D. This Radiation Safety Guide contains "Instructions to Personnel."

UNOGEN, INC.

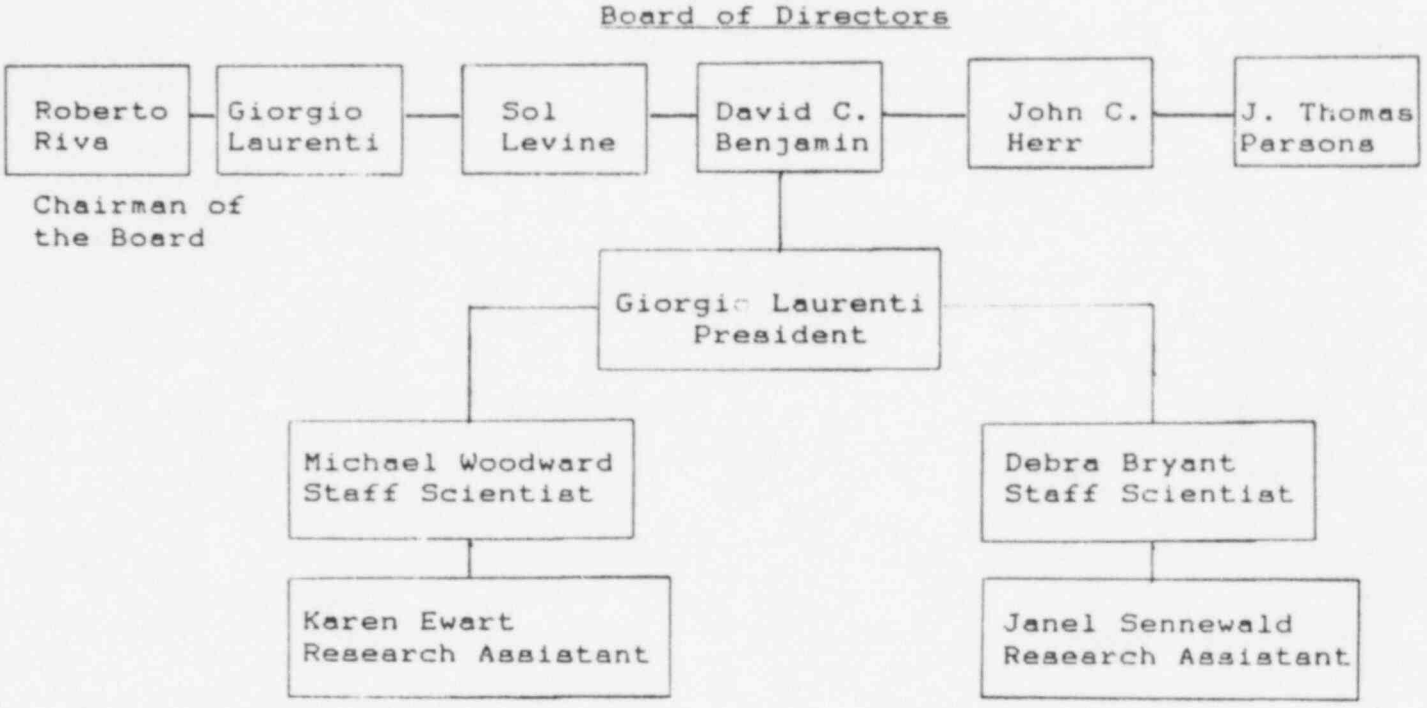
RADIATION SAFETY GUIDE

DATE : June, 1985

APPROVED BY : Brian Copcutt

Brian Copcutt, Ph.D.
Radiation Safety Officer

ORGANIZATION OF UNOGEN, INC.



Technical Staff: Katherine Wright; Scott Parsons

MAY 1985

RADIATION SAFETY GUIDE

INTRODUCTION

This guidebook to radiation safety at Unogen, Inc is issued to all employess who will be working with radioactive materials (RAM). All such employees should read this manual carefully and be familiar with its contents prior to working with RAM.

POLICY

The policy of Unogen is to limit exposure of personnel to sources of ionizing radiation to levels which are as low as is reasonably achievable (ALARA, see appendix IV) and to minimize discharges of radioactive material to the environment. It is the responsibility of every person who uses sources of ionizing radiation to comply with the applicable sections of this GUIDE and to insure that all personnel associated with the use of such sources are instructed in the proper safety procedures and precautions to be employed.

SCOPE AND APPLICATION OF THE GUIDE

The use of radioactive material by Unogen is governed by the conditions of a By-product Material License issued by the Nuclear Regulatory Commission (NRC). The regulations and procedures set forth in this GUIDE are based on NRC license requirements and Federal Regulations, and apply to all persons working for the licensee.

AUTHORIZATION OF RADIOACTIVE MATERIAL USE

No person at Unogen may receive, possess, or use radioactive material except under the direct supervision of those individuals listed in Section 6 of Unogen's NRC application form 313 I or subsequent amendments to this application. Individuals listed in section 6 shall hereafter in this guide be referred to as "Users". All other users of RAM wil be referred to as "RAM users".

LIMITS FOR EXPOSURE AND RELEASES

External Exposure Limits:

No person employed by the Licensee shall receive external radiation in excess of the values listed in Title 10 of the Code of Federal Regulations, Part 20. (see appendix II)

Internal Exposure Limits:

In order to control radiation exposures due to ingestion or

inhalation of radioactive materials, it is necessary to limit the spread of radioactive materials into occupied areas. Radioactive contamination shall not exceed the limits specified in the GUIDE, except for work areas specifically designated and approved by the Radiation Safety Committee.

Release of Radioactive Material to the Environment:

It is the policy of the Licensee to minimize the amount of radioactive material discharged into the environment. All waste disposal shall follow the rules set forth in this guide and in the license application.

RADIATION SAFETY COMMITTEE

A Radiation Safety Committee has been set up by the Licensee and is charged with the following responsibilities:

1. Insuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

2. Insuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

The Committee shall:

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.

2. Review the training and experience of all individuals who use radioactive material (including technologists and scientists) and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC and State regulations and the conditions of the license.

3. Establish a program to insure that all individuals whose duties may require them to work in the vicinity of radioactive material are properly instructed as required by 10 CFR, section 19.12.

4. Review and approve all requests for use of radioactive material by Unogen employees.

5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of

users, and special monitoring procedures (see appendix III).

6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspections, written safety procedures, and the adequacy of Unogen's management control system.

7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

8. Maintain written records of all committee meetings, actions, recommendations, and decisions.

9. Insure that the license is amended when necessary, prior to any changes in facilities, equipment, policies. procedures, and personnel, as specified in the license.

Meeting Frequency

The Radiation Safety Committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

RADIATION SAFETY OFFICER

The Radiation Safety Officer shall be Chairman of the Radiation Safety Committee. His specific duties shall include:

1. Preparation of periodic reports on the status of the radiation safety program at Unogen. These reports shall be received and reviewed by the Radiation Safety Committee.

2. Furnishing consulting services to members of the Unogen staff on all aspects of radiation protection.

3. Providing surveillance of all health physics activities, including the assisting of individuals and supervisors in discharging their responsibilities.

4. Investigating promptly any accident or major spill or alleged misuse, and reporting the episode to all required persons and the Radiation Safety Committee.

5. Supervising and/or providing advice on decontamination in cases of contaminating accidents and giving prompt notification of the results to the Radiation Safety Committee.

6. Providing quarterly monitoring and surveillance for all areas where radioactive material is used and stored.

7. Any additional duties the Radiation Safety Committee may deem necessary to provide effective protection of the general public and the enivironment from unwarranted radiation exposures.

