NRC FORM 313
17-88
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 5-31-87

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.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

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

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

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
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, 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
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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 item)*

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Eastman Pharmaceuticals/Sterling Research Group
25 Great Valley Parkway
Great Valley, PA 19355

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

Off of Route 29 North from Route 202

25 Great Valley Parkway
Great Valley Corporate Center
Great Valley, PA

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

John Nicholson, Radiation Safety Officer

TELEPHONE NUMBER: 215-640-8734

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element 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. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY: 3.F

AMOUNT ENCLOSED: $ 230.00

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 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT 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	TYPED/PRINTED NAME	TITLE	DATE
Albert E Anderson	Dr. Albert E. Anderson	Health, Safefty, & Envir. Officer	7/21/88

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(dollar and/or staff 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)*

- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
APP	Aug. 20	3F	9001170159 881020 REG1 LIC30 37-28076-02 PDR	S. Kimberly
AMOUNT RECEIVED	CHECK NUMBER			DATE
$230	9925			8/31/88

"OFFICIAL RECORD COPY" 15 AUG 1988

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS FOR AECL GAMMACELL 40 IRRADIATOR

Item 5 - Material to be Possessed

1. Cesium - 137 will be the radionuclide in each of the sealed sources.

2. The manufacturer of the two sealed sources is Atomic Energy of Canada Limited. The two sources are Model C161 Type 8 doubly encapsulated sources.

3. The two sources have an activity of 1800 Ci $\pm$ 15% each. The maximum permissible activity per unit, in total, is 4200 Ci.

4. The irradiator is manufactured by Atomic Energy of Canada Limited. The model number is the Gammacell 40.

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS FOR AECL GAMMACELL 40 IRRADIATOR

Item 6 - Purpose for which the Licensed Material will be Used

The irradiator will be used to irradiate cells and mice. It will be used to produce irradiated feeder cells. Tissue culture cells will be grown and irradiated with 1000 to 2000 rads to prevent them from dividing. These cells will be used as a source of growth for other cultures. These cells would be irradiated one to two times per week. Mice will be irradiated with 200 - 300 rads. About ten mice will be irradiated every other week for several months two to three times a year.

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS FOR AECL GAMMACELL 40 IRRADIATOR

Item 7 - individuals Responsible for Radiation Safety Program
Their training and Experience

CURRICULUM VITA JOHN J. NICHOLSON, RSO

Eastman Pharmaceuticals
25 Great Valley Parkway
Great Valley, PA 19355

(215)640-8734

EDUCATION:

B.S., Biology/Education
State University of New York at Buffalo, 1979

B.S., Nuclear Medicine/Radiation Science
State University of New York at Buffalo, 1983

M.S., Radiation Science
State University of New York at Buffalo, 1987

WORK EXPERIENCE:

1983-1988 State University of New York at Buffalo
School of Medicine
Health Physics Office

Assigned as Associate Health Physicist at the SUNY Health Physics Office. The broad scope program included eleven affiliated and associated hospitals in the western New York area. The office was responsible for the radiation protection program for the nuclear medicine clinics, clinical diagnostic labs and the research labs at the hospitals. The program was licensed by both the New York State Department of Health and the Nuclear Regulatory Commission.

This program has over 220 authorized users and over 750 secondary users. The principal radionuclides used in these labs were H-3, C-14, S-35, P-32, Cr-51 and I-125. In the nuclear medicine clinics, Tc-99m, I-131, Ga-67 and Tl-201 were utilized. The licensed amount was 500 mCi for all isotopes except H-3 (3000 mCi) and C-14 (1000 mCi).

Major responsibilities have included the following:

- Performing laboratory inspections on a semi-annual basis, checking compliance with state and federal regulations.

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS FOR AECL GAMMACELL 40 IRRADIATOR

(Item 7 Continued)

- Teaching a Radiation Safety/Radiation Biology course to the students in the Nuclear Medicine Technology program, 1 semester, 2 credit hours.

- Teaching a basic Radiation Safety course to new research personnel, 10 hours.

- Calibrating various survey meter equipment, including GM meters, ionization meters, pocket dosimeters using sealed Cs-137 calibration sources, up to 100 mCi.

- Conducting thyroid bioassays using a NaI well and MCA and urine bioassays by LSC methods.

- Evaluating personnel external radiation exposure using film, TLD and pocket ionization dosimeters.

- Performing swipe surveys of all labs and clinics and performing all the routine sample preparation and counting. The counting instruments included an NaI well with an MCA, an LSC and an automatic gamma counter.

- Handling radioactive waste generated. Waste was sampled and analyzed and handled either on site by incineration or sanitary sewer, or repackaged, compacted and shipped out by a private waste broker.

- Performing leak tests of sealed sources, including Cs-137, Ni-63 and Ra-226 up to 100 mCi.

- Conducting and maintaining inventory records of radioactive material purchased by the research labs.

- Assisting state and federal officials during inspections of the facilities.

- Checking the air flow of chemical fume hoods to be used for I-125 iodination procedures to ensure that the hoods are operating properly and at proper flow levels.

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS FOR AECL GAMMACELL 40 IRRADIATOR

(Item 7 Continued)

- Reviewing applications for new users and new research protocols.

- Obtaining air samples from hoods during iodination procedures to evaluate amount of I-125 released. Charcoal cartridges were counted and amount of activity calculated.

- Developing new radiation safety procedures or amending existing ones as situations or regulations changed.

- Evaluated ash and water samples from the incinerator to check for residual radioactivity.

Thesis title: Eye Dosimetry of Radiopharmacy Personnel Using Thermoluminescent Dosimeter Chips, August, 1987.

The dose to the eyes of radiopharmacy workers was found by using safety goggle frames and TLD chips. These workers handle several hundreds of mCi of gamma-emitting radionuclides every day. A TLD chip reader was used.

