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MS16
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030-33128

July 30, 1993

Sheri Ann Arredondo
Nuclear Materials safety Branch
Division of Radiation Safety
and Safeguards
US Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Ms. Arredondo:

Thank you for sending a complete review of our NRC Isotope application (NRC Docket No. 030-33128, Control No. 117911). Many of the issues raised in your letter of July 13, 1993 were already addressed in our Enzon Radioisotope User Manual. Those that were not originally addressed in the manual have been addressed and put into either this letter, amendments to our original application, or the Enzon Radioisotope User Manual.

I will, however, address every question that you raised in your letter, and reference the action/program as it is addressed in Enzon's Radioisotope User Manual.

1. Description of duties/responsibilities of Radiation Safety Officer: The duties of the Radiation Safety Officer and Corporate Safety Officer are described in Enzon's Radioisotope Safety Manual in section 1.1, pages 2-4.

2. Training program for ancillary personnel: Training for ancillary personnel including maintenance, security, and general laboratory personnel is detailed in sections 2.0-2.4, pages 5-8. Security personnel have additional training since they are the persons who may discover an incident after normal working hours.

3. Period/frequency of training sessions: All workers will be trained annually, or as new regulations, or situations dictate. It is discussed in Enzon's Radioisotope User Manual in section 2.0, page 5.

NMSS/RGNI MATERIALS-002

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AUG 02 1993

4. Describe laboratory equipment used when working with volatile radioactive materials: All work with volatile radioactive materials will be done in a Chemical fume hood with an average face velocity of 100 cfm. When working with isotopes like iodine, an additional mini-plexiglass box with a charcoal filtered exhaust vent will be used. Working laboratory procedures are described in Enzon's Radioisotope User Manual in section 8, pages 40-45.

5. Description of procedures used if radioactive material is used in animals: Enzon does not have an animal facility at 20 Kingsbridge Road. If we were to use isotopes in animals, we would have to use a contract facility and we would be governed by the rules and regulations of that licensed facility. Therefore, Enzon has not developed a policy for handling isotopes in animals.

6. Specify instruments used for counting wipes: Enzon plans to contract the general monitoring to a contract agent like Teledyne Isotopes for general compliance testing. However, when we are monitoring ourselves in house, wipes will be counted in the appropriate instrument (Beta in a liquid scintillation counter (Beckman Instruments), Gamma in a gamma counter (Beckman Instruments)). Descriptions and procedures are described in Enzon's Radioisotope User Manual in section 6.5.1, page 37.

7. Specify survey instrument(s) to detect I^{125}. In the laboratory we will use RPI model 900-44A Geiger counter(s) with NaI crystal probes. Personnel who work with iodine have their thyroids scanned by a contract service like Teledyne. Descriptions of iodine monitoring are detailed in Enzon's Radioisotope User Manual in section 8.1, pages 40-43.

8. Describe calibration procedures and frequency: All instruments are calibrated. Generally, the calibration is at six month intervals and is done by a contract service like Teledyne Isotopes (License # 29-00055-14). Descriptions of these procedures are in Enzon's Radioisotope User Manual in section 10, page 48.

9. Describe the type of dosimetry used, service organization and frequency: All employees working in the laboratories will wear radiation badges. Personnel working with isotopes will also wear ring/finger badges. Badges will be changed monthly, and will be monitored by a contract service like Teledyne Isotopes. Procedures and requirements are described in Enzon's Radioisotope User Manual in section 6.1, page 32.

10. Describe your plans for scanning personnel thyroids: Researchers, who work with I^{125} will have a base line thyroid scan. They will then have their thyroid scanned 24-72 hours after an iodination. Record keeping and assay results are described in detail in Enzon's Radioisotope User Manual sections 6.4 and 8.1, page 34 and page 40.

11. Describe procedures for measuring iodine or tritium released into unrestricted areas: Iodine release is monitored by checking the charcoal filter before and after an iodination with the hand held survey Geiger counter, as well as the researcher's thyroid scan (contract service). If we were to detect any significant amount of iodine release (> 5 times over background) we would check procedures for technical errors and the chemical fume hood for problems. As discussed in Enzon's Radioisotope Safety Manual section 8.1.3, page 40, there is a fixed procedure for monitoring release during an iodination procedure.
Since we do not plan to work with any volatile H^3 products, we do not anticipate any problems. If, however, we were working with a volatile organic or substance, we would try to trap or contain the gases via chemical traps and counting trapped samples for released radioactivity. The Radiation Safety Officer would be responsible for performing such monitoring, documenting the results and keeping records of any problems.

12. Submit a bioassay program for employees handling tritium and carbon in quantities larger than 10 mCi: If an employee were to use >10 mCi of an isotope, the reaction must be performed in the chemical fume hood. If post experimental wipes, or any indication of a spilled reaction occurred, then whole body exposure to volatile H^3 and C^{14} would have to be performed (outside contractor). We would have them trap and count exhaled gases (water and CO_2) from the exposed researcher. Additionally, we would examine the urine for radioactivity. The Radiation Safety Officer would then make a determination as to the degree and severity of the release, and if necessary, would notify the proper authorities.

13. List procedures for monitoring effluent air after iodination: This is discussed in question 11, and procedures are listed in Enzon's Radioisotope Safety Manual in section 8.1.3, page 40.

14. List procedures for working with radioactive iodine: There are specific procedures for working with radioactive iodine. They are listed in Enzon's Isotope Safety Manual in section 8.1, pages 40-43. Additionally, many of the procedures have been discussed in the three previous questions.

15. List procedures for the handling of P^{32}: Special handling procedures for using P^{32} are discussed in section 8.2, pages 44-45 in Enzon's Radioisotope Safety Manual. Additionally, after discussions with the Radiation Safety Officer, Corporate Safety Officer and several of the researchers, we feel that 200 mCi of P^{32} is excessive, and we would like to amend our application Supplement A to 100 mCi of P^{32} on hand.

16. Provide a description of routine survey program: Our survey program is detailed in Enzon's Radioisotope Safety Manual in section 6.5, pages 37-38. Surveys will be monthly, and records kept on hand in the Radiation Safety Officer office. Records will be maintained as required by the NRC and OSHA.

17. Surveys continue: Enzon will monitor a laboratory on a weekly basis only when a researcher used isoptopes above specific limits ($>$ 500 uCi for beta and 100 uCi for gamma). This is described in Enzon's Radioisotope User Manual section 6.5, page 37.

18. Disposal of radioactive waste in the sanitary sewer system: We will dispose of liquid radioactive waste as dictated by the NRC and the state of New Jersey, which ever is more stringent. Records will be maintained of all sewer disposals, and will be available from the Radiation Safety Officer.

19. Describe the maintenance of records: The Radiation Safety Officer will keep all receiving, disposal, training, storage, and effluent monitoring records. The Radiation Safety Officer will turn over to Enzon's Human Resource Department all employee survey records including personal dosimetry and thyroid scan data. All results are available to the employee at any time. These procedures are detailed Enzon's Radioisotope Safety Manual (See appendix A for Forms).

20. Copy of Laboratory instructions: A copy of the laboratory instructions is detailed in Enzon's Radioisotope Safety Manual section 4.2, pages 16-18. General regulations are posted in the radiation laboratory, and will be strictly enforced by the Radiation Safety Officer.

21. Emergency procedures and telephone numbers: Emergency procedures and telephone numbers will be posted in all radioactive use areas and at security locations. These procedures and numbers are also listed at the very front of Enzon's Radioisotope Safety Manual. (All persons working with isotope have their own copy for reference.) No researcher can work in the radiation laboratory without having been trained in emergency procedures.

22. Describe package receiving procedures: Receiving procedures are detailed in Enzon's Radioisotope Safety Manual in section 3.2, pages 11-12. All receiving personnel receive additional training in safety and emergency procedures.

23. Describe package receiving procedures: As discussed in question 21, the receiving procedures are detailed in Enzon's Radioisotope Safety Manual in section 3.2, pages 11-12. All receiving personnel receive additional training in safety and emergency procedures for handling broken or leaking radioactive packages. Additionally, safety equipment and a monitoring Geiger counter kept in the receiving area.

24. Submit a comprehensive description of your disposal procedures: Our disposal procedures are discussed in section 5.0, pages 19-31 of Enzon's Radioisotope Safety Manual.

25. Describe our sewage disposal procedures: Sanitary sewer disposal procedures are discussed in section 5.0, pages 21-22 of Enzon's Radioisotope Safety Manual. Detailed records will be kept to ensure that we do not exceed the specified disposal limits.

26. Supplement F Item 2 sentence was incorrect: It has been corrected. See new Supplement F.

27. Describe decay-in-storage procedures: We will keep radioactive waste for at least 10 half-lives or two years which ever comes first. If after two years, radioactivity is present, we will dispose of the material using a contract disposal service. These procedures are detailed in Enzon's Radioisotope Safety Manual in section 5.8, page 30.

28. Address information notice #90-09: We plan on having a licensed radioactive waste service dispose of any radioactive material if it has been stored for 2 years and has not decayed to non detectable levels. Again, these procedures are addressed in the waste disposal section (5.0) of Enzon's Radioisotope Safety Manual.

29. Supplement B: We regret that there was no information furnished on Dr. Richard Greenwald. His isotope experience history is being supplied. Also, there are two new employees Dr. Masih Hashim and Dr. Mel Silberklang. Please add these scientist to our list of isotope users.

To summarize, the major changes in our Radioisotope License Application are the following:

Amend Supplement A by reducing the P^{32} level from 200 mCi to 100 mCi.
Correct wording in supplement F Item 2
Supplement B Add Drs. Richard Greenwald, Masih Hashim, and Mel Silberklang.

We have answered all the questions to the best of our ability and current understanding of the regulations. If you have additional questions or comments, please feel free to call me at 908-980-4902. I thank you for helping us get this isotope application processed.

Sincerely yours,

Carl Walter Gilbert

Carl Walter Gilbert, Ph.D., R.S.O.
Associate Research Director
Enzymology and Cell Biology

Attachment

cc: Patricia Hudson
Jack McLaughlin, C.S.O.
Dr. Robert G.L. Shorr

SUPPLEMENT A

1. Reference Item #5, NRC Form 313 - amended 28 July 1993

ISOTOPE	PHYSICAL FORM	MAXIMUM ACTIVITY
Carbon-14	Liquid	100 millicuries
Chromium-51	Liquid	50 millicuries
Hydrogen-3	Liquid	300 millicuries
Iodine-125	Liquid	50 millicuries
Iodine-131	Liquid	50 millicuries
Phosphorous-32	Liquid	100 millicuries
Phosphorous-33	Liquid	100 millicuries
Sulfur-35	Liquid	100 millicuries

2. Reference Item #6, NRC Form 313 - amended 15 April 1993

Materials listed in item #5 are for pharmaceutical research and development only. Radioactive materials will be used in the following types of research situations: In vitro cell proliferation assays (H^3, and I^{125}); in vitro cytotoxicity assays (H^3, Cr^{51}, and I^{125}); radiolabeling of synthetic compounds and proteins (H^3, C^{14}, S^{35}, I^{125} and I^{131}), and labeling of cells or cell surfaces for receptor binding experiments (H^3, S^{35}, I^{125} and I^{131}). DNA labeling and sequencing (P^{32}, P^{33}) for cloning and in vitro gene expressions.

Reference Item #7, NRC form 313 - amended 28 July 1993

SUPPLEMENT B

1. The names of the Radiation Protection Officer and Alternate Radiation Protection Officer(s) follow.

   Carl W. Gilbert
   Barbara Czuba
   Masih Hashim
   Barbara Czuba
   Avi Lasdun

2. Senior Scientists who will supervise day to day use of the isotopes are:

   (1) Carl W. Gilbert
   (2) David Filpula
   (3) Marc Whitlow
   (4) Abraham M. Lasdun
   (5) Jack C. McLaughlin
   (6) Richard Greenwald
   (7) Barbara Czuba
   (8) Masih Hashim
   (9) Mel Silberklang

ꝚC FORM 313M

SUPPLEMENT B

Training and Experience of Individuals Listed in Item 7

NAME: Rich Greenwald, Ph.D

Type of Training	Where Trained	Duration of Training	On the Job	Formal College
A. Principles practices of radiation protection	NONE		Yes No	Yes No
B. Radioactivity measurement standardization & monitoring techniques & instruments	NONE		Yes No	Yes No
C. Mathematics & calculations basic to use and measurement of radioactivity	NONE		Yes No	Yes No
D. Biological effects of radiation	NONE		Yes No	Yes No

Experience with Radiation (Actual Use of Radioisotopes or Equivalent Experience).

NAME: Rich Greenwald, Ph.D

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use
C^{14}		J.T.Baker	2-3 months	Synthesis

NRC FORM 313M

SUPPLEMENT B

Training and Experience

NAME: Melvin Silberklang

Social Security # ____________

Type of Training	Where Trained	Duration of Training	On the Job	Formal College
A. Principles practices of radiation protection	MIT	3 hr.	20 yrs	PhD MIT '77
B. Radioactivity measurement standardization & monitoring techniques & instruments	MIT	4 yrs.	20 yrs	
C. Mathematics & calculations basic to use and measurement of radioactivity	MIT	1 hr.		
D. Biological effects of radiation	MIT	4 yrs PhD training		

#8 Experience with Radiation (Actual Use of Radioisotopes or Equivalent Experience).

