

030-08864

NRC FORM 313
10-82
10 CFR 20.22, 23, 24,
25 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3190-0120
Expires 6-31-88

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW

FEDERAL AGENCY FILE APPLICATIONS WITH:
 U.S. NUCLEAR REGULATORY COMMISSION
 DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NRES
 WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS IF YOU ARE LOCATED IN:

CONNECTICUT DELAWARE DISTRICT OF COLUMBIA MARY MARYLAND MASSACHUSETTS NEW HAMPSHIRE NEW JERSEY NEW YORK PENNSYLVANIA RHODE ISLAND OR VERMONT, SEND APPLICATIONS TO:
 U.S. NUCLEAR REGULATORY COMMISSION, REGION III
 NUCLEAR MATERIAL SECTION
 631 PARK AVENUE
 KING OF PRUSSIA, PA 19060

ALABAMA FLORIDA GEORGIA KENTUCKY MISSISSIPPI NORTH CAROLINA NORTH CAROLINA SOUTH CAROLINA TENNESSEE VIRGINIA VIRGIN ISLANDS OR WEST VIRGINIA, SEND APPLICATIONS TO:
 U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
 MATERIAL RADIATION PROTECTION SECTION
 101 MARLYN STREET, SUITE 2000
 ATLANTA, GA 30321

IF YOU ARE LOCATED IN:
 ILLINOIS INDIANA IOWA MICHIGAN MINNESOTA MISSOURI OHIO OR WISCONSIN, SEND APPLICATIONS TO:
 U.S. NUCLEAR REGULATORY COMMISSION, REGION III
 MATERIALS LICENSING SECTION
 700 ROOSEVELT ROAD
 GLEN ELLEN, IL 60137

ARKANSAS COLORADO IDAHO KANSAS LOUISIANA MONTANA NEBRASKA NEW MEXICO NORTH CAROLINA OKLAHOMA SOUTH CAROLINA TEXAS UTAH, OR WYOMING, SEND APPLICATIONS TO:
 U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
 MATERIAL RADIATION PROTECTION SECTION
 611 RYAN PLAZA DRIVE, SUITE 1000
 ARLINGTON, TX 76011

ALASKA ARIZONA CALIFORNIA HAWAII NEVADA OREGON WASHINGTON AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:
 U.S. NUCLEAR REGULATORY COMMISSION, REGION V
 MATERIAL RADIATION PROTECTION SECTION
 1450 MARIA LANE, SUITE 710
 WALNUT CREEK, CA 94690

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate box) <input type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input checked="" type="checkbox"/> C. RENEWAL OF LICENSE NUMBER <u>20-15285-01</u>	2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP Code) Fenwal Inc. 400 Main St. Ashland, MA 01721
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3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.
 400 Main St.
 Ashland, MA 01721

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION John P. O'Leary, Radiation Safety Officer	TELEPHONE NUMBER (617) 881-2000 x2350
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SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11 PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL a. Quantity and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
9. FACILITIES AND EQUIPMENT	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT	12. LICENSE FEE (See 10 CFR 170 and Section 170.31) FEE CATEGORY <u>3B</u> AMOUNT ENCLOSED \$ <u>460.00</u>
13. CERTIFICATION: (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 7 CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMANCE WITH TITLE 10 CODE OF FEDERAL REGULATIONS PARTS 20, 22, 23, 24, 29, AND 60 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 USC SECTION 1001 ACT OF JUNE 25, 1949 IS A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.	

SIGNATURE - CERTIFYING OFFICER <i>John P. O'Leary</i>	TYPED PRINTED NAME John P. O'Leary	TITLE RSO	DATE 4/19/88
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14. ANNUAL FEE < \$2500 \$2500 - \$5000 \$5000 - \$7500 \$7500 - \$10000 \$10000 - \$15000 \$15000 - \$20000 \$20000 - \$25000 \$25000 - \$30000 \$30000 - \$35000 \$35000 - \$40000 \$40000 - \$45000 \$45000 - \$50000 \$50000 - \$55000 \$55000 - \$60000 \$60000 - \$65000 \$65000 - \$70000 \$70000 - \$75000 \$75000 - \$80000 \$80000 - \$85000 \$85000 - \$90000 \$90000 - \$95000 \$95000 - \$100000	15. NUMBER OF SUPPLIES (See 10 CFR 170.31) (Include quantity including articles, containers, etc.) NUMBER OF BEES	16. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Labor and/or material hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial proprietary information furnished to the agency in confidence) <input type="checkbox"/> YES <input type="checkbox"/> NO
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FOR NRC USE ONLY			
TYPE OF FEE REN	FEE LOG May 2 ^I	FEE CATEGORY 3B	COMMENTS 8907310476 881227 RE01 LIC30 20-15285-01 PDR
AMOUNT RECEIVED \$460	RECORD NUMBER 347958	APPROVED BY <i>S. Kimberley</i> DATE 5/6/88	

Information in this record was deleted in accordance with the Freedom of Information Act, exemptions 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100.

"OFFICIAL RECORD COPY" 111

100.51

U.S.

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use, and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.
5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

License number 20-15285-01

Fenwal Inc.
400 Main St.
Ashland, MA 01721

April 19, 1988

5. a. Americium 241

b. Supplied in solid sealed sources, with no single source to exceed 2.5 microcuries. Sources to be obtained from either Amersham Corp. or Nuclear Radiation Development Div. of Mark

c. Total not to exceed 400 millicuries.

6. For use in sealed form in ionization smoke detection devices.

7. John P. O'Leary - Radiation Safety Officer.

8. See IR - 101.

9. See IR - 101.

10. See IR - 101.

11. See IR - 101.

FENWAL INCORPORATED

IONIZING RADIATION
Rules and Regulations for the
Protection of the Health and Safety
of Personnel

Policy No. IR - 1

PURPOSE

It is the purpose of these Rules and Regulations to state the minimum requirements for the use, handling, processing, application, transfer, storage and removal of all sources, materials, instruments, machines, devices, and equipment which produce, generate or emit ionizing radiation to insure the maximum safety of all persons at or in the vicinity of such ionizing radiation.

The Rules and Regulations herein are intended to be in harmony with Federal regulations as they apply.

REFERENCE

- American National Standards Institute Bulletin "Z54.1 - 1963".
- Massachusetts Department of Labor and Industries "Industrial Bulletin No. 5"
- Moore and McDonald's report on Radiation Safety Recommendations for X-Ray Diffraction and Spectrographic Equipment "MORP 68-14".
- U.S. Nuclear Regulatory Commission "Rules and Regulations - Part 10 - Notices, Instructions and Reports to Workers; Inspections".

APPLICATION

These Rules and Regulations shall apply to and in all places of Fenwal Incorporated where sources, materials, instruments, machines, devices, and equipment produce, generate or emit ionizing radiation during the use, handling, processing, testing, application, transfer, storage, or removal thereof.

CONTROLS

1. Each Section of this Policy shall be identified as to Section Number, Revision Number, Issue Date, and Approval (initials).
2. Current release of IR - 101 is as indicated at bottom of this page. Revisions may be issued only after being initialed by Radiation Safety Officer.
3. Policy Distribution to:
Radiation Safety Officer,
Manager Quality Control and Product Reliability,
Separate Sections to such areas of the Fenwal organization as needed.

