APPENDIX A

NRC FORM 313 (1-84) 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.

FEDERAL AGENCIES 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 JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL 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
MATERIAL RADIATION PROTECTION 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
MATERIAL RADIATION PROTECTION 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)*

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER 12-24371-01
- [ ] C. RENEWAL OF LICENSE NUMBER ______

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

International Minerals & Chemical Corp.
1810 Frontage Road
Northbrook, IL 60062

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

International Minerals & Chemical Corp.
1810 Frontage Road
Northbrook, IL 60062

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION: Timothy M. Sullivan

TELEPHONE NUMBER: (312) 480-0200

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 3E — AMOUNT ENCLOSED $ Control 379964

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
Peter N. Gray	Peter N. GRAY	Director Life Sci Research	4 Dec 85

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
			8602190691 860110 REG3 LIC30 12-24371-01 PDR	
AMOUNT RECEIVED	CHECK NUMBER			DATE

PRIVACY ACT STATEMENT ON THE REVERSE

TEAR LINE

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Item 5. Material to be possessed

A. Radionuclide: ^{137}Cs , as cesium chloride in solid form.

B. Sealed source manufacturer and model number:

Atomic Energy of Canada, Limited Model "ISO-1000"

C. Total activity: 600 Curies ± 20% 720

D. Irradiator manufacturer and model number:

Atomic Energy of Canada, Limited
Unit: "Gammacell 1000"
Model: "A"

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Item 6. Purpose for which the irradiator will be used

The gamma-cell 1000 (^{137}Cs source irradiator) will be used:

1. To inactivate lymphocyte cell populations for use in in vivo and in vitro experimental systems.

2. To irradiate mice for use in adoptive transfer experiments.

3. To sterilize biological preparations for parenteral administration to experimental animals.

Additional related uses will be subject to approval by the Radiation Protection Officer.

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Item 7. Individuals responsible for radiation safety program: Their training and experience.

1. Names:

   A. Timothy M. Sullivan, Ph.D.
   Radiation Protection Officer

   B. Anthony F. Abruzzini, Ph.D.
   Research Scientist

2. Training and Experience

   A. Timothy M. Sullivan
   Research Toxicologist

   B.S. Michigan State University
   East Lansing, MI

   M.S., Ph.D. Purdue University
   West Lafayette, IN

Training	Where and by whom	Dates	On the Job	Formal Course
a) Principles of Radiation Protection	Medical College of Georgia (Nuclear Medicine Program)	9/76-8/77	No	Yes
	Purdue University (MS program in Health Physics)	8/77-6/79	No	Yes
b) Radioactivity Measurement	Medical College of Georgia	9/76-8/77	Yes	Yes
	Purdue University	9/77-6/79	Yes	Yes
(On the job training as radiation safety technician and teaching assist.)				
c) Mathematics and Calculations	Medical College of Georgie	9/76-8/77	No	Yes
	Purdue University	8/77-6/79	No	Yes
d) Biological Effects of Radiation	Medical College of Georgia	9/76-8/77	No	Yes
	Purdue University	8/77-6/79	Yes	Yes
(On the job training in radiobiology research)				

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Timothy M. Sullivan, cont.

Experience

Nuclide	Max.Amount	Where	Duration	Type of Use
99-Mo/ 99m-Tc	2 Ci	Medical College of GA	1 yr	Nuclear Medicine Technology diagnostic and therapeutic procedures
67-Ga	50 mCi	"	"	
131-I	50 mCi	"	"	
125-I	20 mCi	"	"	
133-Xe	50 mCi	"	"	
201-Tl	10 mCi	"	"	
60-Co	1000 Ci	Purdue University	2 yr	Irradiation of biological matter
32-P	1 mCi	Medical College of GA	3 yr	Inspection duties as radiation safety technician and teaching lab procedures in bionucleonics
35-S	0.5 mCi	Purdue University	3 yr	
51-Cr	5 mCi	"	"	
137-Cs	5 Ci	"	"	
radio-isotopies of Ni, Ba, Sr.	0.1 mCi	"	"	
14-C	10 mCi	Purdue University, University of South Florida and Intl. Min. & Chem. Corp.	1978-present	Biomedical and toxicological research
3-H	10 mCi			
^{14}C, ^{3}H, ^{125}I	1000 mCi	Intl. Min. & Chem. Corp.	1984-present	Radiation Protection Officer