NAME: Melvin Silberklang

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use
32p	1mCi	MIT UCSF MERCK	2~~0~~6 yrs	Label Cell Culture; Synthesize 32p-nucleotides (chemistry)
35S	~~10~~ 5 mCi	MIT/UCSF/MERCK	2~~0~~8 yrs	Label Cell Cultures, DNA Sequence Analysis
14C	5mCi	MIT/UCSF	8 yrs	In vitro biochemistry
3H	5mCi	MIT/UCSF MERCK	8 yrs	Label cell Culture
125I	1mCi	UCSF MERCK	12yrs	Iodinate Protein

Melvin Silberklang

(signature)

NRC FORM 313M

SUPPLEMENT B

Training and Experience

NAME: Masih Hashim

Social Security # ______________________

Type of Training	Where Trained	Duration of Training	On the Job	Formal College
A. Principles practices of radiation protection	Univ of Wisconsin Univ of Tennessee	4 years 1 yr.	1980-1992	Univ of Wis Univ of Tennessee
B. Radioactivity measurement standardization & monitoring techniques & instruments	same	same	Sch 1963-1980 Job 1980-92 (Pennwalt Pharm + Eastman Kodak)	–
C. Mathematics & calculations basic to use and measurement of radioactivity	as needed		–	–
D. Biological effects of radiation	Univ of Wisconsin Univ of Tenn.	5		

Note - I was member of safety committee for Eastman (Kodak) Pharmaceuticals. I trained staff in using proper shielding, gloves, proper use and disposal of radioisotopes. I practiced for over 10 years working with X-rays, Beta & gamma rays, at different times. I worked as Assoc. Director Drug Safety and Director of Toxicology.

#8 Experience with Radiation (Actual Use of Radioisotopes or Equivalent Experience).

NAME: Masih Hashim, Ph.D.

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use
P^{32}	100 millicuries	The Univ of Wisconsin, Madison; The Univ of Tennessee (Knoxville + Oakridge, Tenn); Eastman Kodak Co.	* Overall 10 years of experience at different times.	Research applications → animal work
P^{33}	100			
I^{125}	100 millicuries			
I^{131}	100 millicuries			
H^3	300			
C^{14}	100			

* I was also the member of safety committee which included radiation, & I have trained staff in radiation safety; I will be involved ...

MHashim

(signature)

* I also have significant experience with ... radiation ... animal

Reference Item 11, NRC Form 313 - amended 28 July 1993

SUPPLEMENT F

1. Radioactive material, after the appropriate forms are signed, will be transferred from the RA storage area to the working laboratory in either plastic bottles/vials or lead shielded vials.

2. Radioactive waste materials will be collected in appropriate waste containers located in the laboratory and then transferred to the waste storage area. The waste storage area is a locked, controlled access area. Radioactive wastes will be collected by individual isotope. Depending on specific activity, aqueous wastes will be held for decay or disposed properly in the sanitary sewerage system in accordance with 10 CFR 20.303, or NJAC 7:28-11.2, whichever is more stringent. Aqueous radioactive waste not allowed to be disposed of in the sanitary sewer system will be held for other proper disposal methods. Other radioactive waste materials will be held until disposed of in accordance with 10 CFR 20.301 (a) or (b). In no case will radioactive waste be held for more than two (2) years from the time it is generated. Time of generation is defined as the time the waste barrel is filled and sealed. Solid waste and organic waste will be disposed as required under a contract with a licensed radioactive waste disposal company (e.g., U.S. Ecology, P.O. Box 7246, 9200 Shelbyville Road, Louisville, KY 40207, Teledyne/Isotopes, 50 Van Buren Ave., Westwood, New Jersey 07675, or other licensed source).

ISOTOPE	HALF LIFE	TYPE OF DECAY	MAJOR RADIATION	APPROXIMATE ENERGIES (MeV)	SHIELD Pb HVL (cm)	SPECIAL PRECAUTIONS
P^{32}	14.3 days	β^-	β^-	1.710	A	
P^{32}	25.3 dyas	β^-	β^-	0.249	A	
I^{125}	59.4 days	E.C.	γ	0.179	B 0.0037 cm	NaI form Volitile
I^{131}	8.0 days	β^-	β^-	0.971	B	
H^3	12.3 years	β^-	β^-	0.186	A	
C^{14}	5715 years	β^-	β^-	0.156	A	
S^{35}	87.2 days	β^-	β^-	0.167	A	
Cr^{51}	27.2 days	E.C.	γ	0.751	B	

<u>SHIELDING:</u>
A = Lucite®
B = Lead

<u>DECAY:</u>
β = beta
E.C = Electron Capture

<u>RADIATION:</u>
γ = gamma ray
β^- = beta particle

ENZON, INC.

RADIOISOTOPE USER MANUAL

7/20/93

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EMERGENCY PROCEDURES

A. <u>Minor Spills</u>

1. Notify persons in the area that a spill has occurred.
2. Determine the boundaries of the spill using a hand held monitor
3. Contain the spill with minor radioactive spill kit.
4. Wearing gloves and using tongs transfer the absorbent paper to a radioactive. waste container. Decontaminate the area using Count-Off, Rad-Wash, or other decontaminant beginning at the border of the spill and working inward. Refer to Appendix C for additional decontaminants.
5. Survey the area with a hand held monitor.
6. If contamination persists repeat cleanup procedures.
7. Notify personnel listed below.

B. <u>Major Spills</u>

1. Clear the area of all personnel not involved with the spill. Insure that all personnel leaving the area are not spreading contamination by checking shoes, clothing, etc. with a hand-held monitor before leaving.
2. Determine the boundaries of the spill with a hand held monitor.
3. Cover the spill with absorbent material but <u>DO NOT</u> attempt to clean up
4. Shield the spill area but only if possible without further contamination or exposure to yourself.
5. Close the room to prevent further contamination and entry of additional personnel.
6. Notify the personnel listed below.
7. Remove any contaminated clothing and shower if necessary.
8. Refer to appendix C for skin decontamination procedures.

IN CASE OF EMERGENCY CONTACT THE FOLLOWING PERSONNEL

Carl W. Gilbert, Ph.D., - Radiation Safety Officer
Extension 4902
Home phone 908-604-6583

Barbara Czuba
Extension 2433
Home phone 908-725-3931

Jack C. McLaughlin - Corporate Safety Officer
Extension 4911
Home phone 201-728-1129
Beeper 908-214-3283

Security Department 4505

<u>PISCATAWAY POLICE/PISCATAWAY FIRE DEPARTMENT 908-562-2333</u>

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APPENDIX D
AGENCIES TO BE NOTIFIED AFTER AN EMERGENCY D-1

1.1 Responsibilities of the Corporate Safety Office, Radiation Safety Officer, and Researchers in the Radiation Safety Program

A. Corporate Safety Officer

1. Develop, implement, and supervise the Enzon radiation safety program.

2. Ensure that Enzon complies with Federal and State regulations concerning the use of sources of radiation.

3. Advise the scientific staff on radiological health issues and on procedures for the safe use of sources of radiation.

4. Identify unsafe working conditions and practices, recommend corrective measures and oversee their implementation.

5. Conduct radiation safety inspections and accident investigations in conjunction with the Radiation Safety Officer.

6. Provide support services such as radioactive waste processing and radioisotope receipt.

7. Conduct radiation monitoring surveys for assessing contamination levels in the workplace, and for assuring compliance with environmental standards.

8. Maintain the personnel dosimetry program to monitor exposure of workers to sources of radiation.

9. Maintain a library of technical references and regulations governing the use of sources of radiation.

10. Interact with Enzon staff, outside consultants and Federal and State agencies in relation to the Enzon radiation safety program.

11. Train all employees in radiation hazards and all laboratory and laboratory support personnel in the safe use and handling of sources of radiation.

12. Issues dosimeters monthly, monitors readings and gives them to the Radiation Safety Officer.

B. Radiation Safety Officer

1. Comply with and enforce all Enzon radiation safety and health policies, procedures and regulations.

2. Interact with the Corporate Safety Officer to maintain a safe workplace and compliance with the appropriate Federal and State regulations.

3. Supervise employees so that safe practices are followed.

4. Conduct radiation safety inspections and accident investigations in conjunction with the Corporate Safety Officer.

5. Review all in-lab radiation safety records and inspect the work environment for compliance with the Enzon radiation safety program.

6. Maintain the appropriate records for radioisotope inventories, contamination surveys, and employee exposure.

7. Issues annual reports on employee exposure.

8. Approve all radioisotope purchases.

9. Advise the Corporate Safety Officer of all spills, accidents and other radiation safety problems.

10. Assist in training all employees in radiation hazards and all laboratory and laboratory support personnel in the safe use and handling of sources of radiation.

11. Supervise dry runs before any new researcher works with radioisotopes or any new procedure is performed.

12. Be present during any new procedure.

13. Ensure that the use of radioactive material is by or under the direct supervision of individuals specifically listed on our license.

14. Ensure that radioactive materials are properly secured against unauthorized removal at all times when not in use.

15. Ensure the terms and conditions of our license are met and all required records are maintained.

16. Chair a Radioisotope Use Committee consisting of representatives from R&D, Engineering, Safety, and Security to review new radioisotope uses and protocols. (See Enzon Chemical Hygiene Plan for new experimental protocol review process.)

C. Researchers Using Radioisotopes

1. Comply with all Enzon radiation safety and health policies, procedures and regulations.

2. Maintain a safe work area through appropriate shielding, monitoring and control procedures.

3. Notify the Radiation Safety Officer before beginning any unfamiliar or new procedure.

4. Perform any unfamiliar or new procedure only under the direction of the Radiation Safety Officer after a dry run under supervision.

5. Correct any deficiencies found during safety inspections.

6. Complete all required records when working with or disposing of radioisotopes.

7. Report all spills, accidents, and problems to the Radiation Safety officer and the Corporate Safety Officer.

8. Follow appropriate hygiene and safe work practices.

9. Become familiar with the hazards associated with the use of sources of radiation.

2.0 TRAINING

All Enzon employees and contractual personnel will receive instruction about radioisotope safety, handling and emergency procedures commensurate with their job function and responsibility. Training for those who use radioisotopes will be held annually. If there is a change in regulations that affect Enzon employees or contracted personnel they will be informed immediately.

2.1 NEW EMPLOYEES

During regular orientation, all new employees will be given an orientation by the Corporate Safety Officer concerning the nature of radiation and radioisotopes. During this orientation, new employees will be asked to complete the INSTRUCTION ON RADIOISOTOPES Form (see Appendix A-1, form 12000) certifying they have received the above information.

All forms will be kept with the employee's records by the Radiation Safety Officer.

2.2 Training of Contractual Personnel

All long-term contractual personnel, e.g., janitorial services, will be given a short introduction to radiation and radioactive materials. This introduction will be given in English and any other language necessary so the workers will be fully aware of the nature and dangers of radiation and radioisotopes.

Basic emergency numbers will be posted in the work areas with the emergency procedures from the front of this manual. Additionally, these workers will not have normal access to areas where radioisotopes are stored and used. However, if they must enter these areas, they will be accompanied by a researcher who has had detailed radioisotope use training. Retraining will be done annually.

Their instruction will include:

1. Safety procedures, included detailed explanations of the dangers and hazards of radioactive materials. A general safety video will be shown.

2. Handling procedures. Although they should never be in an area where radioisotopes are stored or used, they will be instructed in safety handling procedures.

3. Emergency procedures which will cover what to do if there is a fire in the building or in the radioactive use or storage area, what to do if there is an accidental spill, and who to call if they believe there is an emergency.

The contractor should send the same trained worker(s) if work is necessary in radioisotope areas. If these workers are unavailable, i.e., sick, vacation, only workers trained in radioisotope safety will be allowed to cover.

2.3 Training of Ancillary Personnel

All Enzon personnel who work in, or may be called upon to work in, the Research facility will be given a short introduction into the handling and use of radioactive materials. This introduction is general in nature and meant to inform workers of the need to stay away from restricted areas where radioisotopes are stored or used. Basic safety and emergency procedures will be taught. Additionally, these workers will not have normal access to areas where radioisotopes are used and stored. If they must enter these areas, they will be accompanied by a researcher who has had detailed radioisotope use training. Retraining will be done annually.

Their instruction will include:

1. Safety procedures, included detailed explanations of the dangers and hazards of radioactive materials. A general safety video will be shown.

2. Handling procedures. Although they should never be in an area where radioisotopes are stored or used, they will be instructed in safety handling procedures.

3. Emergency procedures which will cover what to do if there is a fire in the building or in the radioactive use or storage area, what to do if there is an accidental spill, and who to call if they believe there is an emergency.