USERS OF RADIOACTIVE MATERIALS

A chain of responsibility relative to the safe use of radioactive material exists from individual users to the Radiation Safety Committee. This chain is independent of other administrative lines of control within the organization. However, the Radiation Safety Committee recognizes the right of any administrative entity within the organization to impose additional restrictions, qualifications, and/or regulations regarding the use of radioactive material.

Responsibilities of isotope users are as follows:

ALL USERS

Each individual at Unogen, regardless of his or her job description who has any contact with radioactive material is responsible for:

1. Being familiar with the this Radiation Safety Guide.

2. Keeping his exposure to radiation and that of those working under his supervision as low as possible, and specifically below the Maximum Permissible Exposure as listed in 10 CFR, Part 20 (see appendix II). Laboratory air and water concentrations shall be maintained below the levels listed in 10 CFR, Part 20.

3. Wearing the prescribed exposure monitoring equipment such as film badges and ring badges in restricted areas.

4. Having precautionary area surveys made at frequent intervals with a suitable survey meter.

5. Limiting the use of radioisotopes authorized to him to individuals working under his direct supervision and to the location specified on the license application.

6. Keeping current working records of the receipt and disposition of isotopes in his possession including use, waste disposal, transfer, storage, etc. These records will be audited quarterly by the Radiation Safety Officer or his designee.

USER:

All Users at Unogen, as listed in item 6 of the license application, will receive adequate training prior to receiving designated user status. This training shall consist of on-the-job training and/or formal course work in (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, and (e) applicable Federal regulations.

In addition to the terms listed above for all RAM users, Users are responsible for:

1. Adequate planning. Before a study is performed the User should determine the types and amount of radioactive material to be used. This will generally give a good indication of the protection required. The procedure must be well outlined. In most cases before the procedure is actually performed with radioactive materials, it should be rehearsed so as to preclude slip-ups or unexpected circumstances. In any situation where there is an appreciable radiation hazard, the Radiation Safety Officer shall be consulted before proceeding.

2. Being readily available when radioisotopes are used under their supervision.

3. Instructing those persons for whom they are responsible in the use of safe techniques and in the application of approved radiation safety practice.

4. Complying with the regulations governing the use of radioactive materials as established by the Nuclear Regulatory Commission and as recommended by this GUIDE.

5. Reporting any incident or unusual occurrence related to the radioactive material under their supervision. Verbal reports shall be made promptly to the appropriate officer of the company. In the case of minor incidents this will be sufficient. However, in the event of a significant incident, a User will be required by the Radiation Safety Committee to prepare a written report.

TECHNICAL ASSISTANTS AND LABORATORY WORKERS

All other persons who will work directly with RAM shall, prior to working with such material in the absence of a User, receive specific training and instruction in (a) radiation safety

and (b) use of radioactive materials. This training will be administered by the Radiation Safety Officer and will consist of a minimum of three hours of formal classroom training in addition to on-the-job training. Further, a determination of competency to work with RAM without the presence of supervisory personnel will be made by the Radiation Safety Committee prior to independent use of RAM by any individual.

INSTRUCTIONS TO PERSONNEL WORKING WITH RADIOACTIVE MATERIAL

Section I - Laboratory apparel and safety-related equipment.

A. All employees will be issued a laboratory jacket. These jackets are to be worn whenever entering restricted areas and removed prior to exit. The main purpose of these jackets is to prevent the spread of contamination. It is therefore imperative that employees not leave radioactive work areas while still wearing laboratory jackets.

B. All employees are required to wear disposable non-sterile latex gloves when working with RAM in the lab. The gloving technique consists of wearing two pairs of gloves: an inner pair of gloves and a frequently-changed outer pair of gloves. Gloves should be carefully removed to avoid contaminating skin surfaces. All gloves should be disposed of in the radioactive waste containers. Employees should never wear gloves used in the restricted area out into the non-restricted area. Gloves should always be worn over finger ring badges.

C. Remote pipettes will be provided. <u>Never pipette radioactive material by mouth.</u>

D. For emergency use, disposable face masks will be available in the restricted area in the same location as the portable radiation detectors.

Section II - Handling Radioactive Liquids or Uncontained RAM

Radioactive Liquids and uncontained RAM shall always be worked with inside the fume hood. Appropriate remote handling equipment will be used as necessary. Plexiglas shielding is available and should be use when working with greater than 100 microcuries of P-32.

Section III - Radiation Survey and Monitoring Procedures

a. All preparation and RAM work areas will be surveyed daily with a low-range, thin-window G-M survey meter and decontaminated if necessary. Contamination will be considered present when exposure levels exceed 0.1 mR/hr above background.

b. All other laboratory areas and RAM waste storage areas will be surveyed weekly.

c. The weekly surveys will consist of measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

d. A permanent record will be kept of all survey results, including negative results. The record will include:

1. Location, date, and type of equipment used.
2. Name of person conducting the survey.
3. Measured exposure rates and locations.
4. Detected contamination levels.
5. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

e. In addition to the individual Users' survey program described above, the Radiation Safety Officer or his designee will perform a comprehensive radiation protection survey quarterly. Portable survey meters sufficiently sensitive to detect 0.1 mR/hr will be used routinely in checking surface contamination and dose rates in work and storage areas and their surroundings. A program of smear samples, counted by a liquid scintillation system sufficiently sensitive to detect 500 dpm per 100 cm2 for the contaminant involved will be used for the surveying of low-energy beta-emitting radionuclides such as tritium and carbon-14. The records shall include:

1. Location, date and type of equipment used.
2. Name of person(s) conducting the survey.
3. Drawing of area surveyed, identifying relevant features such as storage and waste areas where radioactive materials are present.
4. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective actions).
5. Detected contamination levels, keyed to locations on drawing.
6. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

f. Areas will be cleaned if the contamination level exceeds 500 dpm/100 square centimeters or 0.1 mR/hr depending on the survey method.

Section IV - Transfer of Radioactive Materials

All RAM transferred between buildings, rooms and areas within rooms shall be transported in tightly-sealed, well-shielded containers. No open or unrestricted containers shall be utilized for this purpose.

Section V - Storage of RAM

All RAM containers shall be conspicuously marked with a label listing the type of radionuclide(s) present and a dated activity. This label shall bear colors and markings consistent with requirements set forth in 10 CFR section 20.203. Storage areas shall be conspicuously marked with additional signs as required by 10 CFR sections 20.203 and 20.204. All equipment contaminated with RAM shall be labeled with signs, decals or other conspicuous means. Labelling shall not be required for laboratory containers used transiently in procedures provided that such equipment is stored in a labelled place after use until it is decontaminated.

Section VI - Posting of Areas where RAM are used

A. Proper labeling of laboratories, areas, and equipment

1. A "CAUTION RADIOACTIVE MATERIALS" sign will be conspicuously posted on the doors to laboratories where radioactive materials are being used or stored. The name and home telephone number of the individual responsible for the posted area shall be shown in the designated place on the sign in order to facilitate contact in case of emergency. The signs shall not be removed from any room except by the Radiation Safety Officer following an inspection survey.

2. Storage areas shall be conspicuously marked with additional signs as required by 10 CFR sections 20.203 and 20.204.

3. All equipment contaminated with radioactive material shall be labeled with signs, decals, or other conspicuous means. Labeling shall not be required for laboratory containers such as beakers, flasks, and test tubes, used transiently in laboratory procedures during the presence of the User, provided, however, that such equipment is stored in a labelled place after use until it is decontaminated.

Section VII - Personnel Monitoring Devices

All full and part-time Unogen employees will be issued a film badge for whole-body dosimetry. Individuals who are at risk of exposing their hands and arms to ionizing radiation will also be issued a ring dosimeter. Use of these devices shall be explained to the individual by the User or the Radiation Safety Officer when the devices are issued. They will be replaced at regular intervals. Results of an individual's personnel dosimetry will be available to each employee.

