

Administration

Castle Memorial Hospital

640 Ulukahiki Street, Kailua, Hawaii 96734

Telephone: (808)261-0841

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REGIONAL

February 14, 1983

License No. 53-16929-01

Herbert E. Book, Chief
Fuels Facilities and Materials Safety Branch
U. S. Nuclear Regulatory Commission
Region V.
1990 N. California Boulevard
Suite 2002, Walnut Creek Plaza
Walnut Creek, California 94596

Re: Notice of Violations issued to Castle Memorial Hospital dated
December 14, 1982

Dear Mr. Book:

In response to your letter dated January 17, 1983 regarding the
N.R.C. inspection on December 14, 1982, I submit the following infor-
mation.

As a result of our inspection nine violations were given. I
will respond to each one in the order of appendix A of your letter.

A. 10 CFR 20.207 (a) The unfortunate mishap of leaving a key in
the door to the restricted area was a very rare incident and to the
knowledge of myself and the Radiation Health Physicist, it was the
first incident. In an effort to prevent a recurrence I have made the
technician responsible aware of the severity level of this violation
and possible N.R.C. disciplinary action. He has since kept the key
with him when he is out of the facility.

B. License Condition 12 - Use of licensed materials by authorized
users.

Since December 14, 1982 Dr. Michael Gutknecht has ceased
his use of licensed material until he is added to the list of
authorized users. A letter dated January 20, 1983 was sent to the
N.R.C. requesting an amendment for this purpose.

C. License Condition 12 - Sealed Source leakage testing.
Leak tests for the Cs¹³⁷ source are presently current and have been
since May 4, 1982. This test is scheduled every six months by the
Radiation Health Physicist.

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D. License Condition 20 - Daily contamination surveys.

Daily contamination surveys ^{have been} done daily since December 14, 1982. These tests are done at the end of each work day. They include the injection table, preparation unit, disposed latex gloves, and the technician's hands. These are all documented. The documentation of these surveys will be reviewed weekly by the Radiation Safety Officer.

F. License condition 20 - Xenon charcoal trap leakage tests.

A leakage test of the Xenon charcoal trap was performed on January 12, 1983 by the Radiation Health Physicist. A test of this trap is scheduled to be done every three months hereafter. A report of this will be presented at each of the quarterly M.I.C. meetings.

F. License condition 20 - Xenon exhaust fan air flow rates measurement.

An air flow rate of the Xenon exhaust fan was performed by this hospital's engineering department. The air flow rate was 800 C.F.M. The rate was adjusted to 1,000 C.F.M. A similar measurement and, if necessary, adjustment is scheduled to be done every six months hereafter with the engineering department.

G. 10 CFR 20.301 Disposal of licensed materials.

Since December 14, 1982 no I¹²⁵ radioactive waste material has been disposed that is above 25 cpm or background levels. All I¹²⁵ waste material will be kept for a minimum of $10\frac{1}{2}$ lives. The Radiation Safety Officer will review disposal records of the R.I.A. laboratory each quarter.

H. 10 CFR 30.51 Records of the transfer of byproduct materials between licensed users.

Records of the transfer of radioactive ^{materials} materlas (including Mo/Tc generators) to the Pacific Radiopharmacy L.T.D. are being kept. All transfers of any radioactive materials to any licensed user will be kept for a period of five (5) years after such transfer.

Shipment records will include the identity and activity of the material, to whom it is transferred, the date of shipment, and the name of the ^{person} making the transfer.

I. License condition 20 Storage of byproduct waste material.

Since December 14, 1982 the storage of I¹²⁵ waste material has been in a specifically designated area. Each container is identified to contents and marked "caution radioactive materials". The area is directly under the counter where the R.I.A. tests are performed.

J. 10 CFR 19.11 (a) Posting of documentation in the R.I.A. laboratory.

Since December 14, 1982 the documents required by 10 CFR 19.11 (a) and the notice authorized by 10 CFR 19.11 (b) have been posted in the R.I.A. laboratory and these will remain posted.

K. 10 CFR 19.11 (c) (d) Posting of "Notice to Employees" Form NRC-3 in the R.I.A. laboratory.

Form NRC-3 was posted in the R.I.A. laboratory on December 14, 1982 and will remain posted.

Attached you will find a copy of the last M.I.C. meeting minutes. We began the necessary steps to correct the violations noted prior to this meeting on January 12, 1983. As of this date, I believe we have corrected all of the violations and are presently within full compliance of our license.