PROFESSIONAL ORGANIZATIONS: Health Physics Society
Campus Radiation Safety Officer Organization

SUMMARY: John Nicholson's experience in irradiator use is limited to having performed leak and safety checks on a Gammacell 40 unit at Roswell Park Memorial Institute Buffalo, NY. During graduate work at the University of Buffalo, he attended a laboratory session on the use of operations of this unit. In addition, Mr. Nicholson will attend the training session on the operation and maintenance of the Gammacell 40 conducted by AECL personnel during the two day installation period. This training session will be at least eight hours in duration with four hours being direct hands-on instruction. (Curriculum Vita attached.) Currently, Mr. Nicholson is the Radiation Safety Officer at Eastman Pharmaceuticals under NRC license number 37-28076-01 and PA-DER license PA-531.

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS FOR AECL GAMMACELL 40 IRRADIATOR

(Item 7 Continued)

The senior research scientist authorized to supervise the use and operation of the irradiator will be Dr. Adele Vessey, Ph.D. Dr. Vessey has used a similar irradiator, the J.L. Sheperd Model 81-14, at the University of Rochester, prior to joining Eastman Pharmaceuticals. She used the irradiator for research purposes on a regular basis from April 1981 to August 1986. This 6,000 Ci Cs-137 unit was used to irradiate cell cultures and small animals.

Dr. Vessey's training in radiation safety includes the following:

1. 40-hour training course to Case Western Reserve University in Cleveland, Ohio in 1970.

2. 4-hour course at the Cleveland Clinic, Cleveland Ohio in 1976.

3. 4-hour course at the University of Rochester, Rochester N.Y. in 1985.

4. 4-hour session at Eastman Kodak, Rochester N.Y. in 1987.

5. 4-hour session at Eastman Pharmaceuticals, Great Valley PA., in 1987.

These courses included the following topics:

1. Fundamentals of radiation protection and safety practices.

2. Use of detection and measuring devices.

3. Calculations in measuring radioactivity.

4. Biological effects of radiation.

She will also be required to attend the training session conducted by AECL personnel during the two-day installation period.

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS FOR AECL GAMMACELL 40 IRRADIATOR

Item 8 - Training Provided to Other Users

1. At Eastman Pharmaceuticals, an initial ten-hour basic radiation safety course is required for all individuals who will be using radioactive material or operating radiation producing devices. An outline of the training program is attached. The safety course is divided into five sessions (Sections I - V in table of contents). Each session covers one section and is two hours in duration. During the final session, an hour long final exam is given.

   A copy of the final exam and an answer key are attached. A minimum grade of 75 is considered passing. Individuals who do not pass the exam are not allowed to work with radioactive materials. Individualized instruction by the RSO will be given to personnel failing the exam. They will be required to complete the problem sets after each chapter and review their answers with the RSO. Additional reference and reading material may be provided. After completing this remedial session, the individual will be allowed to take the exam again. This initial ten hour session will be conducted by John Nicholson.

   In addition to the basic radiation safety course, AECL will be providing a training session during the two-day installation period. This training session will be required for the RSO and all personnel planning to use the irradiator. AECL has indicated the following topics will be covered in at least a eight-hours total training session:

   Irradiator Design
   Safety Principles
   Safety Systems
   Source Production
   Transportation and Use
   Actual Hands-On Experience
   Emergency Procedures

   The on-the-job training session will be conducted by AECL personnel during the installation period. Attached is a copy of AECL's NRC license. AECL has indicated that this training will be conducted by one of the people listed in Item 12 Page 2 of the license.

   AECL will provide Eastman Pharmaceuticals RSO with manuals, reference material, handouts, and other relevant material from their training classes. Subsequent on-the-job training sessions for irradiator use will be conducted by the Eastman Pharmaceuticals RSO and/or his designee.

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS FOR AECL GAMMACELL 40 IRRADIATOR

(Item 8 Continued)

A personnel file will be maintained for each individual who has attended the basic radiation safety course and the irradiator safety and use course. Information will be kept regarding the date of course completion and the exam score obtained. This file will be updated as that individual attends yearly refresher courses on site or other training sessions or seminars at other facilities. This file will be maintained as long as the individual remairs an employee of Eastman Pharmaceuticals.

A copy of Eastman Pharmaceuticals/Sterling Drug, Inc. Basic Radiation Safety Course Exam is included.

ITEM 8

Radiation Safety Office

RADIATION SAFETY TRAINING MANUAL

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ITEM 8

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   B. Basis for the Current Radiation Exposure Limits
   C. Derivation of the Age-Proration Formula 5(N - 18) Rem
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ITEM 8

III. SOURCES AND EFFECTS OF RADIATION (Continued)

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ITEM 8

IV. RADIATION PROTECTIONS AND LABORATORY TECHNIQUES (Continued)

ITEM 8

EASTMAN PHARMACEUTICALS/STERLING RESEARCH GROUP

BASIC RADIATION SAFETY EXAMINATION

Name:_____ **Date:**_____

Department:_____

Part I. Multiple choice questions may have more than one correct response. Circle the correct response(s).

1. The structural difference between various nuclides of an element are due to different numbers of:

   a) electrons

   b) protons

   c) neutrinos

   (d) neutrons

2. Beta decay results in:

   a) decrease in atomic number and mass number of nucleus.

   b) decrease in atomic number.

   (c) increase in atomic number.

   d) increase in atomic number and mass number.

   e) increase in atomic number and decrease in mass number.

3. One millicurie equals:

   (a) 3.7×10^{7} dps.

   b) 3.7×10^{10} dps.

   (c) 2.22×10^{9} dpm.

   d) 2.22×10^{6} dpm.

   e) none of the above.

ITEM 8

4. The decay constant, , is equal to:

   a) A/N

   b) $0.693/T_{1/2}$

   c) 0.693/t

   d) e^{-NT}

5. Gamma rays interact with matter by:

   a) direct ionization.

   b) compton scattering.

   c) pair production.

   d) photoelectric effect.

