

0398  
M2

# Nuclear Medicine Associates, Inc.

April 24, 1984

Patricia C. Vacca  
Material Licensing Branch  
Division of Fuel Cycle and  
Material Safety  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555

Re: Control #16016  
'84 MAY 11 P3:30

Dear Ms. Vacca:

This letter is in response to your request for further information regarding the new license application for Ohio Isotopes, Inc. The items in this response are intended to correspond numerically to the questions in your letter dated March 1, 1984.

1. A. The new name the organization has incorporated under is "Ohio Isotopes, Inc."
- B. All commitments made in the October 10, 1983 application filed by Centra-Pharm, Inc. are accepted as binding by Ohio Isotopes, Inc.
- C. All procedures, instructions and other documents prepared in support of the October 10, 1983 license application that specify the name "Centra-Pharm, Inc." will be changed to reflect the name "Ohio Isotopes, Inc."
2. The possession limits desired are provided on the marked copy of Enclosure 1 for the various items.
3. Authorization is requested for Mr. George Hinkle and Mr. Robert D. Yatsu as users for Groups I - V. Please refer to NRC license #34-18174-MD for Mr. Hinkle's training and experience. Please refer to NRC license #35-19008-MD for Mr. Yatsu's training and experience.
4. Mr. Lefevre is listed as the President and day-to-day radiation safety officer of the organization. Among his responsibilities and duties will be active participation in all aspects of the daily operation of the radiopharmacy. The radiation safety officer's duties will constitute approximately 15% of Mr. Lefevre's responsibilities. Other duties, such as calling on accounts, may require Mr. Lefevre to leave the premises. During his absence, an authorized user, designated by Mr. Lefevre, will assume the duties of the RSO and ensure compliance with the NRC's regulations consistent with the terms and conditions of the license.

8509130427 850827  
REG3 LIC30

PDR



5. Included as part of Enclosure #2 is a list of tenants located in the same building as Ohio Isotopes, Inc. Additionally, a map and pictures of surrounding area provides detailed information about the neighborhood in which Ohio Isotopes, Inc. is located.

The operation of a nuclear pharmacy does not conflict with local codes or zoning laws.

Local fire departments will be informed that Ohio Isotopes, Inc. intends to operate a radiopharmacy located at 2937 Switzer Road, Columbus, Ohio 43219. The letter that will be sent informing the fire departments of said location, along with a facilities diagram, is included as Enclosure #3. Additionally, the enclosed guide for emergency handling of a radioactive fire will be sent with the letter to the fire department.

6. A. Revised drawings, Enclosure #4, a & b have been provided to show the new location of the exhaust vent and a change in placement of a door leading to the hot lab area. To provide equivalent limited access, a lockable door will be at each end of the hallway connected to the hot lab. The Xenon program is resubmitted in it's entirety due to restricted area volume changes and a request for a possession limit of 1500 mCi of Xenon-133 instead of original 2 Curies.
- B. A lockable wooden box will be constructed using 1/2" plywood, to house all radioactive lead waste containers. This lockable box will control access to Position 8 and secure the radioactive wastes from unauthorized removal.
- C. Weekly area surveys, performed by Ohio Isotopes, Inc., will include surveys along common walls with tenants in adjacent suites. These surveys will be conducted from Ohio Isotopes, Inc. suite. The radiation levels will be such that 10 CFR 20.105(b)(1) and (2) for unrestricted areas can be satisfied prior to being attenuated further by the common wall, which consists of 10" concrete block. A lead sheet of at least 1/2" thickness will be placed along the common wall where dose drawing stations are positioned. Ohio Isotopes, Inc. elected not to post film badges at specified intervals along common walls due to a courier in one adjacent suite which stores radioactive materials for a short period while they are awaiting delivery. Consequently, any reading above that which is normally received, for the area being surveyed, will be investigated immediately.

- D. A radioiodine fume hood, manufactured by Atomic Products contains a charcoal filter which traps 98% of the volatile Iodine-131. Two of these filters will be used simultaneously to ensure essentially 100% trapping efficiency so that there will be no release of radioactive iodine to the environment.
7. Authorization is requested to dispose of records for dose calibrator accuracy, constancy and linearity checks, survey meter calibration, instrument calibration and quality assurance and training for occupational and non-occupational personnel, two years subsequent to an NRC inspection of these records.
8. The package receipt procedures (i.e., page 2 of Item #13) and the emergency procedures (i.e., page 1 of Item 16) will contain up-to-date information on how to contact the appropriate individuals.
9. A. The procedures for safely opening packages containing radioactive material, outlined in Item #14, submitted in application dated October 10, 1983, will apply to all packages including those containing prepackaged in-vitro kits.
- B. The footnote on page 1 of Item #14 is an error and should not exist. The intent of paragraph e(2) on page 1 of Item #14 is to mean materials ordered, materials received and packing list are all in agreement.
10. A. Section I.A. of page 2 of Item #18 should be revised to read: "Radioactive wastes picked up will be comprised of plastic syringes, needles, needle covers and vials which have been used by client nuclear medicine departments. This waste may contain any radionuclide that Ohio Isotopes, Inc. is authorized to distribute."
- B. Ohio Isotopes, Inc. intends to use a double shipper's certificate for shipping radiopharmaceuticals and subsequent return waste form clients. *Sample of certificate is Enclosure # 4 C, Stan R. Egan, President.* Part I of the double shipper's certificate will be properly completed and kept by Ohio Isotopes, Inc. as a record of dispensed radiopharmaceuticals, applicable surveys and wipe tests.
- Parts 2, 3 and 4 will be received by the client. Part 2 is intended to serve as a receipt record for the client.

