

DEC 27 1990

In Reply Refer To:
License: 05-01401-02
Docket: 030-01234/90-01

Veterans Administration Medical Center
ATTN: Fred Salas
Medical Center Director
1055 Clermont Street
Denver, Colorado 80220

Gentlemen:

Thank you for your letter of October 11, 1990, in response to our letter and attached Notice of Violation both dated September 11, 1990.

Your response of October 11, 1990, was not in the format requested in the last paragraph of the Notice of Violation sent to you on September 11, 1990. You were specifically requested to reply for each violation: (1) the reason for the violation if admitted, (2) the corrective steps which have been taken and the results achieved, (3) the corrective steps which will be taken to avoid further violations, and (4) the date when full compliance will be achieved.

We have reviewed your reply of October 11, 1990, and find it responsive to the concerns raised in our Notice of Violation for Violations 1, 4, 5, and 7, however, your responses to Violations 2, 3, and 6 have deficiencies. Please address items (3) and (4) mentioned above for the failure to measure air ventilation rates of Violation 2. The response to Violation 3 did not address items (3) and (4) mentioned above and your Attachment 2 identified in your October 11, 1990, letter for this violation appears to be for receipt of generators because there is no reference to shipment of generators on this form. You also failed to address items (3) and (4) for Violation 6. Please respond to Violations 2, 3, and 6 by addressing the items in the sequence given above.

Please respond to this letter within 10 days of the date of this letter.

Should you have any questions concerning this letter, we will be pleased to discuss them with you.

Sincerely,

Original Signed By:
LAWRENCE A. YANDELL
Law
A. Bill Beach, Director
Division of Radiation Safety
and Safeguards

cc:
Colorado Radiation Control Program Director

bcc: (see next page)

*RIV:NMLS	* C:NMSIS	D:DRSS
WLHolley:ch	CLCain	ABBeach
/ /	/ /	12/24/90

*Previously Concurred

9101040031 901227
REG4 LIC30
05-01401-02 PDR

IE-07

Veterans Administration Medical Center -2-

bcc w/copy of licensee letter:

DMB - Original (IE-07)

RDMartin

ABBeach

LAYandell

MRodriguez, OC/LFDCB (MS 4503)

CLCain

WLFisher

WLHolley

NMSIS

MIS System

RIV Files (2)

RSTS Operator



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
1055 Clermont Street
Denver CO 80220

OCT 11 1990

Mr. A. Bill Beach
U.S. Nuclear Regulatory Commission
Region IV
Division of Radiation Safety and Safeguards
611 Ryan Plaza Drive, Suite 100
Arlington, TX 76011

In Reply Refer To: 554/114

RE: License #05-01401-02

Dear Mr. Beach:

This is in response to your letter of September 11, 1990. Since the NRC inspection on August 23-24, 1990, we have investigated the reasons for the cited violations and have taken appropriate corrective action on the following:

1. Weekly Contamination Surveys - This violation occurred because the radiation safety officer felt that the daily surveys with a GM detector were adequate for the detection of contamination. We have instituted a new procedure effective immediately which includes wipe testing and is in accordance with 10 CFR 35.70(e). See Attachments 1, 1.a. and 1.b.

2. Collection Systems Inspections - The failure to measure air ventilation rates occurred because the Engineering Service was unaware of this requirement. Engineering Service has been informed of the requirement and will perform air flow measurements every 6 months. The failure to check the operation of the Ventil-Con xenon trap occurred because we were not aware of this requirement. The unit's manual does not describe the xenon trap in detail and the required maintenance was not apparent to us. Since the inspection, however, xenon imaging has been completely discontinued at the Denver VA Medical Center and the Ventil-Con has been removed from service.

3. Radioactive Package Surveys - The violation concerning radiation surveys of generators occurred because the nuclear medicine technologists assumed that the information on the decay tables provided by the vendors was sufficient. A new generator procedure form which includes surveying requirements is now being used. See Attachment 2.

4. Dose Calibration Inspections - We have always performed daily constancy checks on the dose calibrator. Although we were aware of the 5% variation limit and checked it daily, the violation occurred because the log book did not have the actual 5% range indicated. This deficiency has been corrected by amending the dose calibrator log book to include the 5% values for a Cs-137 source.