Prepared by

John P. Henry
Radiation Safety Officer

Date

4/11/88

Approved by

Carl Swanson
Vice President,
Quality Assurance

Date

4/21/88

Section No. Index
Issue Date 4/11/88Rev No. B
Approved: JPOFENWAL INCORPORATED
INDEXSection
No.Title

1. Definitions
2. Employee Qualifications and Health Provisions
3. Safety, Administration Of
4. Safety Precautions, Personal Hygiene
5. Survey Instruments and Controls
6. Film Badge - Radiation Monitoring
7. New or Revisions to Manufacturing/Test Areas
8. Radiation Survey Procedures - Manufacturing Areas
9. Wipe Test
10. Maximum Permissible Exposure
11. Manufacturing Plan
12. Manufacturing Layout - Restricted Area
13. Training Program
14. Procurement
15. Receiving - Inspection of Radium Sources
16. Sealed Sources
17. Storage of Radioactive Material
18. Waste Disposal
19. Repairs to Equipment and Work Areas
20. X-Ray Laboratory
21. Notification of Accidents, Material Accountability
22. Record Retention
23. Procedures and Standards for Ionization Smoke Detector
RSD-98
24. Radiation Safety Officer - Job Description

Section No. 1 REV NO. B
Issue Date 4/11/88 Approved JPS**DEFINITIONS**

1. Absorbed dose shall mean the amount of energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. (It shall be expressed in rads or submultiple thereof.)
2. Airborne Radioactive Material shall mean airborne radioactive material in any form, such as dusts, fumes, vapors, mists, gases, or smokes.
3. Americium (241) - Silvery metallic element artificially produced which emits Alpha-Beta particles.
4. Analytical X-Ray Equipment: Any device which utilizes X-rays for the purpose of examining the microstructure of materials. This includes all types of X-ray diffraction and spectrographic equipment.
5. Body Burden shall mean the amount of radioactive material fixed in the body at any time.
6. Calendar Quarter shall mean:
 - A.) A period of not less than 12 or more than 14 complete consecutive calendar weeks.
 - B.) A period of three (3) consecutive calendar months. Once he has established the method to be used to determine calendar quarters, no employer shall change his method without prior permission from the Commissioner.
7. Commissioner shall mean Commissioner of Labor and Industries.
8. Controlled Area shall mean a defined area, access to which is controlled for the purpose of radiation protection.
9. Critical Organ shall mean that part of the body that is most susceptible to radiation damage under the specific conditions considered.
10. Curie shall mean the standard unit used in measuring the activity of a radioactive substance, and shall be numerically equal to 3.7×10^{10} disintegrations per second. Commonly used sub-multiples of the curie are: The microcurie (one millionth of a curie), $\mu\text{c} = 3.7 \times 10^4$ disintegrations per second, and the millicurie (one thousandth of a curie), $\text{mc} = 3.7 \times 10^7$ disintegrations per second.

11. High Radiation Area shall mean any area accessible to personnel in which there exists radiation at such levels that a major portion of the body could receive, in any one hour, a dose in excess of 100 millirems.
12. Industrial Establishments at Fenwal Incorporated shall include manufacturing establishments, factories, work shops, mechanical establishments, laboratories, mercantile establishments, and all other buildings or parts thereof where manufacturing, assembly, storage, research, testing, transfer and removal are carried on.
13. Interlock: A device for precluding access to an area in which radiation is present by automatically reducing the exposure rate upon entry by personnel or parts of their body.
14. Ionizing Radiation shall mean and include alpha and beta particles, protons, neutrons, gamma and X-ray, and all other which produce ionization directly or indirectly, but not electromagnetic radiation other than gamma and X-rays.
15. Installation shall mean the area of radiation hazard under the administrative control of the person or organization possessing the source of radiation. A part of or an entire industrial establishment may be designated as an installation.
16. Maximum Permissible Exposure shall mean that amount of exposure to radiation set for regulatory purposes, which in the light of present knowledge is not expected to cause appreciable bodily injury to a person during his lifetime.
17. Mercantile Establishments shall mean any premises used for the purposes of trade, in the purchase or sale of any goods or merchandise.
18. Place of Employment shall mean every place, whether indoors or out, or underground, and the premises appurtenant thereto, into, in or upon which any employee goes, or remains, either temporarily or regularly in the course of his employment.
19. Qualified Expert: Shall be determined by the authority having jurisdiction, or a qualifying board set up for that purpose. Qualified experts at Fenwal are those (professional Physicists) who conduct radiation surveys on our X-ray apparatus, being sent by the Massachusetts Department of Occupational Hygiene, and/or by an approved radiation survey facility.
20. Rad shall mean the standard unit used in measuring the absorbed dose, and shall be numerically equal to 100 ergs per gram. A common sub-multiple is the millirad (mrad), which is one thousandth part of a rad.
21. Radiation Machine shall mean any device, instrument, equipment, or machine which is designed to produce any of the radiation as defined herein.

22. Radiation Safety Officer shall mean a person(s) who, to the satisfaction of the Commissioner, by training and experience having sufficient knowledge of radiation problems and the control of Health hazards, is able to perform dependable radiation protection surveys, and has been sufficiently instructed and trained to manage the application of all protective techniques applicable to the control of radiation hazards within an installation, and to assume all responsibilities required of him by these rules and regulations.
23. Radiation Survey: Shall be a survey by, or under the supervision of, a qualified expert.
24. Radioactive Material shall mean any material, either solid, liquid, or gas, which emits ionizing radiation spontaneously.
25. Radium (226) - White metallic element that emits alpha particles and gamma rays.
26. Rem shall mean a measure of the dose of any ionizing radiation to body tissue in terms of its estimated biological effect relative to a dose of one roentgen of X-ray.
27. Roentgen: Shall be the quantity of X- or gamma radiation such that the associated corpuscular emission per 0.001293 gram of air produces in air, ions carrying one electrostatic unit of electricity of either sign, and shall be designated by the symbol "r". A common sub-multiple is the milliroentgen which is one thousandth part of the roentgen and shall be designated by the symbol "mr".
28. Sealed Source shall mean any radioactive material that is encased in and is to be used only in a permanent container in a manner intended to prevent leakage of the radioactive material and yet permitting the radioactive material to be used as a source of radiation.
29. Survey shall mean the evaluation of the radiation hazard incident to the use, handling, processing, application, transfer, storage, and removal of all sources, materials, instruments, machines, and equipment which produce, generate, or emit ionizing radiation.
30. Shall: Where "shall" is used for a provision specified herein, that provision is intended to be mandatory.
31. Should or Is Recommended: Is used to indicate provisions which are not mandatory but which are here recommended as good practice.
32. Diagnostic Type Protective Tube Housing means an X-ray tube housing so constructed that the leakage radiation at a distance of 1 meter from the target cannot exceed 100 milliroentgens in 1 hour when the tube is being operated at any of its specific ratings.

33. Environment means all portions of man's earthly surroundings (including the atmosphere) frequentable and/or utilized directly or indirectly by man.
34. Exposure Dose means the dose potential to deliver an absorbed dose at a specific place or location.
35. Film Badge means a packet of appropriately sensitized material and filters used to determine amounts of ionizing radiation.
36. Filter means a device which when placed in a beam of ionizing radiation will absorb preferentially the less penetrating ionizing radiations.
37. Half-Value Layer (hvl) means the thickness of an absorber required to reduce a beam of ionizing radiation to one-half its incident intensity.
38. Occupancy Factor means the factor which, for purposes of evaluating the hazards from ionizing radiation, may be used when making allowances for the percentage of time an individual occupies a specified area.
39. Occupational Dose means the absorbed dose received by an individual whose duties of employment directly or indirectly may result in exposure to ionizing radiation in the course of said employment.
40. Person means an individual, partnership, association, syndicate, company, firm, trust, corporation, department, bureau, agency, organization, institution, political subdivision, or any other entity recognized by law as the subject of rights and duties.
41. Personnel Monitoring Equipment means devices designed to be worn or used for the purpose of evaluating the exposure dose of individuals (e.g., Film Badges, pocket chambers, pocket dosimeters and film rings).

Section No. 2
Issue Date 4/11/88Rev. No. B
Approved JPOEMPLOYEE QUALIFICATIONS AND HEALTH PROVISIONS1. Selection of Workers

Persons who are neat and careful are preferred as radioisotope workers, since they are less likely to be involved in accidents or spread contamination.

We must identify accident prone workers. Persons failing to develop radiation protection skills and who have a bad record of involvement in contamination incidents or overexposure should not be used; nor should persons who have a history of sudden physical seizures, such as fainting.

2. Instruction of Workers

All radiation workers shall be precisely informed of the materials which they are to handle and of the hazards connected with the work. They shall be instructed in local safety and radiation protection rules and shall be expected to observe these rules. The employee shall be instructed in the use of readings from monitoring instruments. He shall report any injury of unusual incident so that the possibility of overexposure or internal deposition can be investigated.

