



NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

DEC 31 1992

License: 30-26860-01
Docket: 030-29613

New Mexico State University
Primate Research Institute
ATTN: Preston A. Marx, Ph.D.
Director
P.O. Box 1027
Holloman AFB, New Mexico 88330

Gentlemen:

SUBJECT: RESPONSE TO NRC INSPECTION REPORT NO. 030-29613/92-01
(NOTICE OF VIOLATION)

Thank you for your letter of November 30, 1992, in response to our letter and attached Notice of Violation both dated November 9, 1992. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation. With regard to Violations A and B.1, note that your letter to NRC dated December 14, 1992, requesting an amendment to your license to correct these items is currently under review. Full compliance for these violations will not become effective until you have received a license amendment to effect these changes. We will review the implementation of your corrective actions during a future inspection to determine whether full compliance has been achieved and will be maintained.

Sincerely,

Charles L. Cain, Chief
Nuclear Materials Inspection Section

cc:
New Mexico Radiation Control Program Director

9301120086 921231
PDR ADOCK 03029613
C PDR

TEO7

bcc w/copy of licensee letter:

DMB - Original (IE-07)

JLMilhoan

LJCallan

JPJaudon

MRodriguez, OC/LFDCB (4503)

WLFisher

CLCain

MRShaffer

NMIS

MIS System

RIV Files (2)

REHall, URFO

RIV:NMIS	C:NMIS <i>JK</i>			
MRShaffer <i>MA</i>	CLCain <i>for</i>			
12/30/92	12/31/92			

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DEC 17

NEW MEXICO REGIONAL PRIMATE RESEARCH LABORATORY
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November 30, 1992

U.S. Nuclear Regulatory Commission
Regional Administrator, Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Subject: Reply to Notice of Violation (NRC Inspection Report No. 30-29631/92-01,
License No. 30-26860-01).

Gentlemen:

The purpose of this letter is to respond to the Notice of Violation dated November 9, 1992, and to provide for each violation: 1) the reason for the violation, 2) the corrective steps that have been taken and the results achieved, 3) the corrective steps that will be taken to avoid further violations, and 4) the date when full compliance will be achieved. The responses to each violation are enclosed and appear in the order cited.

Sincerely,

Ishmael Sanchez
Radiation Safety Officer, PRL

Enclosures:

cc: Preston Marx, Ph.D.
Keith Minton
Radiation Safety Committee Members
Radiation Safety File

93-0439
93-0439
93-0439

Reply to a Notice of Violation

Violation:

- A. License Condition 11.B specifies that the Radiation Safety Officer for this license is Mr. Agegnehu Gettie.

Contrary to the above, an individual other than Mr. Gettie had served as Radiation Safety Officer since October 1991.

Response:

1. Reason for the violation:

Because of a newly appointed Radiation Safety Officer (RSO), licensee requested an amendment dated October 2, 1991, which requested a change in the position of Radiation Safety Officer (RSO) from Mr. Agegnehu Gettie to Mr. Ishmael B. Sanchez. License No. 30-26860-02. The newly appointed Radiation Safety Officer was not aware that the NRC had not received his qualifications (training and experience). Though the NRC had requested the information in a letter to the Director of Primate Research Institute-NMSU, Dr. Preston A. Marx, dated January 16, 1992, the Radiation Safety Officer was never made aware of this request by the Director's Office or Associate Director's Office. It seems that the letter was copied to the Associate Director's with a memorandum asking for a response, and the then Associate Director, who has since resigned, failed to convey this information to the RSO. The NRC contacted the RSO telephonically on September 29, 1992, concerning the NRC's request for information in reference to this amendment and made the RSO aware of the letter dated January 16, 1992. The RSO requested a copy of the letter from the Director's Office in writing and verbally, but the Director's Office could not locate it. Finally, on October 14, 1992, the RSO requested a copy of the letter from the NRC which he received on October 19, 1992.

2. Corrective steps taken:

It is my understanding that the Region IV NRC Office never received or misplaced a letter addressed to them outlining the Radiation Safety Officer's qualifications. Therefore, the Radiation Safety Officer, Ishmael B. Sanchez, qualifications have been again submitted to the NRC Office, Region IV. Furthermore, the Associate Director's and Director's Office staff have been made aware of the importance of all correspondence received from the NRC and that the RSO should receive a copy.

3. Corrective steps that will be taken to avoid further violations:

The RSO will be copied all correspondence that the Director's Office receives. Additionally, through periodic contact with the NRC regional office, the RSO will be more alert if replies to amendments are not received from the NRC in a timely manner.

4. Date when full compliance will be achieved:

These corrective steps have been implemented as of December 2, 1992.

Violation:

- B. License Condition 19 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated November 7, 1986, and subsequent letter dated January 9, 1987.

1. Item 9, "Facilities and Equipment," of the application specifies the areas where radioactive materials are to be received, used, and stored. These areas only include designated rooms within Building 1264, North Area, Holloman Air Force Base, New Mexico.