6. A charged particle interacts with matter by:

   a) a compton scattering.

   b) photoelectric effect.

   c) excitation and ionization.

   d) pair production.

7. The activity of a radioactive sample is measured in which of the following units?

   a) Roentgens

   b) Curies

   c) Rems

   d) Rads

8. The Rem is equal to:

   a) Roentgens x Quality Factor.

   b) Roentgens x Rads

   c) Roentgens/Quality Factor

   d) Rads x Quality Factor

ITEM 8

9. An exposure to 1 mR of gamma, 10 mRad of particles, and 5 m Rad of fast neutron radiations would give an individual a dose equivalent of:

   a) 16 mRem.

   b) 16 uCi.

   c) 61 mRem.

   d) 61 mRads.

10. When using portable instruments, you should:

   a) read the operator's manual.

   b) check the batteries and detector operability.

   c) extend the probe cord to its fullest length when monitoring.

   d) determine the detector s efficiency.

11. Ion chamber type instruments are best suited for:

   a) radiation field intensity measurements.

   b) radioactive contamination monitoring.

   c) determination of radiation energy.

   d) identification of radioisotopes.

12. GM type instruments are best suited for:

   a) radiation field intensity measurements.

   b) radioactive contamination monitoring.

   c) determination of radiation energy.

   d) identification of radioisotopes.

ITEM 8

13. What instrument(s) would be most appropriate for detecting the following?

	GM	Ion Chamber	NaI Gamma Counter	Liquid Scintillation Counter
a) Non-removable surface contamination.	(X)	( )	( )	( )
b) X-rays from a dental machine.	( )	(X)	( )	( )
c) H-3 labeled water.	( )	( )	( )	(X)
d) A P-32 labeled nucleotide.	( )	( )	( )	(X)
e) A Cr-51 labeled protein.	( )	( )	(X)	( )
f) A Mn-54 labeled bacteria.	( )	( )	(X)	( )
g) A 10 mR/Hr radiation field of beta and gamma rays.	( )	(X)	( )	( )

14. A 0.05 uCi standard yields 89,200 counts in two minutes. The counter background is 200 cpm. What is the efficiency of the detector?

a) 80%

b) 60%

(c) 40%

15. If a sample was counted for 10 minutes and yielded 20,000 counts, the standard deviation of the countrate would be:

a) ± 100 cpm.

b) ± 3.16 cpm.

c) ± 141 cpm.

(d) ± 14.1 cpm.

ITEM 8

16. Gamma (NaI) and liquid scintillation detection is based upon what physical property?

a) radiolysis of an organic solvent

b) absorption of electromagnetic energy

c) emission of visible light

d) ionization of a gas

17. Quenching in a liquid scintillation system results in:

a) a loss in efficiency.

b) less light reaching the photomultiplier tube.

c) shifting of the beta spectrum to lower energy values.

d) an increase in pulse height.

18. The primary indirect effect of ionizing radiation upon biological target is:

a) erythema response.

b) free radical formation.

c) leukogenic response.

d) target absorption of the radiation.

19. The $LD_{50/30}$ for humans is approximately

a) 100 mRem.

b) 1 Rem.

c) 25 Rem.

d) 450 Rem.

e) 850 Rem.

ITEM 8

20. The primary cause of death following an $LD_{50/30}$ in humans is directly associated with irreparable and irreversible damage to:

a) the nervous system.

b) the heart, liver and kidneys.

c) the hematopoietic organs (blood tissue producing).

d) the skeletal bone.

21. Which of the following cells are correctly grouped from radiosensitive to radioresistant?

a) lymphocytes (white blood cells), endothelial cells (cells lining the GI tract), nerve cells

b) nerve cells, lymphocytes, endothelial cells

c) endothelial cells, lymphocytes, nerve cells

d) endothelial cells, nerve cells, lymphocytes

22. Late effects (5-20 years) of a large exposure to ionizing radiation may result in:

a) deaths as predicted by the LD_{50} concept.

b) carcinogenesis.

c) a change in skin pigmentation.

d) significant blood changes.

23. Immediate effects (within 30 days) of a large exposure to ionizing radiation may result in:

a) bacterial infections.

b) deaths.

c) development of tumors.

d) erythema.

ITEM 8

24. Radiation damage to the body depends on:

a) the type and energy of the radiation.

b) the absorbed dose.

c) the time the radiation was distributed.

d) the area of the body affected.

25. An acute dose of 1 Rem to the whole body may result in:

a) significant blood changes.

b) nausea, vomiting.

c) sterility.

d) no observable effects.

26. Film badge results are reported in units of:

a) Rads.

b) mR/Hr.

c) Rems.

d) mCi.

27. Film badges cannot detect H-3, C-14 or S-35 because:

a) they are pure beta minus emitters.

b) they have beta energies below the sensitivity of the film.

c) they have beta energies above the sensitivity of the film.

d) the specific ionization of the beta particles is too low.

ITEM 8

28. The purpose of filters in a film badge holder is to:

a) help in identifying the type and energy of radiation.

b) determine the amount of radiation exposure.

c) shield the film from radiation exposure.

d) determine the identity of radioisotopes to which the badge was exposed.

29. Film badges and other personnel dosimeters should be worn:

a) generally, between the neck and waist.

b) on the area of the body where exposure to radiation is likely.

c) on only the person to whom it was issued.

d) for extremity monitors, on the inside of protective gloves.

30. A radioactive package displaying a DOT "Radioactive Yellow II" warning label with a Transport Index of 0.2 means that:

a) the transport vehicle requires placarding.

b) the radiation level at the surface of the package is 0.2 mR/hr.

c) the radiation level at 3 feet from the package is 0.2 mR/hr.