(Passed Part 1 of the American Board of Health Physics Certification Examination and Member, Health Physics Society)

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Timothy M. Sullivan, cont.

Irradiator Experience:

Dates: January, 1978 - June, 1979

Irradiator: 1000-Curie ^{60}Co exposed source

Where: Purdue University, School of Pharmacy
Department of Bionucleonics

Use: In vitro experiments measuring the sensitivity of melanoma cells to combined ^{60}Co irradiation and hyperthermia. Use of the source required working knowledge of remote source activation, failsafe mechanisms, dosimetry and exposure rate determinations.

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2. Training and Experience

B. Anthony F. Abruzzini, Ph.D.
Research Scientist

B.A. The Johns Hopkins University
M.S.E. The Johns Hopkins University
Ph.D. University of Florida College of Medicine

Training	Where and by whom	Dates	On the Job	Formal Course
a) Principles	Johns Hopkins	9/71-9/75	Yes	No
	U. Florida	9/75-3/80	Yes	No
	Washington U.	3/80-1/85	Yes	Yes(1980)
b) Measurement	1) As above	As above	Yes	No
	2)		Yes	No
	3)		Yes	Yes(1980)
c) Math	Washington U.	As above	No	Yes(1980)
d. Bio Effects	1) As above	As above	No	No
	2)		Yes	No
	3)		Yes	Yes(1980)

Experience:

Nuclide	Max. Amount	Where	Duration	Type of Use
^{3}H	10 m Ci	Washington U.	4.5 years	Biomedical research
^{14}C	5 m Ci	Johns Hopkins	1.0 years	"
^{125}I	5 m Ci	Washington U.	2.0 years	"
^{51}Cr	5 m Ci	Washington U.	1 year	"
^{135}Cs	200 Ci	Washington U.	3 years	Irradiation of biological matter

Irradiator Experience:

Dates: Nov. 1981-Jan. 1985
Irradiator: Gamma cell 40 ^{137}Cs source irradiator (Atomic Energy of Canada, Ltd.)
Where: The Jewish Hospital at Washington University Medical Center, Dept. of Pathology and Laboratory Medicine
Use: Irradiation of leukocyte populations for use in in vitro experimental systems. Extensive instruction in use of equipment and safety procedures was required to be allowed to use the irradiator.

Item 8. Training provided to other users.

Users under the supervision of a responsible individual (Item 7) will receive training in three stages.

Stage 1: Basic training

All individuals working with radioactive material of any kind are required to participate in a basic training seminar administered by the Radiation Protection Officer. The basic training topics include: types of radiation and biological interactions (1/2 hour); principles and fundamentals of radiation safety in the laboratory (1 hour); NRC and in-house safety practice regulations, including ordering and disposal information (1 hour); and principles and use of radiation detection instrumentation and personnel dosimeters (1/2 hour).

The basic training seminar will require three hours.

Stage 2: Irradiator training

All individuals desiring to use the AEC Gammacell 1000 irradiator will be required to attend a special training seminar on its use. The irradiator training session will begin with the nature of gamma radiation and interactions with matter (1.5 hours), including time-distance-shielding principles, stopping power, and detection methods. Another 1.5 hours will be devoted to a detailed coverage of the design and safe operation of the irradiator. One hour will be used for personal review of the Gammacell 1000 operators manual (Edition 3, April 1984, or as updated).