It is important that workers with radiosotopes be considered as potentially exposed for the remainder of their lifetimes. It should not be assumed that they will work with radioisotopes or radiation for only a few years.

3. Health Provisions

3.1. Employees under the age of 18 or pregnant women shall not be allowed to work in the immediate vicinity in which emission of ionizing radiation may be present.

3.2. A licensed practitioner of medicine (Fenwal Incorporated Company Doctor) shall supervise what ever program is necessary to ascertain that the health of employees working with or near radioactive sources is not affected by over exposure to radiation.

3.3. Preliminary Physical Examination: Every individual working with radioactive sources shall have a complete physical examination before assignment to this kind of work. Examination should include:
A. Medical history

- B. Exposure history
- C. Complete blood count
- D. Chest plate (routine)
- E. Urine analysis

3.4. Blood Count and Urinalysis at Regular Intervals: At regular intervals, complete blood counts shall be taken of all individuals working on the radiation program. Interval shall be six (6) months. Each individual assigned shall submit two (2) urine samples to the clinic. Interval shall be six (6) months.

1. First sample for routine analysis.
2. Second sample shall be delivered to M.I.T. for radioassay analysis.

3.5. Abnormality in Blood Count: Any abnormality in the complete blood count attributable to radioactive exposure should be carefully investigated; such an investigation should include a radiation survey of operating procedures. If the abnormality persists after the correction of any fault in the protection means of operating procedure, consideration should be given to the transfer of the employee to work not involving possible exposure to radiation.

3.6. Persistence of Normal Blood Count: The persistence of a normal blood count shall not be considered grounds for discontinuing radiation monitoring.

3.7. Medical Records: All medical records shall be kept on file in the Clinic under the supervision of a licensed practitioner of medicine.

4. A copy of all Medical Records including original data and each recheck shall be issued to:

The Commonwealth of Massachusetts
Executive Office of Manpower Affairs
Department of Labor and Industries
DIVISION OF OCCUPATIONAL HYGIENE
39 BOYLSTON STREET
BOSTON, MASSACHUSETTS 02116
(Tel. 727-3982)

Section No. 3Rev No. BIssue Date 4/11/88Approved JPOSAFETY - ADMINISTRATION OF1. Supervision

The supervisor of the radiation work area has the responsibility to protect both the workers and the general public from the isotopes being used. He should be familiar with the basic principles of radiation protection. The work of the group should be properly planned in detail commensurate with the degree of hazard. He should see that instructions for standard procedures are available for repetitive jobs and that special detailed procedures are prepared prior to any work involving hazardous quantities of radioisotopes. These procedures should include the principal steps to be taken in the event of an accident involving these materials. He should prepare and revise rules regarding the handling of food in the area, use of protective equipment, wearing of personnel meters, personnel monitoring, storage of radioactive material, etc. He should enforce these rules. The supervisor should train the workers to know and follow these procedures.

2. Resistricitions - Monitoring

- 2.1. The Radioactive area should be restricted to all personnel other than those who are assigned to that area.
- 2.2. The Manufacturing Supervisor has full responsibility for the safety of all personnel assigned to the radioactive facilities and for all visitors who enter the area.
- 2.3. The Radiation Safety Officer shall monitor the enforcement of the policy as stated under paragraphs 2.1. and 2.2.
- 2.4. Radiation film badges must be worn by all personnel who have access to the radiation area. The handling of this service is as detailed under Section 6.

Section No. 4Rev No. BIssue Date 4/11/88Approved JPOSAFETY PRECAUTIONS1. Personal Hygiene

Extreme personal cleanliness and care are needed in work involving radioisotopes. Hands should be washed frequently and they shall be washed before eating, smoking and at the end of each work period. No edibles of any kind - food, gum, candy or beverages - shall be brought into restricted area. Smoking shall be prohibited since radioactive contamination may be transferred to the lips or inhaled as the contamination is burned. Personnel should refrain from using personal items, e.g., pocket knives, handkerchiefs, lipsticks, etc., in the work area. Persons with open wounds in hands should not handle medium.

The hands, other uncovered skin, and clothing should be surveyed frequently during the work with instruments sensitive to the types of radiation involved, and if any contamination is found, immediate steps shall be taken to remove it. Before leaving a contaminated zone, surveys shall be made and the protective clothing should be discarded.

Employees should keep their work areas free from equipment and materials not needed for immediate work. Orderliness is a prime requirement for eliminating the spread of contamination. After use, equipment should be decontaminated or stored in a controlled location. Radioisotopes should be safely disposed of or returned to storage when no longer needed.

2. Handling Procedures and Controls

- 2.1. Approved warning signs must be properly displayed in all areas where there is a radiation hazard.
- 2.2. All containers holding radioactive materials, including sealed sources and standard sources should be labeled with radiation warning tape. The isotope, amount and date should be indicated. Each container shall be equipped with a lock; the key to be held by the Supervisor.
- 2.3. Radioactive material, including portable sources, should be stored in the special area provided, and there should be enough shielding to reduce the radiation level below 5 mrem per hour at the surface of the shield.
- 2.4. Operations with loose radioactive solids, evaporation of

radioactive liquids, handling of radioactive gases and any process that can lead to the creation of airborne activity offers greater protection.

- 2.5. Aseptic techniques shall be used in handling radioactive materials. Gloves or other protective means must be used if there is a strong probability of hand contamination.
- 2.6. A person with breaks in the skin of the hands must medically protect affected areas and gloves must be worn. Permission to work with radioactive material must be obtained from area Supervisor.

3. Safety of Personnel

- 3.1. The employer shall assign to a competent employee the duty of enforcing safety regulations which apply to the operators of radioactive sources and of persons in the vicinity, (Radiation Safety Officer).
- 3.2. The employer shall assign to a competent employee the duty of operating or supervising the operation of all radioactive sources within the limitations noted in the report of the appropriate radiation survey covering the installation/area in question (Supervisor). The duties of this employee shall include:
 - 3.2.1. A daily check of operating conditions to see that they conform in all respects with the normal operating conditions as described in the appropriate radiation survey report for the apparatus/area in question.
 - 3.2.2. Control of daily exposure of workers so as to limit the daily dose of each to 0.1 r (100 mr) or less. The basis of this control shall be the information given in the report covering the appropriate radiation survey.
- 3.3. The employer shall assign to a competent employee the duty of instructing all employees in radioactive areas concerning the danger of overexposure to radiation. The general methods of radiation protection and the means of avoiding overexposure should be explained to personnel; they should be warned against taking unnecessary chances. Safe working practices should be emphasized.
- 3.4. Safety regulations and instructions shall be posted in all radiation areas.
- 3.5. Areas shall indicate the presence of radiation by conspicuous warning signs. Each sign shall bear the standard warning symbol and the words "CAUTION or DANGER" and appropriate explanatory wording such as: RADIATION

AREA or X-RAY AREA.

4. Approved Sign Design

Colors employed: The cross-hatched area of the symbol and required lettering shall be colored purple and the background of the label or sign upon which it appears shall be colored yellow.

Section No. 5
Issue Date 4/11/88

Rev. No. B
Approved [Signature]

SURVEY INSTRUMENTS,
Their Control and Certification

Sub - Section

- A. Instruments retained by Fenwal
- B. Policy and calibration frequency

INSTRUMENTS RETAINED BY FENWAL

1. **Radector**
Manufactured by Jordan Electronic Mfg. Company
Model No. AGB-50-SR
Serial No. 212
Range 0.05 MR/HR to 50R/HR
Asset No. 2-6-253

2. **Digi/Rate**
Manufactured by Reactor Experiments, Inc.
Model No.
Serial No.
Range 0.1 MR/H to 99.9 R/H
Asset No. DR 472

3. **Survey Meter**
Manufactured by Tracerlab
Model No. SU-21
Serial No. 667018
Range
Asset No. 6922

4. **Count Rate Meter**
Manufactured by Ludlum Measurements, Inc.
Model 12
Serial No.
Range - 500 Counts/min., X1, X10, X100, X1000
Asset No.

