MATERIALS LICENSE

Amendment No. 07

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, 36, 39, 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.

301324

Licensee	
1. Cayman Chemical Company, Inc. 2. 690 KMS Place Ann Arbor, MI 48108	In accordance with letter dated May 16, 1996 3. License Number 21-24683-01 is amended in its entirety to read as follows: 4. Expiration Date March 31, 2001 5. Docket or Reference No. 030-29143

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Iodine-125	A. Prepackaged units	A. 2.5 millicuries
B. Hydrogen-3	B. Prepackaged units	B. 100 millicuries
C. Carbon-14	C. Prepackaged units	C. 20 millicuries
D. Phosphorus-32	D. Any	D. 10 millicuries
E. Hydrogen-3	E. Any	E. 1 millicurie
F. Carbon-14	F. Any	F. 1 millicurie

9. Authorized Use:

A. B. and C. For receipt, storage and redistribution of prepackaged units to persons specifically licensed for the type, form and quantity of byproduct material by the Nuclear Regulatory Commission or an Agreement State.

D., E. and F. For research and development as defined by Section 30.4 of 10 CFR Part 30.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 690 KMS Place, Ann Arbor, Michigan.

11. The Radiation Safety Officer for this license is Krishna Rao Maddipati, Ph.D.

D/1

230054

9706230218 970501
PDR ADOCK 03029143
C PDR

COPY MAY 01 1997

JMC 30 SD

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-24683-01

Docket or Reference Number
030-29143

Amendment No. 07

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
A. Gong Chen, Ph.D.	Hydrogen-3, carbon-14, iodine-125, phosphorus-32
B. K. R. Maddipati, Ph.D.	Hydrogen-3, carbon-14
C. J. W. MacDonald	Hydrogen-3, carbon-14
D. Jeffrey K. Johnson, Ph.D.	Hydrogen-3, carbon-14
E. Jennifer L. Johnson, Ph.D.	Hydrogen-3, carbon-14

13. Prepackaged units intended for redistribution shall not be opened by the licensee.

14. This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31 or to persons exempt from licensing pursuant to 10 CFR 30.18.

15. Licensed material shall not be used in or on human beings.

16. This license does not authorize the manufacture and packaging of radiochemicals for distribution.

17. 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.

A. Application dated March 26, 1986; and

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-24683-01

Docket or Reference Number
030-29143

Amendment No. 07

17. (Continued)

B. Letters dated May 4, 1987, August 8, 1987, May 16, 1988, May 25, 1990, January 16, 1991, March 30, 1993, June 18, 1993 (with attachments), March 4, 1997, and April 9, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAY 01 1997

By _____
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02410
STATUS CODE: 0
FEE CATEGORY: 3P
EXP. DATE: 20010331
FEE COMMENTS: REDISTRIBUTION
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: CAYMAN CHEMICAL COMPANY INC.
RECEIVED DATE: 960517
DOCKET NO: 3029143
CONTROL NO.: 301324
LICENSE NO.: 21-24683-01
ACTION TYPE: AMENDMENT

56

2. FEE ATTACHED
AMOUNT:
CHECK NO.: ~~X~~ * Addl info 399992 - 56

3. COMMENTS

SIGNED D. Hersey
DATE 5-28-96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 07 IS ENTERED /__/)

1. FEE CATEGORY AND AMOUNT: 3P 3M FEE NOT REQUIRED

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

3. OTHER

SIGNED SC
DATE 6/3/96

1996 MAY 29 AM 10:57

RECEIVED
JUN 10 1996
REGION III

$1500 fee paid for under cd 399992

Log May 13 III
Remitter
Check No.
Amount
Fee Category 3P 3M
Type of Fee AMND
Date Check Rec'd 5-28-96
Date Completed 6-3-96
By: SC

CAYMAN CHEMICAL

May 16, 1996

Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60352-4351
Attn.: Ms. Colleen Casey

Reference: Amendment of cur NRC license. Control No. 399992

Dear Ms. Casey,

We have recently submitted an application to amend to our NRC License No. 21-24683-01. The control number for this application is 399992. In the application we forgot to include the isotope ^{14}C, which we plan to use along with other radionuclides listed in section 5 of our amendment application. As we discussed over the phone, there is also a change in the RSO. Because of these changes, I am enclosing two new copies of the entire amendment application (except for NRC form 313) to replace the old ones. I hope this application is complete and meets all the requirements of NRC guidelines.

If you have any questions regarding the application, please contact me at 313-662-6756.

Thanking you,

Sincerely,

Krishna Rao Maddipati

Krishna Rao Maddipati, Ph.D.
Director, Research and Development

CAYMAN
CHEMICAL

690 KMS Place
Ann Arbor, MI
48108 USA

Phone:
(800) 364-9897
(313) 662-6756

Fax:
(313) 662-6896

ADD'L Info - 399992
FEE NOT REQUIRED

RECEIVED
MAY 17 1996
REGION III

301324

5. Radioactive material (in addition to isotopes listed in the original license 21-24683-01):

	Element/ Mass No.	Chemical form	Max. amount
5a.	^{33}P	DNA and RNA nucleotide phosphates	20 mCi
5b.	^{32}P	DNA and RNA nucleotide phosphates	75 mCi
5c.	^{35}S	amino acids and nucleotides	40 mCi
5d.	^{3}H	[^{3}H] eicosonoids	100 mCi
5e.	^{14}C	[^{14}C] eicosanoids	20 mCi

6. Purpose(s) for which licensed Material will be used (in addition to isotopes listed in the original license 21-24683-01):

	Element/ Mass No.	Chemical form	Purpose
6a.	^{33}P	DNA and RNA nucleotide phosphates	DNA probe labelling and sequencing
6b.	^{32}P	DNA and RNA nucleotide phosphates	DNA probe labelling and sequencing
6c.	^{35}S	amino acids and nucleotides	Proteing labelling and DNA sequencing
6d.	^{3}H	[^{3}H] eicosonoids	In vitro experiments to monitor recovery and study metabolism. Pre-packaged units containing ^{3}H labelled eicosanoids and fatty acids obtained from a manufacturer authorized to distribute the mateiral in accordance with a specific license issued pursuant to Section 32.71 of 10 CFR Part 32 or under equivalent regulations of an Agreement State.
6e.	^{14}C	[^{14}C] eicosanoids	In vitro experiments to monitor recovery and study metabolism. Pre-packaged units containing ^{14}C labelled eicosanoids and fatty acids obtained from a manufacturer authorized to distribute the mateiral in accordance with a specific license issued pursuant to Section 32.71 of 10 CFR Part 32 or under equivalent regulations of an Agreement State.

7. Individual(s) responsible for radiation safety program and their training and experience.

7.1 Authorized Users for Medical Use

None. All work will be performed *in vitro*.

7.2 Authorized Users for Nonmedical Use

See ATT 7.2.1, 7.2.2, 7.2.3, and 7.2.4. The primary user of radioactive material will be Krishna Rao Maddipati, Ph.D. (ATT 7.2.1).

7.3 Radiation Safety Officer

Krishna Rao Maddipati has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

5-16-96
(date)

Kirk Maxey, M.D.
President, Cayman Chemical Company

8. Training For Individuals Working in or Frequenting Restricted Areas.

Cayman Chemical Company - Training Policies

All individuals who work in, or frequent, a Restricted Area or who use radioactive materials will receive appropriate training. The level of training will be appropriate to the duties of the individual who works with radiation. Training may be abridged for personnel (e.g., Shipping or Security personnel) whose duties require less potential exposure or less involved procedures.

1. Personnel will be instructed before assuming duties with, or before assuming duties in the vicinity of, radioactive materials.

2. Refresher training will be provided annually.

3. Personnel will be retrained as appropriate whenever there is a significant change in their duties, the regulations, or the terms of the NRC license.

4. Individuals will receive two types of training:

   a. general training on the nature of radiation, risks, protective measures (as specified below). This training is the responsibility of the RSO.

b. training on how to safely perform the specific steps of particular procedures. This training is the responsibility of the authorized user.

5. The RSO will maintain records of the content of training and the individuals who received the training.

General training syllabus

General training will comprise the following topics.

1. Radiation physics. Information on the basic nature of radioactive decay, radioactive materials, properties of ionizing radiation, and interactions of radiation and matter.

2. Radiological health quantities and units.

3. Biological effects of radiation.

4. Risks from exposure to low-level radiation.

5. Control of radiation exposure. Protecting from external exposure. Protecting from internal exposure. Protective devices. General rules of handling radioactive materials and good laboratory practices.

6. Areas at Cayman where radioactive material is transferred, used, or stored. Notices, signs and labels. Radiation monitoring programs.

7. The role of the RSO and the authorized user.

8. Radiation dose limits, MDPH and NRC. Other important applicable regulations and terms of the license. Rights and responsibilities of employees.

9. Facilities and Equipment

9.1. Annotated Drawing

See ATT 9.1.

9.2 Survey Instrument Calibration

Cayman Chemical Company Policy - Survey Instrument Calibration

1. Survey instruments used for health protection purposes will be calibrated annually and after every servicing.

2. Survey instruments which read in radiological health units (e.g., mR/hr) shall be calibrated with a radioactive source. Survey instruments which respond only in cpm will not be used for health protection purposes (they could be used, for example, to look for a lost source).

Procedure

1. The source used must be approximately a point source.

2. Either the apparent source activity or the exposure rate at a given distance from the source must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Institute of Standards and Technology.

3. A source that has approximately the same photon energy as the environment in which the calibrated instrument will be employed should be used for the calibration.

4. The calibration source should be of sufficient strength to produce an exposure rate of about 30 mR/hr at 100 cm.

5. The inverse square law and the law of radioactive decay must be used to correct for change in exposure rate due to changes in distance or source decay.

6. A record will be made of each survey meter calibration.

7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs by the calculated exposure rate by less than ten percent.

8. Three kinds of scales are frequently used on survey meters.

    a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.
    b. Meters that have a multi decade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

    c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and no less than two points

on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

9. Readings above 1,000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.

10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.

11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The record of the calibration will include:

    a. The owner or user of the instrument;

    b. A description of the instrument that includes manufacturer, model number, serial number, and type of detector;

    c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;

    d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced calibration factor (calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;

    e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);

    f. The angle between the radiation flux field and the long axis or long dimension of the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux direction and a specified dimension of the instrument;

    g. For detectors with removable shielding or build-up cap, an indication of whether the shield or cap was in place during the calibration;

    h. The apparent exposure rate from the check source;

    i. the name of the person who performed the calibration and the date on which the calibration was performed.

12. The following information will be attached to the instrument as a calibration sticker or tag:

    a. The source used to calibrate the instrument;

    b. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);

c. For each scale or decade, one of the following:

(1). The average correction factor
(2). A graph or graphs from which the correction factor for each scale or decade may be deduced, or
(3). An indication that the scale was checked for function but not calibrated, or an indication that the scale was inoperative.

d. The angle between the radiation flux and the detector during calibration;

e. The apparent exposure rate from the check source.

Note: One word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker or tag.

Cayman Chemical Company may have its survey meters calibrated by a reputable vendor which can perform calibrations to the above standard.

9.3. Dose Calibrator Calibration

N/A

9.4 Personnel Monitor Program

Cayman Chemical Company Policy - External Personal Monitoring

1. Every individual who is occupationally exposed to external ionizing radiation in a manner which is likely to result in a radiation dose in excess of ten percent of any applicable limit will be required to wear an individual radiation monitor (e.g., film badge or thermoluminescent (TLD) dosimeter). In addition, at the discretion of the Radiation Safety Officer, other individuals may be monitored.

2. Individuals who handle radioactive material will be issued a TLD ring monitor if the dose to the fingers is likely to exceed ten percent of the applicable limit.

3. The RSO will promptly review all exposure reports to look for workers whose exposure is unexpectedly high or low, and to ensure that exposures are as low as reasonably achievable (ALARA). This review does not apply to backup monitor records, for example, pocket ionization chambers when the monitor of record is a film or TLD dosimeter.

4. External dosimeters will be processed by a contractor which meets the National Voluntary Laboratory Accreditation Program (NVLAP) standard for radiation dosimetry.

References

[1]Code of Federal Regulations, Title 10, Part 20, Paragraph 20.1201, *Occupational dose limits for adults.*

[2]Code of Federal Regulations, Title 10, Part 20, Paragraph 20.1502, *Conditions requiring individual monitoring of external and internal occupational dose.*

9.5 Imaging Equipment

N/A

9.6 Other Equipment and Facilities

Criteria for Facilities and Equipment for Radiation Research Laboratories, Cayman Chemical Company

General Criteria

Approval or disapproval by the Radiation Safety Committe of proposed use of radioactive material will depend on adequate facilities and equipment to be provided by the user to insure ALARA exposures and compliance with regulatory requirements.

Each laboratory will be evaluated case-by-case. Acceptable criteria for facilities and equipment will depend on the categories of laboratory described.

Low Level Tracer Laboratories (less than 100 mCi)

1. Benches, sinks, walls, and floors. Provide benches, sinks, walls, and floors with smooth, nonporous, and easily decontaminated surfaces.
2. Absorbent Bench Paper.
   Provide absorbent, plastic-backed (or equivalent), and easily discarded bench paper on the bench surface for catching and disposing small amounts of contamination from drips or spills from laboratory apparatus and glassware.
3. Laboratory Coats and Gloves
   Provide protective laboratory coats and rubber or disposable plastic gloves to avoid direct contact with radioactive materials.
4. Radioactive Waste Containers
   Provide specially labeled containers for laboratory radioactive wastes. These containers may be shielded as necessary, placed near the waste-generating area and distant from the area frequently occupied by personnel.
5. Sinks for Radioactive Washing or Effluents
   a. Designate special sinks to receive any small amounts of radioactive washings or effluents.
   b. Keep records of estimated amount of radioactive disposal in these sinks to ensure compliance. The disposal limit of each radioactive isotope used in each laboratory will be determined by the RSO in accordance with NRC regulation Section 20.303 of 10 CFR Part 20. These sinks should be connected to the main pipes. They should not be connected to open channels or devices resulting in the accumulation of radioactivity.
6. Sharp Corners, Cracks or Pores
   Design laboratories with a minimum of sharp corners, cracks, or porous surfaces where radioactive material can lodge.
7. Plumbing, Traps, and Ductwork
   Design plumbing, traps, and ductwork to avoid radioactive contamination build-up that can create sources of external radiation exposure, cross-contaminate drinking water or air-supply lines.
8. Ventilation

a. Provide adequate ventilation for processing of radioactive materials that may lead to airborn contamination by volatilization, dispersion of dust, spraying or splattering.
b. Airflow should be at least 100 ft. per minute.
c. Provisions should be made for shutting down the ventilation system in the event of accidents to contain radioactivity.

9. Separate Room for Coats and Belongings
Provide separate rooms for coats and personal belongings to avoid contamination.

10. Lighting
Provide adequte lighting for laboratory areas to avoid spills and other accidents resulting in contamination build-up.

Facilities For Use of Alpha Emitters

High quality factor of alpha particles may require some special provisions for use of alpha emitters.

1. Glove Box
Provide a glove box as may be required and shielded as necessary, to contain alpha emitters.

2. Leaded Gloves
Provide leaded gloves as may be required to prevent from radiation exposure.

3. Shielding
Provide bench-top lead shields as may be necessary to be determined by the RSO.

4. Remote Handling Equipment
Provide tongs, forceps, or other remote handling equipment.

High-level Beta-Gamma Laboratories (equal to or greater than 100 mCi)

In addition to the minimum criteria required for low-level tracer laboratories, the minimum criteria for high-level beta-gamma laboratory in possession of at least 100 millicuries of radioactive materials include the following requirements:

1. Drip Tray
Provide suitable drip trays that can be easily cleaned for handling radioactive materials where spills may occur. These drip trays may be covered with absorbent plastic-backed (or equivalent) material to soak up minor spills.

2. Lead shields
Provide bench-top lead shields for low energy gamma emitters or high-level radioactivity. Lead sheets with adequate thickness may be used. Protective viewing windows with adequate thickness may be used. Protective viewing windows with adequate leaded glass in combination with the lead shielding should be provided as necessary.

3. Remote Handling Equipment
Provide as necessary, tongs, forceps, or other remote handling equipment.

4. Leaded Gloves
Provide leaded gloves as necessary.

5. Laboratory Shoe Covers
Provide special disposable shoe covers if floors are likely to be contaminated.

Radioiodine Use

In order to prevent thyroid uptake by the personnel, special safety measures are required for handling I^{125}. In addition to the minimum criteria required for low-level tracer laboratories and those required for high-level beta-gamma laboratories, the following criteria will be satisfied:

1. Ventilation and Fume Hoods
   a. Provide adequate ventilation so that handling of radioiodine is limited to the area with airflow of at least 100 ft/min. Fume hoods may be required unless ventilation is adequate.
   b. Provide adequate filtration of both intake air and exhaust air to avoid increasing environmental exposures as necessary.
   c. Fume hoods, if required, should be designed to avoid eddy currents that would disperse radioactive materials outside the hood area.
   d. If appreciable levels of activity is used, as determined by the RSO, the hood should have its own exhaust system to avoid transmission of airborn contamination to other laboratories.
2. Radioactive Waste Storage
   Provide radioactive waste containers which may be effectively enclosed to prevent airborn contamination of radioiodine.

10. Radiation Safety Program

10.1 Radiation Safety Committee/Radiation Safety Officer

Cayman Chemical Company - Radiation Safety Committee Bylaws

Policy
Radioactive material will be used safely, in accordance with NRC and State of Michigan regulations, and in accordance with our NRC license and MDPH registration. To achieve this objective, the following procedures are established.

Procedures

1. The Radiation Safety Officer (RSO) will be appointed by Dr. Kirk Maxey, President, Cayman Chemical Company.

2. Application to the RSO to use radiation and radioactive material should be made in writing by the proposed user. The application should include the radionuclide identity, radionuclide chemical and physical form, the activity which will be possessed and the maximum activity which will be used per procedure, and a safety evaluation of the proposed activity. The safety evaluation should address the adequacy of the training and experience of the proposed users, the adequacy of facilities and equipment, the administrative controls to be instituted to ensure safety, forseeable reasonable accident scenarios, and procedures to be followed in the event of an accident.

3. The RSO is responsible for the safety of all radioactive materials at Cayman Chemical Company, whether regulated by NRC or the State of Michigan. The RSO is responsible for:

   a. providing general surveillance over all activities using radiation or radioactive material, and acting as the executive of Cayman Chemical's policies.

   b. formulating policies which result in occupational exposure, public exposure, and releases of radioactive material to the environment which are as low as reasonably achievable (ALARA).

   c. directing authorized users to conduct a safety analysis of operations before operations are started and at any time after operations are approved.

   d. reviewing and approving/disapproving operations involving the use of radiation based upon the risks and benefits of the proposed operation, the adequacy and conclusiveness of the safety analysis provided by the project supervisor, the adequacy of facilities and equipment, the training and experience of project personnel, the operating and emergency procedures, and the adequacy of engineered and administrative controls, and the ALARA principle.

   e. discontinuing operations not meeting safety standards.

   f. ensuring that operations are conducted in accordance with applicable state and federal laws and requlations and our license and registrations.

g. reviewing annually, the policies and procedures of the radiation safety program, and the adequacy of their implementation.

h. posting signs and notices, and keeping safety records.

References

[1]Code of Federal Regulations, Title 10, Part 33, Paragraph 33.14 *Requirements for issuance of a Type B license of broad scope.*

10.2 ALARA Program

Cayman Chemical Company Policy - ALARA Program

Cayman Chemical Company is committed that individual and collective occupational radiation doses, radiation doses to members of the public, and releases of radioactive materials to the environment, be maintained as low as reasonably achievable (ALARA).

Procedures

To meet the policy stated above, the following procedures are adopted.

1. Occupational radiation doses, both collective and individual, releases of radioactive materials to the environment, and doses and potential doses to members of the public (e.g., radiation levels in unrestricted areas), and records of surveys will be reviewed quarterly by the RSO.

2. The ALARA principle will be one of the considerations in reviewing and approving operating procedures submitted to the RSO by authorized users and proposed authorized users.