2.4 Training of General Laboratory Personnel

All new employees who will be handling radioactive material (researchers, security and receiving) will be given a half-day training session on handling radioisotopes. This session will cover radioisotope safety, surveying containers and work areas, safe practices and procedures when handling radioisotopes, radioisotope disposal procedures and emergency procedures. The procedures used at Enzon will comply with both the United States Nuclear Regulatory Commission's and the New Jersey Bureau of Radiation's Rules and Regulations. At the end of training those employees will complete the INSTRUCTION ON RADIOISOTOPE SAFETY Form (see Appendix A-2, form 12001) certifying they have completed this session. Retraining will be done annually

All female employees using radioisotopes will be notified of the hazards of using radioisotopes and that the maximum dose during an entire pregnancy is 0.5 rem. They will be given a copy of 10 CFR 20.1208 and will sign the INSTRUCTION CONCERNING PRENATAL EXPOSURE Form (see Appendix A-3, form 12002) acknowledging they have been told of the hazard and exposure risks to developing embryo and fetus.

3.0 PROCEDURES FOR ORDERING AND RECEIVING RADIOISOTOPES

3.1 Ordering Radioisotopes

When a researcher has determined the radioisotope he/she wishes to use, he/she will complete a REQUEST FOR PURCHASE ORDER FORM (see Appendix A-4, form 12003) and submit the request to his/her supervisor for approval along with a purchase requisition. After the supervisor returns the signed forms to the researcher, the researcher then submits the forms to Radiation Safety Officer. The Radiation Safety Officer compares the requested activity against the current inventory of that radioisotope and all outstanding purchase orders and, if the requested activity when added to the activity on hand will not exceed the total inventory limits listed in Table I, the Radiation Safety Officer signs the request and keeps a Xerox copy of both the Request for Purchase Order and the Purchase Requisition. The researcher submits the originals of both forms to R&D Administration.

If the requested activity of the radioisotope will exceed the inventory limits, the Radiation Safety Officer will contact the researcher, inform him/her of the situation and assist in resolving the problem. Researchers should note that the Purchasing Department will not place an order for radioisotopes unless accompanied by the approval of the Radiation Safety Officer.

TABLE I

Radioisotopes and Inventory Limits Allowed by Enzon Radioactive Materials License

ISOTOPE	PHYSICAL FORM	MAXIMUM TOTAL ACTIVITY
Carbon-14	Liquid	100 millicuries
Chromium-51	Liquid	50 millicuries
Hydrogen-3	Liquid	300 millicuries
Iodine-125	Liquid	50 millicuries
Iodine-131	Liquid	50 millicuries
Phosphorous-32	Liquid	100 millicuries
Phosphorous-33	Liquid	100 millicuries
Sulfur-35	Liquid	100 millicuries

3.2 Receipt of Radioisotopes

When a radioisotope arrives at Enzon, the Receiving Department inspects for degradation of package integrity (the package is crushed, wet or damaged). If the package is noticed to be damaged, it will be refused. If the package is intact, the receiver places it in a Lucite® container and monitors the outside of the package for radioactivity no later than three hours after receiving it or within 3 hours from the beginning of the next day if it is received after hours. If radiation levels are found to be >200 millirem/hour, or at three feet from the external surface of the package in excess of 10 millirem/hour, the receiver will place a Lucite® box over the package, quarantine and leave the area, and notify the Radiation Safety Officer and the Corporate Safety Officer who will investigate and notify the appropriate NRC office listed in Appendix D and the final delivery carrier. If radiation levels are <200 millirem/hour, the receiver, after entering the information on the RADIOISOTOPE RECEIVING FORM (see Appendix A-5, form 12004), places the package in its Lucite® box in a quarantine area and immediately notifies the Radiation Safety Officer, or authorized alternate, of receipt of the shipment. The Radiation Safety Officer, or authorized alternate, reports to the Receiving Department within two hours to collect the radioisotope shipment and the signed RADIOISOTOPE RECEIVING FORM. The radioisotope shipment is removed to the radioactive work area where the package is again monitored for external radiation and the accompanying forms checked. At this point, the Radiation Safety Officer, or authorized alternate, completes the RADIOISOTOPE RECEIVING FORM and notifies the requisitioner that the radioisotope has arrived.

All RADIOISOTOPE RECEIVING FORMS will be filed with the Radiation Safety Officer within 48 hours.

It is the responsibility of each researcher to maintain his/her own inventory records of the various shipments of radioisotopes so he/she may complete the required paperwork when disposing of the radioisotopes.

Whenever any radioisotope material is removed from inventory, the researcher removing it will update the RADIOISOTOPE INVENTORY FORM for that radioisotope.

All RADIOISOTOPE INVENTORY FORMS will be filed with the Radiation Safety Officer when completed.

4.0 GENERAL RULES FOR SAFE USE OF RADIOISOTOPES

4.1 Nature of Radiation Hazards

Safe use of radioactive materials and sources can be accomplished if the hazards involved are recognized and understood and the proper precautions are employed. Basic safety procedures involve protection against external and internal radiation exposure. Suitable protection can be provided by a combination of several general rules.

1. Plan the experiment to use minimal amounts of radioisotopes.
2. Maintain adequate distance between the source of radiation and the researcher.
3. Limit the time the researcher is exposed to radioactive materials and sources.
4. Utilize adequate shielding when working with radioisotopes and other sources of radiation.
5. Limit the spread of contamination caused by accidental spills.

Certain basic facts are generally accepted about the biological effects of ionizing radiation. It is beyond the scope of this manual to give an extensive discussion of these effects, but a few of the fundamental principles are presented below.

1. The biological effects of radiation are primarily due to its ionizing effect which can cause injury or death to living cells.
2. All types of cells and tissues are affected by ionizing radiation. However, different tissues vary in radiosensitivity and ability to recover from radiation damage. The degree of damage to any particular tissue depends upon the type of radiation, the method by which

the tissue is exposed, and the amount of radiation absorbed.

3. In addition to early effects of exposure there are marked cumulative effects and late changes. These long-term or cumulative effects have no detectable threshold area and, as the term applies, are cumulative over the entire lifespan of the individual concerned.

4. In the field of radiation safety, two basic types of radiation hazards are recognized: external and internal. The source of an external hazard may be an X-ray machine, an accelerator, a radioisotope, or other material or equipment that emits gamma rays, X-rays or neutrons. Alpha, proton, deuteron, and beta particles, emitted from accelerating equipment or other materials, are also external hazards to a varying degree dependent upon their energy range and source.

5. Internal radiation radioisotopes enter the body through inhalation, ingestion, an open wound, or the pores of the skin. From the internal dose standpoint, all radioactive materials are considered hazardous. Different radioisotopes concentrate in different tissues or organs. For example, I^{125} is absorbed primarily by the thyroid gland and Sr^{90} is absorbed primarily into the bone causing injury to the blood-forming organs. Symptoms of radioactive injury may occur in a few days or weeks or may not appear for years if small amounts of radioisotopes have been absorbed.

6. Although the whole body is seldom subjected uniformly to external radiation, it is still necessary in the interest of safety to assume that this always occurs on exposure and to regard such an exposure as a 'total' body dose rather than a 'limited' body dose. Obviously, however, this does not apply when the radiation dose received is given to the wrist, finger, or some other bodily appendage when the body's main portion is shielded.

   Therefore, it is imperative that persons engaged in laboratory operations involving the use of radioisotopes be aware of the fact that an internal as well as an external radiation hazard exists.

7. Researchers should strive at all times to maintain exposure to ionizing radiation 'as low as reasonably achievable' (ALARA). When working with radioactive

materials, researchers must constantly be aware of the interrelationships of time, distance and shielding.

By incorporating these factors into any actions involving radioisotopes, researchers will be able to minimize the exposure they receive from radioactive materials.

In order to maintain the ALARA concept, investigations of exposure to individuals will be instituted when (1) a researcher receives an exposure of 100 millirem or more to any part of the body during a one-month period as measured by a dosimeter; (2) a member of the support staff (Security, Receiving, and Maintenance) staff receives any exposure during a one-month period; (3) a declared pregnant worker receives any exposure during a one-month period.

Based on the outcome of this investigation, the appropriate measures will be instituted to reduce or eliminate exposure in future operations.

According to Federal regulations, the maximum permissible dose for declared pregnant women is 0.500 rem, whole body, for the 9 month gestation period. As such, a woman who has voluntarily informed her supervisor, in writing, of her pregnancy along with the estimated date of conception may have her work situation reviewed by the Radiation Safety Officer and the Corporate Safety Officer to ensure she is properly protected from radiation exposure.

4.2 General Safety Procedures

Appendix B is a listing of the radioisotopes that Enzon is currently licensed to use for biomedical research. Also included for each radioisotope in the list is the following information: type of decay, energies associated with the decay, type and amount of shielding required for safe use, and any special precautions, other than standard safe laboratory practices, that should be taken when working with that radioisotope. Before working with any radioisotope, the researchers will review the information provided about that radioisotope to minimize the amount of radiation exposure he/she could receive when working with it and discuss it with the Radiation Safety Officer. If it is a procedure new to the researcher, he/she will go through a dry run under the Radiation Safety Officer's supervision before any work is begun with the radioisotope.

When working with radioisotopes, researchers are to follow the following safety procedures:

1. The following activities are not permitted in Enzon laboratories: eating, chewing gum, drinking, smoking, mouth pipetting, wearing contact lenses, and applying makeup.

2. No food or beverages will be stored in a refrigerator or freezer containing radioactive materials.

3. At a minimum, wear safety goggles, a lab coat and two pairs of disposable latex gloves. Wearing two pairs of gloves provides:

   (a) A "double layer" of protection from the radioisotope. Depending upon the medium in which the radioisotope is contained, one pair of gloves may not stop skin contamination due to the permeability of the radioisotope through glove material. Two pairs of gloves can reduce skin contamination by a considerable degree.

(b) In the case of contamination of the outer pair of gloves, remove the gloves, and dispose of them in the appropriate container. This may prevent contamination of the skin. Remove uncontaminated inner pair of gloves, wash hands, put on two pairs of new gloves and continue.

4. When handling radioactive material, the researcher will wear a ring-type (TLD) dosimeter on the dominant hand under the disposable latex gloves. The wide part of the ring is worn on the palm side of the hand.

5. When working with radioisotopes the researcher should keep in mind that ionizing radiation travels in all directions; therefore, shields are to be placed between the radioisotopes and the researcher and also on either side and behind the radioisotope. By doing this the researcher protects not only him/herself from radiation exposure but also fellow employees working beside him/her or on the opposite lab bench.

6. All benches where radioisotopes will be used are to be covered with both a Teflon® coated lab bench cover and plastic backed absorbent paper. By using both of these lab bench covers, the researcher will ensure that the work area can be cleaned and decontaminated easily.

7. The researcher should limit the radioisotope work to one section of the lab bench. This will make cleanup easier and reduce the area of contamination. The area is to be shielded and labeled.

8. Keep all pipetting aids, tubes, etc. used in radioisotope work within the radioisotope work area. By using only one set of instruments for radioisotope work, the researcher will minimize the possibility of contaminating other, non-radioisotope experiments and reduce the work involved with cleanup. Instruments designated for radioisotope use should be labeled with tape bearing the standard radiation warning symbol to ensure they are not used in other experiments.

9. Researchers will leave the radioisotope in the protective lead pigs supplied by the manufacturer. This is to be done both during the actual handling of the radioisotope and when the radioisotope is stored in the freezer or storage container.

10. All areas where radioisotopes are used will be surveyed with a survey meter by the researcher, decontaminated at the completion of the experiment by the researcher and surveyed again to be sure the areas have been decontaminated.

11. When researchers intend to use radioisotopes during the course of an experiment they will inform their co-workers of the intended radioisotope use. If during the course of a long experiment the researcher must leave the bench for an extended period of time during the day, he/she should suitably identify the area with labels bearing the standard radiation symbol. Radioactive materials, instruments, and work areas should be labeled with the standard radiation symbol to ensure that a co-worker does not accidently remove any radioactive materials, or in any way receive unnecessary radiation exposure.

13. When transporting a radioactive material or radioisotope from one lab to another lab in the same building, the researcher will not carry the material or radioisotope by hand. The material or radioisotope will be placed in a leak-proof/shock-proof container which is clearly labeled "Radioactive Materials" and carried to the intended lab.

14. After handling any radioisotope researchers will thoroughly wash their hands. To determine if there is any contamination remaining on their skin, researchers will check their hands with a survey meter.

15. When a researcher must work in "off hours", he/she will inform his/her supervisor of such work plans. The employee must, upon entering the building, sign in, and if the guard is on duty inform him/her that radioactive material will be used in the laboratory. The researcher (if possible) should check in with security on a regular basis, during the "off hours" work. If a problem arises, the researcher will notify security, and both will follow the appropriate emergency procedure posted in the radioisotope laboratory and at the security desk. These emergency procedures are also in the front of this manual.