The clients will be instructed as indicated below:

"Ohio Isotopes, Inc. has been licensed by the U.S. Nuclear Regulatory Commission to pick up those materials which after use, represent radioactive waste. Only those materials supplied to you by Ohio Isotopes, Inc. may be returned to the pharmacy as waste.

A. Syringes, needles and needles covers:

1. After injection return the needle cover to the needle, remove the syringe from the syringe shield and return the syringe to the unit dose shield provided. Make sure the needle cover is firmly seated on the needle.

2. Place the unit dose shield in the case provided for return to the pharmacy.

B. Unit dose vials:

1. After use return the vial to its original shipping container and place in the case provided.

2. In those situations (usually I-131 therapy doses) where material has been delivered to you in appropriate D.O.T. packaging, return the vial to its container, replace in packaging, and seal.

C. Returning packages:

We will utilize the provision of the new D.O.T. regulation 49 CFR 173.421, Limited Quantities of Radioactive Materials. The regulation states if a package meets the following requirements, it is excepted from the specification packaging, marking and labeling requirements.

1. The radiation level at any point on the external surface of the package does not exceed 0.5 mR/hr;

2. The nonfixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in 49 CFR 173.443(a)(660 0 dpm/300cm<sup>2</sup>);



3. The amount of radioactivity being returned in the package does not exceed the limits specified below:

<u>Radionuclide</u>	<u>Limited Shipment Quantity</u> <u>(LSQ)(mCi)</u>
Co-57	9
Co-58	2
Cr-51	60
Ga-67	10
I-123	5
I-125	7
I-131	1
In-111	2.5
Mo-99	2
P-32	3
Tc-99m	10
Tl-201	20
Xe-133	100
Yb-169	8

The above values have been derived from information contained in 49 CFR 173.423 Table 7 and 49 CFR 173.435 Table of A<sub>1</sub> and A<sub>2</sub> values for radionuclides.

When shipping more than one kind of radioactive material, simply use the lowest mCi quantity assigned for the materials being shipped.

Example: If Tc-99m and P-32 were being shipped in the same package, only 3.0 mCi of total activity could be shipped.

Other requirements of this regulation are satisfied by Ohio Isotopes, Inc. present packaging.

Part 3 of the Shippers Certificate is to be completed by the client and held on file as record of shipment. In order to complete the shipping certificate and maintain Limited Shipment Quantities, three functions must be completed by the client.

1. Insure that the waste being returned does not exceed the specified limits for Limited Shipment Quantities.

2. Insure that the radiation level at any point on the surface of the package does not exceed 0.5 mR/hr.

3. The activity being returned for each dose must be recorded on Part 3 of Shipper's Certificate. This will allow assurance that the activity in the package being returned does not exceed Limited Shipment Quantities.

For used radiopharmaceutical products the activity being returned can be estimated as shown below:

Assume 5% remaining in the syringe allowed to decay 1 day (for Tc-99m, 4 half lives)

$$0.05 \times 0.0625 = 0.003$$

Therefore, the activity from a 25 mCi dose is:

$$25 \times 0.003 = 0.075 \text{ mCi}$$

It may be necessary to hold UNUSED Tc-99m doses for 48 hours, 8 half lives, to ensure the total activity returned does not exceed Limited Shipment Quantities.

Be sure that the amount of activity recorded on Part 3 of the Shipper's Certificate is recorded the same on Part 4. Part 4 of the Shipper's Certificate will be the pharmacy's receipt record of materials shipped from the client.

When the delivery personnel from Ohio Isotopes, Inc. pick up the shipping cases they will slip a clean cover over the case to ensure that the surface is contamination free. This cover will also have the appropriate labeling on it which will identify it as a Limited Shipment Quantity package.

We recommend that this procedure be posted for easy reference.