3. Modifications to operating and maintenance procedures will be made if they reduce radiation exposures unless, in our opinion, the cost is unjustified. A record of modifications which have been made to meet the ALARA principle and modifications which have been considered but which have not been made due to cost will be kept by the RSO.

4. The RSO will annually review the radiation safety program. One element of this review will be to examine radiation safety programs, policies, procedures, and user operating procedures from the ALARA standpoint.

5. Occupational radiation exposures will be reviewed regularly by the RSO, to evaluate whether exposures are consistent with ALARA. A record of this evaluation will be made. Investigational levels are established as follows: Investigational Level I, 10 percent of any applicable limit; Investigational Level II, 30 percent of any applicable limit. To permit a quarterly ALARA review, annual limits will be prorated to a quarterly basis. This scheme produces the following table:

Investigational Levels (mrem/quarter)		
	Level I	Level II
Total Effective Dose Equivalent (TEDE)	125	375
Lens of eye	375	1125
Shallow dose equivalent to skin or extremity (SDE)	1250	3750

Table 1. Investigational levels.

   a. Except when deemed appropriate by the RSO, no further action will be taken in cases where an individual's quarterly dose is less than Investigational Level I as given in Table 1.

   b. In cases where an individual's quarterly dose is greater than or equal to Investigational Level I but less than Investigational Level II, the RSO will review the circumstances and report the results of the review following the quarter when the dose was recorded. No

action related specifically to the exposure is necessary unless deemed appropriate by the RSO. The RSO will review each such dose in comparison with those of others performing similar tasks as an index of the ALARA program quality and will record the review.

c. In cases where an individual's quarterly dose is equal to, or greater than, Investigational Level II, the RSO will investigate the circumstances and causes in a timely manner and, if warranted, will take corrective action. A report of the investigation, any actions taken, and a copy of the individual's Form NRC5 or its equivalent will be recorded by the RSO following completion of the investigation.

d. In a case where a worker's dose needs to exceed an existing investigational level, a new, higher, investigational level may be established for that individual on the basis that it is consistent with good ALARA practice. Justification for the new investigational level will be documented. The RSO will review the justification and must approve or disapprove of all revisions of investigational levels.

6. Records of radiation surveys in restricted and unrestricted areas will be reviewed quarterly by the RSO to monitor that radiation fields and contamination levels meet standards and are ALARA.

7. The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. These individuals will be informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

8. Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow. The ALARA concept will be an element of these procedures. The RSO will establish a method whereby workers may make suggestions on improving health physics practices in operating procedures.

9. The RSO will investigate all known instances of deviations from good ALARA practices and, if possible, determine the causes. When the cause is known, the RSO will implement program changes to maintain doses ALARA.

10. Authorized users will consult the RSO during the project planning phase to ensure that procedures are developed that will maintain doses ALARA.

11. The ALARA principle, and its relationship to work practices and work conditions, will be an element of the training program which will be routinely provided to radiation workers. Workers will be instructed in the recourse available if they feel that ALARA is not being promoted on the job.

Responsibility

1. Development of policies and procedures to meet the ALARA goal is the responsibility of the RSO.

2. Implementation of ALARA policies as they relate to authorized users is the responsibility of the authorized users and the RSO, who will assert authority to maintain practices consistent with ALARA.

References

[1]Code of Federal Regulations, Title 10, Part 20, Paragraphs 20.1101(b), and 20.1101(c) *Radiation Protection Programs.*

Management Commitment

We, the management of Cayman Chemical Company, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our company.

I hereby certify that this institution has implemented the ALARA Program set forth above.

5-16-96
(date)

Kirk Maxey, M.D.
President, Cayman Chemical Company

K. R. Maddipati 5/16/96
(date)

Krishna Rao Maddipati, Ph.D.
Radiation Safety Officer
Cayman Chemical Company

10.3 Leak Test

Cayman Chemical Company - Leak Tests of Sealed Sources

Cayman Chemical Company is not requesting at this time to possess any sealed sources.

If we wish to possess sealed sources, a procedure for leak testing them will be submitted with the application to possess such sources.

10.4 Safe Use of Radiopharmaceuticals

N/A

10.5 Spill Procedures

Cayman Chemical Company - Spill Procedures

1. **Estimate the activity spilled.** Initiate a major or minor spill procedure based upon the activity spilled.

Radionuclide	Millicuries
H-3	100
C-14	20
S-35	40
P-32	10
P-33	10
Fe-55	20
I-125	1

Table 1. Spills greater than the tabulated activity are major spills. Spills less than the tabulated activity are minor spills.

For major spills of liquids or solids.

1. **Clear the area.** Notify all persons not involved in the spill, and who will not be needed, to leave the room.

2. **If you are contaminated or injured, call for help.** If you are contaminated enlist a colleague to attend to steps 3 -5 below. If injured, take care of your own medical needs first. Use the available safety equipment such as the eyewash. Discard contaminated clothing and use an emergency shower if necessary. Skin contamination is most effectively removed by washing *gently* (so as not to break the skin) with mild soap and lukewarm water. Later, use a diluted radioactive decontaminant such as Isoclean to remove the final traces of radioactivity. If radioactivity remains, some can be removed by covering the skin with plastic to induce perspiration and subsequently washing away the perspiration.

3. **Prevent the spread.** Cover the spill with absorbent paper. Pay particular attention to the possibility of radioactive powders becoming airborne (in this case, use damp paper. Do not attempt to clean up the spill now. If clothes or shoes are contaminated, leave them in the

contaminated area. Limit the movement of personnel so that the contamination is not spread. If possible, and if the radiation level is low (e.g., pure beta emitters), mark the area of the spill with a marker or tape.

4. **Shield the source if possible.** This should be done only if it can be done without spreading contamination and there is no significant increase in radiation exposure (i.e., radiation level is low [pure beta emitter] and you are not contaminated).

5. **Secure the area.** Lock the room or enlist the assistance of a colleague to prevent access by others.

6. **Notify the RSO immediately.** The RSO will supervise spill cleanup and will prepare a report of the incident.

For minor spills of liquids or solids.

1. **Notify.** Notify persons in the area that a spill has occurred.

2. **Prevent the spread.** Prevent the spread by covering the spill with absorbent paper. If a powder was spilled, use damp paper to prevent the powder from becoming airborne.

3. **Clean up.** Clean up the spill using disposable gloves and absorbent paper (e.g., paper towels). Wipe from the outside of the contaminated area towards the center; wiping in a circular motion tends to spread contamination. Carefully fold the paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Use a dilute soap or decontaminating solution such as Isoclean for the final stages of the cleanup. Change gloves often, placing contaminated gloves in the trash bag.

4. **Survey.** Survey the spill area with an appropriate low-range radiation detector. A GM counter is appropriate for P-32, P-33, and I-125. For tritium, S-35, and C-14, wipe tests counted on the liquid scintillation counter will be necessary. Check hands, clothing, and shoes for contamination.

5. **Report the incident to the RSO.** The RSO will follow up on the successful cleanup of the spill and will complete a report giving the details of the spill.

10.6 Ordering and Receiving

Cayman Chemical Company Policy - Ordering

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive material before the order is placed with a supplier. Purchasing will not proceed with an order for radioactive materials unless it is also signed by the RSO.

2. Prior to authorizing a purchase of radioactive materials, the RSO will ensure that the acquisition of the material is consistent with the possession limits, chemical form, and physical form authorized by our license. The RSO will also ensure that the material will be used by an individual named in the license and for the purposes authorized.

3. The RSO will establish and maintain a record keeping system which will identify the isotope, activity, chemical and physical form, supplier, and the authorized user. The RSO will also provide a method of ensuring that the ordered material was, in fact, ordered through proper channels.

4. No radioactive materials may be brought to the Cayman site without the express approval and prior knowledge of the RSO.

5. The RSO will inform and train Receiving and Security personnel as to where and how to deliver received packages of radioactive materials during normal working hours and off-hours.

6. If deliveries are to be made during off-hours, the RSO will inform carriers of where to make deliveries.

Cayman Chemical Company Policy - Receipt of Radioactive Packages

1. Instructions to Receiving Personnel:

   a. Receiving or Security personnel on duty may accept delivery of packages containing radioactive material from any carrier. Radioactive packages which contain substantial quantities of radioactive material can be recognized by the DOT Radioactive White I, Yellow II, or Yellow III label. Some packages contain small enough quantities of radioactive material so that they do not need to be labeled with the White 1, Yellow II, or Yellow III label. These packages may be identified by the shipping papers or invoice.

   b. Packages containing radioactive material should be visually inspected for any sign of damage (such as leaking, crushed, torn, wet). If the package shows signs of damage, immediately deliver it on the bench in room 12B. Use handling techniques specified by the Radiation Safety Officer (RSO). Immediately call the RSO or one of the other individuals listed below.

   If the package appears undamaged, deliver it to the refrigerator of room 12B or the freezer of room 12A. Make sure the room is locked when you leave. Notify the authorized user that a radioactive package has arrived. If the authorized user is unavailable, notify the RSO. If the package is received after normal working hours, leave a message or the invoice for the authorized user designated on the packing slip so that the package will be sure to be checked at the start of the next working day.

   If the package is a Yellow II or a Yellow III package, do not handle it for a prolonged period. Transport it using a cart.

   If Receiving or Security personnel have any questions on how to follow this policy, contact the RSO.

   Persons to contact for an emergency off hours:

Radiation Safety Officer	**Krishna Rao Maddipati Ph.D.**	**313-741-9758**
Authorized user	**Jeff Johnson Ph.D.**	**313-996-1281**
Authorized user	**Jim MacDonald**	**313-971-4170**

10.7 Opening Packages

Cayman Chemical Policy

Receipts of packages containing radioactive materials bearing a DOT Radioactive White I, Yellow II, or Yellow III label, or packages which are wet, crushed, or damaged, will be monitored as required by federal regulations.[1] Maximum radiation levels[2] and contamination levels[3] are specified by federal regulations.

It is the policy of Cayman Chemical Co. to monitor all incoming packages of radioactive materials.

Monitoring will consist of exposure rate measurements and wipe test surveys of the inner and outer shipping container.

Materials

Liquid scintillation counter (LSC) or well counter
Geiger-Mueller (GM) Counter
Ionization chamber survey meter or GM counter calibrated in mR/hr
Filter disks or alcohol pads for wipe tests
Forceps or tongs
Protective gloves

Procedure

1. For packages in apparently good condition, the Receiving personnel will, upon receipt, deliver packages which contain radioactive material to room 12A or room 12B. These packages will be delivered unopened. If a package appears damaged, crushed, or wet, Receiving personnel will deliver the package to a designated location in room 12B using techniques specified by the Radiation Safety Officer (RSO). In the case of an apparently damaged package, Receiving will immediately notify the RSO. If a package cannot be delivered promptly, Receiving will notify the RSO.

2. The monitoring of WHITE I, YELLOW II, and YELLOW III packages must be done within three hours of receipt or, if the package is not received during working hours, within three hours of the start of the next working day. All packages should be monitored (surveyed) promptly after receipt.

3. Surveys will be performed by qualified personnel designated by the RSO. Before making a survey, make sure that the survey instrument has been checked that day with the appropriate check source and is functioning properly. Detailed procedures are as follows:
   a. Turn on the survey meter(s) and allow to stabilize. Record the background reading. With this reading and all others, the actual numerical value must be recorded, not "same as background" or "less than ..."

   b. Wear gloves when surveying packages.

c. Visually inspect the package for any sign of damage (e.g., wet, torn, crushed). If damage is noted, stop. Notify the RSO.

d. Measure the exposure rate at three feet from the package and record. Verify that the exposure rate at three feet is equal to, or less than the transportation index on the package. If the exposure rate at three feet is greater than the transport index, or if it is greater than 10 mR/hr, stop. Follow the notification procedure in paragraph 4.

e. Measure the exposure rate at the surface of the package and record. If the exposure rate at the package surface is greater than 200 mR/hr, stop. Follow the notification procedure in paragraph 4.

f. Open the package and check the inner container for breakage, wetness, or discolorization which could indicate leakage.

g. Wipe test a 100 square cm area of both the external surface of the shipping container and the external surface of the lead shield of the inner container. If there is no lead shield, wipe test the inner container.

h. Assay the wipe tests using an appropriate, calibrated counter. For pure beta emitters, a liquid scintillation counter is appropriate. For photon emitters, a sodium iodide well counter or liquid scintillation counter may be used. Assay a background (blank) specimen also. Calculate the disintegrations per minute as follows.

$$\text{dpm} = \frac{\text{gross cpm} - \text{background cpm}}{\text{efficiency}}$$

i. Record the data in the radioactive shipment receiving log.

j. If the activity on the wipe of the outer shipping box exceeds 2200 dpm, follow the notification procedure in paragraph 4. If the activity on the wipe of the inner container exceeds 2200 dpm, notify the RSO.

k. With the source container removed, monitor the packaging materials with the appropriate detector. For pure beta emitters, a GM counter must be used. If the packaging materials show any radioactivity, handle them as radioactive waste. If the packaging material is not contaminated, obliterate labels indicating radioactivity, remove the packing slip or invoice if needed, and discard the remainder as ordinary trash.

4. Notifications. If any of the measurements of exposure rate or of removable contamination exceed the specified limits, notify:

a. the Radiation Safety Officer

b. NRC Region III office. The NRC must be notified by telephone (NRC Region III's phone number is 708-829-9500).

c. the final delivering carrier.

References

[1]U.S. CFR Title 10 Part 20, Paragraph 20.1906, *Procedures for receiving and opening packages.*

[2]U.S. CFR Title 10 Part 71, Paragraph 71.47, *External radiation standards for all packages.*

[3]U.S. CFR Title 10 Part 71, Paragraph 71.87, *Routine determinations.*

10.8 Unit Dosage Records

N/A

10.9 Multidose Vial Records

N/A

10.10 Molybdenum Concentration Records

N/A

10.12 Area Survey Procedures

Cayman Chemical Company Policy - Area Surveys

Area surveys will performed in all laboratory areas where radioactive materials are stored, handled or used, areas where a spill has occurred, areas where leaking radioactive containers are known to have been present (e.g., Shipping if a package has leaked), the radioactive waste storage area, and other areas designated by the Radiation Safety Officer.

The quantities of radioactive material licensed for possession by Cayman do not emit significant photon radiation. Consequently, area survey efforts will be done by wipe test and will be directed towards discovering contamination incidental to laboratory experiments and unsuspected spills or leakages.

Procedures

1. Wipe tests will be performed routinely on a monthly basis for all areas which reasonably could be contaminated with radioactive material. This includes radioactive material storage and use areas and the radioactive waste storage area.

2. When an experiment is in progress, the experimental area will be posted with the "Caution - Radioactive Materials" sign. Such areas will be treated as radioactive by the staff, and will not be considered non-radioactive until proven to be uncontaminated by wipe tests. Wipe tests will be performed promptly upon completion of the experiment.

3. The wipe test procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). Equipment used to assay the radioactivity on wipe samples shall be calibrated, using standards

traceable to the National Institute of Standards and Technology (NIST), in such a way that the dpm of wipe test samples can be calculated from the measured cpm.

4. The RSO shall be immediately notified if the results of wipe tests are unexpectedly high or exceed action levels.

5. Areas found to exceed the action levels (Table 1.) will be decontaminated to levels below those specified in Table 1. before return to service. If an area cannot be decontaminated to levels less than those specified in Table 1. the RSO will take further steps to remove the radioactive material and/or to restrict use of the area.

Action Levels in dpm/100 cm^2		
	P-32, P-33, I-125	**H-3, C-14, S-35, Fe-55**
Unrestricted areas, personal clothing	**200**	**2,000**
Restricted areas, protective clothing used only in restricted areas, skin	**2,000**	**20,000**

Table 1. Action levels for radioactive surface contamination.

Records

1. Records of contamination surveys must include:
   a. the date, areas surveyed, and the equipment used
   b. the name or initials of the person making the survey
   c. a drawing of the surveyed areas with a notation of the action levels given in Table 1
   d. measured contamination levels in dpm/100 cm^2
   e. procedures taken for those areas where excessive contamination was discovered and follow up actions taken.

2. The RSO will review the records at least monthly and also promptly in those cases where action levels have been exceeded.

10.13 Air Concentration Control

N/A

10.14 Radiopharmaceutical Therapy

N/A

10.15 Implant Therapy

N/A

10.16 Other Safety Procedures

N/A

11. Waste Management

11.1 Waste Disposal

Cayman Chemical Company Policy - Radioactive Waste Disposal

Radioactive waste will be disposed of by decay-in-storage (DIS), release to the sanitary sewer, evaporative release to the atmosphere, or by transfer to an authorized recipient.

When determining a waste disposal method, the entire impact on the environment and the company's resources will be considered. Factors such as occupational and public radiation exposure, other hazards (e.g., pathogens) of the waste, as well as expense, will be considered.

Procedures - General

1. Prior to disposal of radioactive material which has become non-radioactive due to decay-in-storage (DIS), or non-radioactive packaging materials which bear radioactive markings or logo, all labels indicating radioactive material and the radiation logo must be removed or defaced prior to disposal.

2. Non-radioactive waste such as leftover reagents, boxes, non-radioactive gloves, should not be mixed with radioactive waste. The RSO will occasionally monitor all waste-generating procedures to ensure that radioactive waste is not generated unnecessarily.

3. The RSC and RSO will review all new procedures to ensure that waste generated is a minimum and that generation and handling procedures are consistent with established good practices.

4. Every effort will be made to avoid generating waste which is both radioactive and also hazardous waste under EPA's RCRA regulations. Such waste ("mixed waste") poses especially-difficult disposal problems.

5. NRC exemptions for disposal to the atmosphere or the sanitary sewer only exempt the radioactivity. No exemption in the NRC rules relieves the waste disposer from complying with other waste regulations, such as EPA regulations which govern hazardous waste.

Procedures - Disposal by evaporative release

1. Liquids and gases may be disposed of by evaporative release. However, most of the materials used by Cayman are not volatile; for such materials evaporative release is not an option.

2. The RSO will ensure that disposal to the atmosphere is done in accordance with applicable regulations.[1] Limits on permissible air concentrations apply at the boundary of the restricted area.

3. A record of releases to the atmosphere must be made which includes the date, radionuclide, estimated activity that was released (in millicuries or microcuries), the estimated concentration, and the vent site from which the material was released.

Procedures - Disposal to the sanitary sewer

1. Material released to the sewer must be readily soluble or dispersable biological material. There are daily, monthly, and annual limits.

2. The RSO will ensure that disposal to the sewer is be done in accordance with specific NRC exemptions.[2,3]

3. A record of releases to the sanitary sewer must be made which includes the date, the radionuclides, the estimated activities that were released (in microcuries or millicuries), and the sink at which the material was released.

Procedures - Liquid scintillation waste

1. Liquid scintillation waste may be disposed of as if it were not radioactive if it contains only H-3 or C-14 and the activity concentration is 0.05 microcurie or less per gram of liquid scintillation medium.[3] Other waste laws (e.g., RCRA) still apply. This exemption does not apply to radionuclides other than H-3 and C-14.

Procedures - Decay in storage (DIS)

1. Radionuclides of half life less than 90 days may be disposed of by DIS. This includes P-32, P-33, S-35, and I-125.

2. Since the waste must eventually be surveyed with no shielding, no shielding material may be placed in a waste container.

3. When an waste container (e.g., plastic bag) is full, seal it and tag it with the nature of the contents, the longest-lived radionuclide present, the date, and the initials of the person sealing the container. Transfer this container to the DIS area.

4. Retain the material in a restricted area for ten half lives of the longest radionuclide present in the container.

5. Prior to disposal as ordinary nonradioactive trash:
   a. Check the radiation survey meter for proper operation.
   b. Monitor the waste containers in a low radiation (less than 0.05 mR/hr) areas.
   c. Monitor all surfaces of each individual container, using the most sensitive scale on the meter.
   d. Discard to the ordinary trash only those containers for which the radiation level is indistinguishable from background. Record the date the container was disposed of, the type of waste, the disposal date, and the initials of the person performing the monitoring and disposal. Make sure that no radiation labels are visible.
   e. Containers, for which the radiation survey is above background, must be returned for further DIS or disposed of by transfer to authorized recipient (burial).