16. Any radioactive material not under constant surveillance and immediate control or use of authorized users will be secured in the radioisotope storage area.

5.0 WASTE DISPOSAL

To ensure compliance with regulations, all radioactive waste at Enzon is collected and disposed of by the Radiation Safety Officer. This includes all absorbed liquid, solid waste, and scintillation vials. Researchers will not dispose of any radioactive waste in any manner not approved by the Radiation Safety Officer, e.g., depositing solid waste in an unapproved waste container. Do NOT mix isotopes - one single radioisotope species per container. Listed below are the methods for disposal of all types of radioactive waste.

5.1 Dry/Solid Waste Other than P^{32}

1. Each lab utilizing radioisotopes has been provided with a Lucite® radioactive waste container. This clear plastic container must be used for all dry/solid radioactive waste. Researchers in each lab will line the bottom of the waste container with absorbent paper to prevent leakage in case of a spill.

2. Each waste container is provided with a yellow plastic bag which is the only type of liner to be used for radioactive waste. This bag identifies the use of radioactive materials. Biohazardous waste will be placed <u>only</u> in clear bags with the orange biohazard symbol or in solid orange bags similarly marked, in designated waste cans. This color coding of waste bags

is done to prevent the accidental disposal of biohazardous waste in the radioactive waste container or vice versa. If biohazardous or radioactive waste is placed in the incorrect bag or waste container, it is not collected; instead, the researcher is contacted by the Radiation Safety Officer, informed of the situation and the matter is resolved before the waste is collected.

3. When placing dry/solid waste in a waste container, a researcher is required to complete the SOLID WASTE DISPOSAL RECORD (see Appendix A-7, form 12006), located on or near the waste container, at that time. The researcher fills in the date of the disposal, the radioisotope being disposed, the amount in milli- or microcuries, the lab number where the radioisotope was stored, the form of the waste (glass, paper, rubber, metal, gel, plastic) and signs the disposal form. If the disposal sheet is not completed, the waste will not be collected.

5.2 Disposal by Release into Sanitary Sewer System

1. Radioactive materials may be disposed to the sanitary sewer system providing they are readily soluble or dispersible in water and the quantity released in any one day does not exceed the larger of either the levels

listed in Table II or ten times the levels listed in Table III. The gross quantity of radioactive material released into the sanitary system in one year cannot exceed one curie per year.

2. If the materials meet the above criteria, the researcher will record the information on the DISPOSAL TO SANITARY SEWER SYSTEM RECORD (see Appendix A-8, form 12012) and dispose of the radioactive material. These completed records will be kept and monitored by the Radiation Safety Officer.

TABLE II

MAXIMUM PERMISSIBLE AVERAGE CONCENTRATION OF RADIOACTIVE MATERIALS IN WATER

Radionuclide	μcurie/ml water
Carbon-14	0.02
Chromium-51	0.05
Hydrogen-3	0.1
Iodine-125	$4x10^{-5}$
Iodine-131	$6x10^{-5}$
Phosphorous-32	$5x10^{-4}$
Sulphur-35	$2x10^{-3}$

TABLE III

DISPOSAL QUANTITIES OF RADIOACTIVE MATERIALS

Radionuclide	Microcuries
Carbon-14	50
Chromium-50	50
Hydrogen-3	250
Iodine 131	10
Phosphorous-32	10
Sulphur-35	50

from New Jersey Administrative Code 7:28-11.2

5.3 Other Non-P^{32} Liquid Waste

1. Non-aqueous liquid radioactive waste or aqueous waste that falls outside the guidelines of 5.2 above is collected for off-site disposal. Researchers are provided with gallon plastic bottles. No other containers are to be used for this purpose. Bottles are available from the Radiation Safety Officer.

2. When a researcher disposes of radioactive liquid waste, he/she completes the LIQUID WASTE DISPOSAL RECORD (see Appendix A-9, form 12005) located on or near the liquid waste container. The researcher fills in the date of radioisotope disposal, the radioisotope being disposed, the activity of the liquid waste, added agents, the form of the liquid waste i.e., aqueous or organic, and signs the entry. (Aqueous and organic wastes should be separated even if for the same isotope. See #3 below.) If this disposal log is not completed, the waste is not collected.

3. The researcher must separate aqueous and organic liquid waste into different liquid waste containers. Separate disposal sheets are maintained for each type of liquid waste and are collected along with the liquid waste containers.

4. In addition to the form of the liquid waste (aqueous or organic), the researcher must indicate on the disposal log whether the liquid contains any chelating agents which are greater than 0.1% (w/w). If the liquid contains chelating agents greater than 0.1% (w/w) the weight percentage of the chelating agent will be recorded on the disposal sheet. Some examples of chelating agents are: Chelex® solutions, EDTA, phosphorous salts and salicylates.

5. If a liquid container has any free standing liquid, the liquid must be absorbed or eluded prior to collection. Liquid waste transport and disposal regulations require that all liquids are to be transported and disposed of in twice the amount of absorbent needed to contain the liquid. Depositing only a limited amount of liquid into the container allows the asbestos-free vermiculite to completely absorb the liquid. Also, by packing the disposal drums with additional absorbent (asbestos-free vermiculite), the two times the amount of absorbent requirement is satisfied.

5.4 Scintillation Vials

1. When generating radioactive waste in scintillation vials the researcher must always attempt to reduce the volume of scintillation fluid by using the 6 ml "mini

vials" whenever possible. This insures maximum efficiency in the use of the waste disposal drums into which the vials are eventually deposited.

2. When the researcher is finished with the experiment, scintillation vials are collected, separated according to isotope and placed in a ventilated hood for short term storage. **The scintillation counter is not a storage depot.**

3. A rack of vials should be dated, marked with the amount and type of radioisotope.

4. If a researcher generates scintillation vials with C^{14} or H^3 in quantities of ≤ 0.05 μCi/ml of total liquid, the scintillation vials are to be disposed of separately from other scintillation vials. These scintillation vials containing ≤ 0.05 μCi/ml of total liquid are not disposed of by land burial, but by incineration. If the scintillation cocktail contains a hazardous waste, as defined by NJDEPE or EPA, it will be disposed of according to the appropriate hazardous waste regulation. Disposal of scintillation vials will be recorded on separate SOLID WASTE DISPOSAL RECORDS.

5.5 Phosphorous - P^{32} Waste

1. P^{32} waste is disposed of separately from all other forms of radioactive waste. Researchers are to deposit dry P^{32} waste and scintillation vials containing P^{32} in the plastic bags in the P^{32} waste container. Liquid waste containing P^{32} is to be deposited in the liquid waste containers marked "P^{32} Radioactive Waste." All radioactive liquid waste containing radioisotopes other than P^{32} will be deposited in the liquid waste containers marked for the appropriate radioactive isotope.

2. All disposal of P^{32} waste, whether liquid, solid, or scintillation vials will be recorded on the appropriate P^{32} Waste Disposal Record, LIQUID P^{32} WASTE DISPOSAL RECORD AQUEOUS/ORGANIC (see Appendix A-10, form 12008) for liquid P^{32} waste and SOLID P^{32} WASTE DISPOSAL RECORD (see Appendix A-11, form 12010) for solid P^{32} for solid P^{32} waste. If these forms have not been completed, the radioactive wastes will not be collected and the Radiation Safety Officer will inform the researcher of the situation so he/she can correct it.

5.6 Shielding of Radioactive Waste

1. The Lucite® containers provided for solid waste disposal are effective in shielding beta particle

emitting radioisotopes only. As such they are <u>NOT</u> effective in the attenuation of gamma rays.

2. If a researcher plans to use a gamma emitting radioisotope (see Appendix B), he/she is to contact the Radiation Safety Officer and arrange to have a lead lined waste container or sufficient lead sheeting provided to ensure that the radioactive waste will be properly shielded.

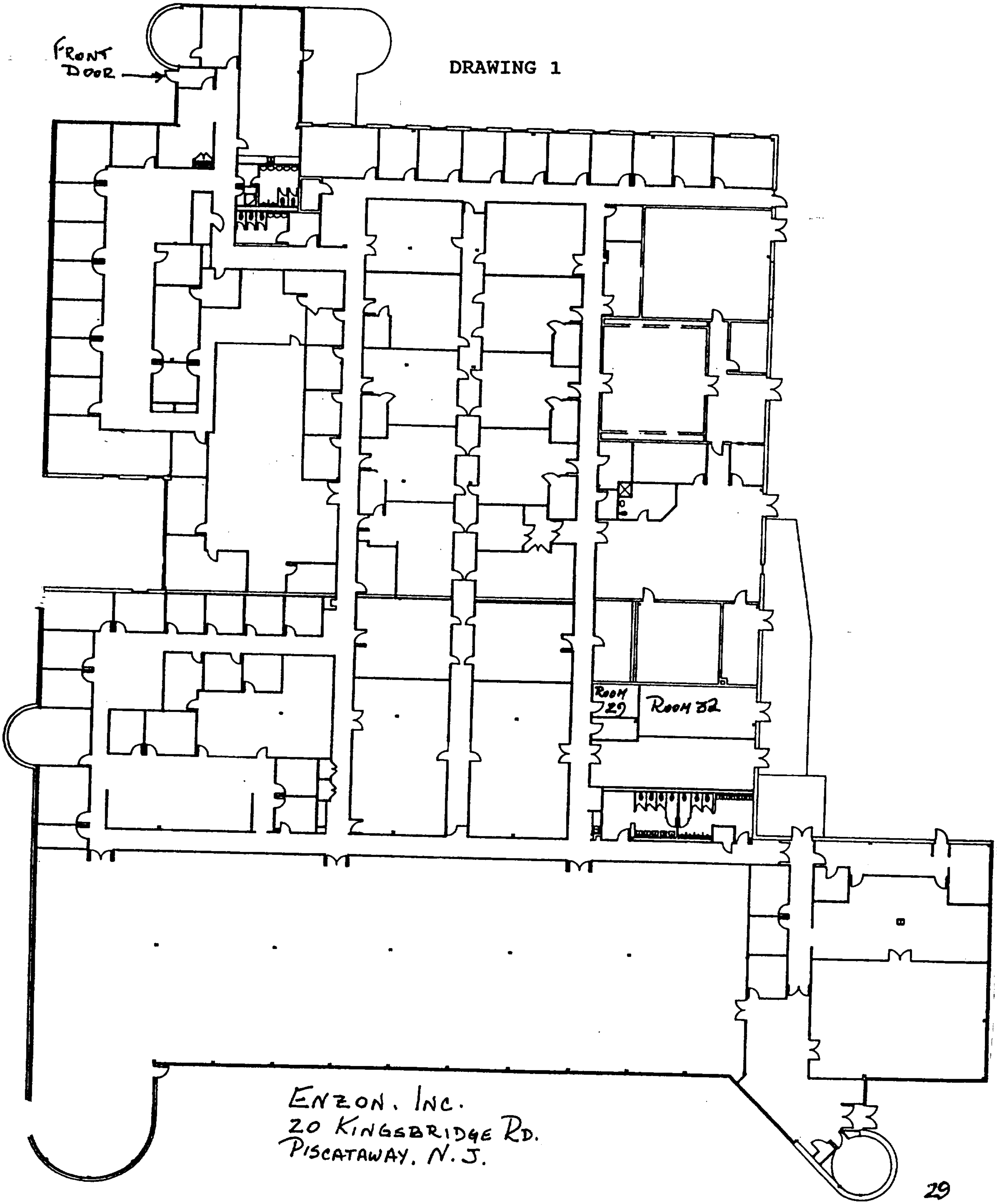
3. In some cases, the liquid waste containers are not stored in the Lucite® waste containers. As such, this liquid waste also requires shielding. Researchers should consult the Radiation Safety Officer to determine the correct type of shielding material for the radioisotope with which they are working.

5.7 Radioactive Waste Management

Radioactive waste (Rad Waste) is generated in the various laboratories that are equipped to perform research using radioisotopes. The Rad Waste is collected, along with the paperwork that goes along with it, from the laboratories and brought to the radioactive materials storage area. An Enzon hazardous materials handler, under the supervision of the Radiation Safety Officer, will go to each laboratory and collect Rad Waste each week. He/she will have a clearly marked cart with proper shielding available to safely move the Rad Waste from the laboratory to the storage area. The radioactive materials storage area contains both the raw materials radioisotopes and the Rad Waste (See Drawing # 1). Room # 32 is for Rad Waste storage and Room # 29 is for raw material radioisotope storage. Room # 32 will be inspected visually once each quarter for container integrity by the Radiation Safety Officer and the inspection will be logged on the RADIATION WASTE INSPECTION RECORD (see Appendix A-12, form 12018).

Both rooms have restricted access. The Rad Waste drums are stored on wooden pallets no more than two tiers high. Each drum is marked for content and date of accumulation. No waste will be held for more than two years from the time of generation. Time of generation is defined as the time the waste barrel is filled and sealed.

