

**Veterans
Administration**

AUG 11 1987

In Reply Refer To: 541/115(W)

U.S. Nuclear Regulatory Commission
Materials Licensing
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Sir:

Our NRC License No. 34-00203-03 was amended on January 14, 1983 (Amendment No. 45) to allow our possession and use of Iodine 125 for bone mineral analysis. We now respectfully request that our license be amended to allow our possession and use of Gadolinium 153 (Gd 153) for bone mineral analysis, said possession and use to be subject to the following conditions:

1. Gd 153 will be used as a sealed source in a Digital Bone Densitometer (DBD) for bone mineral analysis.

a. DBD is manufactured by Lunar; Model DP4-AT.

b. Chemical and/or physical form is GdO_2 .

c. Source model number is of the GD series or any equivalent NRC registered sealed source.

d. Possession limit will be 1800 millicuries.

e. NRC device registration number is NR-430-D-104-S.

2. The Gd 153 will be stored in the DBD; the device will be kept locked and the key entrusted to the Radiation Safety Officer (RSO). The DBD will be adequately shielded and secured against unauthorized use in a restricted area of the Nuclear Medicine Service. This area (room) will be posted in accordance with 10CFR20.203.

3. The DBD will be installed by Lunar's qualified experts, who will also provide 2 days of training. This training covers source installation, source replacement, leak testing, scan operations, data analysis, and interpretation. The authorized user (Suresh Kolli, M.D.), physician user (Ronald Lew, M.D.), and RSO (Steven Landgraf, M.A.) will be present for all training; the nuclear medicine technologists will attend training on scan operations and data analysis as a minimum.

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4. All personnel using the DBD or replacing/installing sources will do so under the authority and direction of Suresh Kolli, M.D., Chief, Nuclear Medicine Service and Chairman, Radiation Safety Committee.

5. Replacement Gd 153 sources will be ordered approximately every 18 months. Source procurement requests will not be processed without the written approval of the RSO.

6. Incoming source shipments that appear damaged or are leaking will be handled in accordance with the procedures outlined in Medical Center Memorandum No. 134-8, "Handling Incoming Radionuclide Shipments" (Appendix A).

7. Incoming sources will have been leak tested immediately prior to shipment, and a certificate to that effect will be enclosed in the source shipping package. Source packages will be monitored and records maintained by the RSO in accordance with current license conditions. The source will be leak tested every 6 months by the RSO, and all leak test records maintained for NRC inspection.

8. Source replacement will be done by the RSO in accordance with Lunar's training, written instructions, and current license conditions. Old sources will be disposed via return to the vendor or shipment for shallow land burial as radioactive waste.

9. In the event that a source should become lost or misplaced, the following steps will be taken immediately:

a. The Chief, Building Management Service and the Chief, Security Service will be informed of the problem and instructed to prevent waste and equipment removal from the facility until a screening system has been implemented by the RSO.

b. The RSO or the Chief, Nuclear Medicine Service will be notified.

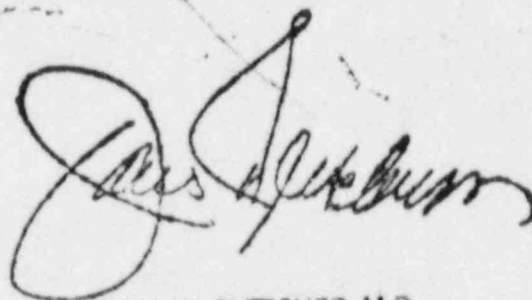
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This amendment request was unanimously approved by our Radiation Safety Committee on July 21, 1987 (Meeting minutes attached, Appendix B). Please direct any questions concerning this request to Mr. Steven W. Landgraf, M.A., Health Physicist/RSO, Nuclear Medicine Service, 115(W), FTS 290-5200.

Sincerely yours,

For William (Bentel)
P. STAJDUHAR, M.D.
Director

Attachments

A large, stylized handwritten signature in black ink, appearing to read "James W. Fletcher".

JAMES W. FLETCHER, M.D.
Director, Nuclear Medicine Service (115)
Veterans Administration
Washington, DC 20420

8/18/87

APPENDIX "A"

VETERANS ADMINISTRATION MEDICAL CENTER
10701 East Boulevard
Cleveland, Ohio 44106

NOV 26 1982

MEDICAL CENTER MEMORANDUM NO. 134-8

SUBJECT: HANDLING INCOMING RADIONUCLIDE SHIPMENTS

1. PURPOSE: To establish policy and procedures for handling incoming radionuclide shipments in accordance with NRC License No. 34-00203-03 and NRC License No. 6217.

