

HUTZEL HOSPITAL 4707 ST. ANTOINE BLVD., DETROIT, MICHIGAN 48201



October 16, 1980

Mr. James G. Keppler
Director
United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Mr. Keppler:

RE: License No. 21-03001-01

Attached please find a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved.

Should you need further clarification, please do not hesitate to contact us.

Sincerely,

Ernest Booth, M.D.
Vice President/Medical Affairs

Kenneth Nowicki, M.D.
Radiation Safety Officer

EB/KN/drw

Attachments

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DETROIT MEDICAL CENTER

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HUTZEL HOSPITAL

LICENSE NO. 21-03001-01

RESPONSE TO NRC CONCERNING ITEMS OF NONCOMPLIANCE

- 1) An amendment to the current license is being written to add all appropriate individuals.
- 2) Radiation Therapy
- 3) A new possession limit has been requested for from licensing.
- 4) A molybdenum-99 contamination check will be performed daily on each generator elution and recorded.
- 5) The medical isotopes committee will meet at regular quarterly intervals as required by the license conditions. Written records will be maintained of all committee meetings, actions, recommendations, and decisions.
- 6) All survey meters will be calibrated annually by Medical Physics Consultants as specified by the license conditions.
- 7) A 5 mCi Co-57 and a 0.2 mCi Cs-137 check source have been obtained and are being used properly in accordance with license conditions. An amendment request has been submitted replacing the 0.05 mCi Co-60 mentioned in the license application with a 0.2 mCi Ba-133 check source.
- 8) Daily constancy checks on the dose calibrator are now being performed. A quarterly linearity check has been and will be performed on a quarterly basis. An accuracy check has been and will be performed annually. All the above mentioned dose calibrator checks will be done according to the license conditions as outlined in Appendix D, section 2.
- 9) Instruction concerning the appropriate parts in Item 12 of the license application will be given to housekeeping, security, maintenance, and all other personnel who may come in contact with radioactive materials.
- 10) Orders will be placed by the heads of each radioactive material using department and will be delivered directly

to each department. An approved list of authorized personnel and ordering limits will be maintained by the purchasing department. Audits of the material records will be performed on a monthly basis by Medical Physics Consultants.

- 11) Package surveys are now being performed in accordance with license conditions. A simplified procedure has been applied for by amendment request.
- 12) No food will be stored in the hot lab refrigerator and smoking will not be allowed in any imaging room or in the hot lab.
- 13) Daily surveys are now being performed in the appropriate areas with the G-M survey meter. Laboratory areas using less than 100 uCi's will be surveyed monthly with a G-M survey meter and a contamination wipe test done. All other laboratory areas will be surveyed weekly with a G-M survey meter and a contamination wipe test done. All these in accordance with license conditions. Surveys at the RIA and Beaver Laboratory will continue being done.
- 14) All barrels at the Beaver Laboratory containing radioactive material will be secured and locked in a restricted and authorized storage area.
- 15) A bioassay procedure (included) for the use of radioiodine has been established.
- 16) An evaluation of the amount of Xe-133 which was discharged to unrestricted areas will be evaluated and results reported. At present Xe-133 is trapped using a charcoal trapping system and monitored with a X-alert room air and trap monitor.
- 17) Radiation Therapy
- 18) A written procedure for Mo-99 breakthrough is on file. This procedure was on file at the time of inspection and was presented for review at the September 15, 1980 meeting between the NRC and Hutzel Hospital.
- 19) A formal written report will be filed with the NRC reporting the loss of contact with the nuclear pacemaker patient.

All procedures will be inspected and audited on a monthly basis by Medical Physics Consultants and written reports maintained and reviewed by the medical isotope committee.

All items will be in full compliance by October 31, 1980.

BIOASSAY PROCEDURES FOR PERSONNEL USING RADIOIODINE AT HUTZEL HOSPITAL

Bioassay of personnel working with radioiodine is necessary under the circumstances outlined in the Nuclear Regulatory Commission Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

Thyroid burdens of personnel will be measured with a thyroid uptake probe. The activity of radioiodine in each person's thyroid gland will be calculated using the following method.

Materials

Thyroid uptake probe, capsules containing I-125 and/or I-131, neck phantom normally used for thyroid uptake studies.

Methods

For each iodine isotope of interest:

- 1) Set appropriate counting window, record setting.
- 2) Adjust high voltage so maximum counts from iodine capsule fall into window.
- 3) Put iodine capsule in phantom and set phantom in front of probe. Counting geometry should be as similar as possible to actual thyroid counting geometry.
- 4) Count for at least two minutes. Be sure to obtain a minimum of 10,000 counts.
- 5) Remove iodine from room and take a 15 minute background count.

Calculations

- 1) The counting efficiency of the thyroid uptake probe can be calculated by the equation:

$$A. \quad EF = \frac{CPS \text{ (uptake probe)}}{DPS \text{ (capsule)}}$$

Where: EF is counting efficiency

CPS (uptake probe) is the counts per second obtained in Step 4 of Methods

* DPS (capsule) is the activity of the iodine capsule in disintegrations per second

- 2) The minimum detectable activity (MDA) of the uptake probe can be calculated by:

$$B. \quad MDA = \frac{\frac{K^2}{T_t} + 2K \left[\frac{R_b}{T_t} \left(1 + \frac{T_b}{T_t} \right) \right]^{\frac{1}{2}}}{60 \text{ seconds/minute} \times EF \text{ (cps/dps)} \times 3.7 \times 10^4 \text{ (dps/uCi)}}$$

Where: $K = 1.65$ at the 95% confidence interval for a one tailed test

T_t = total counting time in minutes

T_b = background counting time in minutes

R_b = background count rate in minutes

The MDA is in units of microcuries (uCi).

To satisfy the requirements of Regulatory Guide 8.20, the bioassay counting system must be able to detect as little as 0.12 uCi of I-125 and as little as 0.04 uCi of I-131. If the counting time for background recommended in Step 5 of Methods, does not yield an MDA low enough to satisfy the NRC requirements, a longer background counting time is required. In addition, if the background count rate measured by the thyroid uptake probe changes significantly, the MDA must be recalculated as the MDA is dependent on the background count rate.

The MDA of the Hutzel Hospital thyroid uptake probe was calculated to be 0.0049 uCi based on a background count rate of 0.7722 counts per second (695 counts per 15 minutes). If the background counts for a 15 minute period increase to more than 750, the MDA should be recalculated according to the procedure described above.

References

1. U.S. Nuclear Regulatory Commission Regulatory Guide 8.20, Nuclear Regulatory Commission, Washington, D.C., 20555
2. Currie, L.A., 1968, Limits for qualitative detection and quantitative determination. Analytical Chemistry 4:3

To determin the thyroid burden in personnel:

1. Take a 15 minute background count on days bioassay measurements are taken. Record background count rate in counts per second.
2. Adjust gain and set window as in Steps 1 and 2 of Methods.
3. Position employee in front of probe and take a two minute count. Divide counts by 120 to get employee count rate in counts per second.
4. Subtract background count rate from employee count rate to get net employee count rate in counts per second.
5. Calculate thyroid burden (TB) in microcuries (uCi).

$$TB = \frac{\text{Net Employee Count Rate (cps)}}{EF \times 3.7 \times 10^4 \text{ (dps/uCi)}}$$

EF = counting efficiency as determined in
methods section

For Hutzel Hospital EF = 7.53×10^{-4} cps/dps

6. Keep a log of background measurements and employee thyroid burdens