31. If you have a source of radiation which emits high energy beta particles only, what is the most appropriate shielding material to use?

a) a container of lead

b) a container of plastic

c) a container of plastic inside a container of lead

d) a container of lead inside a container of plastic

ITEM 8

32. If you have a source of radiation which emits both high energy beta particles and gamma rays, what is the most appropriate shielding material to use?

a) a container o lead

b) a container of plastic

c) a container of plastic inside a container of lead

d) a container of lead inside a container of plastic

33. How many mirocuries are in one millicurie?

a) 0.001 microcuries

b) 0.1 microcuries

c) 100 microcuries

d) 1000 microcuries

34. What is a Roentgen?

a) unit of radiation exposure

b) unit of radiation dose

c) unit of absorbed dose

d) none of the above

35. Which of the following contributes the least to natural background radiation?

a) cosmic rays

b) external terrestrial radiation

c) internally deposited naturally occurring radionuclides

ITEM 8

36. Which of the following is the major contributor to manmade radiation dose that we receive on the average in the U.S.?

a) global fallout

b) nuclear power

(c) medical diagnostic x-rays

d) occupational exposure

37. A technician enters a suspected high radiation area with an operating Geiger counter survey meter. The meter makes a large upscale deflection and then returns to zero. This condition is probably due to:

a) the lack of radiation field.

b) weak batteries.

(c) tube jamming or "saturation."

d) insulation leakage.

38. Of the following radiations, the <u>most penetrating</u> should be:

a) 4.8 MeV alpha.

b) 2.1 MeV beta.

c) 0.1 MeV X ray.

(d) 2 MeV gamma.

39. Shielding against beta radiation is complicated because:

(a) sudden deceleration of betas may produce more penetrating rays.

b) the continuous beta energy spectrum creates neutrinos.

c) beta radiation cannot usually be completely absorbed.

d) deceleration of beta particles produces neutrons.

ITEM 8

40. When decontaminating you should:

a) clean from the center of the spill outwards.

b) clean from the outer edge of the spill towards the center.

c) take wipe samples of the area after decontaminating.

d) b & c

e) all of the above

41. The best method for checking for tritium surface contamination after an experiment is to:

a) use a Gieger counter.

b) use a beta scintillation probe.

c) take several wipe samples and count by liquid scintillation.

d) closely inspect the work area for liquid droplets.

ITEM 8

Part II. Short answer problems and fill in the blank.

1. List the names for the types of radioactive decay processes in whih particles are emitted:

   a) Alpha

   b) Beta (also position)

2. Now, do the same for two types of decay which do not emit particles.

   a) gamma

   b) elation capture

3. A particular radioisotope sample wth a half-life of 30 minutes is determined to have an activity of 10,000 dpm at noon.

   a) What is the value of its decay constant ( )? (show units too) 0.0231 min^{-1}

   b) How many radioactive atoms must have been present in the sample at noon? 432900 atoms

   c) How many dpm will it exhibit at 1:30 PM? 1,250 dpm

4. At what distance should you work from a gamma source which emits 15 mR/hr at 10 cm, and you wish to limit your rate of exposure to 0.15 mR/hr? 100 cm

5. You have determined that the counting system efficiency for your tracer experiment with I-25 is 25%. You decide that you need a counting rate of 1,000 cpm in your final sample. If 10% of the tracer ends up in the final sample, determine the total dpm of I-125 you must use to get the desired 1,000 cpm. 40,000 dpm

6. What are the allowed Federal Exposure Limits for radiation workers? Fill in the table.

Rems per Calendar Quarter	
	Quarterly Limit
Whole Body	1.25
Skin	7.5
Extremities	18.75

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS
FOR AECL GAMMACELL 40 IRRADIATOR

ITEM 8

7. The Federal limit of exposure for the fetus of an occupational radiation worker is 0.5 Rem for the gestation period.

8. Calculate the intensity at 3 meters from an unshielded 20 millicurie I-131 source. 0.49 mR/hr

(Item 8-Training provided to other users, Continued)

NRC Form 374
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No: 14

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	
1. Atomic Energy of Canada Limited	3. License number In accordance with application dated August 27, 1987, 54-00300-12 is amended in its entirety to read as follows:
2. 413 March Road P. O. Box 13500 Kanata, Ontario, Canada K2K 1X8	4. Expiration date December 31, 1990
	5. Docket or Reference No. 030-10623

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. Cesium 137	A. Sealed sources (AECL)	A. See Condition 10
B. Cobalt 60	B. Sealed sources (AECL)	B. See Condition 10

9. Authorized use

A. and B. For storage and/or possession in U.S. Department of Transportation approved shipping containers, AECL source drawers or AECL irradiators incident to the performance of the activities specified below involving AECL irradiator units specified in Condition 10 of this license.

(1) Distribution to persons authorized to receive the licensed material pursuant to terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or any Agreement State.

(2) Installation into and/or removal from AECL irradiator units and package for shipment.

(3) Radiation surveys of irradiator units and facilities.

(4) Leak testing of sealed sources.

(5) Installation, relocation, removal, repair, maintenance, and operation testing of irradiator units.

(6) Instruction of personnel in the operation of AECL Irradiator units.

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(Item 8 - Training provided to other users, Continued)

NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

License number 54-00300-12

Docket or Reference number 030-10623

Amendment No. 14

MATERIALS LICENSE
SUPPLEMENTARY SHEET

CONDITIONS

10. The activities authorized by this license are applicable to the following AECL irradiator units and specifications:

AECL Irradiator Unit Model Numbers	Isotope	Sealed Source Model Number	Maximum Permissable Activity Per Unit (curies)
Gammabeam 100A, 100B or 100C	Cobalt 60	C-230	1,570
Gammabeam 150A, 150B or 150C	Cobalt 60	C-174A or C-174B	6,000
Gammabeam 650	Cobalt 60	C-252	50,000
Gammacell 20	Cesium 137	C-161, Type 4	2,300
Gammacell 40	Cesium 137	C-161, Type 8	4,200
Gammacell 100	Cobalt 60	C-170 or C-171	1,000
Gammacell 200	Cobalt 60	C-170, C-171, C-199 or 200	10,000
Gammacell 220	Cobalt 60	C-166, C-167, C-185, or C-198	26,400

11. Licensed material shall be used only 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.

12. Licensed material shall be used by, or under the supervision of, Roderick Dit Hing Chu, Eric K. Curnow, Francis (Frank) Dowd, Robert George Duncan, F. M. Fraser, Stefan A. Jaeger, Jiri Kotler, V. Eskibashian, Richard G. McKinnon, Peter H. Moloughney, D. A. Russell, Pasquale J. Stefanelli, Albert N. Thurley, H. M. F. Harland, Paul P. Clarke, L. F. Slokovic, S. R. Tape, or A. Shewchenko (Radiation Safety Officer).