Sincerely,

Steven R. Lefevre  
President"

11. Please refer to Enclosure #5, Bioassay Program. - *doesn't*
12. Survey procedures are amended to incorporate as requirements that:
1. Higher than normal readings for any area be investigated and corrected immediately
  2. Areas be either cleaned or posted and restricted from use if the contamination level exceeds 2,200 dpm per 100 cm<sup>2</sup>. - *hub?*
  3. Areas be covered, cleaned, or identified to employees if the contamination level exceed 220 dpm per 100 cm<sup>2</sup> but is less than 2,200 dpm per 100 cm<sup>2</sup>.
13. A. A copy of the pharmacy license issued to Ohio Isotope, Incorporated by the State of Ohio is submitted as Enclosure #6.
- B. Activities will be limited to the preparation of radiopharmaceuticals for delivery on a prescription basis to Physicians in the Central Ohio area.
14. Enclosure #7 contains prescription dispensation labels that are to be combined as one. The actual sample to be used will consist of the information contained on sample one, but the colors will be those of sample two. The prescription dispensing form, when properly completed, will be attached to the radiopharmaceutical container. The bottom portion of the prescription will be attached to the vial or unit dose syringe and will contain the prescription number. This will facilitate proper identification of a vial or unit dose syringe that may become separated from the shield in which it was distributed.

The prescription dispensing label will contain the licensing statement contained in 10 CFR 32.72 (a)(4). It will read "Warning: This radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 35.14 and 35.100 Group \_\_\_\_\_ of 10 CFR Part 35. Syringe containing drug should be kept in this container or within heavier shield." Leaving the specific Group blank will allow for the need of only one label to be printed. Before the radiopharmaceutical is dispensed, the appropriate Group number will be placed in the blank area. The prescription dispensing label consists of a four part copy. Copy 1 is for pharmacy dispensation records. Copies 2, 3, and 4 are attached to the source container and labeled for proper record-keeping.

15. A. For each radionuclide to be distributed the maximum activity in a vial or syringe will be:

	Tc-99m	Xenon-133	I-131	Yb-169 DTPA	P-32	I-125
Vial	300mCi	250mCi/ 5 vials	200mCi	2.5mCi	10mCi	10uCi
Syringe	200mCi		300uCi			

- B. The type of lead syringe carrier shields to be used for Tc-99m in a syringe and I-131 in a syringe are lc-008 and lc-004 respectively. The lead syringe carrier descriptions can be found in Item #15, Appendix A of application dated 10/10/83. (For Tc-99m shield the lead thickness is no less than 0.39 cm. For the I-131 shield, the lead thickness is no less than 0.63 cm.)

The lead shield to be used for Xenon-133 is a lead tube of at least 1/8" thickness (e.g. NEN Xenon vial shield) capable of holding up to 5 vials.

The lead shield to be used for Yb-169 is the manufacturer's shield which is 2" in height by 1 1/2" in diameter by 1/8" thickness.

The lead shield to be used for Tc-99m in a vial is cylindrical and at least 5/32" in thickness (i.e. NEN orange lead shipping shields).

The lead shield used for dispensation of I-131 therapy doses will consist of a cylindrical lead shield of at least 1" thickness.

The dispensing container for P-32 will be the manufacturer's shipping container.

- C. The maximum radiation levels to be expected at the surface of each shielded container when filled with the maximum activity are as indicated below:

Tc-99m in vial = essentially none

Tc-99m in syringe = 0.5mR/hr or less

Xenon-133 = 6.5 mR/hr or less

Iodine-131 in vial = 11 mR/hr or less

Iodine-131 in syringe = 4.6mR/hr or less

Yb-169 in vial = essentially none

I-125 in vial = essentially none

16. A. An on site review of the radiation safety program at Ohio Isotopes, Inc. will be conducted on a quarterly basis by a member of Nuclear Medicine Associates (NMA) of Cleveland, Ohio. This review will consist of:

1. Consultation on problems pertaining to the isotope program.
2. Perform quality assurance programs on well detector.
3. Perform accuracy, constancy, energy and activity linearity checks on dose calibrators as required.
4. Review record system (radioactive shipment, receipt, use and disposal) for NRC, State and D.O.T. compliance, proper techniques for handling procedures and evaluation of health physics program to assure continued safe handling of byproduct materials. Film badge records will be reviewed and action recommended in case of overexposures.
5. Inventory all sealed sources quarterly and wipe/leak test all applicable sources as required.
6. Survey facilities for possible contamination and excessive radiation.
7. If requested, lectures on nuclear medicine techniques and radiation physics.
8. Review and evaluate current NRC license.

Consultants are available during normal working hours, for consultation by telephone or letter and are available for consultation for special visits, if desired.

