

MS-16
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March 22, 1995

Francis M. Costello, Chief
U.S. Nuclear Regulatory Commission
Region I
Medical Licensing Section
475 Allendale Road
King of Prussia, PA 19406-1415

Medi-Physics, Inc.
2636 S. Clearbrook Drive
Arlington Heights, IL 60005
tel (708) 593-6300

Amersham
HEALTHCARE

RE: Docket No. 030-31972
License No. 29-28341-02MD
Application for renewal dated October 28, 1994

Dear Mr. Costello,

On March 21, 1995, Theresa Dardin contacted me and requested additional information regarding the above referenced license which is currently in the process of renewal. Below please find the requested information. The questions have been restated for ease of review.

1. *Regarding Xenon releases please provide the calculations used to determine the clearance time and personnel dose in Item 9 of the application. In addition please estimate the amount released into the unrestricted area.*

Please find these calculations in attachment 1. Calculations for release into the unrestricted area were made using actual weekly inventory.

2. *Please provide an estimate of the iodine releases into the unrestricted area.*

The total concentration of I-131 released into the unrestricted area was determined to be 1.53×10^{-11} $\mu\text{Ci/ml}$ for 1994.

3. *In Item 10.16 entitled Independent Audit Program, the last sentence reads "Individuals performing these audits will not be familiar with the facility's day to day operations." Please clarify that individuals auditing the pharmacy will be independent of the facility's day to day operations.*

Auditors may include, but will not be limited to qualified individuals employed by Medi-Physics' regulatory department and individuals from other Medi-Physics sites. Audit team members will not have direct responsibility for, or involvement in the day to day operations of the facility.

4. *Regarding the addition of authorized users, please submit the training outline for the Video Workbook which is listed as part of Randy Kohen's training.*

Please find the outline for the 'Video Workbook' in attachment 2.

If you any questions or require further clarification, please do not hesitate to contact me at (708)593-6300, extension 381.

Sincerely,



Paula C. Jeter
Sr. Health Physicist
Regulatory Affairs

ATTACHMENT 1

NEW JERSEY XENON CALCULATIONS

1. Input data to calculate Xenon clearance time and exposure from spill

A (mCi) =	20	A (uCi) =	2.00E+04
V (cuft) =	855	V (ml) =	2.42E+07
Q (cfm) =	180	Q (ml/min) =	5.09E+06
DAC (uCi/ml) =	1.00E-04	A/V (uCi/ml) =	8.26E-04
0.1 DAC (uCi/ml) =	1.00E-05	Q/V (1/min) =	2.10E-01

2. Calculated clearance time for Xenon concentration to be cleared to 0.10 times the DAC for a restricted area

$$t = -V/Q \ln (0.1DAC \times V/A)$$

Clearance time(min) = 21

3. Calculated from Xenon spill in I-131 room

Calculations

$$\text{uCi-hours/ml} = C/(Q/V) (1 - \exp(-t(Q/V))) \times 1 \text{ hr}/60\text{min}$$

$$\text{DAC - hours} = \{\text{uCi - hrs/ml}\}/\text{DAC}$$

$$\text{Total 8 hour exposure} = \{\text{DAC - hrs}\} * \{5 \text{ Rem}/2000 \text{ DAC- hrs}\}$$

Results

uCi-min/ml =	3.93E-03
uCi-hour/ml =	6.54E-05
DAC - hours =	6.54E-01
Exposure (mRem) =	1.64

4. Calculated release of xenon into unrestricted areas

Calculations

$$C = A \times .005/V$$

$$A \times 0.005 \text{ (uCi/wk)} = 1.08E+04$$

$$V = Q \times 10800 \text{ min/wk (ml/wk)} = 5.50E+10$$

Results

Average C (uCi/ml) =	1.96E-07
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ATTACHMENT 2