Procedures - Disposal by transfer to authorized recipient

1. Dry solid waste which contains radionuclides with half lives too long for DIS must be disposed of by transferring the waste to an authorized radioactive waste contractor who will arrange for the waste to be buried at a licensed low-level adioactive waste disposal site.

2. Before generating waste, obtain the restrictions on waste form from the burial site operator.

3. Waste for burial must contain absolutely no loose liquids. Loose liquids must be completely absorbed by proper absorbent.

4. For disposal, follow the instructions provided by the burial site operator and the waste disposal contractor.

References

[1]Code of Federal Regulations, Title 10, Part 20, Appendix B, Table 2, Column1.
[2]Code of Federal Regulations, Title 10, Part 20, Paragraph 20.2003, *Disposal by release into sanitary sewerage.*
[3]Code of Federal Regulations, Title 10, Part 20, Paragraph 20.2005, *Disposal of specific wastes.*

11.2 Other Waste Disposal

N/A

ATT 7.2.1

Cayman Chemical Company
Radiation Authorized User Form

Name: Krishna Rao Maddipati, Ph.D.

Title: Director, Research and Development

Date: September 26, 1995

1. Training

Type	Location	Duration	Content
On the Job	The Pennsylvania State Univ University Park, PA	12 hrs	A,B,C,D
On the Job	Wayne State University	3 hr	A,B,C,D

Content Code:
(A) Principles and Practices of radiation protection
(B) Radioactivity measurements, standardization, and monitoring techniques and instruments
(C) Mathematics and calculations basic to the use and measurement of radioactivity
(D) Biological effects of radiation

2. Experience with Radiation (actual use)

Isotope	mCi used at one time	Location	Clock hrs	Type of use
^{3}H	25 mCi	The Pennsylvania State Univ University Park, PA	4 hrs	Sodium Borhydride Reduction of organic compounds
^{3}H	1 mCi	The Pennsylvania State Univ University Park, PA	8 hrs	Enzymatic Reaction
^{14}C	<0.5 mCi	Wayne State Univ Detroit, MI	48 nrs	Enzymatic Reaction
^{3}H	2 mCi	Wayne State Univ Detroit, MI	10 hrs	Enzymatic labeling

ATT 7.2.2

Cayman Chemical Company
Radiation Authorized User Form

Name: James W. MacDonald

Title: Manager, EIA Division

Date: September 26, 1995

1. Training

Type	Location	Duration	Content
Class (Immunolog. Tech.)	Colorado St. Univ, Ft. Collins, CO	1 semester	B,C
Class (Biochem. Lab.)	Colorado St. Univ, Ft. Collins, CO	1 semester	B,C

Content Code:
(A) Principles and Practices of radiation protection
(B) Radioactivity measurements, standardization, and monitoring techniques and instruments
(C) Mathematics and calculations basic to the use and measurement of radioactivity
(D) Biological effects of radiation

2. Experience with Radiation (actual use)

Isotope	mCi used at one time	Location	Clock hrs	Type of use
^{3}H	0.005 mCi	Nat'l Jewish Hospital, Denver, CO	80	Sample Purification

ATT 7.2.3

Cayman Chemical Company
Radiation Authorized User Form

Name: Jeffrey K. Johnson, Ph.D.

Title: Manager, Biochemistry

Date: September 26, 1995

1. Training

Type	Location	Duration	Content
5-credit course	Bemidji State Univ Bemidji, MN	10 weeks	A, B, C, D
Short course	North Dakota State Univ Fargo, ND	4 hr	A

Content Code:
(A) Principles and Practices of radiation protection
(B) Radioactivity measurements, standardization, and monitoring techniques and instruments
(C) Mathematics and calculations basic to the use and measurement of radioactivity
(D) Biological effects of radiation

2. Experience with Radiation (actual use)

Isotope	mCi used at one time	Location	Clock hrs	Type of use
^{14}C	0.005 mCi	North Dakota State Univ Fargo, ND	10 hrs	Labeling experiment
^{32}P	0.02 mCi	North Dakota State Univ Fargo, ND	2 hrs	Nick translation

ATT 7.2.4

Cayman Chemical Company
Radiation Authorized User Form

Name: Jennifer L. Johnson

Title: Biochemistry Research Assistant

Date: September 26, 1995

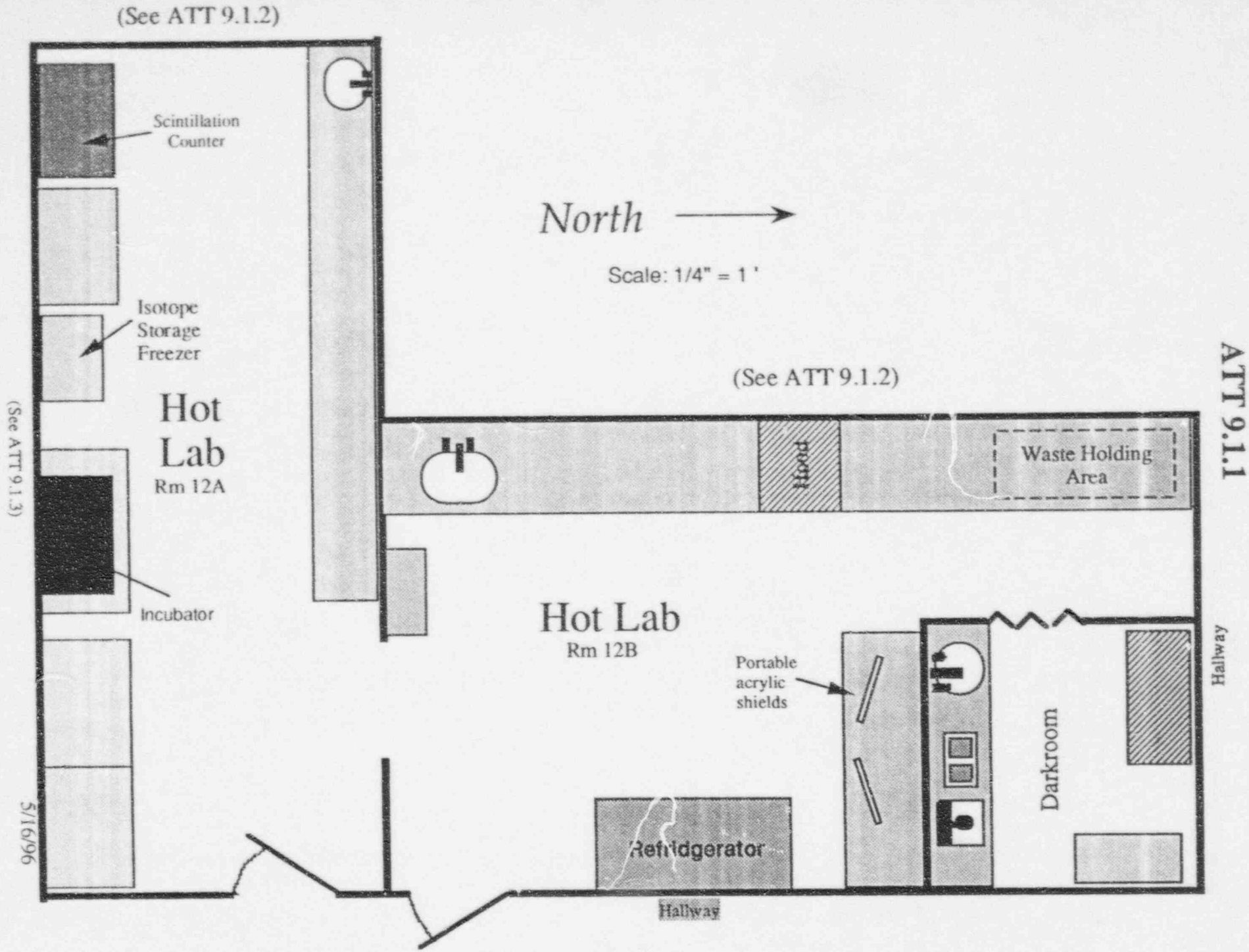
1. Training

Type	Location	Duration	Content
Radiation Therapy	University of Toledo Toledo, OH	9 weeks	B,C,D
Radiation Training	University of Toledo Toledo, OH	1 week	A,B,C

Content Code:
(A) Principles and Practices of radiation protection
(B) Radioactivity measurements, standardization, and monitoring techniques and instruments
(C) Mathematics and calculations basic to the use and measurement of radioactivity
(D) Biological effects of radiation

2. Experience with Radiation (actual use)

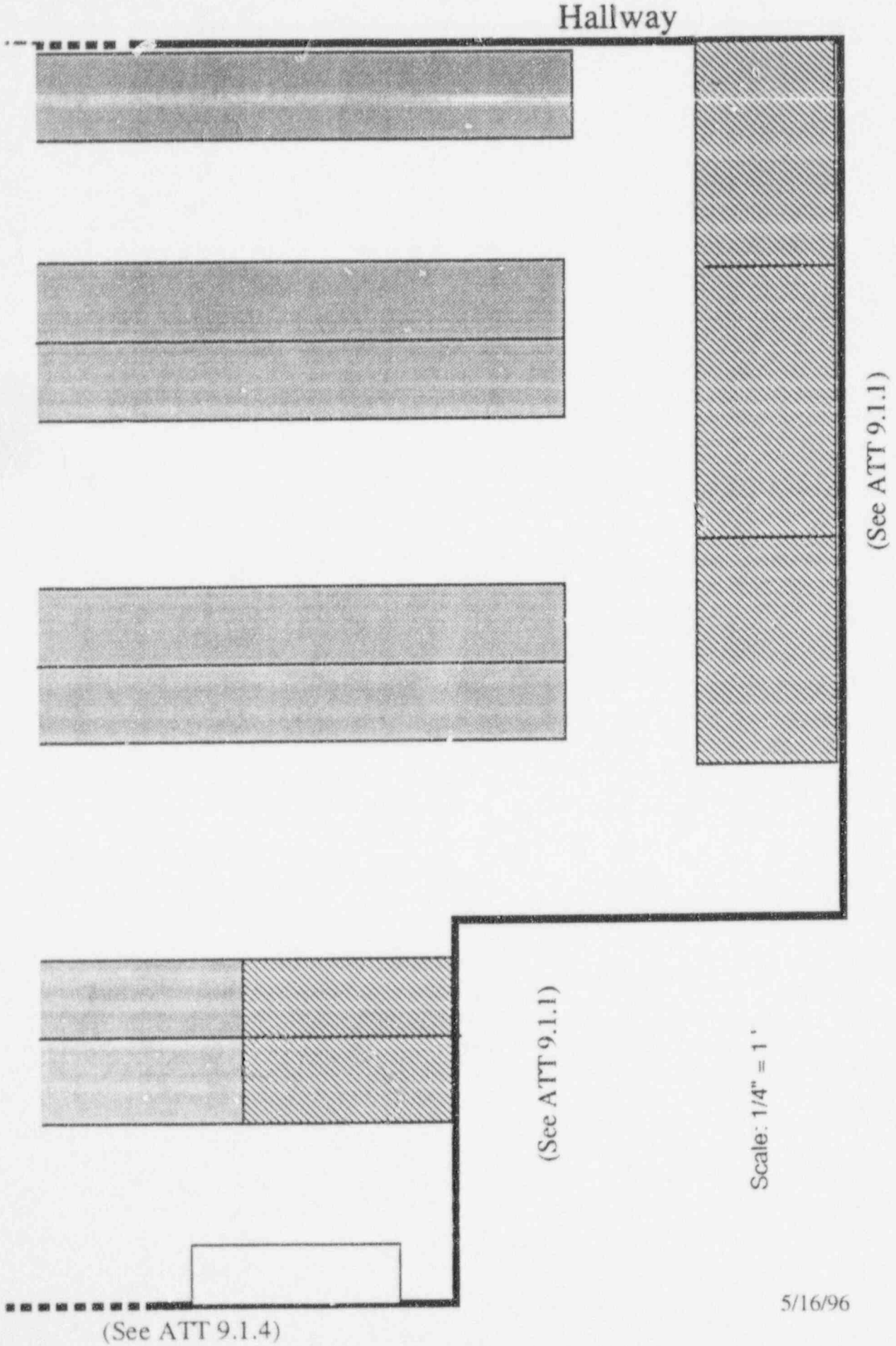
Isotope	mCi used at one time	Location	Clock hrs	Type of use
^{35}S	< 0.005 mCi	University of Toledo Toledo, OH	10 hrs	*in vitro* translation



ATT 9.1.1

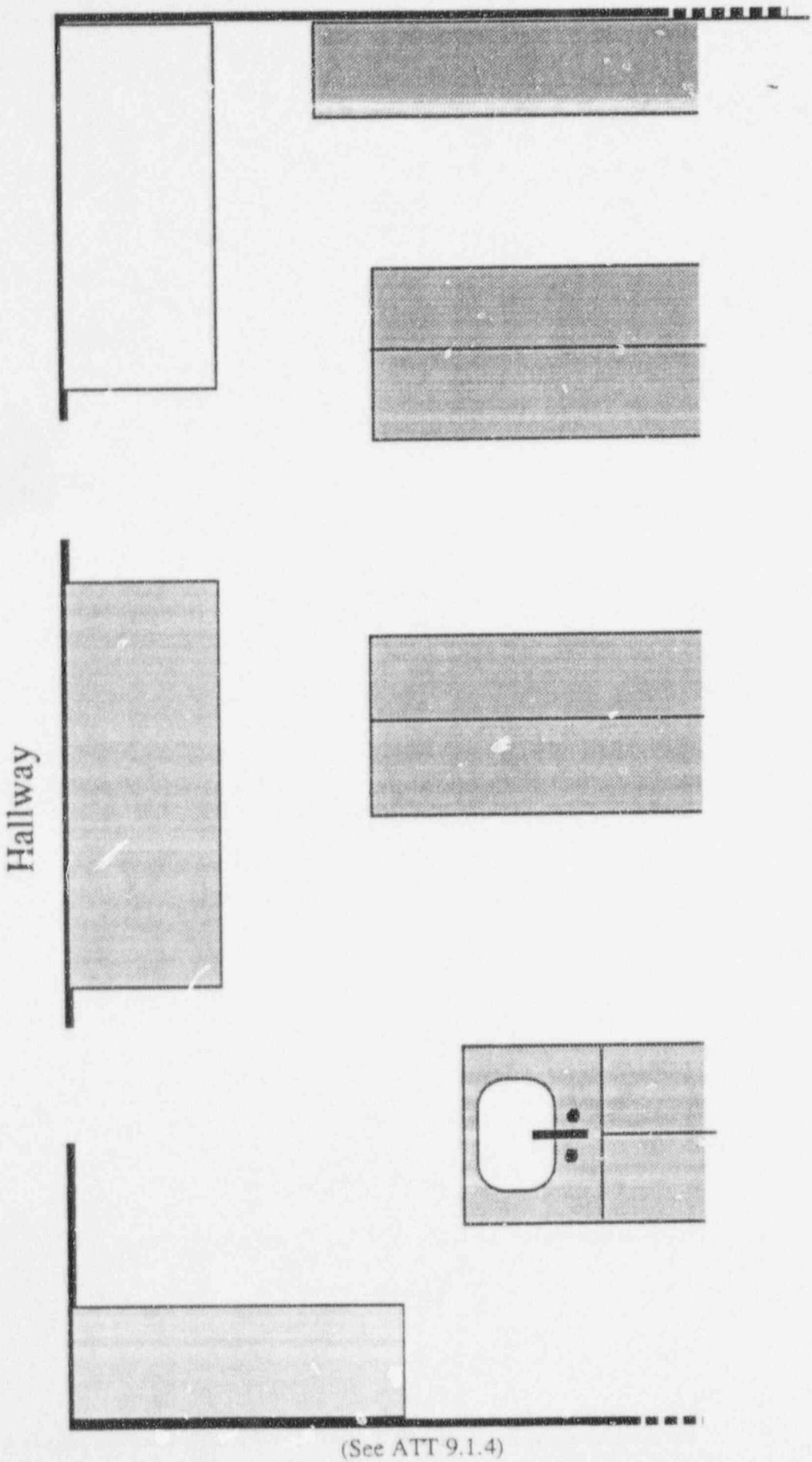
5/16/96

ATT 9.1.2a



5/16/96

ATT 9.1.2b



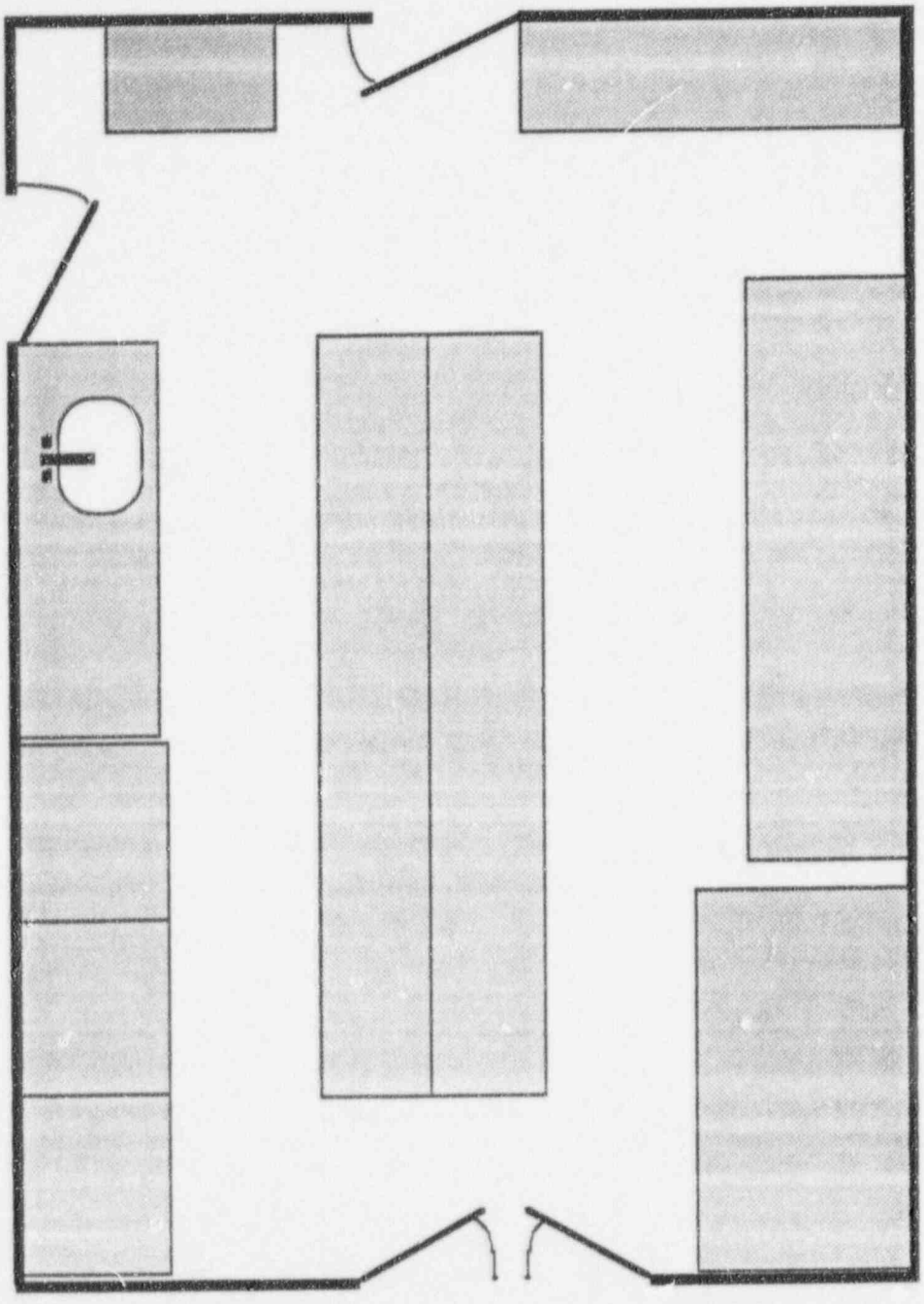
(See ATT 9.1.2b)
Scale: 1/4" = 1 '

(See ATT 9.1.4)

ATT 9.1.3

Scale: 1/4" = 1'

(See ATT 9.1.4)



(See ATT 9.1.1)

Hallway

North

MAY 0 1 1997

K. Rao Maddipati, Ph.D.
Radiation Safety Officer
Cayman Chemical Company, Inc.
690 KMS Place
Ann Arbor, MI 48108

Dear Dr. Maddipati:

Enclosed is Amendment No. 07 to your NRC Material License No. 21-24683-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the mailing address listed on the license changes. (No fee is required if the location of byproduct material remains the same.)