Other services provided include:

- Assistance in applying for NRC license renewals and amendments or State registration
- Aid in keeping license current
- Offer in-service education and annual review programs to technical staff
- Establishment of radiological health physics program and record systems in accordance with NRC and State regulations
- Calibration of survey meters on an annual basis at our Cleveland facility
- Mail monthly newsletters and/or regulatory alerts.
- Provide and maintain pertinent portions of the Code of Federal Regulations

All evaluations are documented by formal reports. For further information regarding this program and/or any other services offered by Nuclear Medicine Associates, Inc., please feel free to contact our Cleveland office at: (216) 641-5799.



- B. There may be a number of consultants from Nuclear Medicine Associates who will provide consulting services to Ohio Isotopes, Inc. over the course of time. This is standard corporate policy for NMA. It is felt the client is provided a wider range of knowledge and experience, in this manner, with regard to evaluation of the radiation safety program.

An amendment application for Nuclear Medicine Associates, NRC license #34-16272-01, had been submitted to the Region III Materials Licensing Section for evaluation on November 11, 1983 which in part would provide an updated users list.

As of the writing of this report, the amendment had yet to be received. Therefore, copies of Supplement A for all individuals not currently listed on license #34-16272-01 are included, as Enclosure #8, along with a list of all consultants currently employed with Nuclear Medicine Associates.

- C. Nuclear Medicine Associates is employed by Ohio Isotope, Inc., in an advisory capacity only. Recommendations for compliance with NRC regulations will be made by NMA but the ultimate responsibility for their implementation will lie with Steve Lefevre, President and RSO of Ohio Isotopes, Inc.

17. A. Sealed calibration and reference sources will be redistributed to Group medical licenses only.

- B. These sources will be obtained only from a manufacturer licensed pursuant to 10 CFR 32.74 or under equivalent Agreement State regulations.

- C. The manufacturer's packaging and labeling will be unaltered. Additionally, the sealed calibration and reference sources to be redistributed will be accompanied by the calibration certificate and the leaflet or brochure supplied by the manufacturer that provides instructions for handling and storage.

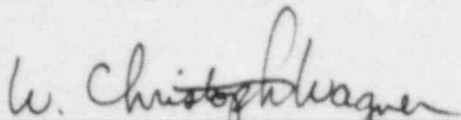
18. A. Only prepackaged in vitro kits as described in 10 CFR 31.11 will be obtained for redistribution to specific licenses.

- B. The labels, leaflets or brochures accompanying the in vitro kits will not reference general licenses, exempt quantities or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11).

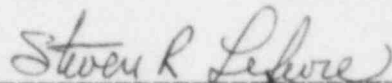
- C. The labeling of these kits will conform to the requirements of 10 CFR 20.203.

I trust this letter of response adequately answers all of the questions you had regarding the new NRC license application for Ohio Isotopes, Inc. dated October 10, 1983. If we can be of further service, please do not hesitate to contact us.

Sincerely,



W. Christopher Wagner  
Consultant  
Nuclear Medicine Associates, Inc.



Steven R. Lefevre  
President  
Ohio Isotopes, Inc.

"a"

Fourteenth Avenue

ZIP CODE 43219  
(NOT OPEN BET CLEVELAND AV &  
N CASSADY AV)  
N CASSADY AV INTERSECTS  
2863 Construction Systems Inc dry wall  
252-0708  
2861 Lutzner & Luft Inc masonry masonry  
252-1522  
2829 Gordon's Transport Inc (Coke Bt)  
mtr carriers 252-7234  
RARIG AV INTERSECTS (NS)

"b"

Switzer Road

ZIP CODE 43219  
2849 G & C Cement Contractors 475-4151  
2930 Avia Salvage Pool auto 476-4386  
2924 Moore Kenneth O 471-5759  
2925 X F Electrical Contractors 252-7437  
2928 Arjay Construction Co Inc 476-1742  
2929  
2930  
2931  
2933  
2935  
2937  
2939  
2941  
2943  
2860 Evans Products Co railroad car parts  
475-6340  
3000 Albers Co diesel eng repr 475-4833  
3020 Four Industries Inc paint 476-5008  
3021 Avia Body Shop 258-4462  
3023 Thomas Roofing Inc roofing & shi  
252-4994  
3130 Ohio James Inc 471-0716

Please refer  
to attached  
outline of  
tenants in  
building.

"c"

Lamb Avenue

ZIP CODE 43219  
2861 Reynolds Plumbing & Heating Co  
471-1333  
2968 C O N C O Corporation (CHEM)  
476-3336  
2977 Seetry Moring Co 475-4814  
2984 Gould Incorporated otc 475-8092  
3003 Gross J E Co mach eq 476-0277  
3008 Gross J E Co (Aldo Sp)  
3077 Gross J E Machine Shop 476-0277  
3021 Sheet Metal Works (APPR) 471-3107  
3033 Sheet Metal Works Ltd Amer Local  
98 welfare-pension funds 471-8071  
3034 Universal Drywall Inc 471-6051  
3038 Sheet Metal Works Ltd Amer Local  
98 (Bldg Traded apprenticeship  
471-8071  
3037 Vacant  
3061a Vacant  
3061b Ink Well The 476-4511  
3061f L-M Printing Co  
3061 Dickman Directory publis  
3061b Accurate Packaging Inc rubber  
products 471-6218  
3061 Buckeye Truck & Tractor Parts Inc  
471-6508  
Patterson Rubber & Supply Co Inc  
rubber products 471-6664  
3103 Manner Harry Co Inc scrap mtl  
471-3186

Rarig - not ACC.

