800 Bethesda, MD 20814-3095

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NO.	TITLE
32	Radiation Protection in Educational Institutions (1966).
35	Dental X-Ray Protection (1970).
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41	Specification of Gamma-Ray Brachytherapy Sources (1974).
49	Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV (1976).
51	Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities (1977).
53	Review of NCRP Radiation Dose Limit for Embryo and Fetus in Occupationally Exposed Women (1977).
54	Medical Radiation Exposure of Pregnant and Potentially Pregnant Women (1977).
57	Instrumentation and Monitoring Methods for Radiation Protection (1978).
58	A Handbook of Radioactivity Measurements Procedures, 2nd ed. (1985).
59	Operational Radiation Safety Program (1978) (see citation #59 for an abstract).
63	Tritium and Other Radionuclide Labeled Organic Compounds Incorporated in Genetic Material (1979).
64	Influence of Dose and Its Distribution in Time on Dose-Response Relationships for Low-LET Radiations (1980).
65	Management of Persons Accidentally Contaminated with Radionuclides (1980).
68	Radiation Protection in Pediatric Radiology (1981).

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- 71 Operational Radiation Safety -- Training (1983) (see citation #58 for an abstract).
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- 73 Protection in Nuclear Medicine and Ultrasound Diagnostic Procedures in Children (1983).
- 74 Biological Effects of Ultrasound: Mechanisms and Clinical Implications (1983).
- Evaluation and Occupational and Environmental Exposures to Radon and Radon Daughters in the United States (1984).
- 79 Neutron Contamination from Medical Electron Accelerators (1984).
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- 85 Mammography: A User's Guide (1986).
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- 88 Radiation Alarms and Access Control Systems (1986).
- 89 Genetic Effects from Internally Deposited Radionuclides (1987).
- 93 Ionizing Radiation Exposure of the Population of the United States (1987).
- Comparative Carcinogenicity of Ionizing Radiation and Chemicals (1989).
- 99 Quality Assurance for Diagnostic Imaging (1988).
- Exposure of the U.S. Population from Diagnostic Medical Radiation (1989).
- Exposure of the U.S. Population from Occupational Radiation Exposure (1989).
- Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use) (1989).
- The Relative Biological Effectiveness of Radiations of Different Quality (1990).
- Radiation Protection for Medical and Allied Health Personnel (1989).

- Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel (1990).
- 108 Conceptual Basis for Calculations of Absorbed Dose Distributions (1991).
- Developing Radiation Emergency Plans for Academic, Medical or Industrial Facilities (1991).
- Calibration of Survey Instruments Used in Radiation Protection for the Assessment of Ionizing Radiation Fields and Radioactive Surface Contamination (1991).
- Exposure Criteria for Medical Diagnostic Ultrasound: I. Criteria Based on Thermal Mechanisms (1992).
- 114 Maintaining Radiation Protection Records (1992).
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- Nonionizing Electromagnetic Radiations and Ultrasound, Proceedings of the Twenty-second Annual Meeting held on April 2-3, 1986 (including Taylor Lecture No. 10) (1988).
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Availability:

ICRP publications are distributed by Pergamon Press, Inc. Information on prices and how to order may be obtained by directing an inquiry to:

Pergamon Press, Inc. 660 White Plains Road Tarrytown, NY 10591-5153

#### ICRP REPORTS

NO.	TITLE
23	Reference Man: Anatomical, Physiological and Metabolic Characteristics (1975).
25	Handling and Disposal of Radioactive Materials in Hospitals (1977).
28	The Principles and General Procedures for Handling Emergency and Accidental Exposure of Workers (1978).
30	Limits for Intakes of Radionuclides by Workers, 8 Volume Set with Index (1990).
30	Limits for the Intake of Radionuclides by Workers, Part 1 (1979)
30	Limits for the Intake of Radionuclides by Workers, Supplement to Part 1 (1980)
30	Limits for Intakes of Radionuclides by Workers, Part 2 (1980)
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30	Limits for Intakes of Radionuclides by Workers, Part 3 (1982)
30	Limits for Intakes of Radionuclides by Workers, Supplements A & B to Part 3 (1982).
30	Limits for Intakes of Radionuclides by Workers, Part 4 (An Addendum) (1989).
30	Limits for Intakes of Radionuclides by Workers, Index (1982)
34	Protection of the Patient in Diagnostic Radiology (1983).
37	Cost Benefit Analysis in the Optimization of Radiation Protection (1983).
38	Radionuclide Transformations: Energy and Intensity of Emissions (1983).
40	Protection of the Public in the Event of Major Radiation Accidents: Principles for Planning (1984).
41	Nonstochastic Effects of Ionizing Radiation (1984).
42	A Compilation of the Major Concepts and Quantities in Use by ICRP (1984).