I have made arrangements with the Director of our Radiological Services to make more provision in personnel man hours necessary to perform the numerous duties of records, surveys, etc.

I have arranged for a more coordinated effort on the part of the Radiation Health Physicist, the Director of Radiology, the technician, the M.I.C. and myself, the Radiation Safety Officer.

I personally will be performing a complete inspection of the facility each quarter and a report of this will be presented at the M.I.C. meetings. I have attached a copy of the form I will be using.

The minutes of each M.I.C. meeting as well as the quarterly review of the R.S.O. will be reviewed by a representative of the hospital administration.

I certify that all information contained in this letter, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.

Sincerely,



Norman Ikemoto, M.D.
Radiation Safety Officer
Castle Medical Center

Subscribed and sworn to before me this 14th day of February, 1983.



Notary Public, _____

Gust

Judicial Circuit,
State of Hawaii

My commission expires: 8/15/86

RADIOISOTOPE COMMITTEE MEETING
Castle Medical Center

Time: January 12, 1983 12:00
Place: Doctors' Dining Room
Present: Norman Ikemoto, M.D., Jerry Farris, Bud Sauder, Don Tolbert,
Rod Knable.

Minutes: The minutes of the October 20, 1982 meeting were reviewed and approved.

Old Business: The status of Dr. Gutknecht's becoming an authorized user was discussed. Dr. Gutknecht has recently been accepted by the NRC to be an authorized user at the Wahiawa General Hospital. We have this week received the license number and we will use this number and request an amendment to our license.

A letter of new MIC membership needs to be sent to the NRC.

New Business: Dr. Ikemoto reported his review of recent exposure records for Nuclear Medicine personnel. Higher than normal exposure was noted for Dr. Lansdale Lau. An investigation into the matter revealed the excessive level of exposure was due to x-ray fluoroscopic work and not nuclear medicine work. Normal levels were noted for Rod Knable.

A summary of the recent NRC inspection on December 14, 1982 and corrective actions were discussed. A list of deficiencies is as follows:

- 1) Xel33 exhaust hood efficiency check not done. Corrective action: On January 11, 1983 CMH air-conditioning engineer Neil Dubose made an air flow study which revealed 800 cfm flow. He adjusted the system performance to meet the 1000 cfm.
- 2) Xel33 Trap Efficiency: No protocol written and there is no record of the one study done in June, 1982. A new protocol was written by Don Tolbert and Rod Knable today, January 12, 1983. An efficiency check was made today and a log of these checks has been started.
- 3) Hot lab access: The key to the hot lab was in the door when the nuclear medicine technician was not present. This incident is noted to be a very rare exception to the routine of keeping the door closed and locked and the key not in sight when authorized personnel are not present.
- 4) Dr. Gutknecht on license: see discussion in old business.
- 5) Records and surveys of shipping and receiving: records of shipping out of the week old "spent" MO/TC generators not done.

Surveys of delivered radioactive packages were missing for all mid week packages and the last two week period for MO/TC gen.

A new log book was started December 22, 1982. This will include all records of items received and shipped, destination and surveys performed.

Surveys will be performed on all items received into the facility including unpackaged radioactive items received during the week.

- 6) Daily surveys of technician hands, prep unit and injection table absorbant paper were not done from 11-12-82 to 12-14-82 one week during this time the facility was not operating. The importance of this survey was discussed and a renewal effort has begun which will consistently perform this daily survey.
- 7) Monthly camera sensitivity consistency checks not done. The method of checking camera sensitivity consistency is not adequate and not documented properly.

A protocol for this check was drawn up January 12, 1983 by Don Tolbert and Rod Knable. This check will be performed monthly.

- 8) MO99 assay training not documented properly. Don Tolbert again went through a training session with Rod Knable as to the procedure for assaying MO99. This training is now documented with Don Tolbert signature given post the successful training.
- 9) Laboratory deficiencies regarding "in-vitro" studies using 1125 included proper posting of NRC signs, radioactive caution markers on each waste package, disposal activity too high, documentation of housekeeping instructions per handling the marked radioactive containers, documentation of lab personnel in the use of the survey meter.

Posting of NRC signs. Posting of caution radioactive material signs was done the day of the NCR inspection. The allowable level of solid waste disposal is being investigated and solutions included shipping the waste to Pacific Radiopharmacy, storing the trash until 10 1/2 lives, or getting an amendment to increase the level of activity allowable for disposal per month at Castle Medical Center. Don Tolbert will work with Bud Sauder at a date to be set for the purpose of training and documenting of housekeeping personnel in trash disposal and lab personnel in the use of the survey meter and trash monitoring.

