RECORD #169

TITLE: Disposal of byproduct Material Used For Certain In-Vitro Clinical or Lab. Testing

FICHE: 08405-262

0257/80

MEMORANDUM FOR: Materials Inspectors

DEC 15 1980

FROM: John D. Kinneman, Chief, Materials Radiological Protection Section, FF&MSB

SUBJECT: DISPOSAL OF BYPRODUCT MATERIAL USED FOR CERTAIN IN-VITRO CLINICAL OR LABORATORY TESTING

Attached is a copy of a Notice sent to all medical licensees by the Materials Licensing Branch.

John E. Glenn

John D. Kinneman, Chief
Materials Radiological
Protection Section

Enclosure: As Stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

NMEALFM

December 1, 1980

TO ALL MEDICAL LICENSEES

DISPOSAL OF BYPRODUCT MATERIAL USED FOR CERTAIN IN-VITRO CLINICAL OR LABORATORY TESTING

This letter is written in response to many inquiries to the Commission from licensees in regards to disposal of wastes generated by in-vitro testing. If you are performing certain in-vitro tests using byproduct materials, including "Bactec", you may be authorized to dispose of the waste in the non-radioactive trash. You should carefully read all of the information contained in this letter to determine if you are eligible and what steps are necessary to gain this authorization. Under the provisions of 10 CFR 31.11 (copy enclosed), a general license may be issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use certain byproduct materials in prepackaged form for in-vitro tests. The provisions of this paragraph exempt most byproduct materials used pursuant to the general license from the requirements of 10 CFR Parts 19, 20, and 21. Because of the exemption from the provisions of 10 CFR Part 20, most radioactive wastes generated in the use of these in-vitro tests may be disposed of as ordinary waste. Before these materials can be discarded in the trash, all radiation labels should be removed and destroyed. The general license covers most in-vitro test kits, including "Bactec".

HOW TO OBTAIN AUTHORIZATION FOR THE GENERAL LICENSE

I. Group Medical Licensees. Under the provisions of 10 CFR 35.14(c) any licensee who is licensed for one or more of the groups in 10 CFR Part 35.100 is also authorized to use byproduct material specified under the general license in 10 CFR 31.11 without filing Form NRC-483 as otherwise required by 31.11. However, licensees are subject to all of the other provisions of 10 CFR 31.11 in their use of in-vitro test materials. Some group medical licensees have specific authorization on their licenses for in-vitro test materials in amounts greater than those specified in 10 CFR 31.11. If you use the general license, you must not exceed the quantities authorized in 10 CFR 31.11 and your operations under the general license must be physically and administratively separate from those conducted under your specific license. If the materials are used under your specific license, you are subject to all the provisions of 10 CFR Parts 19, 20 and 21, including requirements regarding waste disposal.

II. Medical Institutions Possessing Licenses of Broad Scope. Broad scope licensees may file for the general license in accordance with 10 CFR 31.11. They must file a Form NRC-483 and they must maintain all operations carried out under the provisions of the general license separate from those operations carried out under the provisions of their broad license.

III. Other Medical Licensees. Other medical licensees must follow the procedures as outlined in 10 CFR 31.11 and must file Form NRC-483 with the Commission.

Sincerely,

Sandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosure: 10 CFR 31.11