Section VIII - Waste Disposal Procedures

No radioactive wastes shall be disposed of by the conventional methods of disposing of non-radioactive waste. This means specifically that solid wastes may not be placed in the standard waste container to be collected by housekeeping personnel, and that liquid waste may not be discharged into the sewer.

Regardless of the method of disposal, records must be kept showing date, isotope, activity, amount, and method of disposal.

A. WASTE CONTAINERS

To insure that solid and liquid radioactive wastes are kept separate, each laboratory having radioactive waste must be equipped with at least one container for solid dry waste and two for liquid waste.

1. Solid dry waste containers must be kept fitted with a disposable waterproof paper or polyethylene liner. The container must be conspicuously marked as "Radioactive Waste".

2. If the liquid waste containers are glass or ceramic, then they must be maintained in such a manner that if accidently broken, the contents will be retained in a small area (e.g., having it set in a large pan). These liquid containers must possess securely fitting covers or corks, and must be kept closed. In addition, they shall be conspicuously marked as "RADIOACTIVE WASTE". Care should be taken that as waste accumulates in the container, the pH is not altered in such a manner as to generate a gas.

B. Waste Disposal

All radioactive waste will be collected from the labs by Unogen personnel on a timely basis to insure against spillage resulting from overfilled containers.

1. Dry Solid waste. Dry solid waste will be bagged and carried to the waste storage room near the loading

dock. There it will be loaded into a 55 gal. drum for later removal by the contract waste hauler. Permanent records will be kept on the contents of each drum including:

a. The identification of the radionuclides
b. The activity of each radionuclide
c. The date at which the activity was calculated

2. Liquid waste. Liquid waste will be transported to the waste storage room. There it will be mixed with vermiculite in the appropriate drum as described in appendix I. Aqueous and organic liquids will be kept separate in the labs and will be transferred to separate drums in the waste storage area. Records will be kept as outlined above for dry solid waste.

Section IX - Maintenance of Records

All records or surveys, RAM inventory, receipt, disposal, and personnel dosimetry will be maintained by Unogen Inc. as required by the appropriate sections of 10 CFR sections 20.401 and 30.501. These records will be reviewed periodically, but at least annually by the Radiation Safety Committee.

Section X - Sealed Source Leak Tests

No sealed sources with an activity greater than quantities exempted by 10 CFR Section 31.5 will be held by Unogen, Inc. Therefore no sealed source leak tests will be required.

Section XI - Radiation Safety Practices

All Unogen employees shall have adequate training in the safe use of RAM prior to working with the materials in the lab. The following are some of the generally accepted practices for working with such material.

A. SHIELDING OF SOURCES

Radioactive sources or stock materials in the laboratory shall be shielded in such a manner that the radiation level at any exposed surface shall not exceed 200 mR/hr, or 10 mR/hr at one meter from the surface, and the level of the nearest occupied area shall not exceed 5 mR/hr.

B. AEROSOLS, DUSTS, AND GASEOUS PRODUCTS

Experiments involving aerosols, dust, or gaseous products or procedures which might produce hazardous levels of airborne con-

tamination shall be conducted in the fume hood. The fume hood shall have a nominal air flow of 100 feet per minute at the face.

C. WORK SURFACES

All work areas which are likely to become contaminated (bench tops, hood floors, etc.) as well as storage areas and areas adjacent to permanent setups and sinks shall be covered at all times with stainless steel or plastic trays or other impervious materials. For some purposes a plastic-backed absorbent paper will be satisfactory. However, if such paper is used it shall be discarded frequently.

D. PERIODIC SURVEYS OF RADIOACTIVE MATERIAL USE AREAS

The immediate areas (hoods, bench tops, etc.) in which radioactive materials are being used shall be checked for contamination at least as frequently as specified in section III of this Guide. In addition, these areas shall be inspected each and every time there is reason to question the degree of contamination. Records of all surveys shall be kept by the individual users.

Each laboratory shall be equipped with or have immediate access to a monitoring device to be used for personnel and area monitoring.

E. REMOVAL OF EQUIPMENT FROM THE LABORATORY

Once used for radioactive materials, equipment shall not be used for other work or sent from the area to cleaning facilities, repair shops, surplus, or returned to the source of supply until certified by the Radiation Safety Officer to be free of contamination.

F. REPAIR AND MAINTENANCE OF EQUIPMENT IN THE LABORATORY

Equipment to be repaired by shop and maintenance personnel or by commercial service contractors shall be demonstrated to be free of contamination and approved by the Radiation Safety Officer prior to servicing. If it becomes necessary to make emergency repairs on contaminated equipment, the work will be supervised by a member of the Senior Unogen staff who will assure that the necessary safeguards are taken. It is the responsibility of the laboratory personnel to request this supervision from the Senior Staff.

G. CONTAMINATION OF RADIOACTIVE USE AREAS

In general, no radioactive contamination shall be tolerated. Exceptions to this include certain hood trays, dry boxes, stainless steel trays, paper-covered surfaces, or other equipment which is used frequently for radioactive work and which will be clearly marked with the standard radiation hazard signs or stickers. Any contamination that is not confined to protected

surfaces shall be reported immediately to the Radiation Safety Officer. The Radiation Safety Officer will supervise the decontamination of such areas or equipment.

H. DECONTAMINATION OF RADIOACTIVE MATERIAL USE AREAS

Preparations for decontamination shall be begun promptly. Determine the extent and hazard of the contamination. The Radiation Safety Officer may assist in this evaluation. The individual responsible for the contamination will be expected to do most of the cleanup if possible under supervision of the Radiation Safety Officer. The area shall be considered to be contaminated until proven otherwise by adequate test.

I. DECONTAMINATION OF PERSONNEL

A. Notify supervisor and/or the Radiation Safety Officer immediately after the contaminating accident.

B. Wash the area thoroughly for two or three minutes, repeatedly soaping and rinsing. Consideration should be given to the chemistry of the contaminant and an attempt made to find a suitable agent for dissolving it. Any cleansing agent may be used, but synthetic detergents are preferred to soap. Avoid prolonged use of any one decontamination procedure. Irritation of the skin may impede the success of more suitable procedures. Avoid the use of organic solvents. These may make the skin more permeable to contamination.

C. If this procedure is not immediately and completely effective, request additional aid from the Radiation Safety Officer. Special decontamination agents may be used under the direction of a medical officer.

Section XII - Use of RAM in Animals

It is the policy of Unogen, Inc. not to administer radioactive materials in any form to animals.

Section XIII - Emergency Procedures

A. RADIATION EMERGENCY PROCEDURES

1. Minor Spills involving no radiation hazard to personnel.

a. Notify all other persons in the room at once.
b. Permit only the minimum number of persons necessary to deal with the spill into the area.
c. Confine the spill immediately.

1. Liquid Spills - Don protective gloves.
- Drop absorbent paper on spill.

2. Dry Spills - Don protective gloves.
- Dampen thoroughly*, taking care not to spread the contamination.

d. Notify the Radiation Safety Officer as soon as possible.** The RSO may designate a Senior staff member to act on his behalf in all provisions of this section.

e. Permit no one to resume work in the area, or leave the premises, until approval of the RSO is secured.

2. Major Spills involving radiation hazards to personnel.

a. Notify all persons not involved in the spill to vacate the room at once.
b. Make no immediate attempt to clean up the spill.***
c. If the spill is on the skin, flush thoroughly with water. If the spill is on clothing, discard outer clothing at once.
d. Switch off all fans.
e. Vacate the room and prohibit entrance to contaminated area.
f. Notify the RSO as soon as possible giving all details of the spill.**
g. Permit no person to enter or leave the area until the approval of the RSO is secured.
h. Under no circumstances should an untrained person attempt to examine or clean up the radioactive material.

* Water may be used except when chemical reaction with water would generate an air contaminant. Oil should then be used.