DRAWING 1



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5.8 Disposal

Rad Waste disposal is isotope dependent. Some are stored until the level of decay indicates it may be disposed through the sanitary sewer system while others may be removed by a certified Rad Waste handler to a proper off-site disposal location. Table IV gives the method of disposal for the radioisotopes Enzon is licensed to use.

5.9 Other Radioactive Wastes

Gloves, wipes, swabs or other materials that are contaminated with radioactive materials are brought to the central Rad Waste storage area. They are placed in radioactive waste bags which are then placed in the appropriate (by isotope) Rad Waste drum.

TABLE IV

METHOD OF RADIOISOTOPE DISPOSAL

Isotope	Half Life	Method of Disposal
Carbon-14	5715 years	Remove off site
Chromium-51	27.2 days*	Allow to decay - Residue to sanitary sewer if < 10 mg/year
Hydrogen-3	12.3 years**	Remove off site
Iodine-125	59.4 days*	Allow to decay - Residue to sanitary sewer
Iodine-131	8 days*	Allow to decay - Residue to sanitary sewer
Phosphorous-32	14.3 days*	Allow to decay - Residue to sanitary sewer
Phosphorous-33	25.3 days*	Allow to decay - Residue to sanitary sewer
Sulphur-35	87.2 days***	Remove off site if > allowable 0.002 μCi/year

* Total decay is ten (10) half lives with confirmation of counts not above background.

** Dispose of to sanitary sewer system if $\leq$ 0.1 μCi/ml to a maximum of 250 mCi/year

*** Dispose of to sanitary sewer system if $\leq$ 0.002 μCi/ml to a maximum of 500 μCi/year.

NO WASTE SHALL BE STORED ON SITE LONGER THAN TWO (2) YEARS FROM THE TIME OF GENERATION. (Time of generation is defined as the time the waste barrel is filled and sealed.)

6.0 PERSONNEL MONITORING, CONTAMINATION SURVEYS AND SAFETY INSPECTIONS

6.1 Personnel Monitoring Devices

Federal and State regulations require that individuals who could be exposed to sources of radiation in the course of their normal work wear personal monitoring devices (dosimeters). At Enzon, all laboratory personnel are provided with film badge type dosimeters as well as ring type (TLD) dosimeters. Laboratory support, receiving, and building operations personnel are issued badges only. All lab support personnel are required to wear the film badge dosimeters when in a restricted area. Monitoring devices will be supplied by Teledyne Isotopes or an equivalent licensed service.

1. Film badges record the dose received by the whole body. For accurate dose determination the badge should be attached to the researcher's clothing approximately midway between the waist and shoulder. Care should be taken to insure that the film badge holder is not covered with tape or defaced with paint, ink, etc. as these materials can alter the efficiency of the badge.

2. Ring-type (TLD) dosimeters record the radioisotope exposure to the hands and forearms. It is to be worn when laboratory workers are using radioisotopes. The

ring should be worn on the dominant hand with the wide part of the ring on the palm side of the hand. Two pairs of disposable gloves should be worn over the ring and hand whenever a researcher handles radioisotopes. As with film badges, rings must not be covered with tape or defaced as this can alter the accuracy of the reading.

6.2 Distribution of Rings and/or Badges

1. New rings and badges are distributed monthly. When an employee finds a new ring and/or badge in his/her mail slot, he/she should place the old dosimeter in the Corporate Safety Officer's mail slot. In the event that an employee loses his/her dosimeter, he/she should contact the Corporate Safety Officer immediately to get a replacement.

2. Badge dosimeter readings records will be reviewed by the Corporate Safety Officer and records maintained in Human Resources. Each employee assigned a badge or ring type dosimeter will have a DOSIMETER READING RECORD (see Appendix A-13, form 12009) which will be kept by the Corporate Safety Officer.

6.3 Notification and Reports to Individuals

The Radiation Protection Officer will issue a written annual report to everyone who is assigned a dosimeter. This report will contain the person's name, social security number, and the amount of radiation the person has received over the year and will be a copy of the full year's DOSIMETER READING RECORD.

6.4 Monitoring I^{125} and I^{131} Handlers

Radioactive iodine is highly volatile and collects mainly in the thyroid gland. Researchers who handle radioactive iodine or are within a few meters and in the same room as a researcher who is handling the radioisotopes may be given bioassays to determine the concentration of radioactive iodine absorbed by the thyroid.

A bioassay is required when a researcher handles, in open form, quantities of radioactive iodine that exceed those listed in Table V. The quantities shown apply to both the quantity handled at any one time or integrated as the total amount of iodine radioactivity encountered by a researcher over any three-month period. If the quantities handled in open form are less than 10% of those quantities, a bioassay is not required.

As a precaution, every employee who anticipates working with, or coming into contact with, iodine radioisotopes will have a baseline bioassay before working with, or coming into contact with, iodine and the results recorded in the researcher's THYROID

SCAN RECORD (see Appendix A-14, form 12020). This will become the employee's baseline and all subsequent readings will be compared to it (see section 8.7).

TABLE V

ACTIVITY LEVELS ABOVE WHICH BIOASSAY FOR RADIOACTIVE IODINE IS NECESSARY

Types of Operation	Activity Handled in Open Form Making Bioassay Necessary* Volatile or Dispersible	Activity Handled in Open Form Making Bioassay Necessary* Bound to Nonvolatile Agent
Process in open room or bench, with possible escape of iodine from process vessels	1 mCi	10 mCi
Process with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	10 mCi	100 mCi
Process carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	100 mCi	1000 mCi

* Quantities may be considered the cumulative amount in process handled by a researcher in a three-month period.

6.5 Surveys for Contamination

In order for Enzon to ensure a safe work environment with respect to radiation, it is necessary for the radioisotope laboratories to be monitored periodically for radioactive contamination. These surveys are done by the Radiation Safety Officer on a monthly basis unless a laboratory has been used for β >500 μCi or γ >100 μCi. It is the responsibility of the Researchers using β >500 μCi or γ >100 μCi of radioisotope radiation to contact the Radiation Safety Officer and arrange for a weekly laboratory survey. All laboratory surveys will consist of the following:

1. SWIPE TEST - During contamination surveys, swipes are taken from all bench tops, floors, telephones, hoods, door handles and large pieces of equipment. The swipes are counted in a scintillation counter and the researchers are informed of the results by the Radiation Safety Officer. Any swipe showing a reading of ≥200 dpm will be considered contaminated and the responsible researcher informed of the reading by the Radiation Safety Officer verbally and in writing. It is the responsibility of the researcher to decontaminate the area found to be contaminated. Repeat swipes of the contaminated area will be performed two days after the researcher has been informed. If the area continues to give readings of ≥200 dpm, the researcher will again be informed and cleanup will continue until the area shows a reading of <200 dpm. A Beckman Liquid Scintillation Counter, or an equivalent instrument, will be used for β-counts and for γ-counts, a Beckman γ counter, or an equivalent instrument, will be used.

2. INSPECTION FOR UNSHIELDED SOURCES OF RADIATION AND CONTAMINATED INSTRUMENTS - In conjunction with swipe testing, an inspection for contaminated instruments and unshielded sources of radiation is performed using a hand-held survey meter. The survey meter is a standard calibrated G-M tube (Geiger counter) survey meter or a low energy γ scintillator. All bench tops, instruments, waste containers and any device emitting or capable of producing radiation are surveyed. In

addition, any unlabeled tubes, bottles or storage boxes are also surveyed. If any contaminated instruments, bench tops, etc., are found, the responsible researcher will be informed and the researcher is responsible for shielding or decontaminating the contaminated item.

3. RADIATION SAFETY INSPECTIONS - Along with the swipe testing and survey for excessive radiation, the Radiation Safety Officer conducts an inspection of the laboratory. Points covered by the inspection include:

    a. personnel wearing dosimeters

    b. proper disposal and documentation of disposal of radioisotopes

    c. proper shielding during radioisotope use and storage

    d. proper procedures during radioisotope use

    e. use of survey meters during and after radioisotope use.

   Results of the inspection are recorded on the two-sided RADIATION SAFETY INSPECTION REPORT (see Appendix A-15, form 12011) with the original filed with the Radiation Safety Officer, a copy sent to the researcher's supervisor or group leader, and a copy to the Corporate Safety Officer. It is the responsibility of the supervisor or group leader to correct any problems found during an inspection.

7.0 INTERFACILITY TRANSFER OF RADIOISOTOPES

When, during the course of an experiment, a researcher must transport a quantity of radioisotope or isotope tagged material from one facility to another, the researchers shall:

1. Inform the Radiation Safety Officer, the Safety Department, Security, and the recipient of the intended transfer. Security will issue a three-part STRAIGHT BILL OF LADING, marked with a radiation symbol, (see Appendix A-16, exhibit 1) and arrange for transporting the material in the company van.

2. Complete the STRAIGHT BILL OF LADING form to include the type and amount material to be transferred, its radioactivity level, where it's going and to whom it's to be delivered, the date, the researcher's name and signature.

3. Pick up a Lucite® radioisotope container. These containers must be used when transporting radioisotopes between facilities.

4. Package the radioisotope in the container to insure the radioisotope is properly shielded. The material must be packaged to ensure that the radioactive sample cannot leak or be upset in the container.

5. Submit the three-part BILL OF LADING and the package to the Enzon driver for delivery. The recipient will sign upon delivery. Security will keep one part of the form for its records. The other two parts will be delivered with the material.

6. At the receiving site, the researcher will note how much of the material has been used and how it has been used. If any material is left over, its disposition must be noted on the BILL OF LADING.

7. Within 24 hours of all material being used or disposed of and properly noted, one part of the BILL OF LADING will be sent to the Radiation Safety Officer. The third part will be retained by the researcher for his/her records.

8.0 SPECIAL HANDLING

8.1 IODINATIONS

1. During an experiment a researcher may be required to do an iodination. Enzon is required to monitor iodine released to the environment during an iodination to ensure that acceptable environmental limits are not exceeded. All iodinations in quantities < 5 mCi are performed in a hood with a minimal face velocity of 100 cfm (as determined in Enzon's Chemical Hygiene Plan) in a laboratory radioisotope containment area.

2. Before doing an iodination for the first time, the researcher will do a dry run with the Radiation Safety Officer present. The Radiation Safety Officer will again be present for the researcher's first iodination.

3. Twenty-four (24) hours prior to performing an iodination the researcher contacts the Radiation Safety Officer and informs him/her of the intention to perform an iodination. The Radiation Safety Officer will then remove the filters and test the charcoal air samplers located in the fume hood for background iodine by counting the charcoal with a γ counter. After the charcoal has been checked for background radiation, the filters are replaced and the Radiation Safety Officer checks the thyroid of the investigator using a low

energy γ scintillator. The employee is told of the results which are entered on the employee's THYROID SCAN RECORD (Appendix A-14, form 12020). The employee then may begin the iodination.

4. The researcher places all instruments, chemicals etc. he/she expects to use during the iodination in the hood prior to beginning the iodination. At this time the researcher activates the hood fan. The researcher also checks the readings of the rotameters. If the gauges do not indicate the proper readings, the researcher must contact the Radiation Safety Officer so the situation can be corrected prior to performing the iodination. The researcher will ensure that:

   a. The iodination solid waste container is lined with a yellow plastic bag;

   b. There is a liquid waste bottle in the hood;

   c. The work surface of the hood is covered with plastic-backed absorbent paper; and

   d. There are waste disposal forms available for both liquid and solid waste.

5. To enable the Radiation Safety Officer to track I^{125} or I^{131} use the researchers must complete the information requested in the "Iodination Log Book" located in the iodination room. The researcher will fill in the date,

the radioisotope, the start and finish times of the iodination, and the total amount of I^{125} or I^{131} used. This log must be completed within twenty-four (24) hours of the completion of the iodination.

6. When a researcher completes the iodination he/she is responsible for decontamination of the iodination hood. The researcher will dispose of any contaminated material in the proper waste container, complete the required paperwork, decontaminate any contaminated surface in the hood, return the stock of I^{125} or I^{131} to the proper air tight container and turn off the hood fan.

7. Between 24 hours and 72 hours after completion of the iodination, or handling radioactive isotopes, the Radiation Safety Officer will conduct a thyroid check of the employee. If there is any increase in the counts over the baseline recorded on the employee's THYROID SCAN RECORD detected by the scintillator, the employee will be instructed to report for a thyroid scan. Enzon has made arrangements with Teledyne Isotope, or other appropriate, qualified testing facility, to conduct thyroid scans of Enzon employees who may have become contaminated. The Radiation Safety Officer will also inform in writing, the State

Radiation Safety Office and the Corporate Safety Officer of the employee's contamination upon verification.

8. At the completion of the thyroid check the Radiation Safety Officer recounts the charcoal air sample to determine the amount of iodine released during the iodination. This information is recorded in the "Iodination Log Book". The Radiation Safety Officer also monitors the iodination hood for contamination. If any contamination is found, the researcher is responsible for decontamination.