POLICY AND CALIBRATION FREQUENCY

1. Instruments used to monitor radiation leakage shall be of approved design and manufacturer.
2. Instruments shall be certified at established frequency as to their accuracy.
3. Calibration shall be performed by an Approved Laboratory whose Primary instruments have been certified against, and whose accuracy is traceable to N.B.S.
4. If an instrument malfunctions, or there is a question as to its performance, it shall be promptly repaired.
5. Instruments shall be calibrated at intervals not to exceed 6 months.
6. Certifying Laboratory will supply notarized copy of test procedure and test results on completion of calibration program.

Section No. 6 Rev. No. B
Issue Date 4/11/88 Approved YPO

FILM BADGE - RADIATION MONITORING

1. Radiation detection badges shall be worn at all times by all personnel assigned to work in radioactive areas.
2. Each employee shall be assigned a badge number. This number shall be used continuously by that person for the duration of employment in radioactive areas.
3. Badges shall be worn for a one month period. At end of this period, badges shall be mailed to an Independent laboratory for analysis.
4. Reports issued by Independent Laboratory shall be maintained by the Radiation Safety Officer. A copy shall be directed to the Clinic.
5. Any indication of OVEREXPOSURE shall be immediately investigated to determine cause.
6. Radiation Safety Officer will assign to each person one or more lead-lined film badges, suitably identifiable, the exposure side of which has been partially covered with a metallic marker. Either medium-speed dental film or medium fine-grain industrial film shall be used for this purpose. Industrial high-speed film is not suitable and should be avoided.
7. The Monitor film shall be worn throughout each working day for a two week period. It shall be worn on that part of the worker's body which is most likely to be exposed to radiation while carrying out his normal operating routine.
8. Together with the Monitor film, there shall be processed a Control film which has been previously exposed to 0.1, 0.5, and 1.0 r, respectively. The Control film shall have the same type metallic marker as the Monitor film, and the emulsion number of both shall be the same. The Control film technique shall be established and occasionally checked by a qualified expert.
9. The Control film shall be processed in a manner recommended by manufacturer of the film in question. In order to insure the preservation of such film over a period of years, special attention shall be given to the removal of traces of fixing solution from the surface of the film; for this reason, such film shall be washed in running water for not less than 30 minutes before being dried.

10. The photographic density of the Monitor film shall be compared with that of the Control film. Visual comparison is adequate. If the Monitor film shows a greater darkening than the Control film exposed to 0.5 r, consideration shall be given to the possibility that the permissible dosage rate has been exceeded. The shielding and operating methods shall then be investigated and remedial action promptly taken.
11. The processing of the Monitor film shall be conducted by an Independent test laboratory.
12. If a question develops while processing the Monitor film, the test lab shall notify the Fenwal Radiation Safety Officer by telephone or telegraph of the problem and will follow-up with a written detailed report.
13. At the discretion of the Radiation Safety Officer, the Chairman of the Plant Safety Committee, or the Area Supervisor, Film Monitoring badges may be placed at various Work Stations to determine the depth of contamination at these specific points.
14. Spare Film Badges shall be maintained for use by approved visitors to Restricted Area.
 - 14.1. Such Badges shall be issued by the Area Supervisor, who shall enter in Log Book Badge number, Date of Issue, hour, period and person to whom Badge is issued.
 - 14.2. The issue of such a Badge shall Freeze that Badge for the Control Period.
15. Any period during which the Restricted Area sign to the work area is "covered" (indicating no Ionizing Radiation is present), Fenwal personnel may enter area to do maintenance work without need for Monitor Badge.
16. Film supplied and evaluated by:

Landauer Co.
Glenwood Science Park
2 Science Rd.
Glenwood, IL 60425
(312) 755-7000

POLICY IR - 101

Section No. 7
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NEW OR REVISIONS TO MANUFACTURE/TEST AREAS

1. Plans for any new radioactive installation or for changes in any existing installation should be checked and approved by the Radiation Safety Officer to determine whether the proposed radioactive safety features are adequate. The approved plans shall be maintained/filed.
2. Approval of Plans: Before any new installation is placed in operation, a survey shall be made by the Radiation Safety Officer to:
 - 2.1. Classify the installation/area.
 - 2.2. Determine whether the radiation exposure is within the limits set forth above.
3. Survey of New Installation: When changes are made in any existing installation, or when any existing installation is moved to a new location, or when there are changes in the occupancy of adjacent space, a radiation survey shall be carried out to ascertain that no new hazards have been introduced.
4. Report on Survey: No existing radioactive installation shall be assumed to conform with the provisions of this Standard unless a radiation survey has been made and a report to this effect has been placed on file.
5. Elimination of Hazards: The radiation hazards which may be found in the course of a survey shall be promptly eliminated. Equipment or area affected shall not be used until corrections have been made.
6. Filing of Survey Reports: Reports on all radiation surveys shall be filed together with a record of the action taken with respect to the recommendations they contain.

Section No. 8 Rev No. B
Issue Date 4/11/88 Approved JPO

RADIATION SURVEY PROCEDURES - MANUFACTURING AREAS

The survey of Manufacturing areas shall include the following:

1. Installation Inspection: The installation/area shall be inspected to see that it conforms with the plans and specifications therefor relating to radiation protection.
2. Installation Area Inspection: The neighborhood of the installation should be examined in order to determine whether radiation hazards exist.
3. Operating Technique: Study shall be made of operating technique, insofar as it affects radiation hazards.
4. Dosage Rate in Occupied Regions: Dosage rate of radioactive sources shall be measured in each region permitted to be occupied.
 - 4.1. Installation measurements of dosage rate shall be made with the maximum number/controlled radioactive sources in the area.
 - 4.2. A study shall be made of radiation monitoring technique to determine what methods shall be followed.
5. Monthly Radiation Survey shall be made of all radioactive areas using the approved radiation detection instrument.
 - 5.1. Radiation surveys shall be conducted following all maintenance checks and repairs made or change in manufacturing process.
 - 5.2. The results of all Radiation Surveys shall be noted in the Radiation Safety Officer's log book.
 - 5.3. All surveys which indicate radiation leakage in excess of the allowable limits shall be brought immediately to the attention of the Quality Control Manager.

Section No. 9 Rev No. B
 Issue Date 4/11/88 Approved off

WIPE TEST - CONTAMINATION CONTROL

Introduction

Quantitative measurements of surface contamination are difficult because of unknown factors such as self-absorption, geometry, and depths of penetration. However, estimates made by counting Wipes furnish useful information and should be made in order to prevent personnel contamination and to check the spread of contamination. Systematic investigations show that the amount wiped off during Wipe Study is in proportion to the initial activity on the work surface. Normally the fraction removed by the Wipe ranges from 1 to 10% of initial activity.

Procedure

1. All bench and other work surfaces in the Restricted Area and at random in other Manufacturing and Test areas shall be wiped once each week with an absorbant material.
2. Whatman No. 40 filters of 4.25 cm diameter shall be used to collect sample.
3. Wipe the designated area using light pressure with finger tips; wipe an area of about 100 cm squared.
4. Place the Wipe in a clean envelope and identify it as to location and date.
5. Count the Wipe in a fixed geometry using the Ludlum Scintillation Count Rate Meter.
6. Calculate the total disintegration per min/100 cm squared using the following formula:

$$\text{dpm/100 cm}^2 = \frac{\text{Net counts/minute}}{\text{Efficiency}}$$

$$241 \text{ Am Efficiency} = 0.14$$

$$226 \text{ Ra Efficiency} = 0.22$$

7. Contamination shall not be allowed to exceed the safe operating limits as specified under Section 4 of this manual.
8. If contamination exceeds established limits, all personnel

will vacate the area until decontamination of the area has been completed and a resurvey has indicated that the area has been thoroughly cleaned and is again safe to work in.

9. Any Wipe greater than 100 dpm/cm squared shall be brought to the attention of the Quality Control Manager and the Wipe shall then be sent to our consultant for analysis.