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when a decision is made to terminate all activities involving materials authorized under the license.

301324

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when a decision is made to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

   b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   d. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC

requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Evelyn R. Matson
Nuclear Materials Licensing Branch

License No. 21-24683-01
Docket No. 030-29143

Enclosure: Amendment No. 07

DOCUMENT NAME: M:\03029143.CL7

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	N							
NAME	ERMatson:brt								
DATE	04/ 29 /97								

OFFICIAL RECORD COPY

CAYMAN CHEMICAL

April 9, 1997

Krishna Rao Maddipati, Ph.D.
Director, Research and Development/
Radiation Safety Officer

Materials Licensing Section
Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60352
Attn.: Ms. Evelyn R. Matson

Subject: Amendment request to Lic. No. 21-24683-01. **CONTROL# 301324**

Dear Ms. Matson,

I am writing this letter to follow up on our conversation over the phone about our amendment request listed above.

The radioactive materials we intend to distribute are strictly for laboratory research use only. These materials are not for human or veterinary use. Even if the end users perform experiments on human or animal specimens outside the organism (for example, on blood, urine, etc.) they can not draw any diagnostic conclusions for clinical purposes. Because of these limitations on the end users, we request that our license be confined to distribution of the licensed materials to "Specific Licensees" in addition to our own research use.

Additionally, the radioactive materials we obtain from other manufacturers for redistribution will not be opened at our site. We will simply re-label the vials in accordance with NRC regulations and ship them to our licensed customers with the necessary product information.

I hope that the information provided in this letter clarifies all the issues we discussed. If you need any further information please do not hesitate to call me.

Thank you very much for your help and guidance.

Sincerely,

Krishna Rao Maddipati

CAYMAN
CHEMICAL

690 KMS Place
Ann Arbor, MI
48108 USA

Phone:
(800) 364-9897
(313) 662-6756

Fax:
(313) 662-6896

Pm: 4-10-97

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
CONVERSATION RECORD

(X) TELEPHONE (X) OUTGOING ( ) INCOMING ( ) CONVERSATION TIME: DATE: 3/8/97 4

NAME OF PERSON(S) CONTACTED: ORGANIZATION: TELEPHONE NO.:
K.R. Maddipati, Ph.D.
Cayman Chemical
313-662-6756

SUBJECT:
Letter dated March 4, 1997 providing additional information to Control No. 301324

SUMMARY:

Several questions arose when reviewing the deficiency response (Letter dated March 4, 1997)

Does Cayman Chemical obtain prepackaged kits only from a 32.71 authorized distributer. Does Cayman Chemical distribute to general licensees. Are H-3 prostaglandin and fatty acid compounds really used by physicians, veterinarians, hospitals or clinical labs for clinical or laboratory tests?

After discussing the above with Dr. Maddipati, we concluded that Cayman Chemical is not distributing I-125 or H-3 to general licensees and does not intend to distribute C-14 or H-3 prostaglandins and fatty acids to general licensees. All of their customers are specifically licensed. Therefore, with regard to License Item 7, Chemical and physical form, Cayman Chemical can receive any prepackaged unit from any supplier to redistribute to any specific licensee.

Dr. Maddipati agreed to send a letter describing these activities so the license can be updated and amended to reflect their current activities. It is my understanding that their activities include receiving prepackaged, sealed units from a manufacturer like NEN, etc., re-labeling the prepackaged unit with a Cayman Chemical label, enclosing a brochure and redistributing the prepackage unit to specific licensees.

The license will be amended to show these changes.

ACTION REQUIRED:
Please respond in writing within 30 days, provide two copies of your response and refer to Control No. 301324.

NAME OF PERSON DOCUMENTING CONVERSATION: SIGNATURE: DATE:
Evelyn R. Matson 630-829-9822 3/8/97 4

CAYMAN CHEMICAL

March 4, 1997

Krishna Rao Maddipati, Ph.D.
Director, Research and Development/
Radiation Safety Officer

Materials Licensing Section
Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532
Attn.: Ms. Evelyn R. Matson

Subject: Changes to amendment request. Lic. No. 21-24683-01. **CONTROL# 301324**

Dear Ms. Matson,

I am herewith submitting the revised amendment application to our original license (21-24683-01). I have listed below the changes that were made in the application. Please note that, with the revision, the page numbers have changed and the page numbers referred to below correspond to the earlier version submitted on May 16, 1996. Other than the changes indicated below, the remainder of the application is as submitted on May 16, 1996.

In addition to the revised application, I am also submitting typical labels that we plan to use in labeling the containers for your approval. Unfortunately, we do not have colored labels at this time. We plan to obtain blank labels with the colored radiation logo and "CAUTION RADIOACTIVE MATERIAL" pre-printed on the label. We print the rest of the information about the product on the label using our in-house laser printers. The text will be in black. We will submit the labels with colored radiation caution sign as soon as we obtain them. I request you please peruse the text on the labels in the mean time.

We send product information sheets with each product we sell. Typically, these sheets contain technical information about the product, its uses, and a list of references for the end user to follow. I am also enclosing a sample product information sheet for your perusal.

List of Changes to the Amendment Application:

1. On page 1: Items 5a and 5c have been deleted. The maximum amounts on ^{32}P and ^{3}H have been decreased and itemized to reflect the holding limits under different categories. A statement is included to change the license condition for ^{3}H.

2. On page 2: Items 6a, 6c, and 6d have been deleted. The purpose for ^{14}C eicosanoids and fatty acids has been divided into two parts to reflect both the use for research (1) purposes and redistribution. (2)

3. On page 3: Another user has been added to item 7.2 and the primary user has been changed to Dr. Gong Chen. A sentence has been added to the end of first paragraph in item 8 in response to your question #6.

CAYMAN
CHEMICAL

690 KMS Place
Ann Arbor, MI
48108 USA

Phone:
(800) 364-9897
(313) 662-6756

Fax:
(313) 662-6896

Pm: 3-4-97

4. On page 5: Under section 9.1 procedures for securing the licensed materials were added in response to your question #17. Also, under section 9.2, a paragraph containing the description of radioactivity monitoring equipment was added in response to your question #10.

5. On page 7: The last sentence of the first paragraph under item 9.4 was modified to reflect the criteria under which dosimetry devices will be assigned in response to your question #11 and special safety instructions added in response to your question #9.

6. On pages 8 and 11: Since we are not applying for a broad scope license, references to Radiation Safety Committee has been eliminated in response to your questions #7 and 8. Typical laboratory instructions for working in a hot lab were included in response to your question #12.

7. On page 18: Procedures for handling the damaged packages by the receiving personnel have been included in 1.b. in response to your question #15. Also, the phone numbers of the persons to contact in case of an emergency during off hours have been updated.

8. On page 20: The phone number for NRC has been changed to reflect the new area code.

9. On page 21: Paragraphs 1 and 2 under 10.12 - Procedures have been changed to include the modifications suggested by you under your question #14. Item A under your question #14 is covered on page 22 under Records item 2.

10. Since ^{35}S has been deleted from our application, we did not answer the question #13 in the application.

Please feel free to contact me if you need any further information.

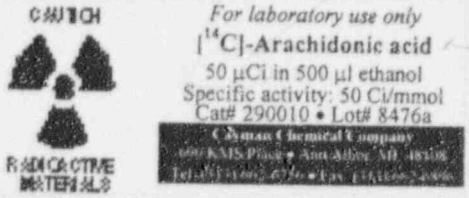
Looking forward to hearing from you soon.

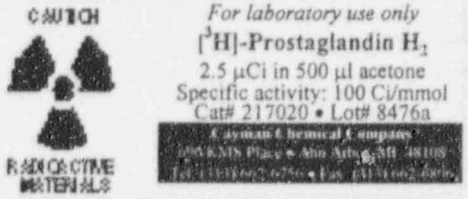
Sincerely,

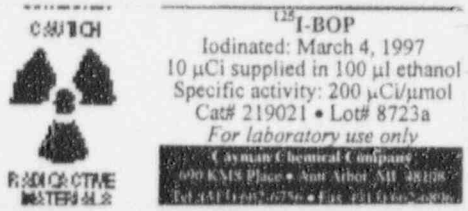
Krishna Rao Maddipati

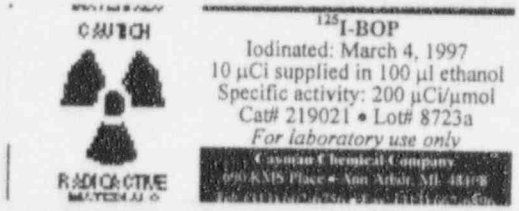
Enclosures:
1. Revised amendment application
2. Proposed labels
3. Sample product information sheet

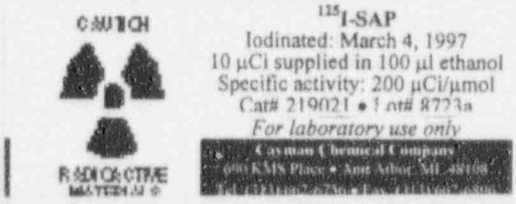
Proposed labels for Cayman Chemical redistributed radioactive products











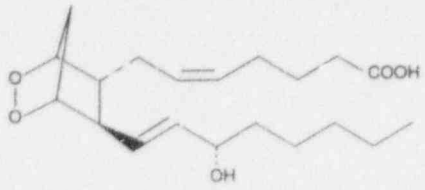
Product Information

CAYMAN CHEMICAL

[^{3}H]-Prostaglandin H_2

Catalog No. 217020 *Lot No. 8476a*

CAS Registry No: 127969-05-5
CA Index Name: Prosta-5,13-dien-1-oic acid, 9,11-epidioxy-15-hydroxy-, labeled with tritium, (5Z,9α,11α,13E,15S)-
MF: $C_{20}H_{32}O_5$
FW: 352.5
Purity: ≥95%
Stability: ≥6 months at -80°C
Supplied as: A solution in acetone
Concentration: 2.5 µCi per 500 µl acetone
Specific Activity: 100 µCi/µmol (as determined on March 4, 1997)



Radioactive Material - Not for human or veterinary use.

Laboratory Procedures

For long term storage, we suggest that [^{3}H]-Prostaglandin H_2 ([^{3}H]-PGH_2) be stored as supplied at -80°C. It will be stable for at least six months.

[^{3}H]-PGH_2 is supplied as a solution in acetone. To change the solvent, simply evaporate the acetone under a gentle stream of nitrogen and immediately add the solvent of choice. Solvents such as ethanol, dimethyl formamide, or acetonitrile purged with an inert gas or nitrogen can be used. Further dilutions of the stock solution into aqueous buffers or isotonic saline should be made just prior to performing biological experiments. However, the half-life of [^{3}H]-PGH_2 in aqueous solutions is approximately 10 minutes at 37°C. Also, ensure that the residual amount of organic solvent is insignificant, since organic solvents may have physiological effects at low concentrations.

PGH_2 is a metabolite of arachidonic acid by prostaglandin H synthase and is the precursor for all 2-series prostaglandins and thromboxanes.[1-4] Handle [^{3}H]-PGH_2 at 4°C at all times to prevent decomposition.

References

1. Hamberg, M., Svensson, J., Wakabayashi, T., *et al.* Isolation and structure of two prostaglandin endoperoxides that cause platelet aggregation. *Proc. Natl. Acad. Sci. USA* **71**, 345-349 (1974).
2. Hamberg, M., Svensson, J., and Samuelsson, B. Thromboxanes: A new group of biologically active compounds derived from prostaglandin endoperoxides. *Proc. Natl. Acad. Sci. USA* **72**, 2994-2998 (1975).
3. Hamberg, M. and Samuelsson, B. Prostaglandin endoperoxides. Novel transformations of arachidonic acid in human platelets. *Proc. Natl. Acad. Sci. USA* **71**, 3400-3404 (1974).
4. Hamberg, M. and Samuelsson, B. Detection and isolation of an endoperoxide intermediate in prostaglandin biosynthesis. *Proc. Natl. Acad. Sci. USA* **70**, 899-903 (1973).

CAYMAN CHEMICAL

Mailing address
690 KMS Place
Ann Arbor, MI
48108 USA

Phone
(800) 364-9897
(313) 662-6756

Fax
(313) 662-6896

E-Mail
cayman@caymanchem.com

WWW
http:\\www.caymanchem.com

5. Radioactive material (in addition to isotopes listed in the original license 21-24683-01):

	Element/ Mass No.	Chemical form	Max. amount
5a.	^{32}P	DNA and RNA nucleotide phosphates	1 mCi per order 250 µCi per experiment 2 mCi in waste storage
5b.	^{3}H	[^{3}H] eicosanoids & fatty acids	5 µCi per experiment 50 µCi in waste storage 100 mCi in sealed containers for redistribution
5c.	^{14}C	[^{14}C] eicosanoids & fatty acids	5 µCi per experiment 50 µCi in waste storage 20 mCi in sealed containers for redistribution

[^{3}H]- and [^{14}C]- eicosanoids & fatty acids are primarily for redistribution. Hence, we request that the possession limit in the license condition item 8B for [^{3}H] be changed to reflect the above maximum amount. Similarly, we request that the term "pre-packaged units" be included in the license condition item 7B.

7. Individual(s) responsible for radiation safety program and their training and experience.

7.1 Authorized Users for Medical Use

None. All work will be performed *in vitro*.

7.2 Authorized Users for Nonmedical Use

See ATT 7.2.1, 7.2.2, 7.2.3, 7.2.4, and 7.2.5. The primary user of radioactive material will be Gong Chen, Ph.D. (ATT 7.2.5).

7.3 Radiation Safety Officer

Krishna Rao Maddipati has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

3-4-97
(date)

Kirk Maxey, MD
President, Cayman Chemical Company

8. Training For Individuals Working in or Frequenting Restricted Areas.

Cayman Chemical Company - Training Policies

All individuals who work in, or frequent, a Restricted Area or who use radioactive materials will receive appropriate training. The level of training will be appropriate to the duties of the individual who works with radiation. Training may be abridged for personnel (e.g., Shipping or Security personnel) whose duties require less potential exposure or less involved procedures. The training includes the topics required by 10CFR19.12.

1. Personnel will be instructed before assuming duties with, or before assuming duties in the vicinity of, radioactive materials.
2. Refresher training will be provided annually.
3. Personnel will be retrained as appropriate whenever there is a significant change in their duties, the regulations, or the terms of the NRC license.
4. Individuals will receive two types of training:
   a. General training on the nature of radiation, risks, protective measures (as specified below). This training is the responsibility of the RSO.
   b. Training on how to safely perform the specific steps of particular procedures. This training is the responsibility of the authorized user.
5. The RSO will maintain records of the content of training and the individuals who received the training.

General training syllabus

General training will comprise the following topics.

1. Radiation physics. Information on the basic nature of radioactive decay, radioactive materials, properties of ionizing radiation, and interactions of radiation and matter.
2. Radiological health quantities and units.
3. Biological effects of radiation.
4. Risks from exposure to low-level radiation.
5. Control of radiation exposure. Protecting from external exposure. Protecting from internal exposure. Protective devices. General rules of handling radioactive materials and good laboratory practices.
6. Areas at Cayman where radioactive material is transferred, used, or stored. Notices, signs and labels. Radiation monitoring programs.
7. The role of the RSO and the authorized user.
8. Radiation dose limits, MDPH and NRC. Other important applicable regulations and terms of the license. Rights and responsibilities of employees.

9. Facilities and Equipment

9.1. Annotated Drawing

See ATT 9.1.

The refrigerators in Rooms 12A & B, where the licensed material will be stored, will be locked and the keys will be available only to the authorized users. In addition, the laboratories designated as 12A & 12B are also locked during off hours to prevent any unauthorized entry.

9.2 Survey Instrument Calibration

Cayman Chemical Company has a TRI-CARB, Model 1550, Liquid Scintillation Analyzer made by Packard Instrument Company. We will be acquiring a VWR Model 3007A or 3100 radiation survey meter as soon as the license is issued. Specifications for the survey meter is attached with this application. Please see attachment ATT 9.2.1.

Cayman Chemical Company Policy - Survey Instrument Calibration

1. Survey instruments used for health protection purposes will be calibrated annually and after every servicing.
2. Survey instruments which read in radiological health units (e.g., mR/hr) shall be calibrated with a radioactive source. Survey instruments which respond only in cpm will not be used for health protection purposes (they could be used, for example, to look for a lost source).

Procedure

1. The source used must be approximately a point source.
2. Either the apparent source activity or the exposure rate at a given distance from the source must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Institute of Standards and Technology.
3. A source that has approximately the same photon energy as the environment in which the calibrated instrument will be employed should be used for the calibration.

4. The calibration source should be of sufficient strength to produce an exposure rate of about 30 mR/hr at 100 cm.
5. The inverse square law and the law of radioactive decay must be used to correct for change in exposure rate due to changes in distance or source decay.
6. A record will be made of each survey meter calibration.
7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs by the calculated exposure rate by less than ten percent.
8. Three kinds of scales are frequently used on survey meters.
   a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.
   b. Meters that have a multi decade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.
   c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.
9. Readings above 1,000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.
10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.
11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The record of the calibration will include:
    a. The owner or user of the instrument;
    b. A description of the instrument that includes manufacturer, model number, serial number, and type of detector;
    c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;
    d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced calibration factor (calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
    e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);
    f. The angle between the radiation flux field and the long axis or long dimension of the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux direction and a specified dimension of the instrument;
    g. For detectors with removable shielding or build-up cap, an indication of whether the shield or cap was in place during the calibration;
    h. The apparent exposure rate from the check source;
    i. the name of the person who performed the calibration and the date on which the calibration was performed.
12. The following information will be attached to the instrument as a calibration sticker or tag:
    a. The source used to calibrate the instrument;
    b. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);

c. For each scale or decade, one of the following:
   (1). The average correction factor
   (2). A graph or graphs from which the correction factor for each scale or decade may be deduced, or
   (3). An indication that the scale was checked for function but not calibrated, or an indication that the scale was inoperative.
d. The angle between the radiation flux and the detector during calibration;
e. The apparent exposure rate from the check source.

Note: One word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker or tag. Cayman Chemical Company may have its survey meters calibrated by a reputable vendor which can perform calibrations to the above standard.

9.3. Dose Calibrator Calibration

N/A

9.4 Personnel Monitor Program

Cayman Chemical Company Policy - External Personal Monitoring

1. Every individual who is occupationally exposed to external ionizing radiation in a manner which is likely to result in a radiation dose in excess of ten percent of any applicable limit will be required to wear an individual radiation monitor (e.g., film badge or thermoluminescent (TLD) dosimeter). In addition, any authorized user that is required to use greater than or equal to 1 mCi of ^{32}P in one week will be required to use whole body monitor as well as ring monitor and observe the following procedures:
   a. the use of low density shielding (e.g. Plexiglas) in order to keep Bremsstrahlung radiation at a minimum.
   b. a mandatory radiation survey and wipe test for radioactive contamination after each use.
   c. a dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the radiation safety officer be present during new procedures, and
   d. the use of eye protection during the entire procedure.
2. Individuals who handle radioactive material will be issued a TLD ring monitor if the dose to the fingers is likely to exceed ten percent of the applicable limit.
3. The RSO will promptly review all exposure reports to look for workers whose exposure is unexpectedly high or low, and to ensure that exposures are as low as reasonably achievable (ALARA). This review does not apply to backup monitor records, for example, pocket ionization chambers when the monitor of record is a film or TLD dosimeter.
4. External dosimeters will be processed by a contractor which meets the National Voluntary Laboratory Accreditation Program (NVLAP) standard for radiation dosimetry.