"d"

Seventeenth Avenue

(NOT OPEN BET BREITWELL AV &  
JOHNSTOWN RD)  
JOHNSTOWN RD INTERSECTS  
N CASSADY AV INTERSECTS  
2996 Seate Plumbing Inc 471-4765  
3016 Penake Lumber Inc 471-5979  
3025 Gould Inc (Wheel) trucking  
3100 Parts & Equipment Warehouse  
automotive parts 475-8280  
3115 Rita Paving Inc 471-2752  
3129 Quality Swimming Pools Inc  
471-1185  
RARIG AV INTERSECTS  
3130 Quick Air Freight Inc (Garage)  
471-4536  
3133 London Chemical Co 476-2105  
3145 Vacant  
3153 McLean Co concrete equip 475-2580

"g"  
Johnstown

2810 Anchor Post Products Inc (R) fence  
471-3035  
2813 Serrano Gulf Serv 258-8868  
2822 Pilgrims Sales & Service Co (Bt) bkr  
252-1522  
2824 Mid-West Snacks Inc 471-8866  
2825 Gross hotel & restr equip 476-0288  
Donald's Place 476-0288  
2828 Nieman H J Inc draperies 475-3770  
2828 Alamo Anamonda alum siding mfr  
471-5122  
2829 Fortner Upholstering Inc 475-8282  
LAMB AV INTERSECTS  
2831 H & H Desk Co otc furn 476-1896  
2833 Feaver J N Co hydraulic pneumatic  
dier 471-4990  
2835 C F Air Freight Inc 471-4439  
E 17TH AV INTERSECTS (ES)  
2831 Anglo Sign Co Inc 475-2300  
2837 Anglo Painted (Graphic Div)  
475-4062  
2841 Vacant  
2845 Vacant  
2847 Veterinary Hospital 471-2561  
2853 Grib Albert F 471-1857  
2893 Williams Pearl E Mrs 471-1630

Tenants of building in which Ohio Isotopes, Inc. is located:

2929 Switzer

Mid-Eastern Geo-Tech, Inc. (614) 221-0277, Tom Murphy  
Perform soil and concrete analysis. No retail traffic.

2931 Switzer

Jack Carsey Builders, (614) 253-9966, Jack Carsey  
Carpenter, uses building for storage of materials for  
projects. No retail traffic.

2933 Switzer

Pressure Connections Corp. (614) 252-1196, Tim Davis  
Middle-man supplier for industrial trade. No retail traffic.

2935 Switzer

West neighbor not occupied.

2937 Switzer

Ohio Isotopes, Inc.

2939 Switzer

Associated Couriers, Inc. (614) 252-0422, Tom Steiniger.  
Delivery of freight.

2941 & 2943 Switzer

Commercial Diving Service, Inc. (614) 299-6169, Diane Dillon.  
2941 unit is for storage; 2943 is for work. No retail trade.

Seventeenth (d)

Lambo (C)

Switzer (b)

Fourteenth (a)

3153 Parolator  
Cousier  
[Carp]

Raria

## Use Construction

NEW  
CONSTRUCTION

Cassady

УМОВИ ТУЧОШ



16a

16a View southwest, Facility(x);  
Lamb-c; Johnstown-g; Switzer-b; 14th-  
a; Cassidy-f; Rt-62-h.



18a

18a View southwest, facility(x);  
Lamb-c; Switzer-b; 14th-a; Cassidy-  
f; Johnstown-g at right.



25a

25a View west(1.tor.);14th-a;  
Switzer-b;Lamb-c;17th-d;Facility  
(x); and Rarig-e.



29a

29a View southeast.Switzer and  
14th avenue. Approx. 1/4 mile to  
residential in background(south)



32a

32a View northeast. 2925 Switzer  
(white roof); facility (x); freight  
parking lot to immediate south.



0398

TO BE PLACED ON OHIO ISOTOPES, INC. STATIONERY

This letter is to inform the fire department that Ohio Isotope, Inc. intends to operate a radiopharmacy business located at 2937 Switzer Road, Columbus, Ohio 43219. The fire department is invited to visit the facility to survey the scope of operation in order to facilitate the actual fighting of a fire, should one occur. Additionally, enclosed is a guide which is intended to provide information with regard to emergency handling of a radioactive fire and possible contamination of fire victims. This letter will be sent annually as a reminder regarding the scope of operation.