Murray Bolton
MIT - Room 20B-238
77 Massachusetts Avenue
Cambridge, MA 02139

10. A Radiation dosage history/log book shall be maintained. If at any time contamination has shown levels in excess of established limits, logbook shall detail TOTAL action taken.
11. Each Quarter in January, April, July, and October, a second set of Wipes is to be taken, sealed in clean envelopes and identified as to location and date of Wipe. They shall then be sent to Fenwal's Radiation Consultant (Mr. M. Bolton). Radiation Consultant will analyze Wipes and issue a report covering observations and recommendations on action to be taken.

Section No. 10 Rev No. B
Issue Date 4/11/88 Approved JPA

MAXIMUM PERMISSIBLE EXPOSURE

1. The exposure of persons to internal and external ionizing radiation shall always be kept at the lowest practicable level.
2. Except as provided below, no employer shall suffer or permit an employee to receive in the course of his work a dose from radiation sources outside the body greater than those specified in Section 4, paragraph 3.2.2.
3. Rates of radiation dose to the tissues of the body from radioactive materials within the body shall be controlled by limiting the average rates at which radioactive materials are taken into the body by inhalation, ingestion or otherwise. No employer shall suffer or permit an employee to work in an atmosphere where the concentration of airborne radioactive materials averaged over 7 consecutive days exceeds a level which, if inhaled continuously during a calendar quarter work period, will result in an effective radiation exposure to the body or any organ thereof greater than the amount specified in Section 4, in paragraph 3.2.2., unless the employee is supplied with, and required to use, appropriate protective equipment.
4. When employees are exposed to radiation from both external and internal sources, either simultaneously or successively, the aggregate dose to any organ shall not exceed 100 percent of the pro-rated amounts in paragraphs 2 and 3.
5. Notwithstanding the provisions of 2, 3, and 4, an employer may, during any calendar quarter, suffer and permit an employee over 18 years of age to receive a quarterly dose greater than a permissible quarterly dose subject to the following requirements:
 - 5.1. During any calendar quarter a dose to the whole body from sources of radiation in the employer's possession, shall not exceed 3 rems; and
 - 5.2. The dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed 5 (N-18) rems where "N" equals the individual's age in years at his last birthday; and
 - 5.3. The employer has determined the individual's accumulated occupational dose and records of such determination are available for inspection by representatives of the Department.
6. Radiation Outside Control Area: The employer shall shield, isolate, protect or otherwise arrange and control every source so that the absorbed dose received by an individual outside the installation cannot exceed 10% of the limits specified above.

Section No. 11 Rev No. B
Issue Date 4/11/88 Approved JPO

MANUFACTURING PLAN

Restricted Area

The restricted area (see Section 12) will be isolated from other Fenwal manufacturing area. Access to this area will be limited to a restricted number of employees over 18 years of age who have been specifically trained under the direction of the Radiation Safety Officer in the precautions and safety requirements for the handling of radioactive sources.

All employees entering the restricted area will be required to wear film badges for such period of time that they remain in the area. Badges for applicable employees will be conspicuously stored outside the entrance to the area. At this same location, a bulletin board will be used to post all applicable documents for employee perusal which relate to the requirements, procedures, precautions, and restrictions of the restricted area and operations therein. A regulation sign will be posted on the door to identify this as a radiation control area.

The manufacturing supervisor of this area will insure that all activities within the area are carried out in accordance with this plan.

Radioactive sources as received and accepted from outside licensed suppliers will be stored in shielded cannisters (1000uci per cannister maximum). Shielded cannisters will be stored in a locked cabinet within the restricted area. Access to the locked cabinet will be controlled by the area supervisor. A sign will be posted on the door identifying the presence of radioactive materials.

As production lots are removed from the cabinet for assembly into products, they will be counted and the inventory log book updated to reflect date, quantity of issue, and factory order number. Issues will be made on a first-in, first-out basis and requirements integrated with Fenwal inventory management programs for control of further procurement.

Sources which have not been assembled into products will be returned to the locked cabinet at the end of each work day.

Sub-Assembly

A printed wiring board sub-assembly containing all the associated electronics, less the radioactive sources will be manufactured,

inspected, and tested in a non-restricted area. These sub-assemblies will be delivered to the restricted area in factory order lots where the sources will be added.

Radioactive sources will be assembled into chambers, chambers assembled to the printed wiring board sub-assemblies, and inspected for workmanship. A metallic enclosure will then be added which will limit the accessibility to the radioactive chambers and complete the assembly activities in the restricted area.

Final Assembly

Completed printed wiring board assemblies will be issued from the restricted area in factory order lots to the non-restricted final assembly area. Here they will be installed in housings, labeled and finally tested per Engineering Specifications, and tested to Quality Control standards. Any rework which requires the removal of the chamber enclosure will be accomplished back in the restricted area.

Finished units will be individually packaged in cardboard cartons. Cartons will be labeled in the prescribed manner and finally stored in a secured section of the finished goods inventory warehouse. Here they will be logged in against their respective factory order numbers and logged out against specific sales order numbers which are traceable to a customer.

Section No. 13 Rev No. B
Issue Date 4/11/88 Approved JPO**TRAINING PROGRAM****1. Procedural Safeguards**

All employees and visitors who enter a controlled area shall be informed of the pertinent requirements and procedures for the protection of themselves and their colleagues against internal and external exposure.

2. Outline of Training Program

- 2.1. Principles and practices of radiation safety.
- 2.2. Radiation measurements, standardization, monitoring techniques, and instruments.
- 2.3. Math. and calculations basic to the use and measurement of radiation.
- 2.4. Biological effects of radiation.
- 2.5. Handling and use of radiation commensurate with types and quantities to be used.
- 2.6. Who is trained, duration of training, periodic retraining.

3. Training - General

- 3.1. General rules and instructions should be written in sufficient detail to handle the radioisotope hazards and should be made available to all employees. There should be a current listing of the supervisor or other persons assigned responsibility for radiation protection and persons to be contacted in various emergencies. Floor plans and drawings of all facilities handling dangerous amounts of radioactive materials should be filed outside the plant. This information should be readily available in case of a fire or an explosion which makes an immediate on-the-spot study of the area impossible.
- 3.2. For repetitive work with radioisotopes, the standard operating procedures should be prepared in writing. They may be incorporated with work procedures and other safety rules. Written instructions aid understanding and compliance. They indicate changes needed due to unforeseen hazards.

3.3. When non-repetitive work or special jobs having unusual hazards must be performed, a careful job-hazard analysis should be made by responsible individuals. Relevant operating procedures should be prepared in writing. Each worker should understand these requirements and should be expected to comply with them during work. The instructions should describe and limit the work to be done; specify necessary personnel monitoring equipment, protective clothing and respiratory protection; state the maximum average radiation survey readings and exposure-time limits. If the readings and limits are not known, the work should not be started until a survey is made; and, if necessary, continuous or intermittent monitoring should be performed. Personnel should be continually informed of these readings and limits during the work to prevent over-exposure. Brief instructions to deal with emergencies should be provided. Instructions should specify any check-out requirements for leaving the area. These instructions would include personal contamination surveys, removal of contaminated clothing, etc.

Section No. 14 Rev No. B
Issue Date 4/11/88 Approved gpa

PROCUREMENT

The sealed radioactive sources will be procured from licensed manufacturers and/or distributors in accordance with Fenwal Engineering Specifications (06-128211-002, 06-233171-001). They will be procured for quantity deliveries in accordance with planned production schedules in order to minimize the inventory on hand at any one time. This quantity will be controlled at a level not to exceed three months supply.

Purchase Order shall specify quantity, method of packaging, method of shipment, method of outer carton identification and other precautionary information as required by law. Labels shall be as described and illustrated in Handbook of Federal Regulations, Transportation of Radioactive Materials, Part 73.

Section No. 15 Rev No. B
Issue Date 4/11/88 Approved fpo

RECEIVING - INSPECTION OF RADIATION SOURCES

Receiving

1. Radioactive Sources as received from Licensed Suppliers will be received in Shielded Cannisters (maximum of 100 uci per cannisters). Cannister will have suitable identification and will be accompanied by standard Shipping forms that will relate to Purchase Order as released by Ferwal's Purchasing Department.
2. The Receiving Clerk will match up the Shipping documents with the Purchase Order and forward all items to the "Restricted Area".
3. Receiving personnel will not open the package/parcel/cannister.