References

[1]Code of Federal Regulations, Title 10, Part 20, Paragraph 20.1201, *Occupational dose limits for adults.*

[2]Code of Federal Regulations, Title 10, Part 20, Paragraph 20.1502, *Conditions requiring individual monitoring of external and internal occupational dose.*

9.5 Imaging Equipment

N/A

9.6 Other Equipment and Facilities

Criteria for Facilities and Equipment for Radiation Research Laboratories, Cayman Chemical Company

General Criteria

Approval or disapproval by the NRC of proposed use of radioactive material will depend on adequate facilities and equipment to be provided by the user to insure ALARA exposures and compliance with regulatory requirements.

Each laboratory will be evaluated case-by-case. Acceptable criteria for facilities and equipment will depend on the categories of laboratory described.

Low Level Tracer Laboratories (less than 100 mCi)

1. Benches, sinks, walls, and floors. Provide benches, sinks, walls, and floors with smooth, nonporous, and easily decontaminated surfaces.
2. Absorbent Bench Paper.
   Provide absorbent, plastic-backed (or equivalent), and easily discarded bench paper on the bench surface for catching and disposing small amounts of contamination from drips or spills from laboratory apparatus and glassware.
3. Laboratory Coats and Gloves
   Provide protective laboratory coats and rubber or disposable plastic gloves to avoid direct contact with radioactive materials.
4. Radioactive Waste Containers
   Provide specially labeled containers for laboratory radioactive wastes. These containers may be shielded as necessary, placed near the waste-generating area and distant from the area frequently occupied by personnel.
5. Sinks for Radioactive Washing or Effluents
   a. Designate special sinks to receive any small amounts of radioactive washings or effluents.
   b. Keep records of estimated amount of radioactive disposal in these sinks to ensure compliance. The disposal limit of each radioactive isotope used in each laboratory will be determined by the RSO in accordance with NRC regulation Section 20.303 of 10 CFR Part 20. These sinks should be connected to the main pipes. They should not be connected to open channels or devices resulting in the accumulation of radioactivity.
6. Sharp Corners, Cracks or Pores
   Design laboratories with a minimum of sharp corners, cracks, or porous surfaces where radioactive material can lodge.
7. Plumbing, Traps, and Ductwork
   Design plumbing, traps, and ductwork to avoid radioactive contamination build-up that can create sources of external radiation exposure, cross-contaminate drinking water or air-supply lines.
8. Ventilation
   a. Provide adequate ventilation for processing of radioactive materials that may lead to airborne contamination by volatilization, dispersion of dust, spraying or splattering.

b. Airflow should be at least 100 ft. per minute.
c. Provisions should be made for shutting down the ventilation system in the event of accidents to contain radioactivity.

9. Separate Room for Coats and Belongings
   Provide separate rooms for coats and personal belongings to avoid contamination.
10. Lighting
    Provide adequate lighting for laboratory areas to avoid spills and other accidents resulting in contamination build-up.

Facilities For Use of Alpha Emitters

High quality factor of alpha particles may require some special provisions for use of alpha emitters.

1. Glove Box
   Provide a glove box as may be required and shielded as necessary, to contain alpha emitters.
2. Leaded Gloves
   Provide leaded gloves as may be required to prevent from radiation exposure.
3. Shielding
   Provide bench-top lead shields as may be necessary to be determined by the RSO.
4. Remote Handling Equipment
   Provide tongs, forceps, or other remote handling equipment.

High-level Beta-Gamma Laboratories (equal to or greater than 100 mCi)

In addition to the minimum criteria required for low-level tracer laboratories, the minimum criteria for high-level beta-gamma laboratory in possession of at least 100 mCi of radioactive materials include the following requirements:

1. Drip Tray
   Provide suitable drip trays that can be easily cleaned for handling radioactive materials where spills may occur. These drip trays may be covered with absorbent plastic-backed (or equivalent) material to soak up minor spills.
2. Lead shields
   Provide bench-top lead shields for low energy gamma emitters or high-level radioactivity. Lead sheets with adequate thickness may be used. Protective viewing windows with adequate thickness may be used. Protective viewing windows with adequate leaded glass in combination with the lead shielding should be provided as necessary.
3. Remote Handling Equipment
   Provide as necessary, tongs, forceps, or other remote handling equipment.
4. Leaded Gloves
   Provide leaded gloves as necessary.
5. Laboratory Shoe Covers
   Provide special disposable shoe covers if floors are likely to be contaminated.

Radioiodine Use

In order to prevent thyroid uptake by the personnel, special safety measures are required for handling ^{125}I. In addition to the minimum criteria required for low-level tracer laboratories and those required for high-level beta-gamma laboratories, the following criteria will be satisfied:

1. Ventilation and Fume Hoods
   a. Provide adequate ventilation so that handling of radioiodine is limited to the area with airflow of at least 100 ft/min. Fume hoods may be required unless ventilation is adequate.
   b. Provide adequate filtration of both intake air and exhaust air to avoid increasing environmental exposures as necessary.
   c. Fume hoods, if required, should be designed to avoid eddy currents that would disperse radioactive materials outside the hood area.
   d. If appreciable levels of activity is used, as determined by the RSO, the hood should have its own exhaust system to avoid transmission of airborne contamination to other laboratories.

2. Radioactive Waste Storage
   Provide radioactive waste containers which may be effectively enclosed to prevent airborne contamination of radioiodine.

10. Radiation Safety Program

10.1 Radiation Safety Officer

Cayman Chemical Company - Radiation Safety Bylaws

Policy
Radioactive material will be used safely, in accordance with NRC and State of Michigan regulations, and in accordance with our NRC license and MDPH registration. To achieve this objective, the following procedures are established.

Procedures

1. The Radiation Safety Officer (RSO) will be appointed by Dr. Kirk Maxey, President, Cayman Chemical Company.
2. Application to the RSO to use radiation and radioactive material should be made in writing by the proposed user. The application should include the radionuclide identity, radionuclide chemical and physical form, the activity which will be possessed and the maximum activity which will be used per procedure, and a safety evaluation of the proposed activity. The safety evaluation should address the adequacy of the training and experience of the proposed users, the adequacy of facilities and equipment, the administrative controls to be instituted to ensure safety, foreseeable reasonable accident scenarios, and procedures to be followed in the event of an accident.
3. The following safe laboratory procedures should be observed by all users of radioactive materials:
   a. Wear laboratory coats or other protective clothing at all times in area where licensed materials are used.

b. Wear disposable gloves at all times while handling licensed materials.
c. For P-32, either after each procedure or before leaving the area, monitor your hands for contamination in low-background area.
d. Do not eat, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
e. Do not store food, drink, or personal effects in areas where licensed material is stored or used.
f. Wear personal monitoring devices (if required by RSO) at all times while in areas where licensed materials are used and stored.
g. Dispose radioactive waste only in designated, labeled, and properly shielded receptacles.
h. Never pipette by mouth.
i. Confine radioactive solutions in clearly labeled containers.
j. Secure all licensed material when not under the constant surveillance and immediate control of the authorized users.

4. The RSO is responsible for the safety of all radioactive materials at Cayman Chemical Company, whether regulated by NRC or the State of Michigan. The RSO is responsible for:
   a. providing general surveillance over all activities using radiation or radioactive material, and acting as the executive of Cayman Chemical's policies.
   b. formulating policies which result in occupational exposure, public exposure, and releases of radioactive material to the environment which are as low as reasonably achievable (ALARA).
   c. directing authorized users to conduct a safety analysis of operations before operations are started and at any time after operations are approved.
   d. reviewing and approving/disapproving operations involving the use of radiation based upon the risks and benefits of the proposed operation, the adequacy and conclusiveness of the safety analysis provided by the project supervisor, the adequacy of facilities and equipment, the training and experience of project personnel, the operating and emergency procedures, and the adequacy of engineered and administrative controls, and the ALARA principle.
   e. discontinuing operations not meeting safety standards.
   f. ensuring that operations are conducted in accordance with applicable state and federal laws and regulations and our license and registrations.
   g. reviewing annually, the policies and procedures of the radiation safety program, and the adequacy of their implementation.
   h. posting signs and notices, and keeping safety records.

References

[1]Code of Federal Regulations, Title 10, Part 33, Paragraph 33.14 *Requirements for issuance of a Type B license of broad scope.*

10.2 ALARA Program

Cayman Chemical Company Policy - ALARA Program

Cayman Chemical Company is committed that individual and collective occupational radiation doses, radiation doses to members of the public, and releases of radioactive materials to the environment, be maintained as low as reasonably achievable (ALARA).

Procedures

To meet the policy stated above, the following procedures are adopted.

1. Occupational radiation doses, both collective and individual, releases of radioactive materials to the environment, and doses and potential doses to members of the public (e.g., radiation levels in unrestricted areas), and records of surveys will be reviewed quarterly by the RSO.
2. The ALARA principle will be one of the considerations in reviewing and approving operating procedures submitted to the RSO by authorized users and proposed authorized users.
3. Modifications to operating and maintenance procedures will be made if they reduce radiation exposures unless, in our opinion, the cost is unjustified. A record of modifications which have been made to meet the ALARA principle and modifications which have been considered but which have not been made due to cost will be kept by the RSO.
4. The RSO will annually review the radiation safety program. One element of this review will be to examine radiation safety programs, policies, procedures, and user operating procedures from the ALARA standpoint.
5. Occupational radiation exposures will be reviewed regularly by the RSO, to evaluate whether exposures are consistent with ALARA. A record of this evaluation will be made. Investigational levels are established as follows: Investigational Level I, 10 percent of any applicable limit; Investigational Level II, 30 percent of any applicable limit. To permit a quarterly ALARA review, annual limits will be prorated to a quarterly basis. This scheme produces the following table:

Investigational Levels (mR/quarter)		
	Level I	Level II
Total Effective Dose Equivalent (TEDE)	125	375
Lens of eye	375	1125
Shallow dose equivalent to skin or extremity (SDE)	1250	3750

Table 1. Investigational levels.

   a. Except when deemed appropriate by the RSO, no further action will be taken in cases where an individual's quarterly dose is less than Investigational Level I as given in Table 1.
   b. In cases where an individual's quarterly dose is greater than or equal to Investigational Level I but less than Investigational Level II, the RSO will review the circumstances and report the results of the review following the quarter when the dose was recorded. No action related specifically to the exposure is necessary unless deemed appropriate by the RSO. The RSO will review each such dose in comparison with those of others performing similar tasks as an index of the ALARA program quality and will record the review.

c. In cases where an individual's quarterly dose is equal to, or greater than, Investigational Level II, the RSO will investigate the circumstances and causes in a timely manner and, if warranted, will take corrective action. A report of the investigation, any actions taken, and a copy of the individual's Form NRC5 or its equivalent will be recorded by the RSO following completion of the investigation.
d. In a case where a worker's dose needs to exceed an existing investigational level, a new, higher, investigational level may be established for that individual on the basis that it is consistent with good ALARA practice. Justification for the new investigational level will be documented. The RSO will review the justification and must approve or disapprove of all revisions of investigational levels.

6. Records of radiation surveys in restricted and unrestricted areas will be reviewed quarterly by the RSO to monitor that radiation fields and contamination levels meet standards and are ALARA.
7. The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. These individuals will be informed that management and the RSO are committed to implementing the ALARA concept.
8. Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow. The ALARA concept will be an element of these procedures. The RSO will establish a method whereby workers may make suggestions on improving health physics practices in operating procedures.
9. The RSO will investigate all known instances of deviations from good ALARA practices and, if possible, determine the causes. When the cause is known, the RSO will implement program changes to maintain doses ALARA.
10. Authorized users will consult the RSO during the project planning phase to ensure that procedures are developed that will maintain doses ALARA.
11. The ALARA principle, and its relationship to work practices and work conditions, will be an element of the training program which will be routinely provided to radiation workers. Workers will be instructed in the recourse available if they feel that ALARA is not being promoted on the job.

Responsibility

1. Development of policies and procedures to meet the ALARA goal is the responsibility of the RSO.
2. Implementation of ALARA policies as they relate to authorized users is the responsibility of the authorized users and the RSO, who will assert authority to maintain practices consistent with ALARA.

References

[1]Code of Federal Regulations, Title 10, Part 20, Paragraphs 20.1101(b), and 20.1101(c) *Radiation Protection Programs.*

Management Commitment

We, the management of Cayman Chemical Company, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our company.

I hereby certify that this institution has implemented the ALARA Program set forth above.

3-4-97
(date)

Kirk Maxey, MD
President, Cayman Chemical Company

Krishna Rao Maddipati 7/4/97
(date)

Krishna Rao Maddipati, Ph.D.
Radiation Safety Officer
Cayman Chemical Company

10.3 Leak Test

Cayman Chemical Company - Leak Tests of Sealed Sources

Cayman Chemical Company is not requesting at this time to possess any sealed sources. If we wish to possess sealed sources, a procedure for leak testing them will be submitted with the application to possess such sources.

10.4 Safe Use of Radiopharmaceuticals

N/A

10.5 Spill Procedures

Cayman Chemical Company - Spill Procedures

1. **Estimate the activity spilled.** Initiate a major or minor spill procedure based upon the activity spilled.

Radionuclide	mCi
H-3	100
C-14	20
P-32	2
I-125	1

Table 1. Spills greater than the tabulated activity are major spills. Spills less than the tabulated activity are minor spills.

For major spills of liquids or solids.

1. **Clear the area.** Notify all persons not involved in the spill, and who will not be needed, to leave the room.
2. **If you are contaminated or injured, call for help.** If you are contaminated enlist a colleague to attend to steps 3 -5 below. If injured, take care of your own medical needs first. Use the available safety equipment such as the eyewash. Discard contaminated clothing and use an emergency shower if necessary. Skin contamination is most effectively removed by washing *gently* (so as not to break the skin) with mild soap and lukewarm water. Later, use a diluted radioactive decontaminant such as Isoclean to remove the final traces of radioactivity. If radioactivity remains, some can be removed by covering the skin with plastic to induce perspiration and subsequently washing away the perspiration.
3. **Prevent the spread.** Cover the spill with absorbent paper. Pay particular attention to the possibility of radioactive powders becoming airborne (in this case, use damp paper. Do not attempt to clean up the spill now. If clothes or shoes are contaminated, leave them in the contaminated area. Limit the movement of personnel so that the contamination is not spread. If possible, and if the radiation level is low (e.g., pure beta emitters), mark the area of the spill with a marker or tape.
4. **Shield the source if possible.** This should be done only if it can be done without spreading contamination and there is no significant increase in radiation exposure (i.e., radiation level is low [pure beta emitter] and you are not contaminated).
5. **Secure the area.** Lock the room or enlist the assistance of a colleague to prevent access by others.
6. **Notify the RSO immediately.** The RSO will supervise spill cleanup and will prepare a report of the incident.

For minor spills of liquids or solids.

1. **Notify.** Notify persons in the area that a spill has occurred.
2. **Prevent the spread.** Prevent the spread by covering the spill with absorbent paper. If a powder was spilled, use damp paper to prevent the powder from becoming airborne.
3. **Clean up.** Clean up the spill using disposable gloves and absorbent paper (e.g., paper towels). Wipe from the outside of the contaminated area towards the center; wiping in a circular motion tends to spread contamination. Carefully fold the paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Use a dilute soap or decontaminating solution such as Isoclean for the final stages of the cleanup. Change gloves often, placing contaminated gloves in the trash bag.
4. **Survey.** Survey the spill area with an appropriate low-range radiation detector. A GM counter is appropriate for P-32, P-33, and I-125. For H-3 and C-14, wipe tests counted on the liquid scintillation counter will be necessary. Check hands, clothing, and shoes for contamination.
5. **Report the incident to the RSO.** The RSO will follow up on the successful cleanup of spill and will complete a report giving the details of the spill.

10.6 Ordering and Receiving

Cayman Chemical Company Policy - Ordering

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive material before the order is placed with a supplier. Purchasing will not proceed with an order for radioactive materials unless it is also signed by the RSO.
2. Prior to authorizing a purchase of radioactive materials, the RSO will ensure that the acquisition of the material is consistent with the possession limits, chemical form, and physical form authorized by our license. The RSO will also ensure that the material will be used by an individual named in the license and for the purposes authorized.
3. The RSO will establish and maintain a record keeping system which will identify the isotope, activity, chemical and physical form, supplier, and the authorized user. The RSO will also provide a method of ensuring that the ordered material was, in fact, ordered through proper channels.
4. No radioactive materials may be brought to the Cayman site without the express approval and prior knowledge of the RSO.
5. The RSO will inform and train Receiving and Security personnel as to where and how to deliver received packages of radioactive materials during normal working hours and off-hours.
6. If deliveries are to be made during off-hours, the RSO will inform carriers of where to make deliveries.

Cayman Chemical Company Policy - Receipt of Radioactive Packages

1. Instructions to Receiving Personnel:

   a. Receiving or Security personnel on duty may accept delivery of packages containing radioactive material from any carrier. Radioactive packages which contain substantial quantities of radioactive material can be recognized by the DOT Radioactive White I, Yellow II, or Yellow III label. Some packages contain small enough quantities of radioactive material so that they do not need to be labeled with the White 1, Yellow II, or Yellow III label. These packages may be identified by the shipping papers or invoice.
   b. Packages containing radioactive material should be visually inspected for any sign of damage (such as leaking, crushed, torn, wet). If the package shows signs of damage, immediately notify the Radiation Safety Officer (RSO) or any of the authorized users listed below. If no one could be contacted immediately, deliver it on the bench in room 12B. Use the following handling techniques:
      1. Wear protective clothing, safety eye glasses and two layers of gloves.
      2. If the package is leaking, transfer immediately to a water proof plastic tub or tray.
      3. Transfer the damaged package by hand by holding on the undamged areas of the package to room 12B. If the package is a Yellow II or a Yellow III package, do not carry by hand. Transport it using a cart.
      4. Remove the outer gloves and leave them immediately adjacent to the package for later survey of radioactivity.
      5. Remove the inner gloves and dispose them in non-radioactive waste container

      If the package appears undamaged, deliver it to the refrigerator of room 12B or the freezer of room 12A. Make sure the room is locked when you leave. Notify the authorized user that a radioactive package has arrived. If the authorized user is unavailable, notify the RSO. If the package is received after normal working hours, leave a message or

the invoice for the authorized user designated on the packing slip so that the package will be sure to be checked at the start of the next working day.

If the package is a Yellow II or a Yellow iII package, do not handle it for a prolonged period. Transport it using a cart.

If Receiving or Security personnel have any questions on how to follow this policy, contact the RSO.

Persons to contact for an emergency off hours:

Radiation Safety Officer	**Krishna Rao Maddipati Ph.D.**	**313-434-5595**
Authorized user	**Jeff Johnson Ph.D.**	**313-483-2797**
Authorized user	**Jim MacDonald**	**313-971-4170**
Authorized user	**Gong Chen**	**313-668-6660**

10.7 Opening Packages

Cayman Chemical Policy

Receipts of packages containing radioactive materials bearing a DOT Radioactive White I, Yellow II, or Yellow III label, or packages which are wet, crushed, or damaged, will be monitored as required by federal regulations.[1] Maximum radiation levels[2] and contamination levels[3] are specified by federal regulations.
It is the policy of Cayman Chemical Co. to monitor all incoming packages of radioactive materials.
Monitoring will consist of exposure rate measurements and wipe test surveys of the inner and outer shipping container.

Materials

Liquid scintillation counter (LSC) or well counter
Geiger-Mueller (GM) Counter
Ionization chamber survey meter or GM counter calibrated in mR/hr
Filter disks or alcohol pads for wipe tests
Forceps or tongs
Protective gloves

Procedure

1. For packages in apparently good condition, the Receiving personnel will, upon receipt, deliver packages which contain radioactive material to room 12A or room 12B. These packages will be delivered unopened. If a package appears damaged, crushed, or wet, Receiving personnel will deliver the package to a designated location in room 12B using techniques specified by the Radiation Safety Officer (RSO). In the case of an apparently damaged package, Receiving will immediately notify the RSO. If a package cannot be delivered promptly, Receiving will notify the RSO.
2. The monitoring of WHITE I, YELLOW II, and YELLOW III packages must be done within three hours of receipt or, if the package is not received during working hours,

within three hours of the start of the next working day. All packages should be monitored (surveyed) promptly after receipt.