Should you have any questions regarding statements in this letter, please do not hesitate to contact Ohio Isotopes, Inc. at 253-3020. Thank you for your attention to this matter.

Sincerely,

Steven R. Lefevre  
President

Enclosure #3

Emergency Handling of Radioactive  
Fires and Accident Victims

Enclosure #3



## QUICK REFERENCE - WHAT TO DO

in the event of a  
Radiological Incident

- (1) Perform life saving rescues and emergency first aid.
- (2) Keep all persons as far away from accident scene as is practical.
- (3) Avoid spreading contamination (i.e., liquid, solid or gas).
- (4) Do not attempt to move or clean up any material involved with the incident.
- (5) Stand upwind of fires.
- (6) Obtain names of all persons involved with the incident.
- (7) Detain all persons involved with the incident at the scene until the Radiological Emergency Response Team arrives.
- (8) Eating, drinking and smoking in the area of the accident should be prohibited.
- (9) Notify:
- (10) Remain calm and wait for arrival of the Radiological Emergency Response Team.

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EMERGENCY HANDLING OF RADIOACTIVE FIRES  
A HANDBOOK FOR FIRE DEPARTMENTS

Introduction:

The following handbook has been written to assist you, the fireman, in properly handling a fire involving radioactive material. Part I briefly describes the types of incidents that may occur, what to do until qualified radiation physicists arrive at the scene and whom to notify regarding the radiological incident. Part II provides essential information for personnel that must handle a radiation accident victim. Appendices A through F provide information pertinent to warning labels, report forms, handling information on radiation quantities and unit and care of radiation survey instruments. A Glossary of Terms is included at the end of this handbook.

It should be noted that the procedures and fire fighting recommendations are not necessarily specific for all types of situations and may vary according to the kind of fire, its location, and the presence of other combustible materials. The fire extinguishing chemicals suggested represent some of the best knowledge on this subject to date.

PART I

I. EXAMPLES OF RADIOACTIVE FIRE INCIDENTS to which you may eventually respond are listed below:

- A. FIRE and/or EXPLOSION which occurs in an area where radioactive materials are used or stored.
- B. RESCUE procedures involving a victim of a radioactive material fire or explosion.

WHOM TO NOTIFY regarding a radiation emergency incident:

- 1. Steven R. Lefevre, President & Radiation Safety Officer, Ohio Isotopes, Inc. (614) 475-0319 during business hours (8:30 a.m. to 5:00 p.m., Monday - Friday).
- 2. The Ohio Department of Radiological Health, (ODHR) at (614) 466-3543.

After hours, weekends and holidays, the ODHR can be contacted by calling the State Highway Patrol at (614) 406-2660 anytime. (Please refer to Appendices B & C for reporting procedures).

II. WHAT TO DO if you arrive at the scene of a radioactive material fire:

- A. Wear proper respiratory protection equipment (e.g., a self-contained breathing apparatus).
- B. Incident involving a fire and/or explosion:
  - 1. Attempt to remove any injured persons upwind and as far away from the burning material as practical (e.g., 200 feet). Administer emergency first aid if necessary. Additional information on handling a radiation contaminated patient is provided at the end of this handbook.
  - 2. If possible, do not attempt to touch, clean up, or walk on any contaminated material that may be present.

\*Note: The procedures listed here are by necessity general and may vary slightly depending on the chemical and/or physical nature of the material involved.

3. Look for any signs, labels or placards that may give you information regarding the chemical or physical nature of the material involved. Radioactive material is usually labeled with one or more of the identifying signs reproduced in Appendix A of this handbook.
  4. Stay upwind of any burning material and avoid breathing any fire or explosion associated airborne material.
  5. Radiation exposure assessments may have to be made prior to proceeding into a radiation area. (Please refer to Appendix F for more information).
  6. Eating, drinking and smoking in the area of the incident SHOULD BE PROHIBITED to avoid internal body deposition of toxic or radioactive material.
- C. Rescue procedures which involve entering a radiation area:
1. Foremost consideration should be given to moving the victim out of the hazardous area. Even when life-saving first aid is required, 5 or 10 seconds spent moving some distance away from the hazardous material may significantly contribute to reducing the exposure of victim and rescue personnel.
  2. Potential personnel exposure to the radiation and/or toxic material must be considered and dose estimates should be made in order to approximate the length of time rescue personnel can remain in the exposure area.\*
  3. The possible need for respiratory protection, protective clothing, dosimetry and instrumentation must be considered (please refer to Appendix E for a list of recommended equipment and procedures to follow in maintaining and using survey and dosimetry equipment).

\*Note: Radiation exposure estimates should be made by an individual adequately trained in radiation protection.