A written examination will be administered to all individuals after the three hours of irradiator training described above. The examination will cover both Stage 1 and Stage 2 of training. Questions to be included in the examination are attached. The minimum passing grade will be 88% (22 of 25 questions). An individual will progress to Stage 3 only upon passing the examination. One hour will be taken after the examination for thorough review with all participants of all question areas.

The irradiator training of Stage 2 will require five hours, including the review.

Persons failing the examination will either retake Basic and/or Irradiator Training as necessary, or, at the discretion of the course instructors, be asked to review problem areas and submit a written report demonstrating acquisition of the required understanding.

After each examination session, wrong answers from all participants will be examined. Areas commonly presenting problems will be identified and improvements made to the Basic and Irradiator training sessions.

Stage 3: On-the-job training

All individuals who pass the written examination after Stage 2 will be eligible to receive on-the-job training in the operation of the irradiator. On-the-job training will consist of apprenticeship during actual operation of the irradiator by a responsible individual from Item 7. Apprenticeship experience will be noted in the users log. A minimum of four hours of on-the-job experience under the direct supervision of a responsible individual will be required.

All phases of training will be administered by Dr. Anthony F. Abruzzini and/or Dr. Timothy M. Sullivan.

Records will be maintained for each individual throughout all stages of training.

ATTACHMENT -- EXAMINATION QUESTIONS

The examination given to all individuals near the completion of Stage 2 - Irradiator Training will be identical or similar to the following. Appropriate answers are entered hand-written.

1. Alpha, beta, and gamma radiations are, in terms of elemental particles, equivalent to what? Helium nucleus, electron, photon

2. Beta radiation energy spectra are polyenergetic whereas those of alpha and gamma radiations are monoenergetic.

3. Rank the three principal types of radiation in order of increasing penetrating power (assuming equal energies). $\alpha < \beta < \gamma$

4. If radionuclide A has a half-life of 15 days, what percentage of the original activity will remain after 45 days? 12.5 %

5. What are the number of neutrons and the number of protons in a nucleus of tritium? Two neutrons, one proton

6. All three types of ionizing radiation interact with matter to produce ionization (or) ion pairs (or) excitation.

7. Safe laboratory use of low energy radiotracers is dependent upon the minimization of contamination.

8. Tritium-labeled thymidine is a more hazardous radiochemical than carbon 14-labeled toluene because the thymidine is a DNA precursor.

9. The spread of contamination during a procedure using a 14C-labeled compound is best monitored by performing a wipe test.

10. What are three methods for the determination of liquid scintillation counting efficiency? internal standard, external standard, sample channels ratio

11. ALARA stands for as low as reasonably achievable.

12. To the nearest whole number, 1mR equals one mrad equals one mrem for beta and gamma radiations.

13. The three factors which affect exposure from a gamma source are time, distance, shielding.

14. Lead is a common shielding material for gamma rays because it has a high atomic number and hence a high attenuation coefficient.

ATTACHMENT -- EXAMINATION QUESTIONS - Contd.

15. The half-value layer for lead shielding of 137Cs radiation is about 0.9 cm. If the unshielded exposure rate from an irradiator source is 300 R/hr at 1 meter, how much lead must be used to reduce the exposure rate below the 20 mR/hr stipulated by ICRP-33?
14 HVL's, or about 13 cm of lead

16. Which is the more quantitative radiation detection instrument, a GM tube or a scintillation counter? scintillation counter

17. It is imperative to keep the irradiator clean and free of spills because spills could result in siezing of the sample rotator or other moving parts.

18. Quantitative leak tests must be performed on an irradiator every six months to ensure that removable source contamination is less than 0.05 microCi.

19. Evidence of 137Cs contamination must be reported immediately to the manufacturer (AEC) and the NRC, as well as appropriate IMC personnel.

20. In case of power failure while the irradiator is in the IRRADIATE position, the AEC Gammacell 1000 will/will not (circled: will not) automatically terminate sample exposure.

