Standard Nuclear Consultants, Ltd.

Nuclear Medicine • Radiology • Industrial Specialists

STAN BUHR
JIM MIKOWSKI
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P.O. Box 362, Manhattan, IL 60442 □ 1340 Balmoral Avenue, Westchester, IL 60153

April 8, 1985

Bill Adam. Ph.D.
Materials Licensing Section
U. S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

RE: Amendment to materials license no. 12-20362-01; Control no. 77430

Dear Dr. Adam:

This is in follow up to your telephone conversation on April 5, 1985 with Stan Buhr concerning our pending materials license amendment application. We request that our license be amended to include authorization to reference our "Medical Users Training for Bone Mineral Analyzer Diagnostic Devices" course when preparing future license applications for use of these devices. The content outline of our eight hour training course is attached and follows the outline of the November 10, 1983 NRC Policy and Guidance Directive FC83-24, "Licensing the Lixiscope and Bone Mineral Analyzer for Human Use." Our training program is specifically geared toward radiation safety aspects for use and handling of I-125 and Gd-153 sources in bone mineral analyzer devices. We believe authorization to reference our training course will expedite the processing of license applications for use of these devices.

As stated in a previous response letter to our pending amendment application, Stan Buhr and I have received device-specific training for the Lunar SP-2 (I-125 sources), and Lunar DP-3 (Gd-153 sources) bone mineral analyzer devices. A copy of this training record is attached.

A sample copy of the examination to be given physicians at the end of the eight hour training period is attached for your review. Passing grade for the exam will be 70%.

We appreciate your advising us to request this addendum to our pending amendment application and look forward to receiving the amendment document.

Thank you.

Sincerely,

Jim Mikowski

Jim Mikowski

MEDICAL USERS TRAINING FOR
BONE MINERAL ANALYZER DIAGNOSTIC DEVICES

I. Basic Radiation Physics and Instrumentation (3 hours)

1. Atomic Structure
2. Decay Process and Types of Emissions (especially gamma radiation)
3. Radioactivity: Definitions and Units (curies, rems, and sub-units)
4. Interactions of Radiation with Matter
5. Half-life, Inverse Square Law and Half-Value Layers (time, distance and shielding)
6. Decay Constant Formula and Use of Decay Tables
7. Inverse Square Law Formula and Examples
8. Calculation of Radiation Dose in Air, Tissue and Bone
9. Radiation Dose: Dose Rate, Time and Average Dose
10. Characteristics of Sealed Sources (compared to radioactive liquids and other physical forms)

II. Radiation Biology (3 hours)

1. Acute and Chronic Exposures
2. Somatic and Genetic Effects
3. Basis of Maximum Permissable Dose
4. Typical Somatic Effects at Various Dose Levels
5. Genetic Effects and Genetically Significant Dose
6. Factors Affecting Biological Damage (dose, dose rate, type of radiation, type of tissue, amount of tissue, biological variation and chemical modifiers)

III. Radiation Protection (2 hours)

1. Principles of Radiation Safety and ALARA Management Program
2. "Standards for Radiation Protection" 10 CFR Part 20 and "Instructions to Radiation Workers" 10 CFR Part 19, and Equivalent Agreement State Regulations
3. License Conditions for Radiation Safety Program
4. Radioactive Shipment Receiving, Opening, Handling, Storage and Security Procedures
5. Radiation Labels and Required Posting and Documents
6. Routine Proper Use, Inventory and Accountability Procedures for Sealed Sources, or Devices Containing Sealed Sources
7. Leak Testing of Sealed Sources and Contamination Control
8. Shipment Returns, DOT Regulations and Supplier Instructions and Forms
9. Radiation Detection Instrumentation
10. NRC Draft Regulatory Guide "Instruction Concerning Radiation Exposure", May 1980 and NRC Regulatory Guide 8.13 "Instructions Concerning Prenatal Radiation Exposure", November 1975
11. 10 CFR 35 "Medical Use of Radionuclides" and NRC Regulatory Guide 10.8 Procedures and License Applications
12. Radiation Safety References, NCRP and ICRP Publications
13. Review and Discussion of the Sealed Source "Device Specific" Manufacturer literature and Instructions

LUNAR RADIATION CORP.

916 WILLIAMSON ST. • MADISON, WI 53703 • (608) 258-8545

Standard Nuclear Consultants, Ltd.
P.O. Box 362
Manhattan, Il 60442

Atten: Stan Buhr and Jim Mikowski

We wish to acknowledge that on Feburary 6, 1985, Stan Buhr and Jim Mikowski attended a formalized four hour training section at LUNAR. The following items were presented and, if appropriate, independently performed by both individuals:

1) Basic Physics of Absorptiometry,

2) Radiation Dosimetry of LUNAR's SP2 and DP3 scanners,

3) Source exchange for both SP2 (I-125) and DP3 (Gd-153) scanners were performed by both individuals,

4) Wipe testing procedures for SP2 (I-125) and DP3 (Gd-153) scanners.