Inspection

1. Inspector will count, inspect, test and match energy potential per Ferwal specifications to verify compliance to the specifications and Invoice quantity before official acceptance is made.
2. Accepted material shall be placed in vault. Quantities accepted will be entered in the inventory log book against Part Number, Purchase Order Number, and date received.
3. Rejected material will be repackaged in prescribed manner and shall be returned to the Vendor. While awaiting shipping authorization, the rejection material will be retained in the vault.
4. A copy of the Receiving Ticket will be forwarded to Purchasing for means of notification of accept/reject quantities.

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Section No. 16 Rev No. B
Issue Date 4/11/88 Approved gfo

SEALED SOURCES

1. Sealed Sources shall be tested for leakage before being put into use.
2. They shall be retested at six month intervals thereafter unless exempted by the Commissioner.
3. If found to leak, the Sealed Source shall be withdrawn and disposed of in accordance with Section 18.

Section No. 17 Rev No. B
Issue Date 4/11/88 Approved JPO

STORAGE OF RADIOACTIVE MATERIAL

1. Radioactive material not in use shall be stored in properly labeled and shielded containers secured against unauthorized access or removal.
2. Vaults used for storing radioactive materials shall be suitably ventilated.
3. Storage containers for radioactive materials shall be structurally sound with due regard to corrosion, radiation, and temperature effects that may develop.
4. An inventory card shall be available to control the maximum material to be issued, person who withdraws same, and date.
5. Unused material returned at end of working period shall be entered on inventory card and placed in locked storage container /vault.
6. Storage vault will be kept locked at all times.
7. TOTAL accountability is required at ALL times for Hazardous materials. These relate to the Radium Source Assembly (Source on Stud), and the Source Assembly in Chamber. Once Chamber is assembled to the Printed Circuit Board, normal manufacturing controls will prevail.
8. Keys to vault will be held by:
 - 8.1. Area Supervisor
 - 8.2. Master Key File

Section No. 18 Rev No. B
Issue Date 4/11/88 Approved 400

WASTE DISPOSAL

1. Waste - Radiation Sources

- 1.1. All waste, rejected Sources, etc. will be retained in a Waste Container that is located in the Manufacturing (Restricted) area.
- 1.2. Container will be identified on the outside with words "Radiation Waste" and will be supplied with a lock. Container shall be kept locked at all times. Key to be held by area Supervisor.
NOTE: This waste container may be held in Radiation Storage Vault if there is sufficient room in vault.
- 1.3. An Inventory Card shall be attached to, or retained inside of Waste Container. No additions to or withdrawal from the Container are to be made unless reflected on Inventory Card.
- 1.4. Disposal will be made by turning material over to a qualified/approved waste disposal company at intervals to insure an accumulation of waste material does not develop.
- 1.5. Material to be disposed of will be held in Containers until proper shipping instructions have been cleared.
- 1.6. Material shall be released for disposal only in prescribed Containers and with proper identification.

2. Waste - Cleaning Material

- 2.1. Wiping cloths, rags, towelettes, etc. shall be placed in a waste receptacle separate from regular Manufacturing waste and debris.
- 2.2. Container shall be suitably marked on the outside.
- 2.3. Materials retained shall be kept separately and delivered to local Incinerator.

WASTE MATERIAL DISPOSAL

All waste, rejected sources etc., shall be retained in a waste container in the Controlled Restricted Area. Container to be labelled with words "Radiation Waste." Container to be locked at all times.

Disposal of rejected sources shall be completed by original vendor. Certification of disposal shall be submitted by vendor to Fenwal Incorporated, Division of Walter Kidde for record filing maintained by the Radiation Control Officer. All shipments of disposed material must conform to recommended Department of Transportation regulations.

Section No. 19 Rev No. B
Issue Date 4/11/88 Approved gpo

REPAIRS

1. Defective Shield or barriers, Storage Vaults, tool, jigs, fixtures, etc. used to process sub-assemblies for Sources shall be promptly repaired.
2. Following each repair, the Radiation Safety Officer shall check out System to insure that repairs are adequate and that the original degree of protection has been restored.
3. If it is then found that the repairs are inadequate, and that no easy solution is at hand, then a qualified expert shall be consulted.
4. Radiation Safety Officer shall maintain a Log book on Repairs which will fully define the problem, the solution, corrective action taken, the date of that action and its effect.

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X-RAY LABORATORY

Sub - Section

- A. Safety Standards
- B. Operating Procedure
- C. Radiographic and Flourosopic Technique
- D. Routine Maintenance

X-RAY LABORATORY SAFETY STANDARDS

The purpose of this bulletin is to establish safety standards for X-ray personnel and visitors.

1. The X-ray Laboratory is a restricted area.
2. The Chief X-ray Laboratory Technician is completely responsible for the safety of the X-ray personnel and/or any visitors entering the laboratory.
3. The main control switch must be turned off in the event of visitors entering the X-ray Laboratory.
 - 3.1. The X-ray machine may be turned on for demonstration purposes only on the approval of the Chief X-ray Laboratory Technician and if all visitors are provided "control badges" and given safety precautions.
4. In the event of operating failure of the transformer, transformer cables and all electrical units, the electrical department shall be notified immediately.
 - 4.1. In the event of failure of the X-ray tube a qualified X-ray repair man shall be notified and necessary repairs are to be made.
5. Energizing of the X-ray tube shall be done by means of the Master Control only. The use of the sliding door and safety interlocks to energize the X-ray system is forbidden.
6. All minor repairs shall be carried out by/or under the supervision of the Chief X-ray Laboratory Technician.
7. The safety gate on the X-ray Laboratory door shall be fully opened before any work is put into or taken out of the X-ray cabinet.
8. In the event that all X-ray Laboratory personnel leave the X-ray Laboratory, or at the conclusion of the day's operation, the main control switch must be turned off and locked.
9. Radiation Film badges shall be assigned and worn at all times by employees designated to operate the X-ray equipment.
 - 9.1. All employees shall be given the identical badge each week as assigned by the Quality Control Office.
 - 9.2. Badges shall be worn for a four week period. At the end of

each period all badges shall be returned to the vendor by Quality Control Office Secretary.

10. A monthly radiation survey shall be made of all X-ray equipment using the Radector Detection Meter.
 - 10.1. Additional radiation surveys shall be conducted following all maintenance checks or repairs to the X-ray equipment.
 - 10.2. Copies of monthly radiation survey report shall be kept on file by the Chief X-ray Laboratory Technician and one copy forwarded to Radiation Safety Officer.
 - 10.3. Records relating to all Film badges shall be analyzed and maintained by the clinic.

X-RAY LABORATORY - OPERATING PROCEDURE

The process of this bulletin is to establish and maintain a standard operation procedure for the X-ray Laboratory.

1. Certification

- 1.1. In compliance with applicable specification requirement, the X-ray Department is certified under Specification MIL-STD-453 by DCASR (Boston Region).
- 1.2. All radiographic inspection shall comply with the special Systems Review Check List A of AMCM-74-21.
- 1.3. Recertification shall be performed every six months.

2. Analysis of Material

- 2.1. The X-ray Laboratory shall sample test to MIL-STD-105, or subject lots to 100% inspection at the discretion of the X-ray Laboratory Supervisor based on process average studies.
- 2.2. All repairable rejected material shall be green tagged and returned to the manufacturing Department for rework.
- 2.3. All rejected material that cannot be salvaged must be destroyed by the X-ray Department and a scrap ticket, Form D101 be made out.
- 2.4. All material that has been reworked shall be returned to the X-ray Department for re-examination.
- 2.5. The Production Planning division shall be notified on all rejections.
- 2.6. All radiographs indicating production rejections shall be routed to the specific departments for review by the foreman and the Production personnel involved.