** The RSO will monitor all personnel involved for bodily contamination and will recommed further steps necessary for final cleanup of the spill.

*** If spill is liquid, and the hands are protected, right the container.

3. Accidents involving radioactive dusts, mists fumes, organic vapors and gases.

a. Notify all other persons to vacate the room immediately.
b. Hold breath and close all windows, escape valves, switch off air circulation.
c. Vacate the room.
d. Notify the RSO at once.
e. Ascertain that all doors giving access to the room are closed and locked. If necessary, post guards to prevent accidental opening of doors.
f. Do not re-enter the room or permit anyone to leave the premises until approval of the RSO is secured.

4. Injuries to personnel involving radiation hazard.

   a. Wash minor wounds immediately under running water, while spreading the edges of the gash.
   b. Report all radiation accidents (wounds, over-exposure, ingestion, inhalation) to the RSO as soon as possible.
   c. Call a physician at once.
   d. Permit no person involved in a radiation injury to return to work or leave the premises without approval of the RSO and the physician.

5. Fires involving radioactivity

   a. Notify all persons in the room and building at once.
   b. Notify the fire department
   c. Attempt to put out fires if radiation hazard is not immediately present.
   d. Notify the RSO.

B. RADIATION EMERGENCY NOTIFICATION

In case of emergency notify the following:

a. Police and/or fire department - 911;
b. D. Bryant, 295-6754 or M. Woodward, 977-8315; and/or
c. B. Copcutt, 978-4666(home), 924-8997(office).

Section XIV - Picking up, Receiving and Opening Packages

A. All packages will be inspected upon receipt for any sign of damage (e.g. wetness, crushed). If any damage is noted the Radiation Safety Officer should be notified and no further processing attempted.

B. All packages will be opened and inspected in accordance with the procedures outlined in 10 CFR section 20.205. If removable radioactive contamination or external radiation levels exceed the limits specified, the Radiation Safety Officer shall be notified immediately.

C. If no damage or high readings are noted the package will be opened and inspected further for internal damage or breakage. It will be verified that the package contents are in agreement with the material requisitioned and the packing slip. Any discrepancies or damages will be brought to the attention of the Radiation Safety Officer.

PACKAGING PROCEDURES FOR RADIOACTIVE WASTE

I.0 GENERAL

I.1 Seven Categories

- Dry Solid Material (DSM)
- Small Volume Liquids (SVL) Scintillation vials only
- Small Volume Liquids (SVL) Other than scintillation vials
- Large Volume Liquids (DWLVL-A) 50 ml or greater of aqueous liquids
- Large Volume Liquids (DWLVL-S) 50 ml or greater of scintillation type liquids
- Animal Carcasses (DWAC) or biological waste
- Dry Solid Compactibles (DSC)

I.2 Items in different categories cannot be mixed.

I.3 The packaging procedure that is used is to be marked on the drum (e.g. DSM-2/83).

I.4 Transuranic waste in excess of 10 nanocuries per gram is not acceptable.

I.5 Gaseous tritium waste must meet certain provisions. Please see the burial site's license for details or call the Radiological Services Department Office.

I.6 Special Nuclear Material requires specific approval and will be accepted only upon special request to the Radiological Services Department Office.

I.7 DO NOT EXCEED THE FOLLOWING WEIGHTS UNLESS SPECIFICALLY AUTHORIZED:

5 gallon container - 100 lbs.
30 gallon container - 300 lbs.
55 gallon container - 480 lbs.

I.8 Special Note:

The chemical composition of the materials disposed must be compatible with the procedures which follow. Any additional hazards of the material must be evaluated to determine if additional packaging is required. If materials are listed in N. Irving Sax's "Dangerous Properties of Industrial Materials", Fifth Edition, Van Nostrand Reinhold, as having a THR=HIGH via any route, except IP or IV, specific approval must be obtained from the State of Washington Radiation Control Program. Contact Steven Black for details.

II.0 DRY SOLID MATERIAL (DSM-2/83)

II.1 Select a 5, 30 or 55-gallon drum.

II.2 Fill to capacity with only dry solid materials. Do not exceed the following weights: 100, 280 or 400 lbs. respectively for 5, 30 and 55-gallon drums.

II.3 Secure drum cover.

II.4 Label drum DSM-2/83, to designate that the drum has been packaged according to these directions.

III.0 SMALL VOLUME LIQUID WASTE (SVL-2/83), Scintillation Vials or Other SVL's

Liquid should not be absorbed directly onto the absorption media (e.i. do not open vials). Any tool or device which contains any amount of liquid (e.g. syringes or test tubes) must be considered small volume liquid waste.

III.1 Select only a 30 or 55-gallon drum; 5-gallon pails are not allowed.

III.2 Line the drum with 4 ml thick poly liner. (See special notes following this section.)

III.3 Using an approved absorbant, alternate layers of absorbant with layers of waste. (See special notes following this section.)

III.4 Twist and seal liner.

III.5 Secure drum cover.

III.6 Label drum SVL-2/83, to designate that the drum has been packaged according to these instructions.

III.7 Special Notes

Two 2 ml liners may be used in place of a single 4 ml liner.

Instead of lining the whole drum, individual 4 ml (or double 2-ml) bags may be substituted, provided each bag is layered as above.

Approved absorbants:

Diatomaceus Earth (Medium Grade)
Super Fine (Diatomite)
Speedi Dry
Hi-Dry
Celatom (M-P78)
Floor Dry 85 Superfine
Instant-Dri
Safe-T-Sorb (Petrasorb)
Vermiculite - Industrial Grade 4 (Zonolite #4)

When layering, the absorbant must be the first layer on the bottom and the last layer on the top. Proper volume ratios must be determined by the generator to be used for the different absorbants.

The amount of absorbant must be capable of absorbing twice the amount of liquid present.

IV.0. LARGE VOLUME LIQUID WASTE (DWLVL-A-2/83 or DWLVL-S-2/83)

All items containing 50 ml or more of liquid may not be disposed in an SVL drum. The liquid must be packaged as follows while the container itself must be either (1) dried and placed in a DSM drum or (2) placed in an SVL drum once the bulk of the liquid is removed.

Note that aqueous and scintillation type fluids are not to be mixed in the same drum. If they are, the drum will be considered a DWLVL-S-2/83 and charged accordingly.

IV.1 Select only the 55-gallon double-walled container for liquid waste.

IV.2 Remove the 55-gallon drum cover.

IV.3 Loosen and remove the bung from the 30-gallon drum which has been filled with Zonolite #4.

IV.4 Pour up to 10 gallons of liquid (ph-6.0 - 9.0) into the absorbant in the 30-gallon drum through the 2-1/2" opening.

IV.5 Replace bung and tighten.

IV.6 Twist and seal poly liner.

IV.7 Secure cover of 55-gallon drum.

IV.8 Label drum DWLVL-A - 2/83 or DWLVL-S - 2/83 (depending on the liquid: A designates aqueous, S designates scintillation type liquids) to designate that the drum has been packaged according to these instructions.

V.0 ANIMAL CARCASSES OR BIOLOGICAL WASTE (DWAC-2/83)

Animal carcasses or biological waste must be disposed using a double-walled container. Be sure when ordering to specify a 55-gallon double-walled container for animal carcasses.

V.1 Select only a 55-gallon double-walled drum.

V.2 Remove inner 30-gallon container and absorbant.

V.3 Line 30-gallon drum with 4 ml poly liner. See Section III.7.

V.4 Package waste into liner using at least one part slaked lime for every 10 parts of absorbant. See approved absorbant list in III.7. Fill completely.

V.5 Twist and seal liner.

V.6 Seal 30-gallon drum.

V.7 Place 30-gallon drum into 55-gallon drum.

V.8 Place absorbant around and covering 30-gallon drum.