Contrary to the above, from February 1991 to October 1992, the licensee had not limited the use and storage of radioactive materials to those areas designated in the license. Specifically, the licensee had also utilized and stored byproduct materials within Building 1204 (Biocontainment Facility).

Response:

1. Reason for the violation:

Because of the misplaced letter, the newly appointed RSO was never aware that the amendment requesting a change to our license to include Virology and Immunology areas (Building 1204) for using and storing radioactive materials was never finalized by your office. Due to the reason discussed in paragraph A.1 above, the RSO was not provided a copy of the letter dated January 16, 1992, or made aware of its contents until October 14, 1992. Consequently, there was no additional information provided to your office at that time.

2. Corrective steps taken:

As stated in your letter of January 16, 1992, you requested that the text, which identifies this change, that is, the addition of Building 1204 for the use and

storage of radioactive materials be clarified precisely. Please, therefore, replace Item #9, Facilities and Equipment, Pages 1-5 of our current license with the enclosed revised text identified as Item #9, Facilities and Equipment, Pages 1-4.

3. Corrective steps that will be taken to avoid further violations:

The RSO will be copied all correspondence that the Director's Office receives. Additionally, through periodic contact with the NRC regional office, the RSO will be more alert if approval for requested amendments are not received from the NRC in a timely manner.

4. Date when full compliance will be achieved:

The corrective steps have been completed as of December 2, 1992.

Violation:

- B. License Condition 19 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated November 7, 1986, and subsequent letter dated January 9, 1987.

2. Item 3 of the licensee's letter dated January 9, 1987, specifies, in part, that the licensee's Radiation Safety Committee shall meet at least on a quarterly basis.

Contrary to the above, the licensee's Radiation Safety Committee did not meet during the 4th quarter 1991, nor the 3rd quarter 1992.

Response:

1. Reason for the violation:

PRL Radiation Safety Committee meet September, 1991 and again in January 1992 but missed the 4th quarter of 1991. The Chairman of Radiation Safety Committee, Dr. Fuller, had resigned and a new RSO had been appointed in October, 1991. Because of these changes, the newly appointed RSO was not aware of this meeting requirement, and since it was the case for the Chairman to call the meetings. The RSO called two meetings for the 2nd quarter of 1992, that was March 30 and April 28, 1992, but inadvertently did not schedule a meeting for the 3rd quarter of 1992. However, the RSO became aware of this in late September and the only convenient time to schedule a Radiation Safety Committee meeting for all members was October 1, 1992, which was held.

2. Corrective steps taken:

Radiation Safety Committee meetings will be scheduled far in advance for the year. Thus, there will be a less likelihood that a quarter meeting will not be held.

3. Corrective steps that will be taken to avoid further violations:

Both the Radiation Safety Officer and the Committee Chairman will be responsible for seeing that all quarterly meetings are held.

4. The Date when full compliance will be achieved:

Corrective steps have been taken as of December 2, 1992.

Radioisotopes will be handled and dosing solutions prepared in Room 201A of Building 1264, Holloman Air Force Base. This room is equipped with cement block walls, acrylic painted ceilings, and tile floor. The room contains an approved noxious fume exhaust hood. The working areas under the hood and the benches are protected by polyethylene-lined, absorbent paper that is changed after each use. Bench space for radioisotope use is outlined with labeled tape. A covered waste can for radioisotopes is labeled and stored. Room contamination is monitored by Liquid Scintillation counting of absorbent wipes taken at random from several areas of the room at regular intervals. Any spillage of radioactive labeled materials is cleaned up and the area decontaminated by Standard Operating Procedure.

Radioactive handling equipment includes micropipetters, while potential radioactive handling equipment includes glassware and temporary disposal for sharp objects.

A "radioactive materials" label is attached to the door of the lab.

Radioisotopes will be handled and dosing solutions prepared in Room 109 in building 1204, Holloman Air Force Base. This room is equipped with cement block walls, acrylic painted ceilings, and tile floor. The room contains an approved noxious fume exhaust hood. The working areas under the hood and the benches are protected by polyethylene-lined, absorbent paper that is changed after each use. Bench space for radioisotope use is outlined with labeled tape. A covered waste can for radioisotopes is labeled and stored. Room contamination is monitored by Liquid Scintillation counting of absorbent wipes taken at random from several areas of the room at regular intervals. Any spillage of radioactive labeled materials is cleaned up and the area decontaminated by Standard Operating Procedure.

Materials containing radioisotopes will be handled and oxidized in Room 543 of Building 1264, Holloman Air Force Base.