9. Employees who perform iodinations or come in contact with iodine radioisotopes on a regular basis will have quarterly thyroid scans. These scans will be performed by Teledyne Isotope, or other appropriate qualified testing facility. Results of the thyroid scan will be entered will be entered in the employee's THYROID SCAN RECORD and will be made available to the employee at the completion of the bioassay. A copy of the results will be kept in the office of the Radiation Safety Officer and at Human Resources.

8.2 PHOSPHORYLATION

1. During an experiment, a researcher may be required to work with P^{32}, P^{33}, or phosphorous labeled compounds. All reactions in quantities <5 mCi must be performed in radioactive designated areas only. Reactions involving quantities >5 mCi of radioactive phosphorous must be performed in a chemical hood with a minimal face velocity of 100 cfm (as determined in Enzon's Chemical Hygiene Plan) in the laboratory radioisotope containment area.

2. Before doing a phosphorylation for the first time, the researcher will do a dry run with the Radiation Safety Officer present. The Radiation Safety Officer will again be present for the researcher's first phosphorylation.

3. The researcher will take all necessary precautions when working with >1 mCi of radioisotope. These include all general safety procedures listed in section 4.2 of this manual, as well as having access to a Geiger counter at all times.

4. When the researcher is finished working with the phosphorous radioisotope, he/she will remove all

disposable paper and survey the laboratory bench, floor, sinks and any other areas that may have become contaminated with a β-detecting Geiger counter. If there were any spills, the researcher will clean them up and report such spills to the Radiation Safety Officer.

5. Waste, both liquid and solid will be properly labeled, placed in the appropriate container, and noted on the proper log sheet.) (See section 5.5 of this manual.)

9.0 RADIATION CAUTION SIGNS AND LABELS - REQUIREMENTS

1. All radiation caution signs and labels shall use the conventional radiation caution colors (magenta or purple on a bright yellow background) and shall display the standard radiation caution symbol (see Figure 1).

2. All radiation caution signs for radiation areas shall have the radiation caution symbol and the words:

   CAUTION

   RADIOACTIVE MATERIAL

3. All containers in which radioactive materials are stored shall have the radiation caution symbol and the words:

   CAUTION

   RADIOACTIVE MATERIAL

4. The area in which radioactive waste is stored shall be labelled:

   RADIOACTIVE

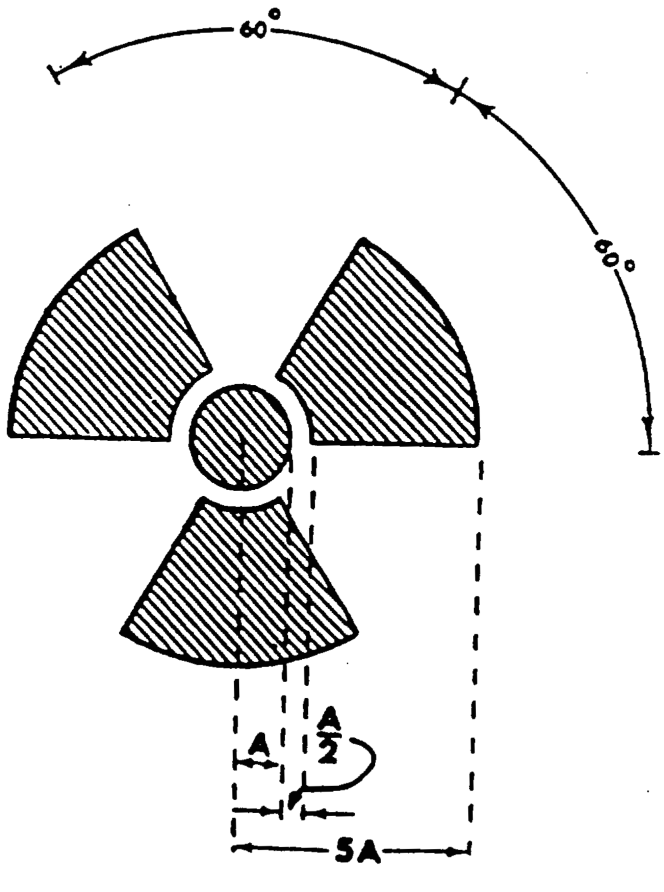
   WASTE

5. In addition to the preceding requirements, radiation caution signs may display further warnings such as "Keep Out", "Danger", "Radioactive Contamination", etc., whenever such warnings are appropriate. In all cases, the Corporate

Safety Department will be responsible for the posting of all radiation areas.

6. Radiation caution signs or labels will be attached to all fume hoods, bacteriological cabinets, containers, laboratory instruments, and other equipment that contain, or are contaminated with, any amount of radioactive material.

FIGURE 1



SPECIFICATIONS (from 10 CFR 20.1901): 1. DIMENSIONS: The standard radiation symbol has the above ratio of dimension, 'A' being any desirable size.

10.0 CALIBRATION OF RADIATION DETECTION INSTRUMENTS

In order to ensure they are functioning properly, all radiation measuring instruments in use will be calibrated on a periodic basis. Hand-held survey meters will be calibrated at six-month intervals by Teledyne Isotopes (license # 29-00055-14) or other qualified facility. When a survey meter requires calibration or repair, it will be collected by the Corporate Safety Officer who will arrange for the calibration. While the survey meter is being calibrated or repaired, researchers will be provided with a replacement meter by the Corporate Safety Officer.

Liquid scintillation and γ counters will be calibrated yearly by the manufacturer's service representative.

Each survey meter will have its own SURVEY INSTRUMENT CALIBRATION RECORD (see Appendix A-17, form 12019) which will be updated whenever it is calibrated, repaired, or retired.

Records of calibrations will be kept on file with the Radiation Safety Officer.

11.0 EMERGENCY PROCEDURES

11.1 Personnel Decontamination

The chief objective in personnel decontamination is to remove the radioactivity from the body as quickly and safely as possible.

1. First, remove all contaminated clothing and monitor the body to specifically locate contaminated skin areas. If the contamination is confined to a small area, i.e., hands and forearms, decontamination may be performed in the local laboratory area. However, if the body is generally contaminated, the person involved will be dressed in expendable clothing and taken to the shower in the first aid room. The Radiation Protection Officer and the Corporate Safety Officer are notified. The contaminated clothing will be collected and disposed of as radioactive waste by the Radiation Safety Officer.

2. Wash contaminated areas thoroughly with soap and water. Do not use a scrub brush. Dry skin completely (especially in the case of alpha contamination) before monitoring. If the contamination remains, repeat the process. If contamination is still present after repeating this process, the Radiation Safety Officer and the Corporate Safety Officer should be consulted.

3. Avoid prolonged use of any one method of decontamination because skin irritation might result and thus impede the success of other procedures as well as lead to possible absorption of contaminated material through breaks in the skin.

4. Appendix C, Part A lists various types of decontamination procedures for personnel who have become contaminated with radioisotopes. The individual should use the first method listed initially and use the remaining procedures in order of presentation until decontamination is achieved. Copies of these procedures are posted in the each radioisotope laboratory and the first aid room. In the event these procedures are not posted in the laboratory, copies are available from the Radiation Safety Officer or the Corporate Safety Officer.

5. After the decontamination procedure has been shown to be effective, the researcher will write an accident report. One copy will go to the Corporate Safety Officer and one to the Radiation Safety Officer. Supplies used in the decontamination procedure will be replaced so the emergency decontamination kit is fully supplied.

11.2 Area and Material Decontamination

In the event of a spill or suspected spill of radioactive material where the material does not become airborne, use common sense, keep calm, protect people, and do not spread contamination (always assume you are contaminated until a survey proves differently). Each laboratory where radioactive material is used will contain a spill kit. The kit will contain five (5) pairs of disposable latex gloves, absorbent paper, paper towels, a yellow disposal bag, tape labeled "Radioactive," cleaning solution and tongs. Use the spill kit along with the following guidelines.

1. Confine the contamination. Localize the spill. If the spill is liquid and your hands are protected, set the container upright and drop absorbent material on the spill. Damp down a dry spill. If your hands are ungloved, use the tongs in the spill kit or put on two pairs of disposable latex gloves.

2. CALL, DO NOT GO FOR HELP, IF POSSIBLE. Do not track contamination about the laboratory. Close the doors and, where possible, adjust the ventilation to prevent the spread of airborne contamination.

3. Appendix C, Part B lists various types of area and material decontamination procedures. The researcher should use the first method listed initially and use the remaining procedures in order of presentation until decontamination is achieved. Copies of these procedures are also posted in each radioisotope laboratory. In the event that these procedures are not posted in a lab, copies are available from the

Radiation Safety Officer or the Corporate Safety Officer.

4. After the spill has been contained, cleaned, surveyed and pronounced safe by the Radiation Safety Officer, the researcher will write an accident report. One copy will go to the Corporate Safety Officer and one to the Radiation Safety Officer. The spill kit will be replenished so it again is fully supplied.

11.3 Extreme Hazards

In the case of extreme hazards, e.g., high radiation levels or the possibility of airborne contamination from dry volatile radioactive materials, EVACUATE the laboratory IMMEDIATELY. If possible turn off the hoods, fans, etc. Close and lock the door or stand guard to prevent entrance to the laboratory. Have the Radiation Safety Officer or the Corporate Safety Officer and Security summoned immediately. If you must leave the area to call, remove your shoes if you suspect contamination and do not touch anything unnecessarily.

11.4 Fire or Explosion

Usually, radioactive materials on hand are of such small quantities that there is little intrinsic danger of fire or explosions. Secondary hazards to fires or explosions would be possible breakage, spillage and spread of radioactive contamination. Employees must be aware of the flammable characteristics of the materials with which they must work. Also, the possibility that certain electrical equipment can cause sparks or excessive heat should be realized so that, as far as possible, departments should use explosion-proof refrigerators, centrifuges, motors, and other electrical equipment.

The Corporate Safety Officer is available for consultation and recommendations concerning fire prevention and assistance in establishing adequate controls.

In the event of fire or explosion:

1. Give the alarm within the building.
2. Call the Fire Department, **9-562-2333**.
3. Make sure the building is evacuated.
4. Have someone meet the Fire Department to show them where the fire is and to explain to them the possible hazards due to the presence of radioactive materials in the area.
5. If there is time, try to extinguish the fire with available equipment and, if possible, safely prevent the involvement of radioactive materials in the incident.

11.5 Radiological First Aid

1. In the event of an internal exposure the following radiological first aid procedures should be used prior to the arrival of medical personnel for the type of exposure listed:

   a) Ingestion - Individuals accidentally swallowing material containing radioisotopes will be treated for poisoning to remove the maximum amount of material as quickly as possible. It is of prime importance to obtain immediate medical attention for the victim. This is done by calling **9-562-2333** for emergency medical care assistance. Designated Enzon emergency response personnel will also be called to stabilize the victim until help arrives. Until direct medical supervision has been obtained it is recommended that vomiting be induced in a conscious person under certain circumstances; however, if the liquid is a solvent or corrosive material do not induce vomiting. Gentle stroking or touching the soft palate (or back of throat) with the finger or tongue depressor will aid vomiting when the stomach is full of fluid. Remove individual to a uncontaminated area of the building as soon as possible. If an emetic is required, give two tablespoons of syrup of ipecac, undiluted. One to three teaspoonful of powdered mustard in a glass of warm water can also be used. An emetic should not be given after poisoning by solvents or corrosive liquids such as alkalies nor should it be given if the victim is vomiting.

b) Inhalation - The following is suggested if air-borne radioactive isotopes are inhaled: material from the nasal passages should be removed with Q-tips. Irrigating nasal passages by sniffing dilute salt solution (½ teaspoon of salt in a glass of lukewarm water) up the nose will remove particles. Gargling with dilute warm salt solution is also recommended. The use of nasal irrigation should be avoided unless under medical supervision. Removal of the remainder of the foreign material in the respiratory tract should be performed under the direct supervision of a qualified physician.

c) Cuts and Punctures - Individuals cut by broken glassware, other sharp objects or injured with hypodermic needles, that are contaminated with radioisotopes should wash the wound immediately under a strong jet of water. The injured individual should contact the Radiation Safety Officer and a determination of the severity of the accident will be made. If warranted, the injured individual will be taken to a hospital emergency room by paramedical personnel for treatment.

12.0 RADIOLOGICAL ACCIDENT REPORTS

When radioisotopes or sources of ionizing radiation are involved in a fire, explosion, theft, loss of control, spill, overexposure of personnel, or any other type of accident, the agencies listed in Appendix D will be contacted as required by law in the manner prescribed below. In all instances where reports must be submitted or notification made to the regulatory agency, commission or bureau listed in Appendix D, or any other requesting agency, the reports and notifications will be made by the Corporate Safety Officer and the Radiation Safety Officer.

12.1 Radiation Protection Accident Reports

1. In the event of any accident, such as those listed above, involving radioisotopes or ionizing radiation, the Radiation Safety Officer and the Corporate Safety Officer shall be notified immediately by telephone.