V.9 Secure 55-gallon drum cover.

V.10 Label drum DWAC-2/83 to designate that drum has been packaged according to these instructions.

VI.0 DRY SOLID COMPACTIBLES (DSC-2/83)

VI.1 Select a 5, 30 or 55 gallon container.

VI.2 Place waste into double 4 mil plastic liners. (Note: For 55 gallon drums, use two sets of double 4 mil bags, each set approximately 27 gallons. If heavy materials are used, please use additional double 4 mil liners and decrease the quantity put into each.)

VI.3 Twist and seal liners.

VI.4 Place double 4 mil bags into the selected container.

VI.5 Replace lid and ring.

VI.6 Secure ring. DO NOT BOLT.

VI.7 Label drum DSC-2/83 to indicate it was packaged in accordance with these instructions.

NOTE: DO NOT DISPOSE OF SHARP OBJECTS.

NOTE: DO NOT DISPOSE OF NON-COMPACTIBLE ITEMS SUCH AS LEAD PIGS OR OTHER METAL OBJECTS IN THESE TYPES OF CONTAINERS.

Revised: 2/83

EXTERNAL PACKAGING INSTRUCTIONS FOR RADIOACTIVE WASTE

I. Determine:

a. Isotope
b. Activity (mCi)
c. Physical state [solid, liquid (bulk or vials), animal carcasses, biological matter or gaseous]
d. Concentration (mCi/gram)
e. Transport Group (I through VII)
f. Form (Normal or Special)

II. Determine the Proper Shipping Name

NOTE: All LSA material which we pick up at your facility is shipped "Exclusive Use."

a. Radioactive Device, n.o.s.
b. Radioactive Material, Limited Quantity, n.o.s.
c. Radioactive Material, Low Specific Activity or LSA, n.o.s.
d. Radioactive Material, n.o.s.
e. Radioactive Material, Special Form, n.o.s.
f. Radioactive Material, fissile, n.o.s.

III. Use Guide to Determine:

a. What specification container is required.
b. What labels are required.
c. Whether a security seal is needed or not.
d. mR/hr limits @ contact.
e. Additional requirements.

RADIOACTIVE MATERIAL PACKAGING GUIDE

MATERIAL DESCRIPTION	CONTAINER TYPE	LABEL REQUIRED	SECURITY SEAL REQUIRED	INTERNAL PACKAGING REQUIRED	mR/hr LIMITS @ CONTACT	COMMENTS
(DSM) DRY SOLID MATERIAL						
a. Radioactive Material, LSA, n.o.s. (exclusive-use)	Unspecified	Radioactive-LSA	no	Unspecified	0-200.0	
b. Radioactive Material, Limited Quantity, n.o.s.	Unspecified	Radioactive	no	Unspecified	0-0.5	mR/hr limits @ contact 0-2.0 if shipped exclusive-use
c. Radioactive Device, n.o.s.	Unspecified	Radioactive	no	Unspecified	0-2.0	
d. Radioactive Material, n.o.s.	DOT 7A-Type A (17H)	Radioactive White I	yes	Braced	0-0.5	Require weight printed on outside of package when in excess of 110 lbs.
		Radioactive Yellow II	yes	Braced	0.5-50.0	
		Radioactive Yellow III	yes	Braced	50.0-200.0	
e. Radioactive Material, special form, n.o.s.	DOT 7A-Type A (17H)	Radioactive White I	yes	Braced	0-0.5	Require weight printed on outside of package when in excess of 110 lbs.
		Radioactive Yellow II	yes	Braced	0.5-50.0	
		Radioactive Yellow III	yes	Braced	50.0-200.0	
(SVL) SMALL VOLUME LIQUIDS						
a. Radioactive Material, LSA, n.o.s. (exclusive-use)	DOT 17H	Radioactive-LSA	no	*See Instructions	0-200.0	
b. Radioactive Materials, n.o.s.	DOT 7A Type A	Radioactive White I	yes	*See Instructions	0-0.5	Require weight printed on outside of package when in excess of 110 lbs.
		Radioactive Yellow II	yes	*See Instructions	0.5-50.0	
		Radioactive Yellow III	yes	*See Instructions	50.0-200.0	
(DWLVL) LARGE VOLUME LIQUIDS						
a. Radioactive Material, LSA, n.o.s. (exclusive-use)	DOT 17H	Radioactive-LSA	no	*See Instructions	0-200.0	
b. Radioactive Material, n.o.s.	DOT 7A Type A (17H)	Radioactive White I	yes	*See Instructions	0-0.5	Require weight printed on outside of package when in excess of 110 lbs.
		Radioactive Yellow II	yes	*See Instructions	0.5-50.0	
		Radioactive	yes	*See Instructions	50.0-200.0	
(DWAC) DOUBLE WALLED ANIMAL CARCASSES						
a. Radioactive Material, LSA, n.o.s. (exclusive-use)	2-DOT 17H	Radioactive-LSA	no	*See Instructions	0-200.0	
b. Radioactive Material n.o.s.	DOT 7A-Type A (2-17H)	Radioactive White I	yes	*See Instructions	0-0.5	Require weight printed on outside of package when in excess of 110 lbs.
		Radioactive Yellow II	yes	*See Instructions	0.5-50.0	
		Radioactive Yellow III	yes	*See Instructions	50.0-200.0	

*SPECIAL NOTE ON SMALL VOLUME LIQUIDS: Scintillation vials and fluids must be packaged separately from all other small volume liquids.

NOTE: n.o.s. means: "not otherwise specified."

IWL-0372-451

APPENDIX II

EXPOSURE LIMITS

The following limits are based on presently available information and cannot be regarded as permanent. It must be recongnized that these are permissible limits and that exposure is to be maintained at the lowest practical level at all times. The reader is refered to CFR 10, Section 20.101 for additional information.

1. EXTERNAL EXPOSURE

   A. Personnel working in restricted areas - REM per calendar quarter.

      (1) Whole body; head and trunk; blood-forming organs; lens of eyes; or gonads 1.25

      (2) Hands and forearms; feet and ankles 18.75

      (3) Skin of the whole body 7.50

   B. General population, individuals under 18 years of age, and pregnant women shall not be permitted doses which exceed 10 percent of the above values.

   C. Personnel working in restricted areas may be permitted to receive doses to the whole body greater than that permitted under (A) above, provided:

      (1) Whole body exposure during any calendar quarter shall not exceed 3 REM; and

      (2) The dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed 5 (N-18) where "N" is the individual's age in years at his last birthday; and

      (3) The individual's accumulated occupational doses to the whole body has been determined on a clear and legible record containing all the information compiled in accord with CFR 10, Section 20.102.

2. INTERNAL EXPOSURE

   Internal exposure and the resulting damage can be controlled only by limiting personnel contact with the contamination. Any area where air, water or surface contamination exceeds permissible limits as

shown in 10 CFR, Section 20, NBS Handbook 69 and Section II of this appendix, shall be designated a radiation zone for purpose of control. The concentration of radioisotopes in the environs shall be kept as low as possible and shall not be allowed to exceed one tenth (1/10) the 168/hr/wk MPC's listed in 10 CFR, Section 20, and NBS Handbook 60.

APPENDIX III

BIOASSAYS

In the event of a reported major spill or other significant incident involving radioactive material, bioassays will be performed as appropriate on personnel who are suspected of having internally deposited radionuclides. These bioassays will be in the form of biological sample assays to detect and quantify the presence of beta emitters in the urine and/or blood.

Records of all bioassays will be kept with records of the situations leading to the need for the bioassays.

FILM BADGES:

Landauer, Inc. will supply film badges for monitoring whole body and skin doses. TLD ring badges may be used to monitor extremity dose if deemed necessary. These will be replaced monthly.