3. Recording and Filing System

- 3.1. All material received by the X-ray Department shall be properly identified to include customer's name, order or project number, quantity of material and manufacturing department.
- 3.2. The identification number of each radiograph shall start with the number one for the first examination conducted at

the beginning of each year. For example, the first radiographic examination in 1975 shall be 75-1. The numbers shall then run in consecutive order for the remainder of the year.

3.3. A daily log book shall be used containing all information as mentioned in Section 3.1.

3.4. All radiographs shall be identified by the use of the standard lead marker.

3.5. All radiographs shall be filed in the standard 10" x 12" size envelopes and filed in numerical order.

4. Customer Returns

4.1. All customer returns received by the X-ray Department shall be fluoroscoped or, when specified, radiographed.

4.2. All discrepancies noted on radiographs of customer returns shall be identified with all-purpose pencil and returned to the Quality Control Laboratory Customer Return Technician for his analysis.

4.3. All radiographs of customer returns shall be kept on file in the Quality Control Laboratory with the laboratory copy of the customer return report.

5. Diagnosis of X-ray Film

5.1. All radiographs shall be reviewed by the X-ray Laboratory Technician in charge.

5.2. All deviations from specifications observed on radiographs shall be marked using all-purpose pencil to indicate the area or areas in question.

5.3. Film shall be routed to the test technician involved for his review.

6. Subcontracts

6.1. All subcontract work shall be cleared through the Sales Department.

6.2. Time consumed on subcontract work shall be entered on the Sales order and signed by the X-ray Laboratory Technician in charge, then sent on to the Accounting Department.

6.3. At the completion of all subcontract examinations, the material and films shall be returned to the Sales Department for proper disposition.

X-RAY LABORATORY - RADIOGRAPHIC AND FLUOROSCOPIC TECHNIQUE

The purpose of this bulletin is to establish a procedure for recording radiographic and flourescopic techniques.

1. Fluoroscopy and Radiography

- 1.1. The operation of the X-ray machine for either fluoroscopic or radiographic purposes shall not exceed 140 kilovolts at 9 milliamperes.
- 1.2. The valued mentioned in 1.1. are for continuous operation.
- 1.3. A chart is to be posted on each X-ray machine for guidance with intermittent use of peak kilovoltages.
- 1.4. Peak kilovoltage shall be used only when deemed necessary in accordance with the tube rating chart.

2. Technique Records

- 2.1. A card index file shall be kept in the X-ray Laboratory listing the various techniques used in the laboratory on the various product Codes.
 - 2.2. Whenever a new technique is established a new card shall be made out and filed as indicated in 2.1.
3. All film shall be properly identified and filed for future use after circulating to persons concerned for their review.
 4. Acceptance of material processed shall be indicated on Form D-185.

X-RAY LABORATORY - ROUTINE MAINTENANCE

The purpose of this bulletin is to establish the basic items in the X-ray Laboratory equipment requiring routine maintenance.

All power shall be locked in the OFF position during inspection and maintenance.

Inspection and maintenance intervals shall be made bi-monthly and shall be performed at more frequent intervals as required.

1. Control Console

1.1. All terminals, wiring and components shall be inspected for security, clearance and safe operation.

1.1.1. Since the control panel must be removed to examine the console, all leads should be checked and redressed for proper clearance on re-assembly.

1.2. Contacts on the master relay shall be cleaned and dressed and the closing sequence adjusted.

1.2.1. Excessively pitted and worn contacts shall be replaced.

1.3. External cables between the console and other units shall be checked for abrasion and wear, particularly where such cable enters the console and other units.

1.3.1. Broken insulation shall be repaired and damaged cables replaced.

2. Cabinet and Tube Housing

2.1. All safety interlock micro-switches shall be inspected for proper operation. Associated wiring shall be inspected for security.

2.2. Cabinet door limit micro-switches and wiring shall be inspected and tested for positive operation.

2.2.1. Micro-switch actuator blades shall be adjusted for proper action.

2.3. Door motor, gearing, and door transport chains shall be inspected for wear and security.

2.3.1. Motor lubrication shall be performed in accord with

the manufacturer's instructions.

2.3.2. Chain lubrication - excess lubricant shall be removed from the chain with a cloth.

3. X-ray Tube Housing and Connections

- 3.1. Tube housing retaining screws, etc. shall be checked for security.
- 3.2. Tube conveyor system shall be checked for proper adjustment.
- 3.3. Power connections to the tube shall be examined for burning, cleaned, and re-secured.
- 3.4. Power cables shall be dressed for minimum contact at point of entry into housing and examined for wear.
- 3.5. Water connections shall be checked for leaks and the drip tape replaced.

4. On completion of internal inspection and maintenance of the Cabinet, the panels shall be replaced and all retaining screws double checked for tightness.

5. Dark Room Equipment

5.1. Routine film dryer maintenance shall include motor lubrication and examination of all moving parts for wear.

6. General items included in routine maintenance

- 6.1. Water connections, tanks, and electrical parts of the film processing unit shall be tested for proper operation.
- 6.2. Stainless steel parts or sections of the processing unit shall be waxed or otherwise protected.
- 6.3. Electrical or plumbing defects shall be reported immediately and handled in accordance with established Fenwal policy.

7. Appropriate records or check sheets shall be maintained to indicate date of inspection, repairs or replacements made and the extent of the inspection and maintenance performed.

8. Inspection maintenance dates shall be entered in the Laboratory log.

9. On completion of routine or emergency maintenance, the X-ray equipment shall not be allowed to be put into production use until tested and passed as safe by examination of the equipment, the maintenance performed and a complete check of the assembly for radiation leakage with a Geiger Counter with tube operating at maximum voltage.

This test shall always be conducted by the Radiation Safety Officer.

STANDARD OPERATING PROCEDURE NO. 4.2.

FENWAL INCORPORATED QUALITY ASSURANCE DEPARTMENT

Radiographic and Fluoroscopic Operation

The purpose of this bulletin is to establish a procedure for processing of products through the X-ray Laboratory, and to provide basic policy for performing Fluoroscopic and Radiographic analysis.

1. Equipment Operation

- 1.1. During continuous operation, the X-ray machine shall not be operated in excess of 140 kilovolts at 5 milliamperes for either Fluoroscopic or Radiographic processing.
- 1.2. Peak kilovolts shall be used only when deemed absolutely necessary.

2. Technique Records

- 2.1. A card file shall be kept in the X-ray Laboratory listing the techniques to be used on the various standard products processed.
- 2.2. When a new technique is established, a new card shall be prepared covering the specific product.

3. All film shall be properly identified by code number and date of processing. A log book shall be maintained for easy reference.
4. All products shall be processed through the X-ray Laboratory for analysis.
5. New products, or the initial production run of a new product, shall be 100% filmed in order to fully evaluate the item and the effect of new assembly tooling, operator training, etc.
6. As production warrants, products shall be handled in accordance with MIL-STD-105 Sampling Tables.
7. Fluoroscopic methods shall be used whenever possible. If items that have been fluoroscoped are found to be defective or are questionable, they shall be filmed.
8. Defective products and film shall be forwarded to the Manufacturing Department in which they were made and shall be used for Corrective Action, film shall be returned to the X-ray Laboratory.

9. Film of production items shall be retained for a period of 5 years. Film of new products, problem investigation, etc. shall be kept indefinitely.

10. Personnel

10.1. Vision - X-ray Technician

- A. Distant vision shall equal 20/30 in at least one eye, either corrected or uncorrected.
- B. Near vision shall be such that the operator can read Jaeger type No. 2 at a distance of 12 inches, either corrected or uncorrected.
- C. Tests to determine vision of the operator shall be performed yearly with records of performance held in Clinic. Supervisor of X-ray Laboratory shall be informed of any problems that occur.

10.2. Health and Safety

- A. Fenwal Incorporated "Rules and Regulations for the Protection of the Health and Safety of Personnel" dated May 12, 1975.
- B. Commonwealth of Massachusetts, Department of Public Health "Rules and Regulations to Control Radiation Hazards", Section 5B, Chapter 111, General Laws.
- C. American Standards Association "Safety Code for the Industrial Use of X-rays" No. Z54.1-1963.
- D. Moore and McDonald's "Safety for X-ray Diffraction and Spectrographic Equipment" No. MORP-68-14.