13. Sealed sources containing licensed material shall not be opened.

14. A. The sources or detector cells specified in Items 7.A. and 7.B. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source or detector cell received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

B. Any source or detector cell in storage and not being used need not be tested. When the source or detector cell is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

(Item 8 - Training provided to otherusers, Continued)

NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

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License number 54-00300-12

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Amendment No. 14

MATERIALS LICENSE
SUPPLEMENTARY SHEET

(14. continued) CONDITIONS

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source or detector cell shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch, 631 Park Avenue, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

15. Written instructions contained in application and attachments dated January 15, 1985 shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for use of licensed material. Any changes in these instructions shall have the prior approval of the U.S. Nuclear Regulatory Commission, Region I, Nuclear Materials Section, 631 Park Avenue, King of Prussia, Pennsylvania 19406.

16. After installation of the irradiator and Cobalt 60 or Cesium 137 source and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine the maximum radiation levels in each area adjoining the irradiation room. A detailed report in duplicate of the results of the surveys shall be sent to the U.S. Nuclear Regulatory Commission, Region I, Nuclear Materials Section, 631 Park Avenue, King of Prussia, Pennsylvania 19406, not later than thirty (30) days following installation of the source.

17. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material".

18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

(Item 8 - Training provided other users, Continued).

NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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License number	54-00300-12
Docket or Reference number	030-10623
	Amendment No. 14

(18. continued) CONDITIONS

A. Letter dated January 10, 1985
B. Application dated January 15, 1985
C. Instruction manuals:

(1) Gammacell 20 dated February 1970.
(2) Gammacell 40 dated January 1976.
(3) Gammacell 100 and 200 dated June 1, 1962.
(4) Gammacell 200 dated March 1970.
(5) Gammacell 220 dated October 1975.
(6) Gammabeam 100 dated December 1970.
(7) Gammabeam 150 dated November 1979.
(8) Gammabeam 650 dated December 1970.

D. Letter dated May 5, 1986
E. Letter dated November 25, 1986
F. Letter dated August 27, 1987

For the U.S. Nuclear Regulatory Commission

Date 28 OCT 1987

By _____
Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS
FOR AECL GAMMACELL 40 IRRADIATOR

Item 9 - Facilities and Equipment

The Gammacell 40 irradiator will be placed in a separate room, exclusively set aside for the unit. The room will be as isolated as possible. Access to the room will be key carded. Only authorized personnel will have key-card access to the irradiator room, by means of their personnel photo ID card. The room will be locked at all times. In addition to the secured room, the entire building is secure from entry by unauthorized personnel. A guard station is located at the entrance way to Building 25. Photo ID must be shown to gain admission to the building.

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS FOR AECL GAMMACELL 40 IRRADIATOR

Item 10 - Radiation Safety Program

Personnel Monitoring Equipment

All individuals authorized to use the Gammacell 40 irradiators will be issued whole body TLD badges and finger TLD rings. They will be required to wear both dosimeters whenever using the irradiator. Dosimeters will be changed on a monthly basis.

Radiation Detection Instrument

Will install inside the irradiator room a wall mounted area monitor. It will be hard wired so that it is operable at all times. It shall have a visible and audible alarm activated when radiation levels exceed 2 mR/hr. The monitor will be positioned so that it will detect any abnormal radiation levels as soon as the irradiator door is cracked open. The monitor will be positioned to allow the user to easily view it while standing next to the unit. In addition, the area monitor will have a remote read out outside of the room near the entrance door. This will allow the user to detect any abnormal levels without entering the room. The area monitor purchased for this purpose is the Ludlum Model 308-1 with remote read out Model 270. The instrument's range is 0.1 to 10,000 mR/hr. The detector is a miniature GM detector, equipped with a check source.

In addition to the area monitor, a portable survey meter will be kept in the irradiator room. This meter will be a Ludlum Model 5. It has two internally mounted GM tubes with a 0-2000 mR/hr range. This meter will be used by research personnel during irradiator use to monitor radiation intensity at various positions. If the area monitor is out of service, the model 5 will be used to monitor intensity as the door is opened.

Both of these meters will be calibrated by Teledyne Isotopes on an annual basis. The meters will be calibrated so that readings are within a $\pm$ 20% range of the actual values over the total range of the instrument. A chart will be included for each calibration showing the results and percent error. A sticker will be affixed to each meter showing the results, date calibrated, and due date for the next calibration. The record of the calibration will be kept for at least two years.

As stated these meters will be calibrated by:

Teledyne Isotopes, Inc.
50 Van Buren Avenue
Westwood, New Jersey 07675
Phone #(201) 664-7070
N.R.C. License #29-00055-06
New Jersey License # NJSL-10123

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS FOR AECL GAMMACELL 40 IRRADIATOR

(Item 10 Continued)

Leak Testing

The leak-test sample will be taken by the RSO, John Nicholson or his designee. The sealed sources in the Gammacell 40 unit shall be tested for leakage and/or contamination at intervals not to exceed six months. The test shall be capable of detecting the presence of 0.005 microcurie of contamination on the test sample. Records of leak-test results shall be kept in units of microcuries and maintained for inspection by the NRC. If the leak-test reveals the presence of 0.005 microcurie or more of removable contamination, use of the irradiator will immediately be discontinued. The unit will be decontaminated and repaired or disposed of in accordance with NRC regulations. A report shall be filed within five days of the test results and sent to:

U.S. Nuclear Regulatory Commission
Region I
Attn: Chief, Nuclear Materials Safety
and Safeguards Branch
475 Allendale Road
King of Prussia, PA 19406

A description of the equipment involved, the test results, and the corrective action taken will be included in the report. In addition, the manufacturer of the unit will be notified immediately by phone if the leak-test results show operator than 0.005 microcuries or more of activity of contamination. Their address is:

Atomic Energy of Canada Limited - RRC
413 March Road
P.O. Box 13500
Kanata, Ontario CANADA K2K1X8
Phone Number (613) 592-2790

The RSO may choose to contact AECL if the leak test is above LLD levels but below the 0.005 reportable level.