APPENDIX IV

PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE AT UNOGEN, INC. TO LEVELS WHICH ARE AS LOW AS REASONABLY ACHEIVABLE

I. Management Commitment

A. We, the management of Unogen, Inc. are committed to the program described in this section for keeping exposures (individual and collective) as low as reasonably acheivable (ALARA). In accordance with this commitment, we hereby establish an administrative organization for radiation safety and develop the necessary written policy procedure instructions to foster the ALARA concept within our organization. The organization will include a Radiation Safety Committee (RSC), and a Radiation Safety Officer (RSO). We are committed to following the guidance provided by U.S. Nuclear Regulatory Guide 8.10.

B. In addition to maintaining doses to individuals as far below the limits as is reasonably acheivable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

II. Radiation Safety Committee (RSC)

A. Review of Proposed Users and Uses

1. The Radiation Safety Committee will thoroughly review the qualification of each potential User with respect to the types and quantities of materials and its uses to assure that the user will be able to take appropriate measures to maintain exposure ALARA.

2. When considering a new use of byproduct material, the Radiation Safety Committee will review the efforts of the User to maintain exposure ALARA. The User should have systematized procedures to insure ALARA, and should have considered the use of special equipment such as shields, rubber gloves, etc., in his proposed use.

3. The Radiation Safety Committee will ensure that the User justifies his procedures and that they will result in ALARA doses (individual and collective).

B. Delegation of Authority

1. The management of Unogen, Inc. will delegate sufficient authority to the Radiation Safety Officer for enforcement of the ALARA concept.

2. The Radiation Safety Committee will support the Radiation Safety Officer in those instances where it is necessary for the Radiation Safety Officer to assert his authority. Where the Radiaition Safety Officer has been overruled, the Committee will record the basis for its action.

C. Review of ALARA Program

The Radiation Safety Committee will review all instances of deviations from the ALARA philosophy and, at least annually, will review the entire radiation safety program in order to evaluate the company's overall efforts for maintaining exposures ALARA. Information in support of the review will normally be supplied by the Radiation Safety Officer.

D. Public Statement of Commitment by the Radiation Safety Committee to ALARA

1. The Radiation Safety Committee will insure that employees are aware of the Radiation Safety Committee's commitment to the ALARA philosophy.

2. The Radiation Safety Committee will demonstrate its commitment to the ALARA concept through the methods employed in its review of proposed Users and uses.

III. Radiation Safety Officer (RSO)

A. Periodic Review and Audit of the Radiation Safety Program for Compliance with ALARA Concepts. Frequent review of procedures will be conducted.

1. The Radiation Safety Officer will review and audit, on a regular basis (at least annually), the effectiveness of the radiation protection program in maintaining doses (individual and collective) ALARA.

2. The Radiation Safety Officer will review exposures of users and occupational workers to determine that their exposures are ALARA.

B. The Radiation Safety Officer's Educational R ponsibilities for an ALARA Program.

1. The Radiation Safety Officer will assure that Users understand the ALARA philosophy and know that management, the Radiation Safety Committee, and the Radiation Safety Officer are committed to implementing the ALARA concept.

C. Cooperative Efforts for Development of ALARA Procedures. Individuals who must work with ALARA concepts will be given opportunities to participate in formulation of the procedures that they will be required to follow.

1. The Radiation Safety Officer will maintain close contact with all Users in order to develop ALARA procedures for working with radioactive materials.

D. Reporting and Reviewing Instance of Deviation from Good ALARA Practices.

1. The Radiation Safety Officer will investigate all instances of deviation from good ALARA practices and, if possible, determine the causes. When the cause is know, the Radiation Safety Officer will propose changes in the program to maintain exposures ALARA.

2. The Radiation Safety Officer will report all significant instances of deviation from ALARA concepts to the Radiation Safety Committee for review.

IV. Users

A. New Procedures Involving Potential Radiation Exposure.

1. The User will consult the Radiation Safety Officer and/or the Radiation Safety Committee before using radioactive materials for a new procedure.

2. The User will consider all procedures thoroughly before using radioactive materials to insure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

B. Responsibility of the User to those he Supervises.

1. The User will thoroughly explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.

2. The user will insure that his occupational workers are trained and educated in good helath physics proactices and in maintaining exposures ALARA.

3. The User will be responsibe to the radiation safety concerns of the individuals that he supervises.

C. Continuing Review of ALARA Concepts by the User.

1. The User will continuously review his procedures to insure that his ALARA program is optimal.

2. The User will maintain contact with the Radiation Safety Officer to insure that he is aware of and employs the most current methods to maintain exposures ALARA.

V. Occupational Worker

A. What the Occupational Worker must Consider about ALARA.

1. The worker will implement ALARA procedures developed by the User and the Radiation Safety Officer.

2. The occupational worker will know that recourse is available if he feels that ALARA is not being promoted on the job.

3. The occupational worker will understand the ALARA concept and will review his own working conditions for the implementation of ALARA principles.

VI. Establishment of Action Level in Order to Acheive Reductions of Individual Occupational Exposures.

Unogen, Inc. herby establishes exposure action levels for all operations which, when exceeded, will trigger investigation by the Radiation Safety Officer. The exposure action levels that we have established are 10% of Maximum Permissible Dose. These levels apply to the exposure of individual workers. This level has been determined based on a thorough analysis of our proposed program.

We will investigate the causes of personnel exposures that exceed our established exposure action level. In the event of a personnel exposure that exceeds 10% of Maximum Permissable Dose (MPD) we will maintain accounts of our investigation for inspection by the NRC. As a minimum, these accounts will include the cause of the exposure, the action taken to correct the situation and the follow-up action taken.

(Signature)

'Giorgio Laurenti
President of Unogen, Inc.

(Signature)

Brian Copcutt, Ph.D.
Radiation Safety Officer

Unogen, Inc.
3050-A Berkmar Drive
Charlottesville, Virginia 22901

NRC FORM 313M SUPPLEMENT A (9-81) — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Brian G. Copcutt, Ph. D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Univ. of Va., Rad. Physics Div. 1976-1977	See Attached CV **	See Attached CV **
b. RADIATION PROTECTION	Texas A&M Univ. & TAMU Cyclotron 1977-1983	See Attached CV **	See Attached CV **
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Texas A & M, College of Engineering, University of Virginia 1977-1983	See Attached CV **	See Attached CV **
d. RADIATION BIOLOGY	" "	" **	" **
e. RADIOPHARMACEUTICAL CHEMISTRY	" "	" **	" **

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Wide	Kilo-Curies	-Texas A&M, College of Vet. Med., & Coll. of Engir.	3 years	Nuclear Med. Research
		-MD Anderson Hospital/Texas A&M Neutron Therapy Prog.	3 years	Health Physics & Radiological
		-Un. of Va.,Dept. of Radiology	1 year	Physics
				" "
		- Un. of Va., Radiation Safety Office	1 year	Health Physics

NRC FORM 313M Supp. (9-81)

** See Addendum to 17

MICHAEL PATRICK WOODWARD

I. Formal Training Pertaining to Radiation

A. Principles and practices of radiation protection.

1. Radiation Safety Course, University of Maryland/ Baltimore County (UMBC).

B. Radioactivity measurement standardization and monitoring techniques and instruments.

1. Physics, UMBC, 1 semester.
2. Biochemistry, UMBC, 1 semester.
3. Cell Biology, UMBC, 1 semester.
4. Radiation Safety Course, UMBC.

C. Mathematics and calculations basic to use of radioactivity.

1. Calculus, UMBC, 2 semesters.
2. Differential Equations, UMBC, 1 semester.
3. Biochemistry, UMBC, 1 semester.
4. Physics, UMBC, 1 semester.
5. Cell Biology, UMBC, 1 semester.
6. Radiation Safety Course, UMBC.