5. Brachytherapy Representative, Radiation Safety Committee - We do not have a Radiation Oncology department at the Denver VA Medical Center, therefore, all brachytherapy procedures on our patients are performed at an outside hospital. We did not think it was necessary to have a radiation

2210300417
10

IC-90-300

therapist on the Radiation Safety Committee since these procedures are rarely performed at this medical center (only 1 brachytherapy procedure was performed here last year). New Radiation Safety Committee members have been appointed in accordance with this regulation and also because of the departure of other committee members during the year. Please see the attached list of the new members on the Radiation Safety Committee. See Attachment 3.


6. Sealed Source Leak Tests - The sealed source leak test was delinquent by 13 days because of the transition between the departure and appointment of radiation safety officers. We are now aware that we must strictly comply with the six month time limit and future testing will reflect this. See the attached form currently being used for sealed source leak tests. See Attachment 4.

7. Survey Instrument Calibration - The violation concerning the use of a dedicated check source for survey instruments occurred because we did not realize this was an actual requirement. We will establish a procedure which is in accordance with 10 CFR 35.51, however, there will be a delay in implementation since new sources must be ordered. We expect to complete the required action by December 31, 1990.

Regarding the concerns over the performance of the radiation safety officer, a physician formally trained in nuclear medicine in addition to radiology has recently been hired to service as Chief of Nuclear Medicine. The new chief will monitor the duties and performance of the radiation safety officer and assure his effectiveness and compliance with all radiation safety requirements.

In summary, radiation safety remains a top priority at the Denver VA Medical Center. We have taken action to assure that all deficiencies are or will soon be corrected. We are now in compliance with all of the cited regulations with the exception of #7 for reasons explained above. New procedure sheets which further clarify policies have been devised and are in use. In addition to helping us adhere to the NRC requirements, we also anticipate their use will provide us with better documentation of radiation safety procedures performed.

Sincerely yours,


Fred Salas
Medical Center Director

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER
DENVER, COLORADOIMAGING SERVICE
MEMORANDUM NO. 115-3

(115)

CONTAMINATION SURVEYS

I. PURPOSE

To specify procedures to be used in performing weekly removable contamination surveys.

II. POLICY

This procedure applies to all areas where radiopharmaceuticals are routinely prepared, stored, or administered. This currently includes, 2D114, 2D120, 2D129a, 2D129b, and 5A119.

III. RESPONSIBILITY

It is the responsibility of the RSO to arrange for the surveys to be conducted.

IV. PROCEDURE

- A. Swipes are indicated on diagrams of each room listed above. Swipe locations may be changed from time to time by preparing a new diagram.
- B. Moisten a swipe with water or alcohol and rub a 100 square centimeter area. Note: a 4 x 4 inch area is approximately 100 square centimeters. Also a wipe using one finger is about one centimeter wide so should be about one meter or just over three feet long.
- C. Swipes are evaluated using either the well counter or the Frisk Tech counter. A one minute count or longer will be used.
 1. Set the discriminator window if using the well counter.
 2. Count back ground and record on the contamination survey form.
 3. Count each swipe and record the net counts.
 4. Calculate the net counts, and the disintegrations per minute dpm per swipe (100 cm). Use the efficiency determined for the instrument and settings used. The efficiency will be determined at least every six months and recorded in the survey book.

4. Action levels are as follows; For Tc-99m, Ga-67, and Tl-201 the action level is 20,000 dpm. The action level for I-131 is 2000 dpm. Since I-131 is used infrequently, contamination will be assumed not to be I-131 unless the multichannel analyzer (MCA) shows activity outside of the Region of Interest (ROI) set up for Tc-99m, Ga-67, and Tl-201. The RSO should be contacted immediately if the action levels are exceeded or activity is detected outside of the ROI mentioned previously or if there is any reason to believe that there is contamination other than I-131, Tc-99m, Ga-67, or Tl-201.