The actual leak-test method for this leak test is as follows:

1. Open the sample cavity door.

2. With a gloved hand and a moistened filter paper, the accessible portion of the perimeter of the upper attenvator will be smeared. (See attached diagram).

3. The upper and lower inspection covers on the left-hand side of the sheet metal enclosure will be removed. (See attached diagram).

4. Two more moistened filter paper smears will be used to wipe around the source drawer mechanical interlocks for both the upper and lower sources.

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS FOR AECL GAMMACELL 40 IRRADIATOR

(Item 10 Continued)

5. The smears will be counted using a Ludlum 2200 sealer ratemeter and a model 44-1 end window G-M detector. The detector has a 1.7 mg/cm^2 mica window. The detector is housed in a Ludlum model 180-9 sample holder to reduce the background. This lead shield is 1.75 inches thick and has a hinged door.

6. Each smear will be counted for 30 minutes, as will background. A plated disk standard yields the following measurements:

12,609	cpm gross (1 minute count)
14	cpm background (ten minute count)
12,595	net cpm standard

The Cs-137 standards is 0.038 uCi on 10-23-86 decay corrected to 5-31-88. This standard equals 81, 311 dpm. The efficiency of the instrument for Cs-137 is 12,595/81,311 x 100. The efficiency equals 15.49 percent.

To Convert to Microcuries:

Net cpm sample/efficiency x 2.22 x 10^6 dpm/uCi. If the results are less than or equal to the minimum detectable activity level (MDAL), the results will be reported as less than or equal to the MDAL.

Operating and Emergency Procedures

Each authorized user of the Gammacell 40 irradiator will receive a copy of the Gammacell 40 operators manual. This will describe the operating and emergency procedures for the unit. The list of topics to be covered in the manual includes:

1. How to become an authorized Gammacell 40 User
2. A general description of the unit (sources, control panel, safety features).
3. Step-by-step procedure for operation of the irradiator for both the automatic and manual mode.
4. Power and air pressure failure
5. Equipment inspection
6. Leak-test procedures
7. Access to the room (door always locked when unattended).
8. Before entering the room, personnel should observe the remote read out by the door. If it indicates the intensity level in the room exceeds 0.2 mR/hr, they should not enter the room. Contact the RSO immediately.
9. Emergency situations
   a) Abnormal levels with remote read out
   b) Abnormal levels during use, detected with portable meter

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS FOR AECL GAMMACELL 40 IRRADIATOR

(Item 10 Continued)

c) Malfunction of source drawer
d) Any event of not occurring during normal operating procedure (control panel lights, source drawer, etc.)

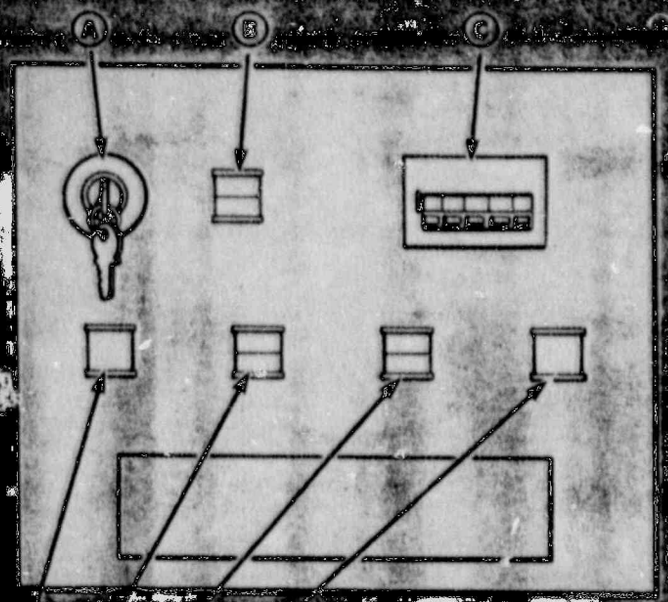
10. Any situation out of the normal parameters is handled by closing the irradiator door, leave the room, lock the door, post a sign warning others not to enter, and contact the RSO. A survey must be performed outside the room to determine if further restriction of the area is necessary to ensure that no one enters the area if levels exceed 2 mR/hr.

11. Maintenance of log book of irradiator use by research personnel.

12. Individual authorized user must oversee the operation of the irradiator at all times while using it.

Current users of Gammacell 40 irradiators at other facilities have noted the intensity within one foot of the irradiator door may approach 2 mR/hr at gonad height during irradiation. At certain points directly on the surface, they have reported intensities close to 10 mR/hr during irradiation.

To keep personnel exposures ALARA, a line will be painted on the floor in the irradiator room, beyond which, the intensity is 0.25 mR/hr. All authorized irradiator users will be instructed to step back behind this line during the irradiation.