This device specific training was provided by LUNAR personnal and served to familiarize the stated individuals with particular Health Physics needs and requirements of LUNAR instruments.

Sincerely,

James A. Hanson, Ph.D.
Vice President

Examination

Name:_____ _____ Date:_____

1. If exposure from a Gd-153 source is 1000 mr/hr at 1 foot, what is the exposure at 6 inches?

2. Which of the following properties is <u>not</u> among the properties of x or gamma rays?

   a. Have power of penetrability.

   b. Travel at the speed of light.

   c. Can ionize gasses.

   d. Can be focused with a lens.

3. Which agency(s) regulate the return of Gd-153 and I-125 sealed sources to the supplier?

   _____ NRC

   _____ FDA

   _____ TWA

   _____ DOT

   _____ EPA

4. What are the primary methods of radiation protection?

   a. _____ b. _____ c. _____

5. Gamma rays originate in:

   a. Chemical bonds

   b. Atomic nuclei

   c. Magnetic fields

   d. Electron clouds

6. X-rays are produced by:

   a. Acceleration of gamma rays

   b. Deceleration of electrons

   c. Gravity

   d. Chemical action

7. Match the following:

Annual occupational whole body MPD	_____	a. 75 Rem
Annual non-occupational whole body MPD	_____	b. 5 Rem
Recommended exposure limit to fetus	_____	c. 0.5 Rem
Annual occupational extremity MPD	_____	d. 0.1 Rem
Average annual background radiation	_____	e. 0.015 Rem
Approximate exposure from absorptiometry examination	_____	f. 10 Rem

8. Which of the following belong to the electromagnetic radiation spectrum?

   a. X-rays

   b. Beta rays

   c. Gamma rays

   d. Electron capture particles

9. In the event of an emergency involving a radioactive source, who should be called first?

   a. Civil defense

   b. Police

   c. Radiation Safety Officer

   d. NRC

10. A radionuclide X undergoes electron capture to the ground state of the stable nucleus Y. The expected radiations are:

    a. None

    b. Only Auger electrons

    c. Characteristic X-rays and Auger electrons

    d. Positrons

11. Gd-153 has a physical half-life of 242 days. If a sample of Gd-153 has an activity of 800 millicuries today, what will its activity be in 90 days?

12. The unit of radiation exposure is the:

    a. Rad b. Rem C. Rat d. Roentgen

13. Regulatory agencies allow an accumulated dose per calendar quarter for the whole body, head, trunk active blood forming organs and gonads of:

    a. 1.25 Rems

    b. 2.0 Rems

    c. 2.5 Rems

    d. 5.0 Rems

14. Which of the following are items required by the NRC when using Gd-153 and I-125 sources?

    a. Leak Testing b. Physical Inventories c. Linearity Checks

15. Radiation has recently been discovered to be more hazardous than thought 10-20 years ago. True_____ False_____

16. If an unshielded source has fallen on the floor, it is OK to pick it up with your fingers and place it back in its shielded container as long as it is done quickly. True_____ False_____

17. According to recent studies, receiving 1.0 Rem of radiation decreases your life expectancy by about:

    a. 1 year b. 1 day c. 1 minute

18. What are the two categories of harmful effects resulting from radiation exposure? _____ & _____

19. In general, the greatest radiation hazard to personnel working with bone mineral analyzers comes from:

    a. Alpha radiation

    b. Beta- radiation

    c. Positron radiation

    d. Gamma/X radiation

20. To protect oneself when handling radiation sources, one should:

    a. Keep your distance from the sources

    b. Keep the sources or yourself shielded

    c. Work quickly

    d. Limit the amount of radioactivity stored

    e. All of the above

21. Which of the following would have the shortest wavelength?

    a. X-rays

    b. β^- rays

    c. Gamma rays

    d. Radar

22. Which of the following properties apply to X or gamma rays?

    a. Highly penetrating

    b. Electrically neutral

    c. Occur in a wide range of wavelengths

    d. All of the above

23. The radiation exposure from an I-125 source is 100 mr/hr at 1 foot from the source. At what distance from the source will the exposure be 0.05 mr/hr?

24. Gamma rays are really:

    a. Alpha particles b. Protons c. Light waves d. Electrons

25. Rank the following bodily responses to increased exposure to radiation: (most sensitive reaction first)

    ___ Lymphocytic depression

    ___ Central nervous system death

    ___ Fetal damage in the first trimester

    ___ Epilation

    ___ Fetal damage in the third trimester

CONVERSATION RECORD

TIME 2:10P | DATE 4/5/85

TYPE
☐ VISIT ☐ CONFERENCE ☑ TELEPHONE
☑ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Stan Bl[illegible]	Stal Nuc. Cons.	

SUBJECT C/N

ROUTING	
NAME/SYMBOL	INT

SUMMARY Requested:

1) Outline of train course for Lunar bore scanner

2.) Length of time for course completion

3) Method of determing competency

ACTION REQUIRED Will respond W/I 30 days.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
	W. J. Cl[illegible]	4/5/85

ACTION TAKEN

SIGNATURE	TITLE	DATE