This room is equipped with acrylic painted hard plaster and cement block walls, acrylic painted ceilings, and sealed cement floor. This room is also equipped with an approved noxious fume exhaust hood and a dual sink/cabinet fixture. Two biological oxidizers are positioned on adjacent desks. The exposed desk top on either side of the oxidizers is covered by polyethylene-lined absorbent paper that is changed after each use. "Radioactive" labeled tape is attached to those areas where radioisotopes are handled. Room contamination is monitored by Liquid Scintillation counting of absorbent wipes taken at random from several areas of the room at regular intervals. Any spillage of radioactive labeled materials is cleaned up and the area decontaminated by Standard Operating Procedure.

Radioactive handling equipment includes disposable pipettes, oxidizer labels and sample containers.

A "Radioactive Material" label is attached to the outside of the door.

Radioisotope activity will be determined by use of a scintillation counter in Room 525 of Building 1264 and Room 109 of Building 1204, Holloman Air Force Base. Building 1204 is located 2 miles south of building 1264 in the quarantine area.

These rooms are equipped with cement block walls, tile floor, and acrylic painted ceilings. A scintillation counter is housed in a corner of each lab with a "Radioactive Materials" label attached to the front of the counter. There is no other radioactive handling equipment contained in this lab.

Room contamination is monitored by Liquid Scintillation counting of absorbent wipes taken at random from several areas of the room at regular intervals. Any spillage of radioactive materials is cleaned up and the area decontaminated by Standard Operating Procedure.

Solutions containing radioisotopes will be prepared in Room 530 in Building 1264 and in Room 109 in Building 1204, Holloman Air Force Base. These rooms are equipped with acrylic painted cement block walls, acrylic painted ceilings, with tile and cement floors. The rooms are also equipped with benches that are protected by polyethylene-lined absorbent paper that is changed after each use. Bench area that is used for radioisotope labeled materials is outlined with "radioactive" labeled tape in each lab.

The labs contain labeled, covered trash cans for radioactive labeled materials and a solvent waste cans that contains liquid radioactive waste materials.

Room contamination is monitored by Liquid Scintillation counting of absorbent wipes taken at random from several areas of the room at regular intervals. Any spillage of radioactive labeled materials is cleaned up and the area decontaminated by Standard Operating Procedure.

Potential radioactive handling equipment includes a shaker bath, and glassware. Cabinets under the sink and benches contain flammables and are clearly marked.

A "radioactive materials" label is attached to the door.

Facilities and Equipment

Radioisotopes will be stored and dosing solutions prepared in Room 525 in Building 1264 and Room 109 in Building 1204, Holloman Air Force Base. These rooms are equipped with acrylic painted hard plaster and cement walls, acrylic painted ceilings, and tile floors. The rooms are also equipped with laboratory benches that are protected by polyethylene-lined absorbent paper that is changed after each use. Bench-top areas for radioisotope use are clearly marked. Radioactive labeled materials are stored in a combination refrigerators/freezers and labeled as such. The freezers/refrigerators contain "radioactive materials" labeled affixed to the front of the doors. Solvent cans for radioactive liquid wastes are labeled and stored in these labs. Room contamination is monitored by Liquid Scintillation counting of absorbent wipes taken at random from several areas from each room at regular intervals. Any spillage of radioactive labeled materials is cleaned up and the area decontaminated by Standard Operating Procedure. Radioactive handling equipments that are marked include a homogenizer and a scintillation counters. Potential radioactive handling equipment includes glassware, a liquid chromatograph, balance, water bath and centrifuges. Cabinets for storing flammables are labeled clearly. A "radioactive materials" label is attached to each door.

General Description of Rooms 101, 102, 103, 104, 105, 201A, 210B, and 212

These rooms have cement block walls, except where interior walls have been erected as room dividers, in which case, the walls are plasterboard on a 2x4 wood frame. The walls and ceiling are acrylic painted. Floors are sealed cement. All working areas are protected by polyethylene-lined absorbent paper that is changed frequently. Radioactive labels are placed on all work areas, room doors and equipment where radioactivity is used. Room contamination is monitored by Liquid Scintillation of absorbent wipes taken at random from several areas of the room at regular intervals. Any spillage of radioactive materials is handled according to the Standard Operating Procedure for decontamination.

Room 201A:

1. An approved noxious fume exhaust hood is used in conjunction with the labelling of protein compounds with I^{125} . Lead blocks are situated to shield the operator.
2. Low level solid waste is stored in approved 55 gallon drums for subsequent shipment. The drums are stored outside storage area in a low-traffic area.

Room 530:

1. Two gamma counters with lead shielding are used to count samples from RIA work.
2. Temporary storage of I^{125} solid waste is provided by two covered waste barrels. When full, the contents are transferred to the shipping containers in Room 201.
3. An approved noxious fume exhaust hood, sinks, shaker and lead breaks for shielding liquid waste are in this room.
4. A refrigerator with freezer is provided in which I^{125} labelled compounds in lead containers are stored.

Room 210B:

1. A large refrigerator is used to store I^{125} in lead containers used in labelling compounds and some H^3 labelled steroids.