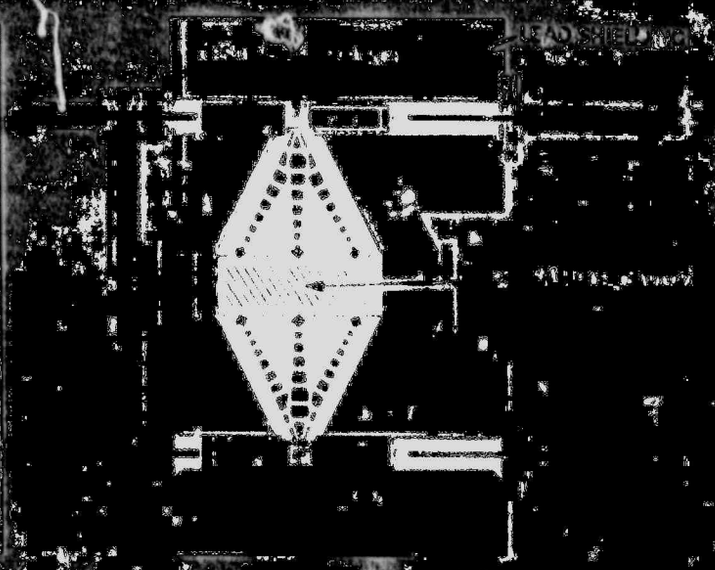


FIGURE 1 SCHEMATIC DIAGRAM

FIGURE 2 ELEVATION CHAMBER DETAIL

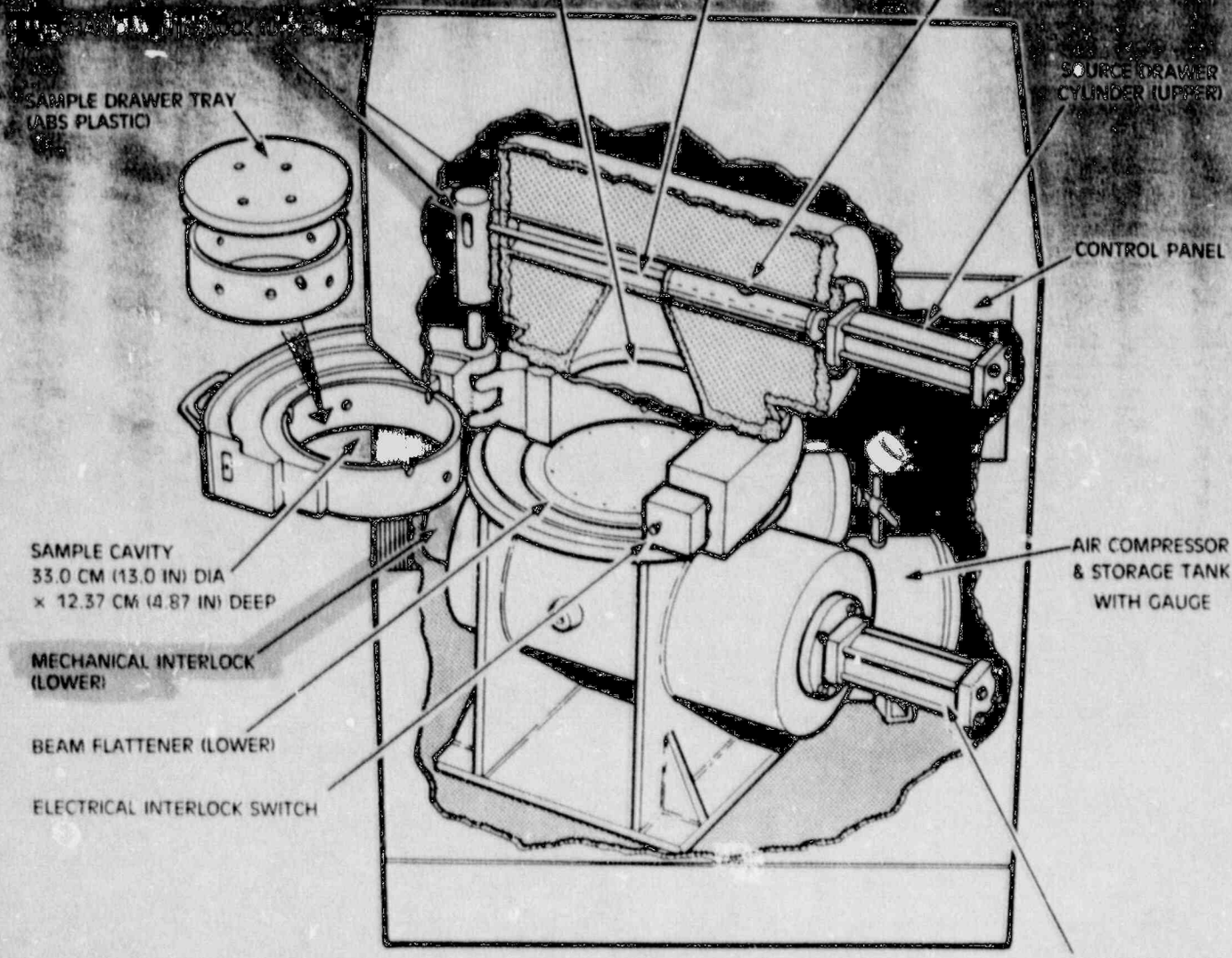
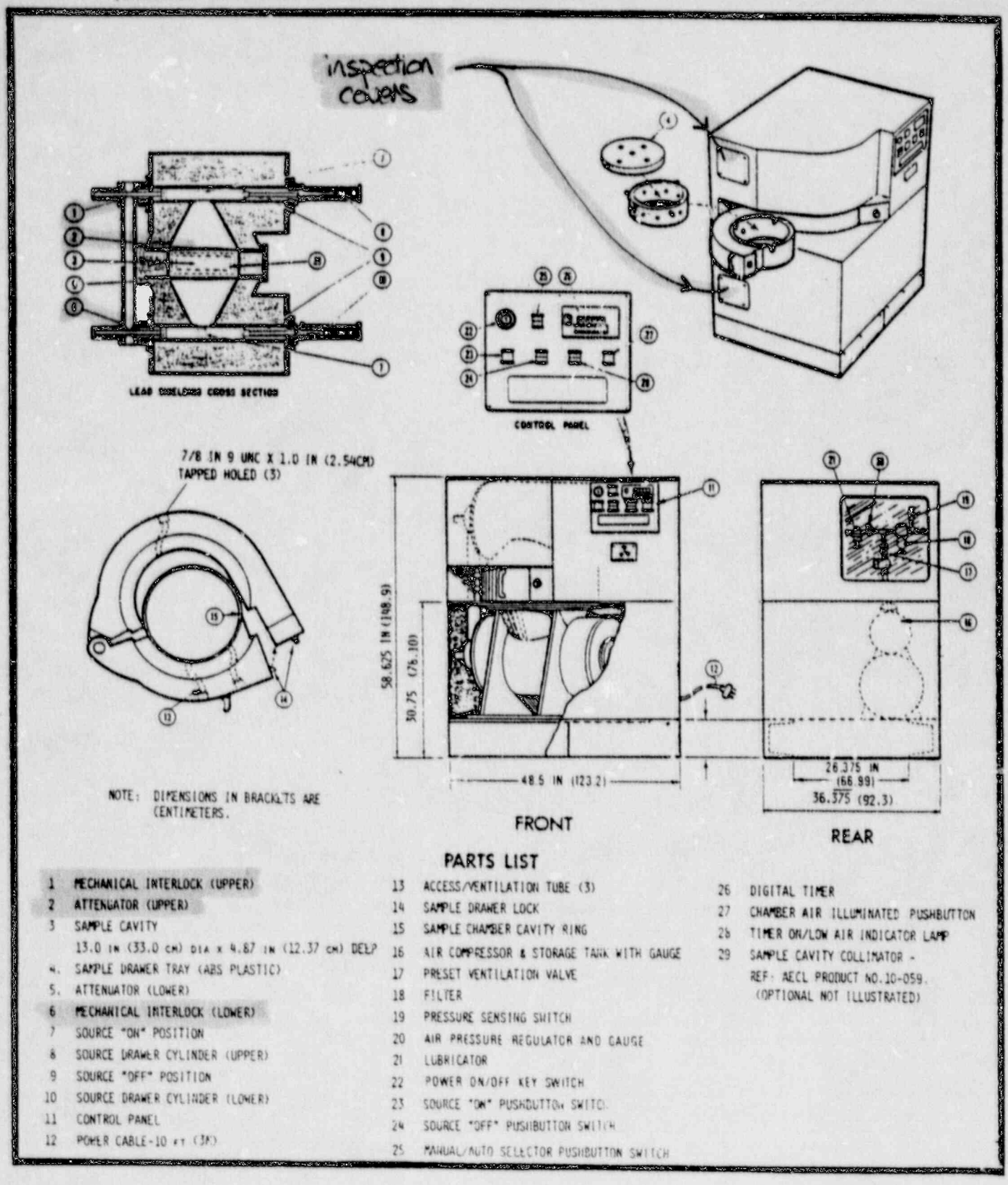