#### Management of Radioactive Material Safety Programs at Medical Facilities

- Protection of the Patient in Radiation Therapy (1985).
- Quantitative Bases for Developing a Unified Index of Harm (1986).
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- 52 Protection of the Patient in Nuclear Medicine (1988).
- Radiation Dose to Patients from Radiopharmaceuticals (1988).
- 55 Optimization and Decision-Making in Radiological Protection (1989).
- Age-Dependent Doses to Members of the Public from Intakes of Radionuclides: Part 1 (1990).
- 57 Radiological Protection of the Worker in Medicine and Dentistry (1990).
- 59 The Biological Basis for Dose Limitation in the Skin (1992).
- 60 1990 Recommendations of the International Commission on Radiological Protection (1991)
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- Annual Limits on Intake of Radionuclides by Workers Based on the 1990 Recommendations (1991)
- -- Risks Associated with Ionising Radiations (1992)

## SELECTED MEDICAL INTERNAL RADIATION DOSE (MIRD) COMMITTEE PUBLICATIONS

Availability:

MIRD Committee publications are distributed by The Society of Nuclear Medicine. Information on prices and how to order may be obtained by directing an inquiry to:

The Society of Nuclear Medicine 136 Madison Avenue New York, NY 10016-6760

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Availability:

NRPB publications are distributed by The National Radiological Protection Board. Information on prices and how to order may be obtained by directing an inquiry to:

The National Radiological Protection Board Chilton, Didcot, Oxon OX11 ORQ United Kingdom

#### NRPB PUBLICATIONS

#### **VOLUME 1 (1990)**

- No. 2 Gut Transfer Factors
- No. 3 Patient Dose Reduction in Diagnostic Radiology

#### **VOLUME 2 (1991)**

No. 1 Board Statement on Clinical Magnetic Resonance Diagnostic Procedures

#### **VOLUME 3 (1992)**

No. 4 Protection of the Patient in X-ray Computed Tomography Radon Affected Areas: Derbyshire, Northamptonshire and Somerset

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- No. 1 Board Statement on the 1990 Recommendations of ICRP
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NRC Information Notice 93-04, Investigation and Reporting of Misadministrations by the Radiation Safety Officer, January 7, 1993.

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NRC Information Notice 93-36, Notifications, Reports and Records of Misadministration, May 7, 1993.

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#### **APPENDIX S** CATEGORIZED LIST OF NRC GENERIC COMMUNICATIONS **PUBLISHED SINCE 1989 FOR MEDICAL PROGRAMS**

[Bulletin (BL); Generic Letter (GL); Inforcement Notice (IN)]

1. Management Control		
IN 89-02	Criminal Prosecution of Licensee's Former President for Intentional Safety Violations	
IN 89-25 Rev. 1	Unauthorized Transfer of Ownership or Control of Licensed Activities	
IN 89-35	Loss and Theft of Unsecured Licensed Material	
IN 89-46	Confidentiality of Exercise Scenarios	
IN 90-01	Importance of Proper Response to Self-Identified Violations by Licensees	
IN 90-14	Accidental Disposal of Radioactive Materials	
IN 90-15	Reciprocity: Notification of Agreement State Radiation Control Directors Before Beginning Work in Agreement States	
IN 90-81	Fitness for Duty	
IN 91-39	Compliance with 10 CFR Part 21, "Reporting of Defects and Noncompliance"	
IN 92-08	Revised Protection Action Guidance for Nuclear Incidents	
IN 92-37	Implementation of the Deliberate Misconduct Rule	
IN 92-38	Implementation Date for the Revision to the EPA Manual of Protective Action Guides and Protective Actions for Nuclear Incidents	
IN 93-14	Clarification of 10 CFR 40.22, Small Quantities of Source Material	
IN 93-60	Reporting Fuel Cycle and Materials Events to the NRC Operations Center	
IN 93-60 Supp. 1	Reporting Fuel Cycle and Materials Events to the NRC Operations Center	
IN 93-73	Criminal Prosecution of Nuclear Suppliers for Wrongdoing	
IN 93-100	0 Reporting Requirements for Bankruptcy	
IN 94-21	Regulatory Requirements When No Operations are Being Performed	
IN 94-47	Accuracy of Information Provided to NRC During the Licensing Process	
IN 94-74	Facility Management Responsibilities for Purchased or Contracted Services for Radiation Therapy Programs	