PJ

Meeting adjourned 1:00 pm

APPENDIX E

INSPECTION BY RADIATION SAFETY OFFICER*

(Preferably conducted in conjunction with hospital administrator)

- I. Licensee: _____
- II. Address: _____
- III. License No.: _____ Expiration Date: _____
- IV. Date of Inspection: _____
- V. Inspection Findings:

The inspection was an examination of the activities conducted under the above license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission's rules and regulations and the conditions of the above license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the Radiation Safety Officer. The following findings resulted from this inspection:

A. Posting of Notices and Signs:

1. Rooms or areas were properly posted to indicate the presence of a RADIATION AREA. (10 CFR Part 20, paragraph 20.203(b))
Yes _____ No _____ N/A _____
2. Rooms or areas were properly posted to indicate the presence of a HIGH RADIATION AREA. (10 CFR Part 20, paragraph 20.203(c))
Yes _____ No _____ N/A _____
3. Rooms or areas were properly posted to indicate the presence of an AIRBORNE RADIOACTIVITY AREA. (10 CFR Part 20, paragraph 20.203(d))
Yes _____ No _____ N/A _____

*Modified from S. M. Brahmavar, S. M. Zubi, J. P. Sullivan, "Compliance Tests and Radiation Safety Procedures for Broad and Specific Medical Byproduct Material Licenses," in Proceedings of the 22nd Annual Meeting of the Society of Nuclear Medicine, 1975. (Available from Dr. S. M. Brahmavar, Department of Pathology, Medical Center of Western Massachusetts, Springfield, Mass.)

4. Rooms or areas were properly posted to indicate the presence of RADIOACTIVE MATERIAL. (10 CFR Part 20, paragraph 20.203(e))
 Yes _____ No _____ N/A _____

5. Containers were properly labeled to indicate the presence of RADIOACTIVE MATERIAL. (10 CFR Part 20, paragraph 20.203(f)(1) or (f)(2))
 Yes _____ No _____ N/A _____

6. A copy of the regulation, "Notices, Instructions and Reports to Workers, Inspections," was properly posted for use by individuals participating in the licensed activities. (10 CFR Part 19, paragraph 19.11(a)(1))
 Yes _____ No _____ N/A _____

7. A copy of the regulation, "Standards for Protection Against Radiation," was properly posted for use by the individuals participating in the licensed activities. (10 CFR Part 20; 10 CFR Part 19, paragraph 19.11(a)(1))
 Yes _____ No _____ N/A _____

8. Copies of the current license, license conditions, and amendments thereto were properly posted. (10 CFR Part 19, paragraph 19.11(a)(2))
 Yes _____ No _____ N/A _____

9. Copies of the documents incorporated into the current license by reference were properly posted. (10 CFR Part 19, paragraph 19.11(a)(2))
 Yes _____ No _____ N/A _____

10. A copy of the operating procedures applicable to licensed activities was properly posted. (10 CFR Part 19, paragraph 19.11(a)(3))
 Yes _____ No _____ N/A _____

11. Posting of documents specified in 10 CFR Part 19, paragraph 19.11(a)(1,2,3) was not practicable; therefore the licensee posted notice that describes the documents and states where they may be examined. (10 CFR Part 19, paragraph 19.11(b))
 Yes _____ No _____ N/A _____

12. Form NRC-3, "Notice to Employees," was posted in a sufficient number of places for use by the individuals who work in or frequent any portion of the restricted areas. (10 CFR Part 19, paragraph 19.11(c))

Yes _____ No _____ N/A _____

13. A copy of any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Subpart B of 10 CFR Part 2 was posted within 2 working days after the receipt of notice. (10 CFR Part 19, paragraph 19.11(a)(4),(e))

Yes _____ No _____ N/A _____

14. A copy of the licensee's response, if any, to a notice of violation, etc. (10 CFR Part 19, paragraph 19.11(a)(4)) was posted within 2 working days after the dispatch of response by the licensee. (10 CFR Part 19, paragraph 19.11(a)(4),(e))

Yes _____ No _____ N/A _____

15. The documents posted in compliance with 10 CFR Part 19, paragraph 19.11(a)(4) and (e) remained posted for a minimum of 5 working days or until action correcting the violation was completed, whichever was later. (10 CFR Part 19, paragraph 19.11(e))

