

APPENDIX A

NOTICE OF VIOLATION

Osteon, Inc.
P. O. Box 430
Wahiawa, Hawaii 96786

License No. 53-23440-01

As a result of the inspection conducted on July 29, 1985 and in accordance with the NRC Enforcement Policy, 10 CFR Part 2, Appendix C, the following violations were identified:

- A. License Condition 20 states, in part, that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in application dated May 18, 1984 and letters dated July 12, 1984, April 16, 1985 and May 3, 1985.

Item 2 of the letter dated July 12, 1984 requires that finger badges be worn by licensee personnel whenever iodine-125 sealed sources are installed into or removed from the bone mineral analyzer. Also, Item 12 of the application dated May 18, 1984 requires the use of thermoluminescent dosimeters (TLD) which shall be exchanged for processing at a frequency of once per month.

Contrary to the above requirements, two licensee employees have been allowed to install and remove sealed sources containing licensed material in conjunction with the use of the sources in bone mineral analyzers on numerous occasions since August, 1984 without providing extremity personnel monitoring. Also, licensed material has been used since August, 1984 by the Radiation Safety Officer who utilized a badge for personnel monitoring which has been exchanged for processing once per quarter.

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

- B. License Condition 18 states, in part, that the licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions". 10 CFR 71.5(a) states that each licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation in 49 CFR Parts 170 through 189.
1. 49 CFR 172.200 requires that each person who transports or delivers to a common carrier for transport a package containing radioactive material shall describe the hazardous material on a shipping paper in a manner prescribed by Subpart C of 49 CFR 172.

Contrary to the above requirement, the licensee without shipping papers, transported by private carrier on December 4, 1984 two sealed sources containing 104 millicuries of iodine-125, and on March 22, 1985, transported five sealed sources containing a total

of 212 millicuries of iodine-125 from the licensee's office and laboratory facility in Wahiawa, Hawaii to 347 N. Kuakini Street, Honolulu, Hawaii.

2. 49 CFR 173.415(a) states, in part, that each shipper of a Specification 7A package must maintain on file a complete documentation of tests and an engineering evaluation or comparative data showing that the construction methods, packaging design, and materials of construction comply with that specification.

Contrary to the above requirement, written documentation attesting to the results of the Specification 7A performance tests performed on the package design were not maintained corresponding to the shipment of licensed material by private carrier on December 4, 1984 and March 22, 1985.

The above items constitute a Severity Level V Violation (Supplement VI).

- C. 10 CFR 20.203(f)(1) and (2) require that each container of licensed material shall bear a durable, clearly visible label identifying the radioactive contents. The label required shall bear the radiation caution symbol and the words, "Caution, Radioactive Material," or "Danger, Radioactive Material".

1. Contrary to this requirement, at the time of inspection, the capsule holder (serial number 573) containing 35 millicuries of iodine-125 which was stored in a cabinet at the licensee's facility in Wahiawa, Hawaii was not labeled with a radiation caution symbol and the words, "Caution or Danger, Radioactive Material."
2. Contrary to this requirement, at the time of inspection, a bone mineral analyzer containing the 145 millicurie iodine-125 sealed source (capsule serial number 689), was unlabeled.

The above items constitute a Severity Level V Violation (Supplement IV).

- D. License Condition 16 states, in part, that each sealed source containing licensed material, other than hydrogen-3, with a half-life greater than thirty days, and in any form other than gas, shall be tested for leakage and/or contamination at intervals not to exceed 6 months. License Condition 16 also states that in the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

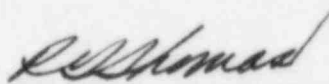
Contrary to the above requirements, a record was not maintained of the leak test performed prior to the receipt on June 17, 1985 of the sealed source (Capsule Serial Number 689), containing approximately 200 millicuries of iodine-125. The sealed source was used in a bone mineral analyzer during the period between June 17, 1985 and the date of inspection, July 29, 1985.

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

Pursuant to the provisions of 10 CFR 2.201, Osteon, Inc., is hereby required to submit to this office within thirty days of the date of this Notice, a written statement of 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 violations; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

AUG 16 1985

Dated



R. D. Thomas, Chief
Nuclear Materials Safety Section