IN 95-51 Recent Incidents Involving Potential Loss of Control of Licensed Material

- IN 96-28 Suggested Guidance Relating to Development and Implementation of Corrective Action
- IN 96-57 Incident-Reporting Requirements Involving Intakes, During a 24-Hour Period that May Cause a Total Effective Dose Equivalent in Excess of 0.05 Sv (5 rem)

#### 2. Radiation Protection

- IN 90-20 Personnel Injuries Resulting from Improper Operation of Radwaste Incinerators
- IN 90-44 Dose-Rate Instruments Underresponding to the True Radiation Fields
- IN 90-62 Requirements for Import and Distribution of Neutron-Irradiated Gems
- IN 92-34 New Exposure Limits for Airborne Uranium and Thorium
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#### Appendix S – Categorized List of NRC Generic Communications Published Since 1989 for Medical Programs

- IN 91-35 Labeling Requirements for Transporting Multi-Hazard Radioactive Materials
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- IN 95-01 DOT Safety Advisory: High Pressure Aluminum Seamless and Aluminum Composite Hoop-wrapped Cylinders
- BL 95-01 Quality Assurance Program for Transportation of Radioactive Material
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- IN 89-13 Alternative Waste Management Procedures in Case of Denial of Access to Low-Level Waste Disposal Sites
- IN 89-24 Nuclear Criticality Safety
- IN 89-27 Limitations on the Use of Waste Forms and High Integrity Containers for the Disposal of Low-Level Radioactive Waste
- IN 90-09 Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees
- IN 90-31 Update on Waste Form and High Integrity Container Topical Report Review Status, Identification of Problems with Cement Solidification, and Reporting of Waste Mishaps
- IN 90-75 Denial of Access to Current Low-Level Radioactive Waste Disposal Facilities
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- IN 93-50 Extended Storage of Sealed Sources
- IN 94-07 Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR Part 20
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#### 6. Nuclear Medicine/Medical

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  CFR Part 20
- IN 94-70 Issues Associated with Use of Strontium-89 and Other Beta Emitting Radiopharmaceuticals
- IN 95-07 Radiopharmaceutical Vial Breakage During Preparation

#### 7. Brachytherapy

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- IN 92-10 Brachytherapy Incidents Involving Iridium-192 Wire In Endobronchial Treatments
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- IN 94-17 Strontium-90 Eye Applicators: Submission of Quality Management Plan (QMP), Calibration, and Use
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#### Appendix S - Categorized List of NRC Generic Communications Published Since 1989 for Medical Programs

- IN 94-74 Facility Management Responsibilities for Purchased or Contracted Services for Radiation Therapy Programs
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  - IN 95-50 Safety Defects in Gammamed 12i Bronchial Catheter Clamping Adapters
  - IN 96-21 Safety Concerns Related to the Design of the Door Interlock Circuit on Nulcetron High-Dose Rate and Pulsed Dose Rate Remote Aferloading Brachytherapy Devices

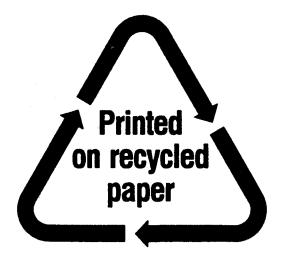
#### 8. Teletherapy

- IN 89-60 Maintenance of Teletherapy Units
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- IN 94-39 Identified Problems in Gamma Stereotactic Radiosurgery
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Copies of NRC Generic Communication may be obtained by contacting the Materials Branch of the appropriate regional office.

NRC FORM 335 (2-99) NRCM 1102, 3201, 3202  BIBLIOGRAPHIC DATA SHEET (See instructions on the reverse)		REPORT NUMBER     (Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.)	
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A Task Force composed of eight U.S. Nuclear Regulatory Commission and two members developed the guidance contained in this report. The purpose of this proach for effective management of radiation safety programs at medical fact sizing the roles of institution executive management, radiation safety committous aspects of program management are discussed and include guidance on sedetermining adequate resources for the program, the use of contractual service companies, the conduct of audits, the roles of authorized users and supervised tification requirements, and a general description of how NRC's licensing, inswork. Appendices provide detailed guidance on specific aspects of a radiation fines terms used throughout the report.	is report is to de lities. This is actee, and radiati- electing the radices such as const d individuals, No spection, and en a safety program	escribe a syst ccomplished ion safety off liation safety sultants and s NRC's reportinforcement p n and the glo	tematic ap- by empha- ficer. Vari- y officer, service ing and no- programs ossary de-
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