2. In all instances involving overexposure of individuals, spills or loss of control of radioisotopes, a written report will be prepared within twenty-four (24) hours after the accident has occurred. This report will be prepared by the Radiation Safety Officer and will contain the following:

   1. The name and location of the organization where the accident occurred.

   2. The name of each individual involved.

   3. The source of the ionizing radiation and, if radioisotopes are involved, the element, chemical and physical form, and the activity level.

   4. A brief description of how the accident occurred.

   5. Corrective steps that will be taken to prevent a recurrence of the incident.

6. A signed statement from each individual involved, relating his/her actions prior to and after the exposure. This statement will be filed with the individual's exposure record which is kept in Human Resources.

APPENDIX A

RADIOISOTOPE FORMS

A- 1 INSTRUCTION ON RADIOISOTOPES (12000)

A- 2 INSTRUCTION ON RADIOISOTOPE SAFETY (12001)

A- 3 INSTRUCTION CONCERNING PRENATAL EXPOSURE (12002)

A- 4 REQUEST FOR PURCHASE ORDER (12003)

A- 5 RADIOISOTOPE RECEIVING FORM (12004)

A- 6 RADIOISOTOPE INVENTORY CONTROL (12007)

A- 7 SOLID WASTE DISPOSAL RECORD (12006)

A- 8 LIQUID WASTE DISPOSAL RECORD (12005)

A- 9 DISPOSAL TO SANITARY SEWER SYSTEM RECORD (12012)

A-10 LIQUID P^{32} WASTE DISPOSAL RECORD (12008)

A-11 SOLID P^{32} WASTE DISPOSAL RECORD (12010)

A-12 RADIOACTIVE WASTE INSPECTION RECORD (12018)

A-13 BADGE DOSIMETER READING (12009)

A-14 THYROID SCAN RECORD (12020)

A-15 RADIATION SAFETY INSPECTION (12011)

A-16 STRAIGHT BILL OF LADING (Exhibit 1)

A-17 SURVEY INSTRUMENT CALIBRATION RECORD (12019)

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INSTRUCTION ON RADIOISOTOPES

This is to acknowledge that I have been given general instruction about radioisotopes. I have been given the opportunity to ask questions about radioisotopes and radiation.

Name

Social Security #

Signature

Date

Instructor

12000(4/1/93)

ENZON, Inc.

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INSTRUCTION ON RADIOISOTOPE SAFETY

This is to acknowledge that I have been given a four (4) hour instructional course on Radioisotope Safety. I have received the Enzon Radioisotope Safety Manual. I have been given the opportunity to ask questions about radioisotopes and radiation.

Name

Social Security #

Signature

Date

Instructor

12001(4/1/93)

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INSTRUCTION CONCERNING PRENATAL EXPOSURE

This is to acknowledge that I was given specific instruction concerning prenatal exposure risks to the developing embryo and fetus. The U.S. Nuclear Regulatory Commission Rules and Regulations 10 CFR 20.1208 has been presented orally and in written form. I was also given the opportunity to ask questions.

I am also aware of my responsibility to notify my supervisor, the Radiation Safety Officer

and the Corporate Safety Officer at my first indication of pregnancy.

____________________ Name

____________________ Social Security #

____________________ Signature

____________________ Date

____________________ Instructor

12002(Rev. 7/19/93)

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REQUEST FOR PURCHASE ORDER

This form must be completed and accompany the Purchase Requisition Form sent to the Radiation Safety Officer.

Requisition Order No. ______________________ Date ______________

Information on Requested Order			Inventory
Principal Radioisotopes	Activity (μCi, mCi, Ci)	Physical and Chemical Form	Activity on Hand* (μCI, mCi, Ci)

Expected delivery date, if known ______________________________

*Corrected Decay activity of requested radioisotopes at time of procurement.

____
Signature of Authorized User

____
Signature of Radiation Safety Officer

12003(Rev. 7/20/93)

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ENZON, Inc.

RADIOISOTOPE RECEIVING FORM

Purchase Order No. ____________________ P.O. Date ________________

Authorized User: ____________________

Principal Radioisotopes	Physical and Chemical Form	Activity (μCi, mCi)

Upon receipt the integrity of the package (was, was not) intact.

ontamination Survey Results:

Package Exterior _____ dpm/100 cm^2
________ Transport Index (millirem/hr at 3 feet)
________ millirem/hr at surface of shipping container

If the integrity of the package was not intact or if the contents of the inner package disagrees with that given on the packing slip contact the Radiation Safety Officer immediately.

Received by:__________________________ Date:________________

__________ millirem/hr at surface of inner container
Inside Contents ___ dpm/100 cm^2

Storage location: Room ________ Bldg. ____________

The contents of the inner package (agrees, disagrees) with the radioisotope and quantity listed on the packing slip.

Signature:________________________________ Date: ______________

Radioactive isotopes are to be used only in experiments and locations for which its use has been approved by .e Radiation Safety Officer.

COPY OF THIS COMPLETED FORM MUST BE SENT TO THE Radiation Safety Officer WITHIN 24 HOURS OF RECEIVING MATERIALS.

12004(Rev. 7/20/93)

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RADIOISOTOPE INVENTORY CONTROL

Radioisotope ______________________________ P.O.# ______________

Date Received ______________________________

Date Received	Amount Used	Amount Remaining	Signature

12007(Rev. 7/20/93)

ENZON, Inc.

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SOLID WASTE DISPOSAL RECORD

Authorized User: ______________ Drum No. *______________

Starting Date: ______________ Shipment Date: ______________

Date	Radioisotope	Amount (μCi)	Lab #	Form (glass, paper, etc)	Signature

*This number is provided by the Radiation Safety Officer when the drum is picked-up.

Attach this form to the disposal drum and make the required entries for each disposal.

The authorized user must keep a file of these forms when they are removed from the disposal drum at the time of the shipment.

The records must be available to the Radiation Safety Officer upon request.

12006(4/1/93)

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DISPOSAL TO SANITARY SEWER SYSTEM RECORD

RADIO-ISOTOPE	VOLUME	DPM/ml	% DAILY ALLOWANCE	DATE	SIGNATURE	ROOM/SINK

12012(7/19/93)

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LIQUID WASTE DISPOSAL RECORD
AQUEOUS/ORGANIC

Authorized User: ____________________ Location: ____________________

Starting Date: ____________________ Shipping Date: ____________________

Date	Radioisotope	Amount (μCi)	Added Agents	Signature

Attach this form to the waste container and make the required entries for each disposal.

The authorized user must keep a file of these forms when they are removed from the waste container at the time of shipment.

The records must be available to the Radioactive Protection Officer upon request.

12005(Rev. 7/20/93)

ENZON, Inc.

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LIQUID P^{32} WASTE DISPOSAL RECORD
AQUEOUS/ORGANIC

Authorized User: ____________________ Location: ____________________

Starting Date: ____________________ Shipping Date: ____________________

Date	Radioisotope	Amount (μCi)	Added Agents	Signature

Attach this form to the waste container and make the required entries for each disposal.

The authorized user must keep a file of these forms when they are removed from the waste container at the time of shipment.

The records must be available to the Radioactive Protection Officer upon request.

12008(Rev. 7/20/93)

ENZON, Inc.

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SOLID P^{32} WASTE DISPOSAL RECORD

Authorized User: ____________________ Drum No. •____________________

Starting Date: ____________________ Shipment Date: ________________

Date	Radio-Isotope	Amount(μCi)	Lab #	Form (glass, paper, etc.)	Signature

•This number is provided by the Radiation Safety Officer when the drum is picked-up.

Attach this form to the disposal drum and make the required entries for each disposal.

The authorized user must keep a file of these forms when they are removed from the disposal drum at the time of the shipment.

The records must be available to the Radiation Safety Officer upon request.

12010(Rev 7/20/93)

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ENZON, Inc.

RADIATION WASTE INSPECTION RECORD

I have inspected the containers in the Radioactive Waste Storage area for leakage and integrity.

______________________	______________________
Date	Signature

12018 (7/20/93)

ENZON, Inc.

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DOSIMETER READINGRECORD

Name ____________________ SS #: ________________

Dosimeter Reading (millirem)							
	Badge Reading (millirem)			Ring Reading (millirem)			
Date	Start	End	Dose	Start	End	Dose	Remarks

This report is furnished to you under the provisions of the Nuclear Regulatory Commission regulation 10 CFR Part 19. You should preserve this report for further reference.

12009(Rev. 7/20/93)

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ENZON, Inc.

THYROID SCAN RECORD

Employee Name: ____________________ Social Security #: ____________________

Baseline Reading: ____________________ Baseline Date: ________________

Date	Thyroid scan number	Instrument	Instrument Baseline	Reading	Scan Preformed By	Comments

12020(7/28/93)

ENZON, Inc.

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RADIATION SAFETY INSPECTION

Inspected by: ____________________ Date:____________

To: ______________________________________

The Radioisotope Laboratory was inspected for the following:

a. Personnel using film badges and rings
b. Proper radioisotope disposal and documentation of radioisotope disposal
c. Proper shielding during radioisotope use
d. Proper procedures during radioisotope use
e. Use of survey meters during radioisotope use.

During the inspection the following was observed:

a. Researchers who were not wearing film badges and/or rings

b. Improper waste disposal or documentation

c. Improper shielding during radioactive isotope use

Straight Bill of Lading 44-301

Carbonless
WilsonJones SNAP-A-WAY FORMS

Original-Not Negotiable **Straight Bill of Lading** Short Form

Shipper's No. ______________

____ Carrier's No. ______________
(Name of Carrier)

RECEIVED, subject to the classifications and tariffs in effect on the date of the issue of the Bill of Lading,

at ______________ 19 ______ From ______________

the property described below, in apparent good order, except as noted (contents and conditions of contents of packages unknown), marked, consigned, and destined as indicated below, which said carrier (the word carrier being understood throughout this contract as meaning any person or corporation in possession of the property under the contract) agrees to carry to its usual place of delivery at said destination, if on its own route, otherwise to deliver to another carrier on the route to said destination. It is mutually agreed, as to each carrier of all or any of said property over all or any portion of said route to destination, and as to each party at any time interested in all or any of said property, that every service to be performed hereunder shall be subject to all the terms and conditions of the Uniform Domestic Straight Bill of Lading set forth (1) in Official, Southern, Western and Illinois Freight Classification in effect on the date thereof, if this is a rail or rail-water shipment, or (2) in the applicable motor carrier classification or tariff if this is a motor carrier shipment.

Shipper hereby certifies that he is familiar with all the terms and conditions of the said bill of lading, including those on the back thereof, set forth in the classification or tariff which governs the transportation of this shipment, and the said terms and conditions are hereby agreed to by the shipper and accepted for himself and his assigns.

Consigned to ____
(Mail or street address at consignee—For purposes of notification only.)

Destination ______________ State ______ Zip ______ County ______________ Delivery Address ★ ______________

★To be filled in only when shipper desires and governing tariffs provide for delivery thereof.)

Route ____

Delivering Carrier ______________ Car or Vehicle Initials ______________ No. ______________

No. Packages	Kind of Package, Description of Articles, Special Marks, and Exceptions	*WEIGHT (Subject to Correction)	Class or Rate	Check Column
	RADIOACTIVE			

Subject to Section 7 of Conditions of applicable bill of lading, if this shipment is to be delivered to the consignee without recourse on the consignor, the consignor shall sign the following statement:
The carrier shall not make delivery of this shipment without payment of freight and all other lawful charges.

____
(Signature of Consignor)

If charges are to be prepaid, write or stamp here; "To be Prepaid."

Received $ ______________
to apply in prepayment of the charges on the property described hereon.

____
Agent or Cashier

Per ______________
(The signature here acknowledges only the amount prepaid.)

Charges Advanced:

$ ______________

*If the shipment moves between two ports by a carrier by water, the law requires that the bill of lading shall state whether it is carrier's or shipper's weight.

NOTE—Where the rate is dependent on value, shippers are required to state specifically in writing the agreed or declared value of the property.
The agreed or declared value of the property is hereby specifically stated by the shipper to be not exceeding
per

†The fibre boxes used for this shipment conform to the specifications set forth in the box maker's certificate thereon, and all other requirements of the Consolidated Freight Classification.

†Shipper's imprint in lieu of stamp; not a part of Bill of Lading approved by the Interstate Commerce Commission.

______________ Shipper, Per ______________ Agent, Per ______________

1

Permanent post-office address of shipper, ______________

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WilsonJones
44-301 3-PART PRINTED IN U.S.A.
Carbonless

STRAIGHT BILL OF LADING

ENZON, Inc.