## PART II

### HANDLING A RADIATION ACCIDENT VICTIM

There are four (4) basic types of radiation exposure that you should know about:

1. Externally emitted radiation that penetrates body tissues. Examples: X-rays, gamma rays, and beta particles.

Precautions to be observed while attending victim:

The victim is not radioactive and poses no hazard to attending persons. Depending on the degree of exposure, the victim may become quite sick and show various symptoms including nausea and vomiting.

2. Radioactive material deposited on the skin and/or clothing. Examples: May emit alpha, beta and gamma radiation (or all three) and be in the form of a solid, liquid or gas.

Precautions to be observed while attending victim:

Anyone touching the victim or handling his clothing may become contaminated. Unless life saving first aid is necessary, handling the victim should be avoided until qualified personnel arrive. If touching or handling the victim is necessary, the hands should be thoroughly scrubbed and washed with detergent and water following contact. If possible gloves (preferably made of impervious material) should be worn while handling the patient. Any additional parts of the body or clothing (e.g. shoes) that come in contact with the victim should receive similar decontamination.

It should be noted that contamination (particularly of the feet and hands) can spread amazingly fast. If transporting the contaminated victim in a vehicle becomes necessary for life saving purposes, the spreading of the contamination must be limited as much as possible (e.g. wrap the patient in a clean sheet or blanket). All persons and objects touched will need to be checked by the Radiation Emergency Response Team for contamination.

3. Radioactive material inhaled, ingested or internally deposited through a wound. Examples: Alpha, beta and gamma (or all three) emitting substances in a solid, liquid or gaseous form may be involved.

Precautions to be observed while attending victim:

Normally, inhaled, ingested or wound deposited radioactive materials do not constitute a serious hazard to attending persons. The quantities consumed are normally low. Contamination problems may arise when vomiting; bleeding or excretion occurs and releases the radioactive material from the body. If this occurs the victim should be handled as if he were externally contaminated with a radioactive liquid.

4. Radioactive material in a solid form that is imbedded within body tissues. Examples: Pieces of metal, glass or wood. This type of contamination usually follows an explosion and may involve particles that emit greater amounts of radiation than the previously mentioned forms of contamination. Gamma, beta and alpha radiation (or all three) are possible.

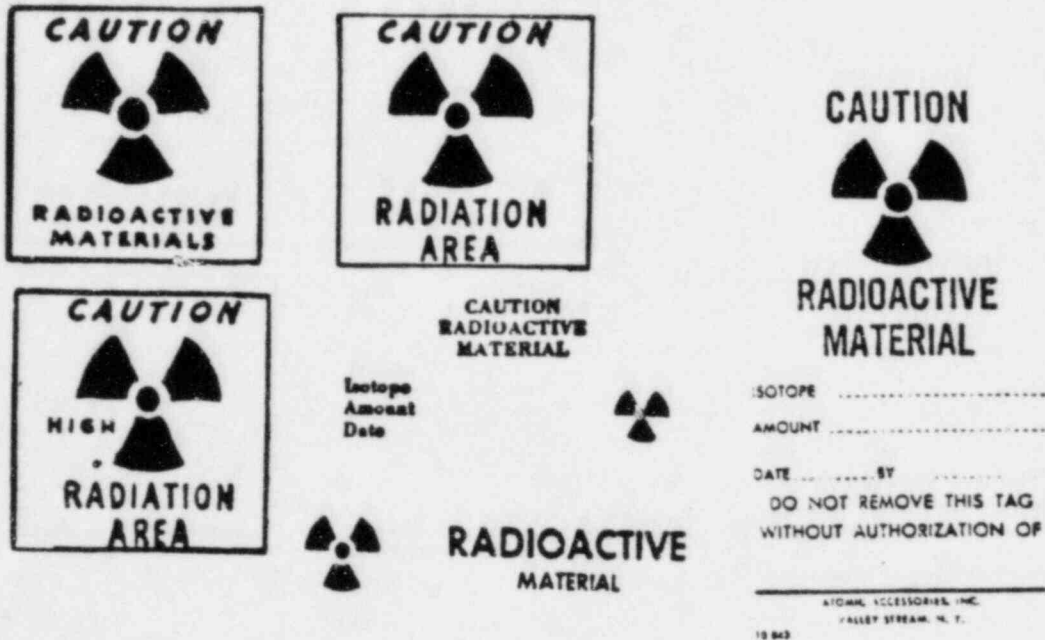
Precautions to be observed while attending victim:

This type of accident is the rarest of the four listed but could be the most hazardous to attending persons should it occur. If possible, contact with the victim should be avoided until the Radiation Safety Officer or qualified personnel arrives.