11. The overall administration and operation of the X-ray Laboratory shall be in accordance with details outlined under MIL-STD-453.

Section No. 21 Rev No. B
Issue Date 4/11/88 Approved feo

NOTIFICATION OF INCIDENTS

1. Investigations

- 1.1. Overexposures, serious accidents and spills of radioactive materials should be investigated impartially to correct, control or eliminate hazardous conditions. Such investigations may indicate defects in previously accepted procedures or equipment so that corrective action may be taken immediately.
- 1.2. The data obtained from such an investigation should be written in detail and made a part of the exposure record of each individual involved. Such information is frequently useful in reviewing the capabilities of individuals for handling radioactive materials, for assessing their total exposure history and for interpreting results from later measurements of excreta.

2. Notification

- 2.1. Radiation Safety Officer shall notify the Commissioner within twenty-four hours by telephone, or telegraph, and shall make an immediate report in writing of any incident involving sources of radiation under his administrative control which may have caused, or threatens to cause:
 - 2.1.1. An exposure to the whole body of any individual to 5 rems or more of radiation; exposure to the skin of the whole body of any individual of 30 rems or more of radiation; or exposure to the feet, ankles, hands, or forearms to 75 rems or more of radiation.
 - 2.1.2. The release of radioactive material in concentrations which if averaged over twenty-four hours would exceed 500 times limits established.
- 2.2. Radiation Safety Officer shall notify the Commissioner within twenty-four hours, by telephone or telegraph, and shall make an immediate report, in writing, of:
 - 2.2.1. The loss or theft of any source of ionizing radiation.
 - 2.2.2. Fires, explosions or other accidents where it is known or believed that radioactive material has

been involved.

- 2.3. Radiation Safety Officer shall make a report, in writing, to the Commissioner within seven days of:
 - 2.3.1. Any additions or removals of sources of ionizing radiation which would alter the inventory of sources recorded on the registration.
 - 2.3.2. Any changes or modification of installations, safety devices, work rules or operating conditions dose of employees.
- 2.4. Radiation Safety Officer shall make a report in writing to the Commissioner within thirty days of each exposure of an individual to radiation or concentrations of radioactive materials in excess of applicable limits as given in appropriate sections and appendices referring to permissible exposure or concentrations in air.
- 2.5. Each report required shall describe the extent of exposure of persons to radiation or to radioactive materials; levels of radiation and concentrations of radioactive material involved; the cause of the exposure, levels or concentrations and corrective steps taken or planned to assure against a recurrence.
- 2.6. Personnel in question of overexposure shall not be permitted in the radioactive areas until definite results are established. Findings and any corrective steps that are required shall be written up and attached to original laboratory report.

Section No. 22 Rev No. B
Issue Date 4/11/88 Approved JPO

RECORDS

1. All records required in this Standard shall be kept on file for the duration of employment of the individual concerned or for five years following termination.
2. A record shall be kept of all data pertaining to radiation monitoring. The records shall include both monitor films or dosage meter readings and shall be adequate to indicate whether the permissible daily dose has been exceeded for the employee in question, in which case there shall be noted in the record the special conditions under which the overexposure occurred, the cause to which it is attributed, and the corrective action taken.

JOB DESCRIPTION

TITLE: Radiation Safety Officer

1. **Function:** The primary function of the Radiation Safety Officer is to insure that all ionizing radiation safety procedures are initiated and maintained as specified in:
 - a. U.S Nuclear Regulatory Commission "Rules and Regulations", Title 10, Chapter 1, Code of Federal Regulations.
 - b. The Commonwealth of Massachusetts Department of Labor and Industries Bulletin No. 5, "Rules and Regulations for the Protection of the Health and Safety of Employees from Occupational Diseases caused by Ionizing Radiation."
 - c. Fenwal Incorporated Policy No. IR 101. "Ionizing Radiation, Rules and Regulations for the Protection of the Health and Safety of Personnel."
2. **Activities:** The Radiation Safety Officer performs various ionizing radiation surveys, sends tests to approved agencies, and monitors the test results. He updates Fenwal regulations to new radiation regulatory agency requirements. He monitors and enforces compliance with Fenwal Ionizing Radiation Policy. He oversees periodic calibration and any necessary maintenance of ionizing radiation monitoring equipment. He files necessary reports with radiation regulatory agencies. He performs receiving inspection tests on incoming ionizing radiation and insures that radioactive waste is properly packaged and returned to the vendor for disposal. He keeps complete records of all ionizing radiation program activities, including all test results, and reviews them as necessary with agency auditors.
3. **Responsibility and Authority:** The Radiation Safety Officer is responsible for:
 - a. Daily inspection of assembly and restricted areas for compliance with required ionizing radiation handling and hygienic procedures.
 - b. Weekly performance of wipe tests in restricted and non-restricted areas, and maintenance of the associated records.
 - c. Quarterly submission of wipe tests to an outside consultant, and review and maintenance of test results.
 - d. Biweekly performance of instrument survey of all ionizing radiation areas, and maintenance of test result records.
 - e. Biannual submission of all ionizing radiation monitoring instruments to an approved outside agency for calibration.

- d. Biweekly performance of instrument survey of all ionizing radiation areas, and maintenance of test result records.
 - e. Biannual submission of all ionizing radiation monitoring instruments to an approved outside agency for calibration.
 - f. Annual submission of a report to the N.R.C. on total shipments of Smoke Detectors by Fenwal Incorporated containing Am-241 material (as specified on Fenwal's license).
 - g. Update the Fenwal Code of Regulations to N.R.C. supplements as received.
 - h. Review badge monitor survey results and maintain records.
 - i. Perform survey of x-ray lab equipment in regard to leakage. Maintain a record of results.
 - j. Insure compliance by Fenwal Clinic to biannual medical procedure requirements for employees on the radiation safety program.
 - k. Review procedures and records of the ionizing radiation program as necessary during in plant audits conducted by the U.S. Nuclear Regulatory Commission and the Department of Labor and Industries, Commonwealth of Massachusetts.
 - l. Performance of receiving inspection on ionizing radiation materials to Fenwal performance and assembly specifications.
 - m. Return to the vendor radioactive waste for disposal, and insuring that material is packaged on compliance with D.O.T. shipping regulations.
 - n. Maintenance of a complete file of the ionizing radiation program including any problems encountered.
 - o. Approval for any new radioactive installation or change to an old one.
 - p. Submission within the specified time any reports to the Commissioner which may be required.
4. General: The Radiation Safety Officer must have, by training and experience, sufficient knowledge of radiation problems and the control of health hazards to be able to dependably perform his duties and to keep adequate records. He should be a neat, careful, and organized person. He must have the ability to write a clear and concise report, express himself clearly, and act as advisor to the Safety Director, the Safety Hygienist, and all personnel involved in the ionizing radiation program at Fenwal.

April 19, 1988

John P. O'Leary - Radiation Safety Officer

Experience / Education

Bachelor of Science degree in Materials Science and Engineering from the Massachusetts Institute of Technology, June 1984.

Attended a week long course entitled "Occupational and Environmental Radiation Protection", given by the Harvard School of Public Health in March, 1988.

Employed at Fenwal since July, 1986 in the Quality Assurance Department.

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

PROGRAM CODE: 03214
STATUS CODE: 2
FEE CATEGORY: 3B
EXP. DATE: 19880531
FEE COMMENTS: ALWAYS

.....

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: FENVAL INCORPORATED
RECEIVED DATE: 380426
DOCKET NO: 3008866
CONTROL NO.: 108757
LICENSE NO.: 20-15285-01
ACTION TYPE: RENEWAL

2. FEE ATTACHED

AMOUNT: 460.00
CHECK NO.: 247958

3. COMMENTS

SIGNED BP
DATE 7/27/88

8. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1-1)

1. FEE CATEGORY AND AMOUNT: 3B \$460

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT -----
RENEWAL ✓ -----
LICENSE -----

3. OTHER -----

SIGNED J. Kimberley
DATE 8/8/88