D. Biological effects of radiation.

1. Genetics, UMBC, 1 semester.
2. Radiation Safety Course, UMBC.

II. Experience with Radiation

1967-1969: As an undergraduate at UMBC I worked in a bacterial genetics laboratory isolating cell division mutants. These mutants were labelled with ^{3}H-Thymidine (1 mCi).

1971-1976: Performed autoradiography experiments with ^{3}H-Thymidine (1 mCi) as a teaching assistant in the Cellular and Subcellular Biology Course at UMBC.

1977-1979: Performed alkylation experiments using ^{14}C-Iodoacetamide (1 mCi) and ^{14}C-N-ethyl maleimide (1 mCi) while a graduate student at UMBC.

1981-1982: Performed incorporation studies using 5 mCi ^{32}P while a post-doctoral fellow at Dartmouth College.

Curriculum Vitae: Debra Bryant

I. Formal Training Pertaining to Radiation

A. Principles and practices of radiation protection.

1. Radiation Safety Course - University of Virginia

B. Radioactivity measurement standardization and monitoring techniques and instruments.

1. Physics, University of Virginia, 2 semester course.
2. Biochemical Techniques, Bowman-Gray School of Medicine, Wake Forest Univerasity, 1 semester course.
3. Biochemistry, Bowman-Gray School of Medicine, Wake Forest Univerasity, 1 semester course.
4. Radiation Safety Course, Univerasity of Virginia.

C. Mathematics and calculations basic to use of radioactivity.

1. Calculus, Univerasity of Virginia, 2 semesters.
2. Physics and physics laboratory, University of Virginia, 2 semesters.
3. Radiation Safety Course, University of Virginia.

D. Biological effects of radiation.

1. Immunochemistry, Bowman-Gray School of Medicine, Wake Forest Univerasity, 1 semester.
2. Advanced Topics in Biochemistry, Bowman-Gray School of Medicine, Wake Forest University, 1 semester.
3. Cell Physiology, Univerasity of Virginia, 1 semester.
4. Radiation Safety Course, Univerasity of Virginia.

II. Experience with Radiation

1980-1983 - As a postdoctoral fellow, I worked in a molecular biology laboratory where I frequently labeled eucaryotic cells with 3-5 mCi of ^{35}S-methionine and/or 25 mCi ^{32}P-orthophosphate. I also did some DNA sequencing involving approximately 1 mCi ^{32}P-labelled triphosphates at any one time.

1983-1984 - As a senior scientist at Oncogen, I was in charge of all incoming radioactive material, i.e., wipe tests for contamination of containers, storage and record keeping. This involved handling the radioactive shipments for approximately 25 scientists. Personally, I was using 10-30 mCi of ^{32}P and 5-10 mCi ^{35}S at any one time.

ADDENDUM TO 17

CURRICULUM VITAE

COFCUTT, BRIAN GIBSON

MAILING ADDRESS: 720 Exton Court, Charlottesville, Virginia 22901

OFFICE ADDRESS: University of Virginia, Environmental Health & Safety, P.O. Box 3425, Edgemont Road, Charlottesville, VA 22903

PHONE: (Office) 804-924-8997
(Home) 804-978-4666

PERSONAL: Marital Satus: Single
Birthday: February 11, 1952

EDUCATION:

B.A., Environmental Science, University of Virginia, 1975

M.E., Biomedical Engineering (specialty in radiological physics), University of Virginia, 1977

Ph.D., Bioengineering (specialty in medical radioactivity applications), Texas A&M University, 1983

FIELDS OF SPECIALIZATION:

Health Physics
Nuclear Medicine
Radiological Physics
Computer Programming

EXPERIENCE:

Radiation Safety Officer and Lecturer, General Faculty, University of Virginia, July 1983 - present.

Research Assistant, Division of Nuclear Medicine, Texas A&M, College of Veterinary Medicine, College Station, Texas, 1980-1983.

Radiological Physicist and Health Physicist for joint M.D. Anderson Hospital - Texas A&M Univeristy neutron cancer therapy project, Colllege Station, Texas, 1977-80.

Research Assistant in Radiological Physics, Division of Radiation Oncology, University of Virginia Medical Center, Charlottesville, VA, 1976-1977.

Health Physicist, University of Virginia Radiation Safety Office, Charlottesville, VA 1975-1976.

CURRICULUM VITAE

PAGE TWO

COPCUTT, BRIAN GIBSON

PROFESSIONAL AND HONORARY SOCIETIES:

President, Virginia Chapter of the Health Physics Society
Society of Nuclear Medicine
American Association of Physicist in Medicine
Health Physics Society
American Nuclear Society
Tau Beta Pi (honorary engineering society)

PUBLICATIONS:

"A Computer Interfaced, Multiple Radioisotopes Counting and Scanning System," Ph.D. Dissertation, Texas A&M College of Engineering 1983.

"Real Time Determination of Rb-81/Kr-81m Ratio as an indication of flow," C. W. Beasley, B. G. Copcutt, D. Hightower, D. R. Gross. Abstract - Soc. Nucl. Med., 29th Annual Meeting, Miami Beach, Florida, 1982.

CURRICULUM VITAE

NAME: Debra L. Bryant

DATE AND PLACE OF BIRTH: January 26, 1955, Martinsville, VA

CITIZENSHIP: United States

EDUCATION:

1976 - B.A. (Biology), University of Virginia, Charlottesville, VA
1980 - Ph.D. (Microbiology), Bowman Gray School of Medicine of Wake Forest University, Winston-Salem, N.C.

CHRONOLOGY OF PROFESSIONAL EXPERIENCE:

1980 - 1983 NIH Postdoctoral Fellow, (with J.T. Parsons) University of Virginia School of Medicine, Charlottesville, VA.

1983 - 1984 Senior Scientist, Oncogen, Seattle, Washington

1984 - pres. Senior Scientist, UNOGEN, Inc., Charlottesville, VA.

RESEARCH EXPERIENCE:

8/76-8/80 Wake Forest University, Winston-Salem, NC

Major Area of Interest: To define altered serological factors in chickens which are directly related to leukemia induced by avian myeloblastosis virus.

Relevant Experience: Extensive tissue culture experience with human and chicken bone marrow; protein chemistry including HPLC, conventional chromatography, differential centrifugation, SDS-PAGE, and IEF; hematology (cell typing).

8/80-12/83 University of Virginia, Charlottesville, VA

Major Area of Interest: Postdoctoral project: Using genetic engineering techniques, construct defined mutations in the arc , oncogene and determine their effect on the gene's transforming potential.

Relevant Experience: Molecular cloning in pBR plasmids and lambda and M13 phages; DNA sequencing: Maxam-Gilbert and Sanger; Mutagenesis by specific restriction enzymes and exonucleases, bisulfite, and synthetic oligonucleotides; Southern and northern blotting; Tissue culture involving avian and mouse fibroblasts; Immunochemistry: immunoprecipitation, plate coating assays, immunoaffinity columns; protein chemistry: SDS-PAGE and autoradiography, two dimensional gel electrophoresis, phosphoaminoacid analysis, kinase assays, interferon assays.

PUBLICATIONS:

Curriculum Vitae: Debra Bryant

1. Bryant, D., Smith, R., Sharma, S., and Dodge, W.: Some circulating factors which influence granulocyte-monocyte production in the chick with myeloblastic leukemia. Can. Res., 40:4031-4036, 1980.

2. Dodge, W., Love, S.J., Bryant, D.L., and Mitchell, R.H.: Properties of colony-stimulating and inhibiting activities of chicken serum. Exp. Hemat. 8:395-403, 1980.

3. Bryant, D., and Dodge, W.H.: Studies on the circulating, colony-stimulatory activities in normal chicks and in chicks with myeloblastic leukemia. Exp. Hemat., 9:457-467, 1981.