V. CONCURRENCES

111B

VI. REFERENCES

10 CFR 35.70(e).

VII. RECISSION

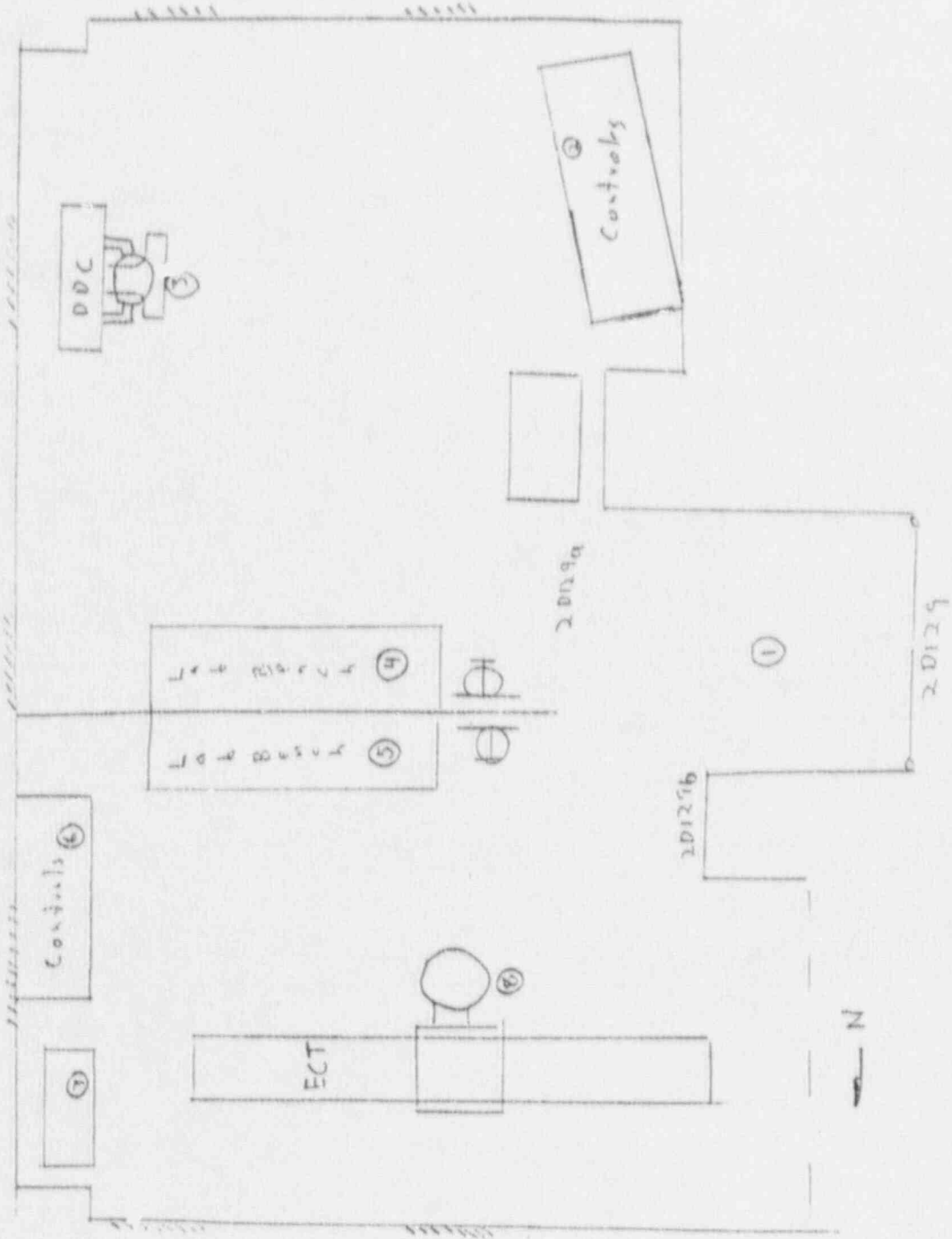
None

VIII. REVIEW DATE

October 1993

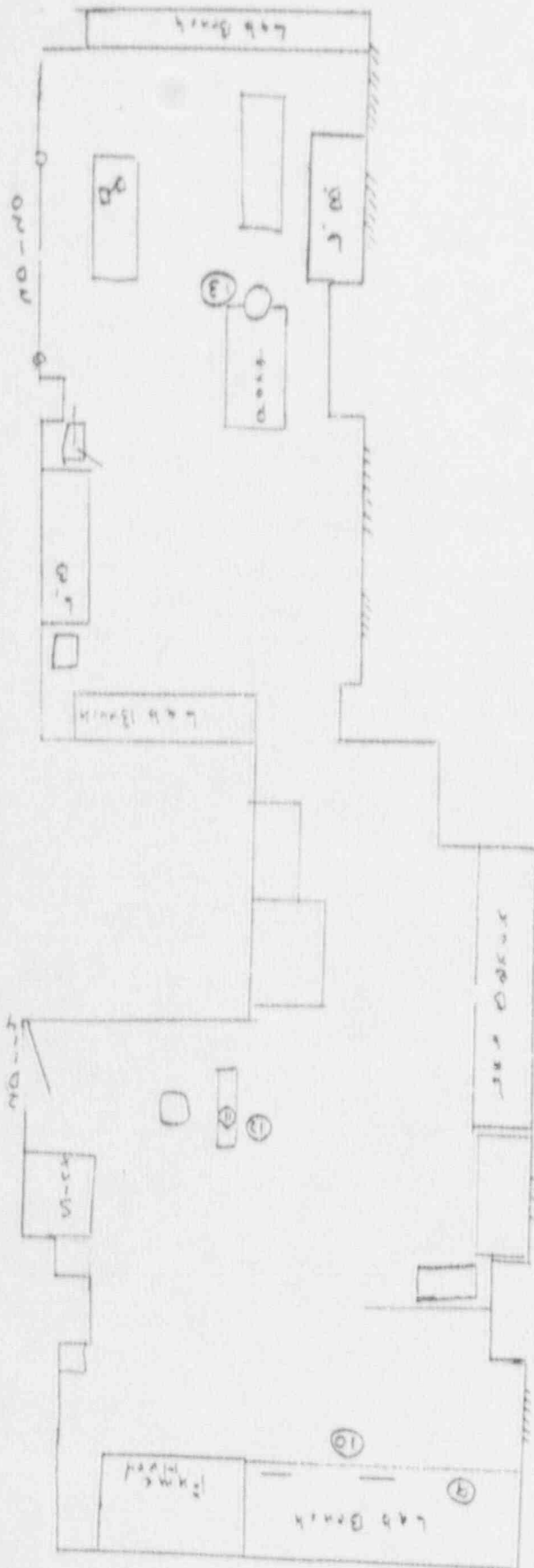
Fred Salas
Medical Center Director

Distribution: A



06/b

Attachment 1.b.



171

LOG OF I RADIATIONS

 ^{99}Mo - $^{99\text{m}}\text{Tc}$ Generator

From _____ To _____

Manufacturer: _____ P.O. No.: _____

Lot (Batch) No.: _____ Initials: _____

Date Received: _____ Time: _____

Package Condition: _____

MEASURED RADIATION LEVEL:

WIPE TEST:

- a. At Surface _____ (200 mr/hr) _____ (cpm)
 b. At One Meter _____ (10 mr/hr)

DATE	TIME	NEN-0.9% SALINE LOT. NO.	$^{99\text{m}}\text{Tc}$ -ASSAY			^{99}Mo -ASSAY			Al ⁺⁺⁺	Initials
			mCi	ML	mCi/ML	μCi	Background	$\frac{\mu\text{Ci-Mo}}{\text{mCi-Tc}}$		
		N/A								

United States Pharmacopeia: 0.15 μCi Mo-99 per mCi Tc-99M10 μg Al⁺⁺⁺ per Ml Tc-99M

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER
DENVER, COLORADO

RADIATION SAFETY COMMITTEE

<u>Member</u>	<u>Service</u>	<u>Routing</u>
Angela Feyerabend, MD - Chairperson	Imaging	115
Peter Vernig - Radiation Safety Officer	Imaging	115
Craig Calvert	Chief of Staff	11A
Ruth Dryer, RN	Nursing	118
Paul Saenger	Research	151
Arnold Schultz, PhD	Laboratory	113
Charles Leonard, MD	Radiation Therapy	UCHSC