2. POLICY: All incoming radionuclide shipments (i.e., those bearing the three-bladed radiation hazard symbol or any description indicating that package contents are radioactive) which are not damaged or leaking shall be received and secured in the following manner:

a. Shipments received at Wade Park shall be immediately delivered to the Nuclear Medicine Service, Ward 53, Room 5316.

b. Shipments received at Brecksville shall be immediately delivered to Building 1, Immunology and Radioassay Unit, Room A-240.

Exceptions to this policy shall require the written approval of the Radiation Protection Officer (RPO) or his alternate and the Supply Officer.

3. WADE PARK PROCEDURES:

a. For all incoming radionuclide shipments received during normal tour of duty, i.e., 8:00 a.m. to 4:30 p.m., Monday through Friday:

(1) Supply Service Warehouse personnel shall immediately inspect and deliver all packages which are not damaged or leaking to the Nuclear Medicine Service. Upon receipt of a package which is damaged or leaking, Supply Service Warehouse personnel shall immediately isolate the package and notify the RPO or the Nuclear Medicine Service.

(2) The RPO or his alternate shall monitor each package according to current license requirements. Pertinent records shall be kept on file in the Nuclear Medicine Service.

(3) The RPO or his alternate shall notify the Approved (final) User, who shall be responsible for picking up his package(s). Shipping papers shall be forwarded to the Supply Service.

3.

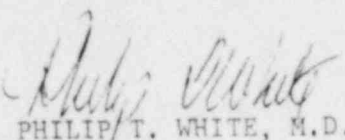
MEDICAL CENTER MEMORANDUM NO. 134-8
SUBJECT: HANDLING INCOMING RADIONUCLIDE SHIPMENTS

(1) Medical Center Police personnel shall immediately inspect and deliver all packages which are not damaged or leaking to the Immunology and Radioassay Unit. All packages shall be placed in the refrigerator. Upon receipt of a package which is damaged or leaking, Medical Center Police personnel shall immediately isolate the package and request the Medical Center Operator to notify the RPO or the Wade Park Nuclear Medicine Service Physician on call.

(2) Each succeeding work day, Radioassay Laboratory personnel shall monitor the package(s) as in 4a(2).

(3) Same as 4a(3).

5. RADIATION PROTECTION OFFICER: Steven W. Landgraf
Wade Park: Extension 7678, 7511/12
Home: Call VAMC Operator
6. REFERENCES: NRC License No. 34-00203-03
NRC Report No. 48, "Radiation Protection for Medical
and Allied Health Personnel"
7. RESCISSION: Medical Center Memorandum No. 134-8, dated August 10,
1981.
8. FOLLOW-UP RESPONSIBILITY: Chief, Supply Service


PHILIP T. WHITE, M.D.
Director

DISTRIBUTION:

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APPENDIX "B"

VETERANS ADMINISTRATION MEDICAL CENTER
10701 East Boulevard
Cleveland, Ohio 44106

RADIATION SAFETY COMMITTEE

July 21, 1987

PRESENT: Steven W. Landgraf, M.A., Acting Chairman, Health Physicist/RSO
Nuclear Medicine Service
Ronald Lew, M.D., Acting Chief, Nuclear Medicine Service
Eugene Z. Hirsch, M.D., Research Service
Jane Kennedy, B.A., Office of the Chief of Staff
Jack Pensky, Ph.D., Laboratory Service

ABSENT: Suresh Kolli, M.D., Chief, Nuclear Medicine Service (excused)
Richard E. Miller, M.D., Medical Service (excused)
Vasudeo G. Diwan, M.D., Radiology Service (excused)
Carmen Aleksic, R.N., Nursing Education (excused)

The meeting was convened at 1:45 p.m. A welcome was extended to Ronald Lew, M.D., Acting Chief, Nuclear Medicine Service.

OLD BUSINESS

1. TOPIC: February 2, 1987 Radiation Safety Committee meeting minutes.
DISCUSSION: None
ACTION: Minutes were approved (5 to 0).

NEW BUSINESS

1. TOPIC: Regulatory changes effective April 1, 1987
DISCUSSION: Mr. Landgraf provided Committee members with handouts outlining just a few of the regulatory changes. It was emphasized that all of these changes pertain to medical use, defined as "the intentional internal or external administration of byproduct material, on the radiation therefrom, to human beings in the practice of medicine." Medical research is therefore not subject to the new regulations. The following new Committee requirements were noted: Quarterly review of all incidents, quarterly review of occupational radiation exposures, annual review of the Radiation Safety Program, quorum must include the RSO and the Management Representative, and the RSO and Management Representative must approve all ministerial changes.
ACTION: The suggestion was made and the Committee agreed to review other regulatory changes at future meetings as necessitated by Committee business.

2. TOPIC: Proposal to request a license amendment to obtain and use a digital bone densitometer.

DISCUSSION: Mr. Landgraf briefly presented Dr. Kolli's proposal to obtain and use a digital bone densitometer for evaluation of metabolic bone disease and the efficacy of relevant therapy.