4. Bryant, D., Whitaker, J., Bruber, K., and Dodge, W.: Characterization of an inhibitor of granulocyte/monocyte colony formation in leukemic chicken plasma. Exp. Hemat., 9:479-488, 1981.

5. Bryant, D., Smith, R., and Dodge, W.: Levels of colony stimulating and inhibiting activities in chicks with myeloblastic leukemia are related to disease progression. Exp. Hemat., 10:249-255, 1982.

6. Bryant, D., and Parsons, J.T.: Site-directed point mutation in the src gene of RSV results in an inactive pp60^{src}. J.Virol., 45:1211-1216, 1983.

7. Bryant, D. and Parsons, J.T.: Site-directed mutagenesis of the src gene of Rous sarcoma virus: Construction and characterization of a deletion mutant temperature-sensitive for transformation. J. Virol., 44:683-691, 1982.

8. Dodge, W.H., and Bryant, D.L.: Characteristics of granulocyte-monocyte (GM) colony formation in the chicken and alterations in GM regulatory factors in viral-induced avian myeloblastic leukemia. In: Advances in Comparative Leukemia Research 1979. (D.S. Yohn, B.A. Lapin, J.R. Blakeslee, Eds.) Elsevier/North-Holland, Inc. New York, Amsterdam, Oxford. pp. 37-38, 1979.

9. Bryant, D. and Parsons, J.T.: Amino acid alterations within a highly conserved region of the Rous sarcoma virus src gene product, pp60^{src}, inactivate tyrosine protein kinase activity. Molecular and Cellular Biology. In press.

10. Parsons, J.T., Bryant, D., Wilkerson, V., Gilmartin, G., and Parsons, S.J.: Site-directed mutagenesis of Rous sarcoma virus pp60^{src}: identification of functional domains required for transformation. In: Cancer Cells, Oncogenes and Viral Genes. Cold Spring Harbor Press. In press.

11. Bryant, D. and Parsons, J.T.: Characterization of Rous sarcoma virus variants encoding src proteins having an altered carboxy terminus. Submitted for publication.

CURRICULUM VITAE

NAME: Michael Patrick Woodward

DATE AND PLACE OF BIRTH: March 27, 1948, Buffalo, New York

CITIZENSHIP: United States

EDUCATION:

1971 - B.A. (Biology), University of Maryland, Baltimore County
1975 - M.S. (Biology), University of Maryland, Baltimore County
1981 - Ph.D. (Biology), University of Maryland, Baltimore County

CHRONOLOGY OF PROFESSIONAL EXPERIENCE:

1981 - 1982 Postdoctoral Fellow, Norris Cotton Cancer Institute, Dartmouth College

1982 Summer Visiting Assistant Professor, Department of Biological Sciences, Dartmouth College

1982 - 1984 Postdoctoral Fellow, Department of Anatomy, University of Virginia

RESEARCH EXPERIENCE:

1/75-1/81 University of Maryland Baltimore County, Catonsville, MD

Dissertation Title: Studies on the protein composition, ultrastructure, and reassembly of coated vesicles.

Relevant experience: Techniques of subcellular fractionation, column chromatography, protein modification: tritium exchange, alkylation, iodination; SDS-PAGE, isoelectric focusing, analytical and density-gradient centrifugation, and fluorescence spectroscopy.

7/81-11/82 Dartmouth College, Hanover, NH

Postdoctoral project: Regulation of actin gene expression in Drosophila tissue culture cells.

Relevant experience: Learned tissue culture techniques, basic immunological techniques: immunoprecipitation, anitbody purification; molecular cloning in pBR 322, Northern and Southern blotting, RNA purification from Drosophila and HeLa cells.

11/82-6/84 University of Virginia, Charlottesville, VA

Postdoctoral project: Biochemical and functional characterization of the flagellar membrane proteins of Chlamydomonas using monoclonal antibodies.

Relevant experience: Acquired the necessary skills to perform mouse-mouse fusions and isolate specific hybridomas. Developed ELISA and

immunoblot protocols which permitted rapid and specific detection of the membrane glycoproteins of Chlamydomonas. Devised a periodate oxidation procedure which permits the identification of carbohydrate epitopes and anti-carbohydrate antibodies. Learned immunofluorescence techniques.

PUBLICATIONS:

1. Woods, J.W., Woodward, M.P., Roth, T.F.: Common features of coated vesicles from dissimilar tissues: Composition and structure. J. Cell Sci. 30 (1978), pp. 87-97.

2. Woodward, M.P., Roth, T.F.: Coated vesicles: Characterization, selective dissociation and reassembly. Proc. Nat. Acad. Sci. 75 (1978), pp. 4394-4398.

3. Woodward, M.P., Roth, T.F.: Influence of buffer ions and divalent cations on coated vesicle disassembly and reassembly. J. Supramol Struct. 11 (1979), pp. 232-250.

4. Woodward, M.P., Roth, T.F.: Involvement of sulfhydryl groups in coated vesicle reassembly. In preparation.

5. Berger, E.M., Woodward, M.P.: Small heat shock proteins in Drosophila may confer thermal tolerance. Exp. Cell Res. 147 (1983), pp. 437-442.

6. Woodward, M.P., Young, W., Bloodgood, R.A.: Rapid detection of carbohydrate epitopes by periodate oxidation of immunoblots. Accepted by the J. Immunol. Meth.

Invited Reviews

1. Woodward, M.P.: Coated vesicle composition and structure. International Review of Cytology. In preparation.

Abstracts

1. Woodward, MP, Young, WW Jr, and RA Bloodgood. 1984. Carbohydrate epitopes on flagellar membrane glycoconjugates. J Cell Biol 99, 176a.

2. Woodward, MP and RA Bloodgood. 1984. Redistribution and shedding of flagellar membrane glycoproteins is stimulated by anti-carbohydrate monoclonal antibodies. J Cell Biol 99, 178a.

ADDENDUM TO ITEM 18

In addition to the individual representing the license applicant (whose signature appears on Form NRC-313), the following individual has executed this certificate on behalf of the applicant named in Item 2 and certifies that all information contained herein, including any supplements attached hereto, is true and correct to the best of his knowledge and belief.

Brian G. Copcutt

Certifying Official (Signature)

Brian G. Copcutt, Ph.D.

Radiation Protection Officer
Title

May 31, 1985
Date

UNOGEN INCORPORATED 1500 AVON STREET EXT., CHARLOTTESVILLE, VIRGINIA 22901 (804) 295-5912

June 4, 1985

U.S. Nuclear Regulatory Commission
Region II
101 Marietta Street, Suite 2900
Atlanta, GA 30303

Gentlemen:

Enclosed you will find our application for a NRC licence and application fee of $700.00. We are a small research and development company which has been in operation for approximately one year. We are now located in an area where use of radioactive materials is not prohibited. We don't anticipate any problems with the application, but should some arise, please contact Brian Copcutt at (804) 924-8997.

Sincerely,

Debra Bryant

Debra Bryant, Ph.D.

Enclosure

~~8510310303~~

#5061/6/6/85
Rec'd
23087
030-28730

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

MEMORANDUM FOR: William O. Miller, Chief, License Fee Management Branch
Office of Administration

FROM: John Potter, Chief, Nuclear Materials Safety Section
Division of Radiation Safety and Safeguards

SUBJECT: LICENSE FEE TRANSMITTAL

A. REGION II:

1. APPLICATION ATTACHED:

Applicant/Licensee: Unogen, Inc.

Application Dated: 5/31/85

Control No.: 250621

License No.: New

2. FEE ATTACHED:

Amount: $700.00

Check No.: 528

3. COMMENTS:

Signed Grant O. Gunn

Date 6/11/85

B. LICENSE FEE MANAGEMENT BRANCH:

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____

Renewal _____

License _____

Signed _____

Date _____