Adding time to life.®

SURVEY INSTRUMENT CALIBRATION RECORD

Instrument: ______________________________

Serial #: ________________________________

Date	Calibrated by	Record on file	Attested by

12019(7/20/93)

APPENDIX B

RADIOISOTOPE INFORMATION

APPENDIX B

RADIOISOTOPE INFORMATION

RADIO-ISOTOPE	HALF LIFE	TYPE OF DECAY	MAJOR RADIATION	APPROXIMATE ENERGIES (MeV)	SHIELD Pb HVL (cm)	SPECIAL PRECAUTIONS
P^{32}	14.3 days	β^-	β^-	1.710	A	
P^{33}	25.3 days	β^-	β^-	0.249	A	
I^{125}	59.4 days	E.C.	γ	0.179	B 0.0037 cm	NaI form Volatile
I^{131}	8.0 days	β^-	β^-	0.971	B	
H^3	12.3 years	β^-	β^-	0.186	A	
C^{14}	5715 years	β^-	β^-	0.156	A	
S^{35}	87.2 days	β^-	β^-	0.167	A	
Cr^{51}	27.2 days	E.C.	γ	0.751	B	

SHIELDING

A = Lucite®
B = Lead

DECAY

β = beta
E. C. = Electron Capture

RADIATION

β^- = beta particle
γ = gamma ray

APPENDIX C

GUIDE FOR PERSONNEL AND MATERIAL DECONTAMINATION

Part A - Personnel Decontamination

Part B - Material Decontamination

APPENDIX C

PART A

Personnel Decontamination Procedures

PERSONNEL DECONTAMINATION

Method	Surface	Action	Technique	Advantages	Disadvantages
Soap & Water	Skin & Hands	Emulsifies and dissolves contaminate	Wash 2-3 minutes and monitor. Do not wash more than 3-4 times.	Readily available and effective for most radioactive contamination.	Continued washing will defat the skin. Indiscriminate washing of other than affected parts may spread contamination.
Soap & Water	Hair	Same as above	Wash several times. If contamination is not lowered to acceptable levels, shave the head and apply skin decontamination methods.		
Lava soap, soft brush, and water	Skin	Emulsifies, dissolves, and erodes.	Use light pressure with heavy lather. Wash for 2 minutes, 3 times. Rinse and monitor. Use care not to erode the skin. Apply lanolin or hand cream to prevent chapping.	Same as above	Continued washing will abrade the skin.
Tide or other detergent (plain)	Same as above	Same as above	Make into a paste. Use with additional water with mild scrubbing action. Use care not to erode the skin.	Slightly more effective than washing with soap.	Will defat and abrade skin and must be used with care.

Method	Surface	Action	Technique	Advantages	Disadvantages
Mixture of 50% Tide and 50% cornmeal	Skin & Hands	Emulsifies, dissolves, and erodes.	Make into a paste. Use with additional water with a mild scrubbing action. Use care not to erode the skin.	Slightly more effective than washing with soap.	Will defat and abrade skin and must be used with care.
5% water solution of mixture of 30% Tide, 65% Calgon, 5% Carbose (carboxymethyl cellulose)	Same as above.	Same as above.	Use with water. Rub for a minute and rinse.	Same as above.	Same as above.
A preparation of 8% Carbose, 5# Tide , 1% Versene and 88% water homogenized into a cream.	Same as above.	Same as above.	Use with additional water. Rub for 1 minute and wipe off. Follow with lanolin or hand cream.	Same as above.	Same as above.
Mix equal volumes of a saturated solution of potassium permanganate (6.4 gm $KMnO_4$/100 mL H_2O) and 0.2N H_2SO_4. Continue with the next step.	Skin, hands, and extremitie s. Do not use near face or other body openings.	Dissolves contaminant absorbed in the epidermis.	Pour over wet hands, rubbing the surface and using hand brush for NOT more than 2 minutes. Rinse with water.	Superior for skin contamination. May be used in conjunction with titanium oxide.	Will remove a layer of skin if in contact with the skin for more than 2 minutes.

Begin with the first listed method and then proceed, step by step, to the more severe methods, as necessary.

Method	Surface	Action	Technique	Advantages	Disadvantages
Apply a freshly prepared 5% solution of sodium acid sulfite (5 gm $NaHSO_3$/100 mL H_2O).	Same as above.	Removes the permanganate stain.	Apply in the same manner as above. Apply for NOT more than 2 minutes. The above procedure may be repeated. Apply lanolin or hand cream when completed.		Same as above.
Flushing	Eyes, ears, nose, and mouth.	Physical removal by flushing.	Roll back the eyelid as far as possible. Flush with large amounts of water. If isotonic irrigant (9 gm NaCl to 1 L H_2O) is available, use it without delay. Apply to eye continually and then flush with large amounts of water. Further decontamination should be under medical supervision.	If used immediately will remove contamination. May also be used for ears, nose, and throat.	When using for nose and mouth, contaminated individual should be warned NOT TO SWALLOW the rinses.

Begin with the first listed method and then proceed, step by step, to the more severe methods, as necessary.

Method	Surface	Action	Technique	Advantages	Disadvantages
	Wounds	Physical removal by flushing.	Wash wound with large amounts of water and spread edges to stimulate bleeding, if not profuse. If profuse, stop bleeding first, clean edges of wound, bandage, and if any contamination remains, it may be removed by normal methods, as above.	Quick and efficient if wound is not severe.	May spread contamination to other areas of body if not done carefully.
Sweating	Skin of hands and feet	Physical removal by sweating	Place hand or foot in plastic glove or booty. Tape shut. Place near source of heat for 10-15 minutes or until hand or foot is sweating profusely. Remove glove and then wash using standard techniques. Or gloves can be worn for several hours using only body heat.	Cleansing action is from inside out. Hand does not dry out.	If glove or booty is not removed shortly after profuse sweating starts and part wash with soap and water immediately, contamination may seep into the pores.

Begin with the first listed method and then proceed, step by step, to the more severe methods, as necessary.

APPENDIX C

PART B

Area and Material Decontamination Procedures

AREA AND MATERIAL DECONTAMINATION

Method	Surface	Action	Technique	Advantages	Disadvantages
Vacuum Cleaning	Dry surfaces	Removes contaminated dust by suction	Use conventional vacuum technique with efficient filter (HEPA).	Good on dry, porous surfaces. Avoids water reactions.	All dust must be filtered out of exhaust. Machine is contaminated.
Water	All nonporous surfaces (metal, painted, plastic, etc.).	Dissolves and erodes.	For large surfaces: Hose with high pressure water at an optimum distance of 15 to 20 feet. Spray vertical surface at an angle of incidence of 30° to 40°. Work from top to bottom to avoid recontamination. Work upwind to avoid spray. Determine cleaning rate experimentally, if possible. Otherwise, use a rate of 4 square feet/minute.	All water equipment may be utilized. Allows operation to be carried out from a distance. Contamination may be reduced by 50%. Water equipment may be used for solutions of other decontaminating agents.	Drainage must be controlled. Not suitable for porous materials. Oiled surfaces cannot be decontaminated. Not applicable on dry contaminated surfaces (use vacuum). Not applicable on porous surfaces such as wood, concrete, canvas, etc. Spray will be contaminated.
	All surfaces	Dissolves and erodes.	For small surfaces: Blot up liquid and wipe water and appropriate commercial detergent.	Extremely effective if done immediately after a spill and on nonporous surface.	Of little value in decontamination of large areas, longstanding contaminants, and porous surfaces.

Begin with the first listed method and then proceed, step by step, to the more severe methods, as necessary.

Method	Surface	Action	Technique	Advantages	Disadvantages
Steam	Nonporous surfaces (especially painted or oiled surfaces)	Dissolves and erodes.	Work from top to bottom and from upwind. Clean surface at a rate of 4 square feet/minute. Cleaning efficiency will be greatly increased by using detergents.	Contamination may be reduced approximately 90% on painted surfaces.	Steam subject to the same limitations as water. Spray hazard makes wearing water-proof outfits necessary.
Detergents	Nonporous surfaces (metal, painted, plastic, etc.)	Emulsifies contaminant and increases wetting power of water and cleaning efficiency of steam.	Rub surface 1 minute with a rag moistened with detergent solution. Use clean surface of the rag for each application. Then wipe with dry rag. Use clean surface of the rag for each application. Use a power rotary brush with pressure feed for more efficient cleaning. Apply solution from a distance with a pressure proportioner. Do not allow solution to drip onto other surfaces. Mist application is all that is necessary.	Dissolves industrial film and other materials which hold contamination. Contamination may be reduced by 90%.	May require personal contact with surface. May not be efficient on long-standing contamination.

Begin with the first listed method and then proceed, step by step, to the more severe methods, as necessary.

Method	Surface	Action	Technique	Advantages	Disadvantages
Complexing Agents	Nonporous surfaces; especially un-weathered surfaces, i.e., no rust or calcareous growth	Forms soluble complexes with contaminated material.	Complexing agent solution should contain 3% (by weight) of agent. Spray surface with solution. Keep surface moist 30 minutes by spraying periodically. After 30 minutes, flush material with water. Complexing agents may be used on vertical and overhead surfaces by adding chemical foam (sodium carbonate or aluminum sulfate).	Holds contamination in solution. Contamination may be reduced by 75% in 4 minutes on unweathered surfaces. Easily stored, carbonates and citrates are nontoxic and noncorrosive.	Requires application for 5 to 30 minutes. Little penetrating power. Of little value on weathered surfaces.
Organic solvents	Nonporous surfaces (greasy or waxed surfaces, paint or plastic finishes, etc.).	Dissolves organic materials (oil, paint, etc.).	Immerse entire unit in solvent or apply by wiping procedure (see Detergents).	Quick dissolving action. Recovery of solvent possible by distillation.	Requires good ventilation and fire precautions. Toxic. Material bulky.

Begin with the first listed method and then proceed, step by step, to the more severe methods, as necessary.

Method	Surface	Action	Technique	Advantages	Disadvantages
Inorganic Acids	Metal surfaces (especially porous deposits, i.e., rust or calcareous growth), circulatory pipe systems	Dissolves porous deposits.	Use dip-bath procedure for movable items. Acid should be kept at a concentration of 1 to 2 N (9 to 18% HCl; 3 to 6% H_2SO_4). Leave on weathered surfaces 1 hour. Flush surface with water, scrub with water-detergent solution and rinse. Leave in pipe circulatory system 2 to 4 hours. Flush with plain water, then a water-detergent solution, and then again with plain water.	Corrosive action on metal and porous deposits. Corrosive action may be moderated by addition of corrosion inhibitors to solution.	Personal hazard. Wear goggles and rubber boots, gloves and apron. Good ventilation required because of toxicity and explosive gases. Acid mixtures should not be heated. Possibility of excessive corrosion if used without inhibitors. Sulfuric acid nor effective on calcareous deposits.
Acid mixtures: hydrochloric, sulfuric, acetic, citric acids, acetates, citrates	Nonporous surfaces (especially with porous deposits), circulatory pipe systems.	Dissolves porous deposits.	Same as for inorganic acids. A typical mixture consists of 380 ml HCl, 91 gm sodium acetate in 3.8 L water.	Contamination may be reduced by 90% in 1 hour on unweathered surfaces. More easily handled than inorganic acid solution.	Weathered surfaces may require prolonged treatment. Same safety precautions as required for inorganic acids.

Begin with the first listed method and then proceed, step by step, to the more severe methods, as necessary.

Method	Surface	Action	Technique	Advantages	Disadvantages
Caustics: sodium hydroxide calcium hydroxide potassium hydroxide	Horizontal painted surfaces	Softens paint, harsh method.	Allow paint remover solution to remain on surface until paint is softened to the point where it may be washed off with long-handled scrapers. (Typical paint remover solution: 38 L water, 1.81 kg NaOH, 2.7 kg boiler compound, 340 gm cornstarch.)	Minimum contact with contaminated surfaces. Easily stored.	Personal hazard - will cause burns. Reaction slow and cannot be used on vertical or overhead surfaces. Not to be used on aluminum or magnesium.
Trisodium phosphate	Vertical or overhead painted surfaces	Softens paint, mild method.	Apply hot 10% solution by rubbing and wiping procedure (see Detergent).	Contamination may be reduced to tolerance in one or two applications.	Destructive effect on paint. Should not be used on aluminum or magnesium.
Abrasion	Nonporous surfaces.	Removes surface.	Use conventional procedures, such as sanding, filing, and chipping. Keep surface damp to avoid dust hazard.	Contaminant may be reduced to as low a level as desired.	Impractical for porous surfaces because of penetration by moisture.
Sandblasting	Nonporous surfaces.	Removes surfaces.	Keep sand wet to lessen spread of contamination. Collect used abrasive or flush away with water.	Practical for large surface areas.	Contamination spread over area must be removed. Contaminated dust is hazardous.

Begin with the first listed method and then proceed, step by step, to the more severe methods, as necessary.

Method	Surface	Action	Technique	Advantages	Disadvantages
Vacuum blasting	Porous and nonporous surfaces.	Removes surface. Traps and controls contaminated waste.	Hold tool flush to surface to prevent contaminant escape.	Contaminated waste ready for disposal. Safest abrasion method.	Contamination of equipment.

Begin with the first listed method and then proceed, step by step, to the more severe methods, as necessary.

APPENDIX D

AGENCIES TO BE NOTIFIED AFTER AN EMERGENCY

UNITED STATES NUCLEAR REGULATORY COMMISSION
475 Allendale Road
King of Prussia PA 19406

24 hour phone 215-337-5000

FTS 215-346-5000

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