3. Surveys will be performed by qualified personnel designated by the RSO. Before making a survey, make sure that the survey instrument has been checked that day with the appropriate check source and is functioning properly. Detailed procedures are as follows:
   a. Turn on the survey meter(s) and allow to stabilize. Record the background reading. With this reading and all others, the actual numerical value must be recorded, not "same as background" or "less than ..."
   b. Wear gloves when surveying packages.
   c. Visually inspect the package for any sign of damage (e.g., wet, torn, crushed). If damage is noted, stop. Notify the RSO.
   d. Measure the exposure rate at three feet from the package and record. Verify that the exposure rate at three feet is equal to, or less than the transportation index on the package. If the exposure rate at three feet is greater than the transport index, or if it is greater than 10 mR/hr, stop. Follow the notification procedure in paragraph 4.
   e. Measure the exposure rate at the surface of the package and record. If the exposure rate at the package surface is greater than 200 mR/hr, stop. Follow the notification procedure in paragraph 4.
   f. Open the package and check the inner container for breakage, wetness, or discolorization which could indicate leakage.
   g. Wipe test a 100 square cm area of both the external surface of the shipping container and the external surface of the lead shield of the inner container. If there is no lead shield, wipe test the inner container.
   h. Assay the wipe tests using an appropriate, calibrated counter. For pure beta emitters, a liquid scintillation counter is appropriate. For photon emitters, a sodium iodide well counter or liquid scintillation counter may be used. Assay a background (blank) specimen also. Calculate the disintegrations per minute as follows.

$$\text{dpm} = \frac{\text{gross cpm} - \text{background cpm}}{\text{efficiency}}$$

   i. Record the data in the radioactive shipment receiving log.
   j. If the activity on the wipe of the outer shipping box exceeds 2200 dpm, follow the notification procedure in paragraph 4. If the activity on the wipe of the inner container exceeds 2200 dpm, notify the RSO.
   k. With the source container removed, monitor the packaging materials with the appropriate detector. For pure beta emitters, a GM counter must be used. If the packaging materials show any radioactivity, handle them as radioactive waste. If the packaging material is not contaminated, obliterate labels indicating radioactivity, remove the packing slip or invoice if needed, and discard the remainder as ordinary trash.

4. Notifications. If any of the measurements of exposure rate or of removable contamination exceed the specified limits, notify:
   a. the Radiation Safety Officer
   b. NRC Region III office. The NRC must be notified by telephone (NRC Region III's phone number is 630-829-9500).
   c. the final delivering carrier.

References

[1]U.S. CFR Title 10 Part 20, Paragraph 20.1906, *Procedures for receiving and opening packages.*

[2]U.S. CFR Title 10 Part 71, Paragraph 71.47, *External radiation standards for all packages.*

[3]U.S. CFR Title 10 Part 71, Paragraph 71.87, *Routine determinations.*

10.8 Unit Dosage Records

N/A

10.9 Multidose Vial Records

N/A

10.10 Molybdenum Concentration Records

N/A

10.12 Area Survey Procedures

Cayman Chemical Company Policy - Area Surveys

Area surveys will performed in all laboratory areas where radioactive materials are stored, handled or used, areas where a spill has occurred, areas where leaking radioactive containers are known to have been present (e.g., Shipping if a package has leaked), the radioactive waste storage area, and other areas designated by the Radiation Safety Officer.

The quantities of radioactive material licensed for possession by Cayman do not emit significant photon radiation. Consequently, area survey efforts will be done by wipe test and will be directed towards discovering contamination incidental to laboratory experiments and unsuspected spills or leakages.

Procedures

1. Wipe tests will be performed routinely for all areas which reasonably could be contaminated with radioactive material. This includes the survey of (frequency indicated in parentheses): radioactive material storage (weekly) and use areas (after each use), waste containers (weekly), and the long term radioactive waste storage area (monthly). In addition to wipe tests, ambient dose rate surveys will also be conducted at the same frequency as described above.
2. When an experiment is in progress, the experimental area will be posted with the "Caution - Radioactive Materials" sign. Such areas will be treated as radioactive by the staff, and will not be considered non-radioactive until proven to be uncontaminated by wipe tests. Wipe tests will be performed promptly upon completion of the experiment. In addition to the wipe survey of the area, the ambient dose rate surveys during the experiment as well as the survey of hands and feet at the conclusion of the experiment will be conducted for the use of ^{32}P.
3. The wipe test procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). Equipment used to assay the radioactivity on wipe samples shall be calibrated, using standards traceable to the National Institute of Standards and Technology (NIST), in such a way that the dpm of wipe test samples can be calculated from the measured cpm.

4. The RSO shall be immediately notified if the results of wipe tests are unexpectedly high or exceed action levels.
5. Areas found to exceed the action levels (Table 1.) will be decontaminated to levels below those specified in Table 1. before return to service. If an area cannot be decontaminated to levels less than those specified in Table 1. the RSO will take further steps to remove the radioactive material and/or to restrict use of the area.

	Action Levels in dpm/100 cm^2	
	P-32, P-33, I-125	**H-3, C-14, S-35, Fe-55**
Unrestricted areas, personal clothing	**200**	**2,000**
Restricted areas, protective clothing used only in restricted areas, skin	**2,000**	**20,000**

Table 1. Action levels for radioactive surface contamination.

Records

1. Records of contamination surveys must include:
   a. the date, areas surveyed, and the equipment used
   b. the name or initials of the person making the survey
   c. a drawing of the surveyed areas with a notation of the action levels given in Table 1
   d. measured contamination levels in dpm/100 cm^2
   e. procedures taken for those areas where excessive contamination was discovered and follow up actions taken.
2. Ambient dose rate survey records must include:
   a. the date, location of survey, and the meter used
   b. results in mR/hr
   c. name and initials of the person conducted the survey
   d. actions taken to reduce the levels if necessary
3. The RSO will review the records at least monthly and also promptly in those cases where action levels have been exceeded.

10.13 Air Concentration Control

N/A

10.14 Radiopharmaceutical Therapy

N/A

10.15 Implant Therapy

N/A

10.16 Other Safety Procedures

N/A

11. Waste Management

11.1 Waste Disposal

Cayman Chemical Company Policy - Radioactive Waste Disposal

Radioactive waste will be disposed of by decay-in-storage (DIS), release to the sanitary sewer, evaporative release to the atmosphere, or by transfer to an authorized recipient.

When determining a waste disposal method, the entire impact on the environment and the company's resources will be considered. Factors such as occupational and public radiation exposure, other hazards (e.g., pathogens) of the waste, as well as expense, will be considered.

Procedures - General

1. Prior to disposal of radioactive material which has become non-radioactive due to decay-in-storage (DIS), or non-radioactive packaging materials which bear radioactive markings or logo, all labels indicating radioactive material and the radiation logo must be removed or defaced prior to disposal.
2. Non-radioactive waste such as leftover reagents, boxes, non-radioactive gloves, should not be mixed with radioactive waste. The RSO will occasionally monitor all waste-generating procedures to ensure that radioactive waste is not generated unnecessarily.
3. The RSO will review all new procedures to ensure that waste generated is a minimum and that generation and handling procedures are consistent with established good practices.
4. Every effort will be made to avoid generating waste which is both radioactive and also hazardous waste under EPA's RCRA regulations. Such waste ("mixed waste") poses especially-difficult disposal problems.
5. NRC exemptions for disposal to the atmosphere or the sanitary sewer only exempt the radioactivity. No exemption in the NRC rules relieves the waste disposer from complying with other waste regulations, such as EPA regulations which govern hazardous waste.

Procedures - Disposal by evaporative release

1. Liquids and gases may be disposed of by evaporative release. However, most of the materials used by Cayman are not volatile; for such materials evaporative release is not an option.
2. The RSO will ensure that disposal to the atmosphere is done in accordance with applicable regulations.[1] Limits on permissible air concentrations apply at the boundary of the restricted area.
3. A record of releases to the atmosphere must be made which includes the date, radionuclide, estimated activity that was released (in mCi or μCi), the estimated concentration, and the vent site from which the material was released.

Procedures - Disposal to the sanitary sewer

1. Material released to the sewer must be readily soluble or dispersible biological material. There are daily, monthly, and annual limits.
2. The RSO will ensure that disposal to the sewer is be done in accordance with specific NRC exemptions.[2,3]

3. A record of releases to the sanitary sewer must be made which includes the date, the radionuclides, the estimated activities that were released (in μCi or mCi), and the sink at which the material was released.

Procedures - Liquid scintillation waste

1. Liquid scintillation waste may be disposed of as if it were not radioactive if it contains only H-3 or C-14 and the activity concentration is 0.05 microcurie or less per gram of liquid scintillation medium.[3] Other waste laws (e.g., RCRA) still apply. This exemption does not apply to radionuclides other than H-3 and C-14.

Procedures - Decay in storage (DIS)

1. Radionuclides of half life less than 90 days may be disposed of by DIS. This includes P-32 and I-125.
2. Since the waste must eventually be surveyed with no shielding, no shielding material may be placed in a waste container.
3. When an waste container (e.g., plastic bag) is full, seal it and tag it with the nature of the contents, the longest-lived radionuclide present, the date, and the initials of the person sealing the container. Transfer this container to the DIS area.
4. Retain the material in a restricted area for ten half lives of the longest radionuclide present in the container.
5. Prior to disposal as ordinary nonradioactive trash:
   a. Check the radiation survey meter for proper operation.
   b. Monitor the waste containers in a low radiation (less than 0.05 mR/hr) areas.
   c. Monitor all surfaces of each individual container, using the most sensitive scale on the meter.
   d. Discard to the ordinary trash only those containers for which the radiation level is indistinguishable from background. Record the date the container was disposed of, the type of waste, the disposal date, and the initials of the person performing the monitoring and disposal. Make sure that no radiation labels are visible.
   e. Containers, for which the radiation survey is above background, must be returned for further DIS or disposed of by transfer to authorized recipient (burial).

Procedures - Disposal by transfer to authorized recipient

1. Dry solid waste which contains radionuclides with half lives too long for DIS must be disposed of by transferring the waste to an authorized radioactive waste contractor who will arrange for the waste to be buried at a licensed low-level radioactive waste disposal site.
2. Before generating waste, obtain the restrictions on waste form from the burial site operator.
3. Waste for burial must contain absolutely no loose liquids. Loose liquids must be completely absorbed by proper absorbent.
4. For disposal, follow the instructions provided by the burial site operator and the waste disposal contractor.

References

[1]Code of Federal Regulations, Title 10, Part 20, Appendix B, Table 2, Column1.
[2]Code of Federal Regulations, Title 10, Part 20, Paragraph 20.2003, *Disposal by release into sanitary sewerage.*
[3]Code of Federal Regulations, Title 10, Part 20, Paragraph 20.2005, *Disposal of specific wastes.*

11.2 Other Waste Disposal

N/A

ATT 7.2.1

Cayman Chemical Company
Radiation Authorized User Form

Name: Krishna Rao Maddipati, Ph.D.

Title: Director, Research and Development

Date: September 26, 1995

1. Training

Type	Location	Duration	Content
On the Job	The Pennsylvania State Univ. University Park, PA	12 hr.	A,B,C,D
On the Job	Wayne State University	3 hr	A,B,C,D

Content Code:
(A) Principles and Practices of radiation protection
(B) Radioactivity measurements, standardization, and monitoring techniques and instruments
(C) Mathematics and calculations basic to the use and measurement of radioactivity
(D) Biological effects of radiation

2. Experience with Radiation (actual use)

Isotope	mCi used at one time	Location	Clock hr.	Type of use
^{3}H	25 mCi	The Pennsylvania State Univ. University Park, PA	4 hr.	Sodium Borhydride Reduction of organic compounds
^{3}H	1 mCi	The Pennsylvania State Univ. University Park, PA	8 hr.	Enzymatic Reaction
^{14}C	<0.5 mCi	Wayne State Univ. Detroit, MI	48 hr.	Enzymatic Reaction
^{3}H	2 mCi	Wayne State Univ. Detroit, MI	10 hr.	Enzymatic labeling

ATT 7.2.2

Cayman Chemical Company
Radiation Authorized User Form

Name: James W. MacDonald

Title: Manager, EIA Division

Date: September 26, 1995

1. Training

Type	Location	Duration	Content
Class (Immunology. Tech.)	Colorado St. Univ., Ft. Collins, CO	1 semester	B,C
Class (Biochem. Lab.)	Colorado St. Univ., Ft. Collins, CO	1 semester	B,C

Content Code:
(A) Principles and Practices of radiation protection
(B) Radioactivity measurements, standardization, and monitoring techniques and instruments
(C) Mathematics and calculations basic to the use and measurement of radioactivity
(D) Biological effects of radiation

2. Experience with Radiation (actual use)

Isotope	mCi used at one time	Location	Clock hr.	Type of use
^{3}H	0.005 mCi	Nat'l Jewish Hospital, Denver, CO	80	Sample Purification

ATT 7.2.3

Cayman Chemical Company
Radiation Authorized User Form

Name: Jeffrey K. Johnson, Ph.D.

Title: Manager, Biochemistry

Date: September 26, 1995

1. Training

Type	Location	Duration	Content
5-credit course	Bemidji State Univ. Bemidji, MN	10 weeks	A, B, C, D
Short course	North Dakota State Univ. Fargo, ND	4 hr	A

Content Code:
(A) Principles and Practices of radiation protection
(B) Radioactivity measurements, standardization, and monitoring techniques and instruments
(C) Mathematics and calculations basic to the use and measurement of radioactivity
(D) Biological effects of radiation

2. Experience with Radiation (actual use)

Isotope	mCi used at one time	Location	Clock hr.	Type of use
^{14}C	0.005 mCi	North Dakota State Univ. Fargo, ND	10 hr.	Labeling experiment
^{32}P	0.02 mCi	North Dakota State Univ. Fargo, ND	2 hr.	Nick translation

ATT 7.2.4

Cayman Chemical Company
Radiation Authorized User Form

Name: Jennifer L. Johnson

Title: Biochemistry Research Assistant

Date: September 26, 1995

1. Training

Type	Location	Duration	Content
Radiation Therapy	University of Toledo Toledo, OH	9 weeks	B,C,D
Radiation Training	University of Toledo Toledo, OH	1 week	A,B,C

Content Code:
(A) Principles and Practices of radiation protection
(B) Radioactivity measurements, standardization, and monitoring techniques and instruments
(C) Mathematics and calculations basic to the use and measurement of radioactivity
(D) Biological effects of radiation

2. Experience with Radiation (actual use)

Isotope	mCi used at one time	Location	Clock hr.	Type of use
^{35}S	< 0.005 mCi	University of Toledo Toledo, OH	10 hr.	*in vitro* translation

ATT 7.2.5

Cayman Chemical Company
Radiation Authorized User Form

Name: Gong Chen, Ph.D.

Title: Manager, Molecular Biology

Date: February 21, 1997

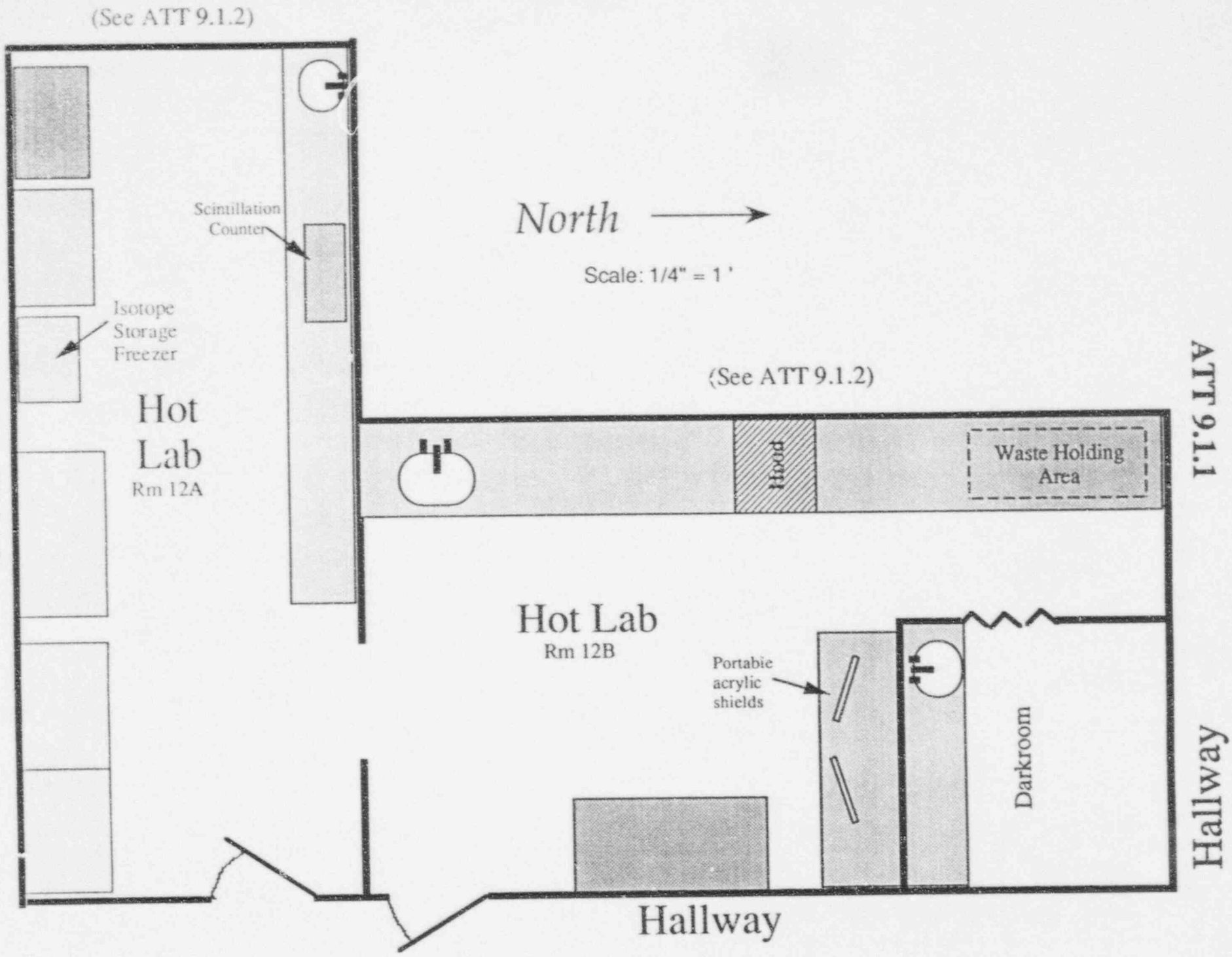
1. Training

Type	Location	Duration	Content
On the job	The Univ. of Glasgow, UK	8 h	A,B,C,D
On the job	The Univ. Strathclyde, UK	8h	A,B,C,D
On the job	University College London, UK	4h	A,B,C,D

Content Code:
(A) Principles and Practices of radiation protection
(B) Radioactivity measurements, standardization, and monitoring techniques and instruments
(C) Mathematics and calculations basic to the use and measurement of radioactivity
(D) Biological effects of radiation

