APPENDIX A

NOTICE OF VIOLATION

Ketchikan General Hospital
3100 Tongass Avenue
Ketchikan, Alaska 99901

License No. 50-19913-01

As a result of the inspection conducted on August 30, 1982, and in accordance with the NRC Enforcement Policy, (10 CFR Part 2, Appendix C), 47 FR 9987 (March 9, 1982), the following violations were identified:

A. License Condition 12. states that licensed material shall be used by, or under the supervision of, Stuart A. O'Byrne, M.D.

Contrary to the above requirement, diagnostic studies using technetium-99m were conducted at Ketchikan General Hospital during Dr. O'Byrne's absence between April 6 and 8, 1982; April 15 through May 1, 1982; May 19 through June 3, 1982; June 10 through July 2, 1982; and July 8 through August 20, 1982. Dr. O'Byrne was not available in Ketchikan during these periods of absence. Several such uses were as described below:

Date	Number of Patients	Activity of Administered Diagnostic Doses of Technetium-99m (in millicuries)
8-20-82	2	4, 5
8-19-82	3	20, 4, 20
8-17-82	2	20, 9
8-16-82	1	20
8-13-82	1	20
7-30-82	2	4, 20
7-29-82	1	20
7-26-82	3	4, 4, 20
7-22-82	1	4
7-20-82	1	4
7-19-82	2	20, 20
7-16-82	1	5

This is a Severity Level IV Violation (Supplement VI).

B. License Condition 17. states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in the application dated October 27, 1981.

Item 10. of the application dated October 27, 1981 states that Appendix D of Regulatory Guide 10.8, Revision Number 1 dated October 1980 will be followed with respect to the dose calibrator.

1. Regulatory Guide 10.8, Revision Number 1, Appendix D. states that tests for instrument accuracy, instrument linearity, and geometrical variation shall be performed at the time of dose calibrator installation.

   Contrary to the above requirement, no tests for instrument accuracy, instrument linearity, or geometrical variation were performed on the Capintec CRC-5 dose calibrator prior to its first use on April 6, 1982.

2. Regulatory Guide 10.8, Revision Number 1, Appendix D. states that linearity tests will be conducted on the dose calibrator on a quarterly basis.

   Contrary to the above requirement, no linearity tests were conducted between April 6, 1982 and August 9, 1982, a period in excess of four months. Furthermore, the linearity test conducted on August 9, 1982 was not completed as described in Regulatory Guide 10.8 in that predicted activities were not calculated and compared with the measured values.

3. Regulatory Guide 10.8, Revision Number 1, Appendix D. states that instrument constancy checks will be conducted on a daily basis and that the results will be logged and plotted on semilog graph paper and compared with expected results.

   Contrary to the above requirement, instrument constancy checks performed between May 4, 1982 and August 30, 1982 were not recorded.

   The above items constitute a Severity Level IV violation (Supplement VI).

C. 10 CFR 35.14(b)(4)(ii) states that any licensee using generators or reagent kits shall cause each elution of technetium-99m from a molybdenum-99/technetium-99m generator to be tested for molybdenum breakthrough contamination by personnel who have been specifically trained to perform the test.

   Contrary to the above requirement, one technician who conducted tests for molybdenum breakthrough contamination between April 6, 1982 and August 30, 1982 was unaware of and had not received specific instruction in the acceptable molybdenum breakthrough contamination limits stated in 10 CFR 35.14(b)(4)(iii).

   This is a Severity Level IV Violation (Supplement VI).

D. License Condition 17. states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in the application dated October 27, 1981.

   Item 17 of the application dated October 27, 1981 states that Appendix I. of Regulatory Guide 10.8, Revision Number 1 dated October 1980 will be followed with respect to area survey procedures.

Regulatory Guide 10.8, Revision Number 1, Appendix I states that permanent records will be kept of the following surveys:

i. daily radiation level surveys in elution, preparation, and injection areas.

ii. weekly radiation level surveys in waste storage and other laboratory areas.

iii. weekly wipe tests to measure contamination levels.

Contrary to the above requirement, there were no records of radiation level surveys or wipe tests to measure contamination levels in the nuclear medicine or waste storage areas.

This is a Severity Level V Violation (Supplement VI).

E. License Condition 17. states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in the application dated October 27, 1981.

Item 9, "Instrumentation," of the application dated October 27, 1981 states that a survey meter will be available with a range of 0 mr/hr to 2.0 R/hr.

Contrary to the above requirement, the survey meters available at the time of the inspection had a maximum range of 100 mr/hr.

This is a Severity Level V Violation (Supplement VI).

F. 10 CFR 20.203(e) states that each area or room in which licensed material is used or stored and which contains any radioactive material in an amount exceeding 10 times the quantity of such material specified in Appendix C of 10 CFR Part 20 shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words: "Caution, Radioactive Materials."

1. Contrary to the above requirement, at the time of the inspection, the Nuclear Medicine imaging room, where 4.6 millicuries of xenon-133 was being stored, was not posted with a sign bearing the radiation caution symbol and the words: "Caution, Radioactive Materials."

   The Appendix C quantity of xenon-133 is 100 microcuries. Ten times this quantity would be one millicurie.

2. Contrary to the above requirement, at the time of the inspection, the waste disposal area in the basement of the hospital, where greater than four millicuries of molybdenum-99 were being stored, was not posted with a sign bearing the radiation caution symbol and the words: "Caution, Radioactive Materials."

The Appendix C quantity of molybdenum-99 is 100 microcuries. Ten times this quantity would be one millicurie.

This is a Severity Level V Violation (Supplement IV).

G. 10 CFR 20.401(a) states that each licensee shall maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required under 10 CFR 20.202.

Contrary to the above requirement, at the time of the inspection, no records were maintained of the radiation exposures received between January 19, 1982 and August 30, 1982 by one individual for whom personnel monitoring is required under 10 CFR 20.202.

This is a Severity Level V Violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Ketchikan General Hospital is hereby required to submit to this office within thirty days of the date of this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further items of noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

OCT 1 1982

Date

R. D. Thomas, Chief
Materials Radiation Protection Section