ACTION: Proposal was approved (5 to 0).

3. TOPIC: Radionuclide protocols

DISCUSSION: The Committee reviewed the following:

a. E. Variyam, M.D.

Dr. Variyam is requesting an amendment to his authorization to use Iodine 125 in vitro in bacterial binding studies. Dr. Pensky will perform the radioiodinations.

b. T. Knauss, M.D.

Dr. Knauss is requesting permission to increase his Hydrogen 3 possession limit to 5 millicuries.

c. Dr. Schlaes, M.D.

While Dr. Schlaes is on sabbatical in France, Mr. Landgraf has asked Zahra Toossi, M.D., to assume responsibility for the continuing use of radioactive material by Dr. Schlaes' laboratory personnel.

ACTION: The Committee approved the above (5 to 0).

4. TOPIC: Animal experimentation room A-36.

DISCUSSION: The Director approved the installation of a new floor and floor drain for Rm. A-36 at Research Service's recent annual Management Briefing, and more recently approved a more comprehensive remodelling plan to include the purchase and installation of wall mounted cabinets and a custom, stainless steel bench, painting, and electrical work. To date, the new floor materials have been ordered and an old soapstone counter has been removed. However, there appears to be a lack of consensus on the parts of Engineering Service and Research Service as to who is responsible for providing funding for the cabinets and bench. Mr. Landgraf has asked the Acting Chief, Engineering Service to look into this matter.

ACTION: Ms. Kennedy will discuss this with the Director to determine who will provide funding for the cabinets and bench.

5. TOPIC: July 8, 1987 site visit by the American Association for the Advancement of Laboratory Animal Care.
DISCUSSION: Although the final report has not been received, the site visit went well. The inspectors were satisfied with the synopsis by Mr. Landgraf on controls relative to the use of radioactive materials in animals, and had no negative comments in this area.
ACTION: None.

6. TOPIC: Review of incidents
DISCUSSION: Two incidents were briefly reviewed:

- a. On February 4, 1987, a technician in a research laboratory spilled approximately 2 microcuries of Carbon 14 in non-aqueous liquid form while performing a bench assay. Contamination was limited to the laboratory bench surface. Decontamination was successful. The technician was instructed by the RSO to follow the required procedure for potential spill containment, i.e., cover bench surfaces with plastic-backed absorbent paper.
- b. On May 1, 1987, the Brecksville to Wade Park shuttle was contaminated by some urine which contained a very low level of radioactivity secondary to patient administration of 0.5 microcuries of Cobalt 57. Richard Tivers, Supervisory Nuclear Medicine Technologist, issued decontamination instructions and performed area exposure rate and removable contamination surveys. The surveys were negative for radiation or radioactivity in excess of background levels. A Pharmacy Service employee who rode the shuttle filled out a Report of Contact form raising concerns about radiation exposure to her unborn child. (Employee was 2 months pregnant at the time.) Mr. Landgraf discussed the incident with Linda Smith of Personnel Service. He informed her that he was convinced that there could be no harmful effects from this incident to the mother or her unborn child for the following reasons: 1) A very small amount of radioactivity was involved, 2) Radiation surveys were negative, and 3) The employee did not get any urine on her skin or clothes. Ms. Smith turned the matter over to Barbara Fleming, M.D.

ACTION: No action necessary on 6.a. Regarding 6.b., the Committee recommends that Nuclear Medicine consider using containers with screw top lids (as opposed to the currently used clip top containers) for Schilling's Test urine collections. Dr. Pensky indicated that Laboratory Service had such containers and could possibly provide them to Nuclear Medicine in limited quantities.

7. TOPIC: Review of quarterly occupational radiation exposure records
DISCUSSION: Occupational exposure records for the 1st quarter of calendar year 1987 were reviewed. All exposures were well below regulatory and ALARA Program limits. It was noted that the major problem with the radiation badge program was the fact that many employees turn in their badges in late; such badges are processed without control badges, resulting in badge report data of very limited reliability.

ACTION: None.

8. TOPIC: Bioassay program
DISCUSSION: Mr. Landgraf informed the Committee that adoption of a bioassay program less strict than the one currently in place will require a license amendment, since most participants are involved in the medical research program. A proposal to calculate the statistical significance of bioassay results and to include such information with future reports was made by Dr. Hirsch and Mr. Landgraf.
ACTION: The Committee approved the proposal to include information on statistical significance of bioassay results in future reports. An alpha risk of .05 was adopted (5 to 0).

The meeting was adjourned at 2:25 p.m.

Recorded and submitted by:

Steven W. Landgraf

STEVEN W. LANDGRAF, M.A.
Health Physicist/RSO
Acting Chairman

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