2. Experience with Radiation (actual use)

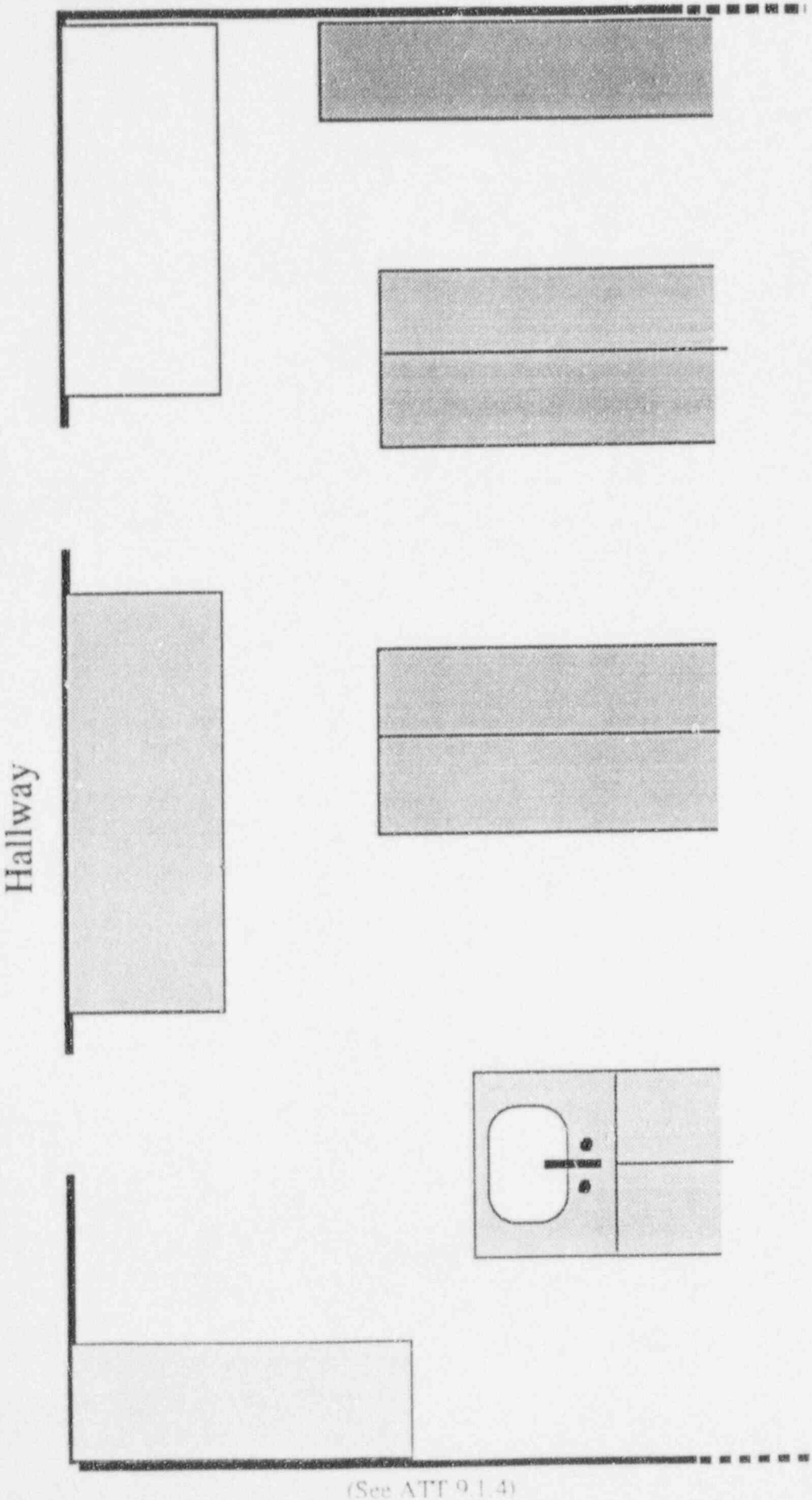
Isotope	Used at one time	Location	Clock. Hours	Type of use
^{3}H	<0.5 mCi	The Univ. of Glasgow, UK	96	Proliferation assay Receptor binding
^{32}P	25 µCi	The Univ. of Strathclyde, UK	48	DNA labeling
^{32}P& ^{35}S	50 µCi	University College London, UK	96	DNA/primer labeling
^{32}P	50 µCi	St. Barts. Medical College, UK	24	DNA labeling


(See ATT 9.1.2)
Scintillation Counter
North
Scale: 1/4" = 1 '
Isotope Storage Freezer
(See ATT 9.1.2)
Hot Lab
Rm 12A
Hood
Waste Holding Area
ATT 9.1.1
(See ATT 9.1.3)
Hot Lab
Rm 12B
Portable acrylic shields
Darkroom
Hallway
Hallway

(See ATT 9.1.2b)

ATT 9.1.2a

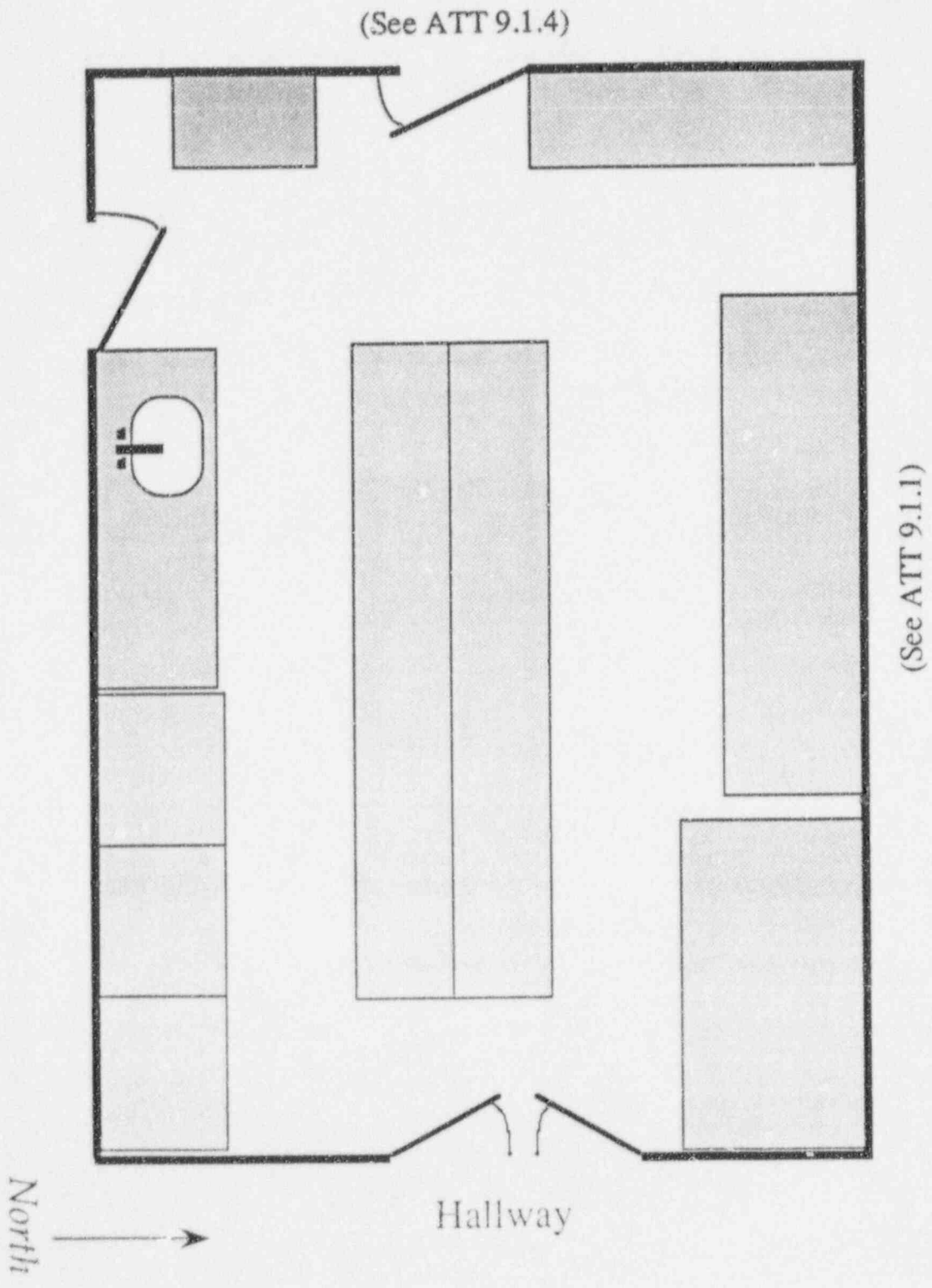
ATT 9.1.2b



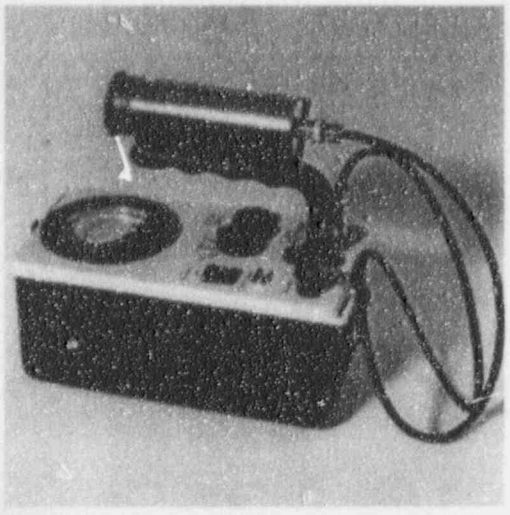
(See ATT 9.1.2b)
Scale: 1/4" = 1 '

ATT 9.1.3

Scale: 1/4" = 1'



VWR Scientific Products On-Line Catalog



Radiation Survey Meters, Dosimeter Corporation

Radiation Survey Meters, Dosimeter Corporation

Two rugged models for use in the lab or the field with value in life science, industrial, and health care settings. Both models respond to radiation from ^{14}C, ^{32}P, ^{35}S, ^{125}I, ^{131}I and other isotopes with similar energies. The probe for both is a 115 x 35 mm end-window Geiger tube with a 6.8cm^2 window and sensitive to alpha radiation with energies >3 MeV, beta >45 keV, and gamma >6 keV. Its case is stainless steel and aluminum. Both probes can be clipped to the instrument or be deployed at the end of a 30" cable.

Model 3007A comes in a rugged aluminum case to protect against rough handling. It incorporates an easy-to-read analog meter with two scales, 0-0.5 mR/h and 0-300 cpm; a range selection switch (Off, x1, x10, x100), a battery check, speaker on/off switch, and a sealed splash proof speaker. The meter operates on two D-cells plus a 9-volt battery for the speaker to avoid battery drain if the instrument is left on.

Model 3100 comes in an equally tough case but features an LCD with both digital and bar graph displays. On a 0-1 scale the modes include cpm, total counts, mR/h, and total mR with x1, x10, x100, and x1000 ranges. Counting is microprocessor controlled. The unit also features a variable high-voltage and single-channel analyzer capability. A built-in alarm circuit with both red LED and audible alarms can be set anywhere from 2 to 100% of full scale for threshold monitoring. One 9 Volt battery required for operation.

Ordering Information: Both units come complete with probe and cable, carrying strap, and instructions. Operating temperature range: -10 to 50°C. The manufacturer provides a two-year warranty on each meter and a six-month warranty on the probe (window excepted).

To Place Your Order

Enter a quantity in the box below, then click the "Update Order" button. That will take you to a shopping basket page where you can edit your order and view the totals.

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
CONVERSATION RECORD

(X) TELEPHONE (X) OUTGOING ( ) INCOMING ( ) CONVERSATION TIME: DATE: 2/5/97

NAME OF PERSON(S) CONTACTED: ORGANIZATION: TELEPHONE NO.:

K.R. Maddipati, Ph.D.
Cayman Chemical
313-662-6756

SUBJECT:

Letter dated May 16, 1996 requesting an amendment to Lic. No. 21-24683-01.
Control No. 301324

SUMMARY:

Please submit the following additional information:

1. We discussed possibly lowering the possession limit for P-32 and describing how much will be in waste storage, how much will be used in experiments, and an estimate of the largest order you might place at one time. This will allow me to better assess radiation safety risks.

2. We discussed possibly lowing the H-3 possession limit and specifying how much will be a) used for redistribution b) stored as waste and c) used in experiments. Again, this will allow me to assess potential safety issues.

3. Confirm that you intend to redistribute C-14 prepackaged units and specifically state that they will be distributed in accordance with your already existing license procedures that cover I-125 and H-3 redistribution.

4. Instead of adding another listing on the license for redistribution of H-3 eicosanoids and fatty acids, you should request an increase in the possession limit in License Condition Item 8.B. to account for the new products. In addition, you should request License Condition Item 7.B be changed to add "prepackaged units" in addition to the already authorized "prepackaged *in vitro* diagnostic kits".

5. Please provide the name, qualifications and training of your new proposed RSO.

6. Please modify your training program described on page 3 and 4 of your letter to include the topics required by 10 CFR 19.12. You may simply state that these topics will be covered.

7. The May 16, 1996, letter makes several references to a Radiation Safety Committee. Please clarify if you will establish a committee. If you will, describe its members, duties, meeting frequency, etc. You are not required to have a committee since you are not authorized as a broad scope license at this time (broad scope licensees can approve their own users and facilities independent of NRC review). Many licensee elect to have a committee anyway.

8. Regarding Facilities, page 8 of your letter, please note that the Radiation Safety Committee will not be authorized by the NRC to approve facilities without NRC review and approval. The criteria submitted is very good and should be followed for all facilities approved by the NRC.

9. In support of your request for more than one millicurie of phosphorus-32, (by authorized users during research) submit special safety instructions to be provided to individuals. Your procedures should include:

   a. the use of low density shielding (e.g., plexiglass) in order to keep Bremsstrahlung radiation at a minimum,

   b. a mandatory radiation survey and wipe test for radioactive contamination after each use,

   c. the use of finger extremity monitors for procedures that involve one millicurie or more,

   d. a dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the radiation protection officer be present during new procedures, and

   e. the use of eye protection for procedures that involve 10 millicuries or more.

10. Specify the radiation detection instruments that you have available. Include the type (GM, scintillation counter, gamma counter, etc.), the type of probe attachment if applicable (pancake for P-32, I-125, etc.), the types of radiation detected, the range (milliroentgens per hour or counts per minute), and the intended use (monitoring, surveying, assaying or measuring).

11. The May 16, 1996 letter, states that dosimetry devices will be assigned if it is determined that workers are likely to receive in excess of 10% of the maximum whole body or extremity exposures. Please describe how you will determine which individuals are likely to exceed 10% of the regulatory limits. These criteria should consider both routine handling and accidents which are likely to occur, such as spills. If you wish, you may determine the need for dosimetry based on the radionuclides and quantities handled by the individual (e.g. P-32 use greater than 1 millicurie including stock vials).

12. Please provide a copy of your laboratory instructions. Typical instructions should include:

   a. Wear laboratory coats or other protective clothing at all times in areas where licensed materials are used.

   b. Wear disposable gloves at all times while handling licensed materials.

   c. For P-32 and P-33, either after each procedure or before leaving the area, monitor your hands for contamination in low-background area.

   d. Do not eat, drink, smoke or apply cosmetics in any area where licensed material is stored or used.

   e. Do not store food, drink or personnel effects in areas where licensed material is stored or used.

   f. Wear personnel monitoring devices (if required by RSO) at all times while in areas where licensed materials are used or stored.

g. Dispose of radioactive waste only in designated, labeled and properly shielded receptacles.

h. Never pipette by mouth.

I. Confine radioactive solutions in clearly labeled containers.

j. Secure all licensed material when not under the constant surveillance and immediate control of the authorized users.

13. In support of your request to dispose of licensed material with half-lives greater than 65 days by decay-in-storage, submit the information requested in the attached "Guidance to Licensees Regarding Requests to Dispose of Radioactive Waste by Decay-In-Storage (Non-Medical Waste)".

14. Regarding the Area Survey Procedures, page 21 of the May 21 letter, please modify to include, in addition to wipe survey, that ambient dose rate surveys will be conducted for use of P-33 and P-32. Surveys should be conducted by users of their feet and hands after each use and of the laboratory use areas at least weekly if less than 1 millicurie is used per experiment. Stock vial storage (weekly), work stations (day of use), waste containers (weekly), and long term waste storage areas (monthly) should be surveyed to assure radiation levels are kept to a minimum. Specify how often each of these areas will be surveyed. The recommended frequencies are included in parentheses.

A. Describe the records that will be kept of results. Should be in mr/hr., include date, location, results, meter used, actions taken to reduce levels if necessary.

15. Page 18 of the May 16 letter describes receipt procedures for radioactive packages. The procedure states that if package arrive and are damaged, the person should use the handling techniques specified by the RSO (Item 1.b.) Please describe those techniques so I may assess their adequacy.

16. Page 20 of the May 16 letter. The telephone number for the NRC should be changed to read 630-829-9500 and please note that 10 CFR 20.1906(d) requires you to notify the carrier should a package be contaminated.

17. 10 CFR 20.1801 requires that licensed material be secured against unauthorized removal from the place of storage. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance over materials in unrestricted areas that are not in storage. In your application, you did not indicate how you will secure licensed material. Describe how you will preclude the unauthorized removal of licensed material from the place of storage and in unrestricted areas.

ACTION REQUIRED:

Please respond in writing within 30 days, provide two copies of your response and refer to Control No. 301324.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Evelyn R. Matson 630-829-9822		2/5/97

VOID SHEET

TO: License Fee Management Branch

FROM: RIII - COLLEEN C. CASEY

SUBJECT: VOIDED APPLICATION

Control Number: 39999 2

Applicant: CAYMAN CHEMICAL CO.

License Number: 21-24683-01

Docket Number: 030-29143

Date Voided: MAY 14, 1996

Reason for Void: Licensee needs time to resubmit amendment request in entirety due to significant personnel change and additional request - Voided after partial review. Licensee wants us to keep the original fee which action now & will re-activate until re-submission in a few weeks to a month. Further agreed on 5/17/96.

Colleen C. Casey 5/14/96
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

___ Refund Authorized and processed

✓ No Refund Due

___ Fee Exempt or Fee Not Required

Comments: _____

_____

_____

Log completed ✓

Processed by: SAC 6/12/96

ML 0/1
30
SD

140060

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02410
STATUS CODE: 0
FEE CATEGORY: 3P
EXP. DATE: 19960331
FEE COMMENTS: REDISTRIBUTION
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

B. APPLICATION ATTACHED
APPLICANT/LICENSEE: CAYRAN CHEMICAL COMPANY
RECEIVED DATE: 960229
DOCKET NO: 3029143
CONTROL NO.: 399992
LICENSE NO.: 21-24683-01
ACTION TYPE: AMENDMENT

56

C. FEE ATTACHED
AMOUNT: 1500
CHECK NO.: [illegible]

D. COMMENTS

SIGNED D. Harvey
DATE 3-11-96

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

F. FEE CATEGORY AND AMOUNT: 3P 3M $1500

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

H. OTHER

SIGNED
DATE March 13, 1996

Log March 20
Remitter
Check No 13211
Amount $1500
Fee Category 3P 3M Upgraded
Type of Fee APP
Date Check Rec'd 3/19/96
Date Completed 3/13/96
By

give Copy to Linda when completed

RECEIVED
MAR 22 1996
REGION III

NRC FORM 313
U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB NO. 3150-0120
EXPIRES 6-30-98

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS MANDATORY INFORMATION COLLECTION REQUEST: 3.5 HOURS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
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:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION REGION III
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:

MATERIAL RADIATION PROTECTION SECTION
U.S. NUCLEAR REGULATORY COMMISSION REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

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 JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate box)

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER 21-28683-01
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Cayman Chemical Company
690 KMS Place
Ann Arbor, MI 48108

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

Cayman Chemical Company
690 KMS Place
Ann Arbor, MI 48108

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION — TELEPHONE NUMBER

Camilla A. Mauzy, Ph.D. — (313)662-6758

5. RADIOACTIVE MATERIAL
(a) Element and mass number (b) Chemical and physical form and (c) Maximum amount that 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. LICENSING FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY 3M — AMOUNT ENCLOSED $1500.00

13. CERTIFICATION (Must be completed by the APPLICANT and/or the PERSON WITH LEGAL AUTHORITY TO BIND THE APPLICANT UNDER FEDERAL LAWS)
I hereby certify that all statements and representations made in this application are true and correct and that all material facts have been stated in this application and that the applicant understands that all statements and representations made herein 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, 36, 39, 40, and 70, and that all information contained herein is true and correct to the best of their knowledge and belief.
A willful false statement or representation is punishable under 18 U.S.C. Section 1001 and could result in the imposition of criminal penalties.