Yes _____ No _____ N/A _____

Date of Receipt of Violation: _____

Date of Dispatch of Response: _____

Date of Corrective Action: _____

Date on Which Documents Were Posted: _____

Date on Which Documents Were Removed: _____

B. Records and Reports:

1. Records of current occupational radiation exposures of individuals were properly maintained on Form NRC-5. (10 CFR Part 20, § 20.401)

Yes _____ No _____ N/A _____

2. Records of individual accumulated occupational dose were maintained for each radiation worker on Form NRC-4. (10 CFR Part 20, § 20.102)

Yes _____ No _____ N/A _____

3. Records of radiation surveys of all the working areas where the licensed material is used were maintained. (10 CFR Part 20, paragraph 20.201(b) or 30.43(d))

Yes _____ No _____ N/A _____

Frequency of Survey: _____

Date of Last Survey: _____

4. Records of disposal of licensed radioactive material were properly maintained. (10 CFR Part 20, §§ 20.301, 20.302, 20.303)

Yes _____ No _____ N/A _____

Frequency of Disposal: _____

Date of Last Disposal: _____

5. Records of receipt, transfer, and disposal of licensed material were properly maintained. (10 CFR Part 30, § 30.51; Part 40, § 40.61)

Yes _____ No _____ N/A _____

6. Records of leak tests were maintained as prescribed in the license. (10 CFR Part 34, paragraph 34.25(c))

Yes _____ No _____ N/A _____

Frequency of Leak Test: _____

Date of Last Leak Test: _____

7. Records of isotope inventories were properly maintained to comply with item #8 of byproduct material license. (10 CFR Part 30, paragraphs 30.51(b) and (d))

Yes _____ No _____ N/A _____

Frequency of Isotope Inventory: _____

Date of Last Inventory: _____

8. Utilization logs of each isotope received were properly maintained. (10 CFR Part 34, § 34.27)

Yes _____ No _____ N/A _____

9. Records of calibration of radiation survey instruments as required by the conditions of license were properly maintained. (10 CFR Part 30, paragraphs 30.51(b) and (d))

Yes _____ No _____ N/A _____

Frequency of Calibration: _____

Date of Last Calibration: _____

10. Records of bioassay tests were maintained on all individuals per requirements of license. (10 CFR Part 20, § 20.108)

Yes _____ No _____ N/A _____

Frequency of Bioassay Test: _____

Date of Last Bioassay Test: _____

11. Records of the wipe-test data and results on determination of concentrations of radioactive material present in the working areas were properly maintained. (10 CFR Part 20, paragraph 20.201(a))

Yes _____ No _____ N/A _____

Frequency of Wipe Test: _____

Date of Last Wipe Test: _____

C. Operating Procedures and Manuals:

1. The institutional radiation safety instruction program for all radiation workers and hospital employees is operational and effective. (10 CFR Part 19, § 19.12)

Yes _____ No _____ N/A _____

Frequency of Radiation Safety Instruction: _____

Date of Last Instruction Program: _____

2. A radiation safety procedures manual is written and copies are made available for the use of all the radiation workers, personnel involved in patient care and others who may handle radioactive material. (10 CFR Part 19, § 19.12)

Yes _____ No _____ N/A _____

3. Procedures for picking up, receiving, and opening the packages containing radioactive material are available and are in routine use. (10 CFR Part 20, § 20.205)

Yes _____ No _____ N/A _____

4. The Radiation Safety Committee meetings are held at periodic intervals to review the medical isotope program at the institution.

Yes _____ No _____ N/A _____

5. The local fire and police officials are informed of the location and nature of radioactive materials in the institution.

Yes _____ No _____ N/A _____

Frequency of Familiarization by Fire and Police Officials: _____

Date of Last Visit: _____

D. Administrative Actions:

1. No items of noncompliance or unsafe conditions were found.

Radiation Safety Officer: _____

Signature and Date: _____

2. The following items of noncompliance related to each of the above sections were found.

Section A: _____

Section B: _____

Section C: _____

Radiation Safety Officer: _____

Signature and Date: _____

3. The Radiation Safety Officer has explained and I understand the items of noncompliance listed in Item 2 of this section. The items of noncompliance will be corrected within the next ___ days.

Chairman, Radiation Safety Committee: _____

Signature and Date: _____

Reviewed by:

_____ Date _____

Hospital Administrator