Nuclear Pharmacy Certificate Program Videocassette - Workbook

<u>Instructor and Material</u>	<u>Clock Hours</u>
Dr. Robert Landolt - Radiation Protection	RP 16
<i>Terms and Units</i> <i>Protection from External Exposure</i> <i>Portable Survey Instruments</i> <i>Personnel Monitoring</i> <i>Internal Dose Calculations</i> <i>Contamination Control</i> <i>Waste Management</i> <i>Packaging, Labels and Placards</i> <i>10 CFR Standards for Protection Against Radiation</i> <i>10 CFR Notices, Instructions, and Reports to Workers</i>	
Mr. Jim Ponto	RPI 4 RP 2 MA 4 RC 8
<i>Drugs & Radiopharmaceuticals Part 1</i> <i>Drugs & Radiopharmaceuticals Part 2</i> <i>Drugs & Radiopharmaceuticals Part 3</i> <i>Criteria for Product Selection</i> <i>Instrumentation Quality Assurance</i> <i>Technetium Chemistry/Radiolytic Decomposition</i> <i>Pediatric Dosage Calculations/Adverse Reactions to Radiopharmaceutical</i> <i>Record Keeping</i> <i>Preparation & Dispensing of Radiopharmaceuticals</i>	
Dr. George Hinkle	RPI 1 RC 1
<i>Radiolabeled Antibodies for Diagnosis & Therapy</i>	
Dr. William Goeckeler	RPI 1 RC 1
<i>Development of a New Radiopharmaceutical for Metastatic Bone Disease</i>	
Dr. Paul Simms	RPI 4
<i>Radionuclide Production Part 1</i> <i>Radionuclide Production Part 2</i>	

RP = 16 + 2 + 18
 RPI = 4 + 1 + 1 + 4 + 10
 MA = 4 + 4
 RC = 8 + 1 + 1 + 10

Nuclear Pharmacy Certificate Program Videocassette - Workbook

Instructor and Material

Clock Hours

Dr. Stan Shaw - Radiation Biology and Protection

**RB 20
RP 8**

- Energy Transfer*
- Mechanisms of Change*
- Aqueous Radiation Chemistry*
- Target Theory and Dose-Response*
- Radiation Effects on Macromolecules*
- Radiation Effects on Cells*
- Acute Effects*
- Delayed Effects*
- Genetic Effects*

28

Dr. Wayne Kessler - Instrumentation

**RPI 8
MA 2**

- Spectrometry*
- Counting Efficiency*
- Coincidence Loss*
- Background*
- Liquid Scintillation Counting*
- Statistics of Radioactivity*

10

RB = 20
 RP = 8 + (8)
 RPI = 8 (8)
 MA = 2 (2)

Nuclear Pharmacy Certificate Program Videocassette - Workbook

Instructor and Material

Clock Hours

Dr. James Cooper

RPI 4
RP 2
MA 2

- Tc-99m Generator Principles Part 1*
- Tc-99m Generator Principles Part 2*
- Quality Assurance of Radiopharmaceuticals Part 1*
- Quality Assurance of Radiopharmaceuticals Part 2*

Dr. Stan Shaw - Physics and Overview

RPI 30
RP 2
MA 4
RC 12

- Radiation Energy*
- Atomic Structure*
- Nuclides*
- Radioactive Decay and Half-Life*
- Ideal Radionuclide for Imaging*
- Modes of Radioactive Decay*
- Interaction of Ionizing Radiation with Matter*
- Radiation Detection Methods*
- Radiopharmaceuticals Characteristics and Chemistry*
 - Central Nervous System*
 - Lung*
 - Liver and Hepatobiliary*
 - Spleen*
 - Heart*
 - Bone*
 - Kidney*
 - Endocrine System*
- Miscellaneous Procedures and Radiopharmaceuticals*
- In Vivo Radiopharmaceuticals Not Requiring Imaging*
- Therapy Radiopharmaceuticals*

56

$$\begin{aligned}
 RPI &= 4 + 30 \\
 RP &= 2 + 2 \\
 MA &= 2 + 4 \\
 RC &= 12
 \end{aligned}$$

34
4
6