FIGURE 3 COMPONENT PARTS



NOTE: DIMENSIONS IN BRACKETS ARE CENTIMETERS.

PARTS LIST

1 MECHANICAL INTERLOCK (UPPER)
2 ATTENUATOR (UPPER)
3 SAMPLE CAVITY
13.0 IN (33.0 CM) DIA x 4.87 IN (12.37 CM) DEEP
4. SAMPLE DRAWER TRAY (ABS PLASTIC)
5. ATTENUATOR (LOWER)
6 MECHANICAL INTERLOCK (LOWER)
7 SOURCE "ON" POSITION
8 SOURCE DRAWER CYLINDER (UPPER)
9 SOURCE "OFF" POSITION
10 SOURCE DRAWER CYLINDER (LOWER)
11 CONTROL PANEL
12 POWER CABLE-10 FT (3M)
13 ACCESS/VENTILATION TUBE (3)
14 SAMPLE DRAWER LOCK
15 SAMPLE CHAMBER CAVITY RING
16 AIR COMPRESSOR & STORAGE TANK WITH GAUGE
17 PRESET VENTILATION VALVE
18 FILTER
19 PRESSURE SENSING SWITCH
20 AIR PRESSURE REGULATOR AND GAUGE
21 LUBRICATOR
22 POWER ON/OFF KEY SWITCH
23 SOURCE "ON" PUSHBUTTON SWITCH
24 SOURCE "OFF" PUSHBUTTON SWITCH
25 MANUAL/AUTO SELECTOR PUSHBUTTON SWITCH
26 DIGITAL TIMER
27 CHAMBER AIR ILLUMINATED PUSHBUTTON
28 TIMER ON/LOW AIR INDICATOR LAMP
29 SAMPLE CAVITY COLLIMATOR -
REF: AECL PRODUCT NO.10-059.
(OPTIONAL NOT ILLUSTRATED)

FIGURE 1

SUPPLEMENT TO THE APPLICATION FROM EASTMAN PHARMACEUTICALS FOR AECL GAMMACELL 40 IRRADIATOR

Item - 11 Waste Management

NRC regulations, Section 20.301(a) of 10 CFR Part 20, specify the general requirements for disposal of the licensed material in the irradiator. Disposal of this material, when it becomes necessary, will be by transfer of the material to the original supplier, Atomic Energy of Canada Limited NRC license number 54-00300-12.

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: _____
STATUS CODE: 3
FEE CATEGORY: _____
EXP. DATE: 0
FEE COMMENTS: _____

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: EASTMAN PHARMACEUTICALS
RECEIVED DATE: 880815
DOCKET NO: 3030757
CONTROL NO.: 109418
LICENSE NO.:
ACTION TYPE: NEW LICENSE

2. FEE ATTACHED $230
AMOUNT: _____
CHECK NO.: _____ 9925

3. COMMENTS

SIGNED _____
DATE 8/23/88

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED) ✓

1. FEE CATEGORY AND AMOUNT: 3Z $230

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT _____
RENEWAL _____
LICENSE ✓

3. OTHER _____
_____

SIGNED D. Kyslinger
DATE 8/31/88