TYPED OR PRINTED NAME — TITLE — DATE

Kirk M. Hamilton, MP — President — 2-28-96

RECEIVED
FEB 29 1996
REGION III

3-1-96-12

CHEMICAL

February 28, 1996

Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Sirs:

We are submitting two copies of a new proposed amendment to Cayman Chemical Company NRC License No. **21-24683-01.**

In addition to the materials listed in our current license, we are adding several new isotopes, and will be using small amounts of the isotopes for research purposes. In accordance with NRC fee regulations, we are also submitting an application fee in the amount of $1500.00 for this amendment which will expand our use to the 3M category.

All research will be done on the premises (690 KMS Place) and comprise *in vitro* experimentation only.

If you have questions regarding the application or usage, please feel free to call or fax me.

Sincerely,

Camilla A. Mauzy

Camilla A. Mauzy, Ph.D.
Manager, Molecular Biology Div.
Cayman Chemical Co.

CAYMAN
CHEMICAL

690 KMS Place
Ann Arbor, MI
48108 USA

Phone:
(800) 364-9897
(313) 662-6756

Fax:
(313) 662-6896

5. Radioactive material(in addition to isotopes listed in original License 21-24683-01):

	Element/ Mass No.	Chemical form	Max. amount
5a.	^{33}P	adenosine-[^{33}P]-triphosphate	10 mCi
5b.	^{33}P	deoxynucleotide-[^{33}P]- triphosphate	10 mCi
5c.	^{32}P	Adenosine 5'-[α-^{32}P]-triphosphate, triethylammonium salt	25 mCi
5d.	^{32}P	Adenosine 5'-[γ-^{32}P]-triphosphate, triethylammonium salt	25 mCi
5e.	^{32}P	deoxynucleotide-α-[^{32}P]-triphosphate	^5 mCi
5f.	^{35}S	L-[^{35}S]-methionine	20 mCi
5g.	^{35}S	Deoxyadenosine 5'-α-[^{35}S]thiotriphosphate, triethylammononium salt	20 mCi
5h.	^{3}H	[^{3}H] eicosonoid(s)	100 mCi

6. Purpose(s) for which licensed Material will be used (in addition to material uses listed in original License 21-24683-01):

	Element/ Mass No.	Chemical form	Purpose
6a.	^{33}P	adenosine-[^{33}P]-triphosphate	DNA Probe labelling
6b.	^{33}P	deoxynucleotide-[^{33}P]-triphosphate	DNA Probe labelling, sequencing
6c.	^{32}P	Adenosine 5'-[α-^{32}P]-triphosphate, triethylammonium salt	DNA Probe labelling
6d.	^{32}P	Adenosine 5'-[γ-^{32}P]-triphosphate, triethylammonium salt	DNA Probe labelling
6e.	^{32}P	deoxynucleotide-α-[^{32}P]-triphosphate	DNA sequencing
6f.	^{35}S	L-[^{35}S]-methionine	Protein Labelling
6g.	^{35}S	Deoxyadenosine 5'-α-[^{35}S]thiotriphosphate, triethylammononium salt	DNA Sequencing
6h.	^{3}H	[^{3}H] eicosonoid(s)	Development of product line

7. Individual(s) responsible for radiation safety program and their training and experience.

7.1 Authorized Users for Medical Use

None. All work will be performed *in vitro*.

7.2 Authorized Users for Nonmedical Use

See ATT 7.2.1, 7.2.2, 7.2.3, 7.2.4, and 7.2.5. The primary user of radioactive material will be Camilla A. Mauzy, Ph.D. (ATT 7.2.1).

7.3 Radiation Safety Officer

Camilla A. Mauzy has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

2-28-96
(date)

Kirk Maxey, M.D.
President, Cayman Chemical Company

8. Training For Individuals Working in or Frequenting Restricted Areas.

Cayman Chemical Company - Training Policies

All individuals who work in, or frequent, a Restricted Area or who use radioactive materials will receive appropriate training. The level of training will be appropriate to the duties of the individual who works with radiation. Training may be abridged for personnel (e.g., Shipping or Security personnel) whose duties require less potential exposure or less involved procedures.

1. Personnel will be instructed before assuming duties with, or before assuming duties in the vicinity of, radioactive materials.

2. Refresher training will be provided annually.

3. Personnel will be retrained as appropriate whenever there is a significant change in their duties, the regulations, or the terms of the NRC license.

4. Individuals will receive two types of training:

   a. general training on the nature of radiation, risks, protective measures (as specified below). This training is the responsibility of the RSO.

NRC FORM 374 (7-94) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 06

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, 36, 39, 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.

398149

Licensee	
1. Cayman Chemical Company, Inc. 2. 690 KMS Place Ann Arbor, MI 48108	In accordance with letter dated February 7, 1995 3. License Number 21-24683-01 is amended in its entirety to read as follows: 4. Expiration Date March 31, 1996 5. Docket or Reference No. 030-29143

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Iodine-125	A. Prepackaged in vitro diagnostic kits obtained from a manufacturer authorized to distribute the in vitro kits in accordance with a specific license issued pursuant to Section 32.71 of 10 CFR Part 32 or under equivalent regulations of an Agreement State	A. 500 microcuries
B. Hydrogen-3	B. Prepackaged in vitro diagnostic kits obtained from a manufacturer authorized to distribute the in vitro kits in accordance with a specific license issued pursuant to Section 32.71 of 10 CFR Part 32 or under equivalent regulations or an Agreement State	B. 500 microcuries

UNITED STATES NUCLEAR REGULATORY COMMISSION

210070

9503210485 950302
PDR ADOCK 03029143
C PDR

COPY

Printed on recycled paper

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-24683-01

Docket or Reference Number
030-29143

Amendment No. 06

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
C. Iodine-125	C. Prepackaged units containing I-125 labeled prostaglandins obtained from a manufacturer authorized to distribute the material in accordance with a specific license issued pursuant to Section 32.71 of 10 CFR Part 32 or under equivalent regulations of an Agreement State.	C. 2 millicuries

9. Authorized Use:

A., B. and C. For receipt; for storage; for redistribution pursuant to Section 32.71, 10 CFR Part 32, to persons generally licensed pursuant to Section 31.11, 10 CFR Part 31, [illegible] under equivalent Agreement State regulations; and for redistribution to persons [illegible]ifically licensed for the type and quantity of material by the Nuclear Regulato[illegible]mission or an Agreement State.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 690 KMS Place, Ann Arbor, Michigan.

11. Receipt, storage and redistribution of licensed material shall be by, or under the supervision of, Kirk M. Maxey, M.D.

12. Prepackaged in vitro diagnostic test kits shall not be opened or used by the licensee.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-24683-01

Docket or Reference Number
030-29143

Amendment No. 06

13. The licensee shall maintain records of information important to safe and effective decommissioning at the address specified in Condition 10. per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

14. 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.

A. Application dated March 26, 1986; and

B. Letters dated May 4, 1987, August 8, 1987, May 16, 1988, May 25, 1990, January 16, 1991, March 30, 1993 and June 18, 1993 (with attachments).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAR 2 1995

By Deborah A. Fastura
Materials Licensing Section, Region III

COPY

MAR 0 3 1995

Cayman Chemical Company, Inc.
ATTN: Kirk Maxey, M.D.
Radiation Safety Officer
690 KMS Place
Ann Arbor, MI 48108

Dear Dr. Maxey:

Enclosed is the NRC license or license amendment which you requested.

You are encouraged to carefully review your license or amendment upon receipt as special conditions may have been added to ensure that the changes requested meet NRC requirements.

Any future correspondence relating to your license should specifically reference your license number to expedite your inquiry.

Should you have any questions regarding your new license or amendment or require clarification, please contact the Materials Licensing Section at (708) 829-9887.

Sincerely,

Original Signed By
Deborah A. Piskura
Nuclear Materials Licensing Section

License No. 21-24683-01
Docket No. 030-29143

Enclosures: As stated

DOCUMENT NAME: M:\03029143.CL5
To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DRSS/RIII							
NAME	DAPiskura:bt							
DATE	03/ /95							

OFFICIAL RECORD COPY

398149

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02410
STATUS CODE: 0
FEE CATEGORY: 3P
EXP. DATE: 19960331
FEE COMMENTS: REDIS.RIBUTION
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: CAYMAN CHEMICAL COMPANY
RECEIVED DATE: 950213
DOCKET NO: 3029143
CONTROL NO.: 398149
LICENSE NO.: 21-24683-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 0
CHECK NO.: 0

3. COMMENTS
mailing address change
SIGNED D. Henry
DATE 2-14-95

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

1. FEE CATEGORY AND AMOUNT: 3P FEE NOT REQUIRED

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

3. OTHER

SIGNED SC
DATE 2/17/95

1995 FEB 16 PM 4:27

CAYMAN CHEMICAL

February 7, 1995

U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

RE: Change of Licensee Address for Materials License Number 21-24683-01

To Whom It May Concern:

I would like to request that the address you currently show on the above referenced license be changed. The new licensee address should read the same as Item 10 in the Condition Section of our License - 690 KMS Place, Ann Arbor, MI 48108.

Thank you for your assistance with this matter. Please contact me if you have any questions or if I can be of further assistance to you.

Sincerely,

Kirk M. Maxey, M.D.
President

RECEIVED BY LFDCB
Date Feb. 10, 1995
Log 2b9 III
By SC
Date Completed 2/17/95

FEE NOT REQUIRED

RECEIVED
FEB 13 1995
REGION III

CAYMAN
CHEMICAL
690 KMS Place
Ann Arbor, MI
48108 USA

Phone:
(800) 364-9897
(313) 662-6756

Fax:
(313) 662-6896

NRC FORM 374
(10-88)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 05

MATERIALS LICENSE

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, 39, 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.

3911937

Licensee	
1. Cayman Chemical Company, Inc.	In accordance with letter dated March 30, 1993 3. License number 21-24683-01 is amended in its entirety to read as follows:
2. 2280 Peters Road Ann Arbor, MI 48103	4. Expiration date March 31, 1996
	5. Docket or Reference No 030-29143

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Iodine-125	A. Prepackaged in vitro diagnostic kits obtained from a manufacturer authorized to distribute the in vitro kits in accordance with a specific license issued pursuant to Section 32.71 of 10 CFR Part 32 or under equivalent regulations of an Agreement State.	A. 500 microcuries
B. Hydrogen-3	B. Prepackaged in vitro diagnostic kits obtained from a manufacturer authorized to distribute the in vitro kits in accordance with a specific license issued pursuant to Section 32.71 of 10 CFR Part 32 or under equivalent regulations or an Agreement State	B. 500 microcuries

ML 3

COPY 2 LM

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 21-24683-01

Docket or Reference number: 030-29143

Amendment No. 05

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
C. Iodine-125	C. Prepackaged units containing I-125 labeled prostaglandins obtained from a manufacturer authorized to distribute the material in accordance with a specific license issued pursuant to Section 32.71 of 10 CFR Part 32 or under equivalent regulations of an Agreement State.	C. 2 millicuries

9. Authorized Use:

A., B. and C. For receipt; for storage; for redistribution pursuant to Section 32.71, 10 CFR Part 32, to persons generally licensed pursuant to Section 31.11, 10 CFR Part 31, or under equivalent Agreement state regulations; and for redistribution to persons specifically licensed for the type and quantity of material by the Nuclear Regulatory Commission or an Agreement State.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 690 KMS Place, Ann Arbor, Michigan.

11. Receipt, storage and redistribution of licensed material shall be by, or under the supervision of, Kirk M. Maxey, M.D.

12. Prepackaged in vitro diagnostic test kits shall not be opened or used by the licensee.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
21-24683-01

Docket or Reference number
030-29143

Amendment No. 05

13. The licensee shall maintain records of information important to safe and effective decommissioning at the address specified in Condition 10. per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

14. 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.

A. Application dated March 26, 1986; and

B. Letters dated May 4, 1987, August 8, 1987, May 16, 1988, May 25, 1990, January 16, 1991, March 30, 1993 and June 18, 1993 (with attachments).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date September 3, 1993

By Cynthia Pinzon
Materials Licensing Section, Region III

COPY

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR [redacted]S USE)
INFORMATION FROM LTS

PROGRAM CODE: 02410
STATUS CODE: 0
FEE CATEGORY: 3P
EXP. DATE: 19960331
FEE COMMENTS: REDISTRIBUTION
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: CAYMAN CHEMICAL CO., INC.
RECEIVED DATE: 930405
DOCKET NO: 3029143
CONTROL NO.: 394937
LICENSE NO.: 21-24683-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: [illegible]
CHECK NO.: [illegible]

3. COMMENTS

SIGNED [illegible]
DATE [illegible]

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

1. FEE CATEGORY AND AMOUNT: 3P 1240

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

3. OTHER

SIGNED [illegible]
DATE 4-8-93

RECEIVED
APR 15 1993
REGION III

KMS Fusion, Inc.
700 KMS Place
P.O. Box 1567
Ann Arbor, MI 48106-1567
(313) 769-8500 FAX (313) 769-1775

KMS

July 20, 1993

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Sirs:

Enclosed is documentation on the close-out survey of rooms 333 and 334 in the east wing of the KMS Facility at 700 KMS Place, Ann Arbor, Michigan.

Approximately 300 wipe tests were taken in each of the two rooms on February 15, 1993. All of these wipe tests assayed at less than 100 dpm per 100 cm^2. The KMS Radiation Safety Committee (meeting March 3, 1993) approved release of these two rooms for unrestricted use pending completion of a satisfactory area radiation survey. This survey was conducted March 17, 1993 and disclosed no radiation above background. The area survey was conducted with a Victoreen 450P, a sensitive pressurized ion chamber.

Both surveys were complete before occupancy of the areas by Cayman Chemical, Inc.

These two rooms were used as the RSO laboratory for low-level assays (stack effluent, bioassay, environmental, wipe tests, calibrations, etc). Only small quantities of tritium were allowed in the labs. All sealed sources are accounted for; thus the possibility of an unknown source being present in the labs is negligible. The RSO laboratories were purposely located in the east building so that low-level radiometric assays could be performed with minimal interference with the higher level operation which were being conducted in laboratory areas located in the west wing.

Sincerely yours,

John C Widman

John C. Widman, CHP
Chairman, Radiation Safety Committee

JUL 2 6 1993

MATERIALS LICENSE

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. Cayman Chemical Company, Inc. 2. 2280 Peters Road Ann Arbor, MI 48103	3. License number 21-24683-01 4. Expiration date April 30, 1991 5. Docket or Reference No. 030-29143

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Iodine-125	A. Prepackaged in vitro diagnostic kits obtained from a manufacturer authorized to distribute the in vitro kits in accordance with a specific license issued pursuant to Section 32.71 of 10 CFR Part 32 or under equivalent regulations of an Agreement State	A. 20 microcuries total possession limit

9. Authorized Use

A. For receipt and storage; and for redistribution pursuant to Section 32.71, 10 CFR Part 32, to persons generally licensed pursuant to 31.11, 10 CFR Part 31, or under equivalent licenses of Agreement States.

CONDITIONS

10. Licensed material shall be received and stored at the licensee's facilities located at 2300 Peters Road, Ann Arbor, Michigan.

11. Receipt, storage and redistribution of licensed material shall be by, or under the supervision of, Kirk M. Maxey, M.D.

12. Prepackaged in vitro diagnostic test kits shall not be opened or used by the licensee.

1/1

COPY 2 ML.30
AS 4/24/86

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 21-24683-01
Docket or Reference number: 030-29143

13. 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.

A. Application dated March 26, 1986.

For the U.S. Nuclear Regulatory Commission

Date APR 24 1986

Original Signed
By Evelyn R. Maston
Materials Licensing Section, Region III

COPY

APR 24 1986

Cayman Chemical Company, Inc.
ATTN: K. M. Maxey, M.D.
President
2280 Peters Road
Ann Arbor, MI 48103

Gentlemen:

Enclosed is your NRC License Number 21-24683-01 in accordance with your request.

Please note that in accordance with 10 CFR Part 30, Section 30.41, you must verify prior to transfer, that the transferee is authorized to receive iodine-125 pursuant to the general license issued by 10 CFR Part 31.11.

Please review the enclosed document carefully and be sure that you understand all conditions. You must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Possess radioactive material only in the quantity and form indicated in your license.

3. Use radioactive material only for the purpose(s) indicated in your license.

4. Notify NRC in writing of any change in mailing address.

5. Request and obtain appropriate amendment if you plan to change ownership of your organization, change locations of radioactive material, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. Any amendment request should be accompanied by the appropriate fee specified in 10 CFR Part 170.

6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material prior to your expiration date.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions and representations in your license application will result in enforcement action against you in accordance with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

If you have any questions or require clarification of any of the above stated information, contact us at (312) 790-5625.

Sincerely,

Original Signed By
Evelyn R. Matson
Materials Licensing Section

Enclosure(s):
1. License No. 21-24683-01
2. 10 CFR Parts 19, 20, 30 and 31
3. NRC-3

RIII
ERM
Matson/cm
4/22/86

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)

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

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

CAYMAN CHEMICAL COMPANY INC.
2280 PETERS ROAD
ANN ARBOR, MICHIGAN 48103

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

2280 and 2300 PETERS ROAD
ANN ARBOR, MICHIGAN 48103

8606190200 860424
REG3 LIC30
21-24683-01 PDR

APR 24 P3:27

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION: Kirk M. Maxey, M.D.

TELEPHONE NUMBER: 313-662-6756

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. (see adendum)

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT. (see adendum)

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY 3P
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
Kirk M. Maxey	KIRK M. MAXEY, M.D.	President	3-26-86

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 including all affiliated contractors)

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (labor 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

RECEIVED
MAR 31 1986
REGION III

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
Application	Apr 7 III	3P	CONTROL NO. 80999	
AMOUNT RECEIVED	CHECK NUMBER		MAR 31 1986	DATE
$230	1358			4/10/86

CAYMAN CHEMICAL

Cayman Chemical Company
2280 Peters Road
Ann Arbor, Michigan 48103

March 26, 1986

APPLICATION FOR MATERIAL LICENSE: ITEMS 5-11.

5. Radioactive material

The material will be in the form of I^{125}, as iodinated tyrosine esters of various prostaglandin molecules. There will be a maximum of 1uC per kit, and a maximum of 20uC total material present at the facility at any one time. The iodination chemistry itself will not be performed here. Only the purified labeled molecules will be present. These will be redistributed to general licensees without further weighing, measuring, or chemical alteration.

6. The material will be distributed to general licensees in kit form, for use in in vitro assays for Prostaglandins and related biomolecules. The kits will be obtained from a manufacturer authorized to distribute in vitro kits in accordance with a specific license issued pursuant to 10 CFR 32.71. The manufacturer's packaging and labeling will not be altered in any way. Each re-distributed kit will be accompanied by the manufacturer-supplied package insert, providing radiation safety instructions for general licensees.

7,8. Dr. Kirk M. Maxey, M.D. will be responsible for the radiation safety program. In addition to his academic training, he has completed a radiation safety course sponsored by the large pharmaceutical firm where he was previously employed. At present, he will be the only employee involved in handling the materials present in the in vitro kits.

9. Since at present Cayman Chemical is not anticipating a need to open or alter the pre-packaged containers containing the I^{125} labeled material, there will be no special facilities for this purpose. The laboratory is of standard design, conforming to OSHA requirements for an open biochemical laboratory. Radiation safety monitors will be worn by all personell who work in the laboratory, as required. (10.)

11. I^{125}-containing wastes derived from use or accidental breakage of the kit materials can be disposed of in the normal sanitary sewer system, according to Title 10 CRF, part 20:303. Solid wastes and glassware will be disposed of in a normal manner.

10.(cont.) The following additional precautions will be taken:
a. All radioactive materials will be stored in a specially designated area with a mandatory in/out inventory system operated by computer with redundant manual backup.
b. Approved warning signs will be posted in this area, and in the designated work area.
c. There will be no smoking or eating in the storage or work area.
d. Plastic gloves will be worn when handling the kits.

CONTROL NO. 80999