

## MATERIALS LICENSE

Amendment No. 3

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with letter dated August 13, 1985	
1. Osteon, Inc.		3. License number 53-23440-01 is amended in its entirety to read as follows:	
2. P.O. Box 430 Wahiawa, Hawaii 96786		4. Expiration date August 31, 1989	
		5. Docket or Reference No. 030-21081	
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	
A. Iodine 125	A. Sealed sources (AECL C-235)	A. Not to exceed 800 millicuries per source	
9. Authorized use			
A. For use in AECL Model C-236 source holders for the development of a bone mineral analyzer.			
For storage, use, and/or possession incident to:			
(1) Installation into or removal from Osteon Model SPSHA 110 or 220 bone mineral analyzers.			
(2) Repair, servicing, testing, demonstration and training in the use and operation of Osteon Model SPSHA 110 or 220 bone mineral analyzers.			

## CONDITIONS

10. Licensed material shall be used only at 649 California Avenue, Suite 102; Wahiawa, Hawaii 96786, or at 347 N. Kuakini Street; Honolulu, Hawaii 96817. In addition, activities specified in Items 9A(1) and 9A(2) may be conducted at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.
11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation".

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CONDITIONS

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12. A. Except for training in the use and operation of Osteon Model SPSHA 110 or 220 bone mineral analyzers, licensed material shall be used by, or under the supervision and in the physical presence of, Philip J. Manly, Richard Wasnich, M.D., John M. Vogel, M.D., Fred Kolb, Elaine Burton, Phil Ross, or other personnel who have completed the training program described in the letter dated April 16, 1985 and who have been approved by Philip Manly.
- B. Training in the use and operation of Osteon Model SPSHA 110 or 220 bone mineral analyzers may be conducted in the physical presence of Philip J. Manly, Richard Wasnich, M.D., John M. Vogel, M.D., or other persons who have been certified by the American Board of Health Physics and who have acknowledged in writing that they have read and understood Sections 3.6 through 3.12 of the OsteoAnalyzer Model SPSHA 110 Operation Manual dated July 1985, or who have been specifically named on a license issued by the NRC or an agreement state for the medical use of the device.
- C. The licensee shall maintain records of the training and experience of each individual employed by Osteon or trained by Osteon to use the Osteon Model SPSHA 110 or 220 bone mineral analyzers.
13. Sealed sources containing licensed material shall not be opened.
14. Licensed material shall not be used on human beings or in products distributed to the public.
15. This license does not authorize distribution to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR 35.
16. A. (1) 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 six months. 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.
- B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

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- C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within five (5) days of the test with the U. S. Nuclear Regulatory Commission, Region V, Office of the Regional Administrator, 1450 Maria Lane, Suite 210, Walnut Creek, California 94596, describing the equipment involved, the test results, and the corrective action taken.
- D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Commission or an Agreement State to perform such services.
17. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of licensed material, location of sealed sources and the date of the inventory.
18. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions".
19. Repair or servicing operations may be conducted on the Model SPSHA 110 or 220 bone mineral analyzers if the source is first removed from the device and placed in a fully shielded storage condition.
20. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated May 18, 1984 and letters dated July 12, 1984, April 16, 1985 May 3, 1985, and August 13, 1985. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date AUG 26 1985

By Beth A. Riedlinger  
Health Physicist (Licensing)  
Nuclear Materials Safety Section  
Region V