21. It would take approximately (ten minutes, two hours, eight hours, one day) (circled: two hours) of exposure to the unshielded Gammacell 1000 source at a distance of one meter to obtain a lethal radiation dose.

22. The IMC radiation safety program includes two types of personnel dosimeters, whole body film badges and ring tld's.

23. A calibrated survey instrument will be used to monitor the irradiator for possible shielding failure, sealed source displacement, or other such failure at what times?
Before and after each use.

24. In a high radiation field, a GM tube can become saturated and give a reading of zero.

25. Biological effects of ionizing radiation are thought to be mediated through the generation of free radicals from water molecules.

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Item 9. Facilities and equipment

A. Location

The AEC Gammacell 1000 is proposed to be located in Room 139 of Building 9 of the IMC Research facility located at 1810 Frontage Road, Northbrook, Illinois. The room will be locked at all times. Keys will be held by the Radiation Protection Officer and in the master key file in the central office (Room 124). Access to the irradiator room will be restricted. The room will be kept locked at all times the irradiator is not in use. The entire facility is under 24-hour surveillance. These security measures and the sheer weight of the irradiator make it highly unlikely that unauthorized removal of the 137Cs source could occur.

No areas surrounding Room 139 are continuously occupied.

B. Equipment

Radiation detection instruments, as described in the license amendment application, include a Micromedic model Apex gamma counter and five calibrated Ludlum model 3 survey meters. Film and tld personnel dosimeters are used and exchanged monthly.

Item 10. Radiation safety program

10.1 Personnel monitoring equipment

All personnel using the irradiator will be required to wear both a whole-body film dosimeter and a ring tld. Both are supplied by R. S. Landauer and exchanged monthly, as per the license amendment application.

10.2 Radiation detection equipment

Five Ludlum model 3 survey instruments are available. All will be maintained in proper calibration as per the license amendment and have a sensitivity of about 0.1 mR/hour. Calibrations to within +/- 20% of actual exposure rates will be performed by Health Physics Associates, Ltd., under NRC License 12-09160-01. Records will be maintained of the results of calibration and the date of last calibration for each instrument. The due date for the next calibration will be affixed to each instrument. Calibration will be performed yearly under the amended license, and after any servicing. Records will be kept indefinately, with a minimum of two years.

10.3 Leak testing

Leak testing will be performed at least every six months. The AEC Gammacell 1000 Operator's Manual specifies a wipe test procedure which will be followed. The wipes will be obtained and sent to Health Physics Associates, Ltd. (NRC License 12-09160-01, address: 3304 Commercial Avenue, Northbrook, IL 60062) who will evaluate the sample and report the results. Kit model C8, supplied by Health Physics Associates, Ltd., will be used. The test wipe smears will be taken by the individuals specified in Item 7.

10.4 Operating and emergency procedures

AEC supplies a detailed operator's manual. The manual will be reviewed thoroughly by any individual using the irradiator. Copies will be made available to all users. Step-by-step operation instructions will be provided by the manufacturer's operator's manual.

Additional written procedures will be given to and followed by all users. Included with the additional instructions will be the requirement for whole-body film and ring tld dosimeters and the requirement that the door to the irradiator room remain locked when the irradiator is not in use. The procedures will make it clear that all users are responsible for knowledge of the leak test schedule and results. It will be standard written procedure that a GM tube survey will be conducted both before and after each use of the irradiator.

The written procedures will include a section on emergency response. Since GM surveys will be taken before and after each use, no opportunity will be lost to detect abnormal radiation levels. Procedures will be defined for any user to delineate and restrict the

10.4 Operating and emergency procedures - Contd.

affect area, based on exposure rates above two mR/hr. The procedures for notifying responsible individuals will be clearly detailed.

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Item 11. Waste management

Disposal of the ^{137}Cs source will be by transfer to a NRC-authorized recipient, such as Atomic Energy of Canada, Ltd., or ADCO Services, Inc.