APPENDIX A  
RADIATION CAUTION SIGNS AND LABELS

## APPENDIX A

## RADIATION CAUTION SIGNS AND LABELS



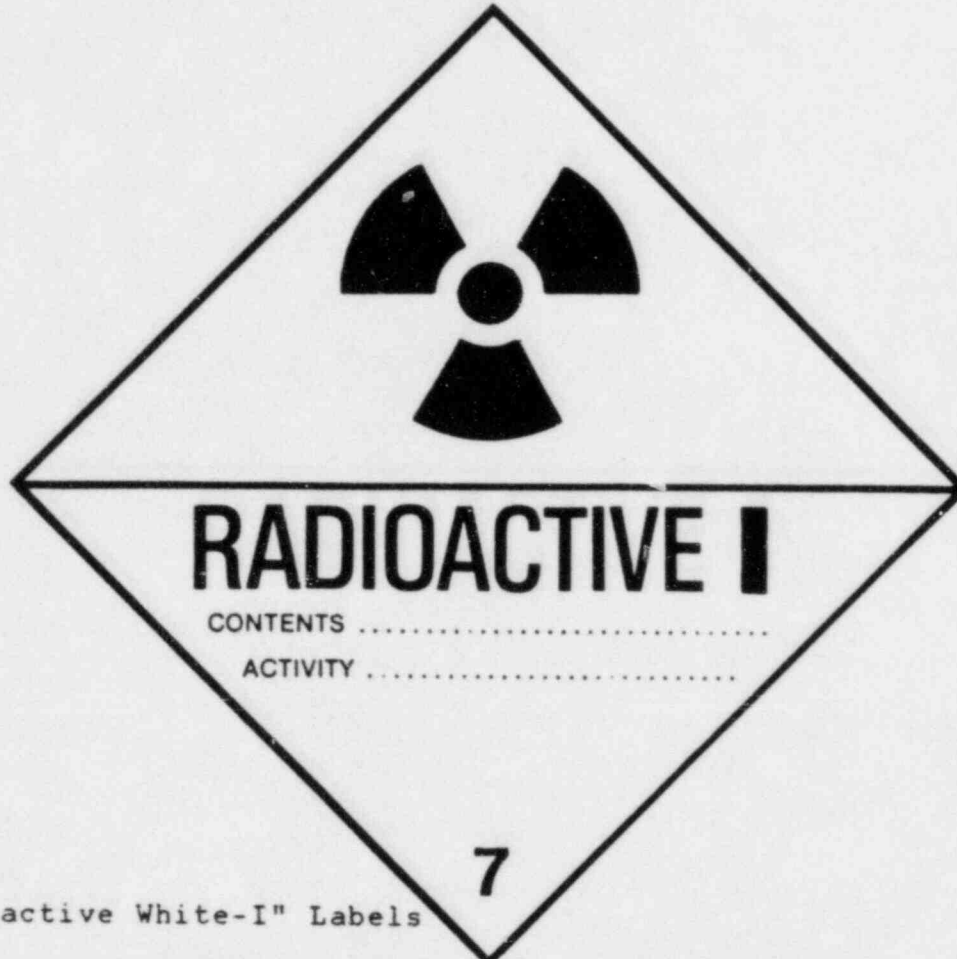
The color scheme of the radiation caution signs and labels above will normally be purple or violet symbols and lettering on a yellow background.

DEPARTMENT OF TRANSPORTATION (D.O.T.) PLACARDING  
AND LABELING REQUIREMENTS



Highway vehicles used for transport of packages bearing Radioactive Yellow-III labels (see page 17) must be placarded by the carrier, or by the shipper for sole use vehicles containing full loads of low specific activity materials. Placards as shown must be applied on the front, rear and each side of the vehicle.

APPENDIX A  
DEPARTMENT OF TRANSPORTATION (D.O.T.) PLACARDING  
AND LABELING REQUIREMENTS (CONTINUED)



"Radioactive White-I" Labels

Label must be white in color. The single vertical bar on the lower half of the label must be bright red in color. Labels must be applied on two opposite sides of each package having a dose rate not exceeding 0.5 millirem per hour at any point on the external surface of the package. Not authorized for Fissile Class II or III packages.



APPENDIX A  
DEPARTMENT OF TRANSPORTATION (D.O.T.) PLACARDING  
AND LABELING REQUIREMENTS (CONTINUED)



"Radioactive Yellow-II" Label

The upper half of the label must be bright yellow and the bottom half must be white. The two vertical bars on the lower half of the label must be bright red in color. Labels must be applied on two opposite sides of:

- (1) Each package having a dose rate not exceeding 50 millirem per hour at any point on the external surface of the package and not exceeding 1 millirem per hour at 1 meter from the external surface of the package; or
- (2) Each package for which the transport index does not exceed 1.0 at any time during transportation.

APPENDIX A  
DEPARTMENT OF TRANSPORTATION (D.O.T.) PLACARDING  
AND LABELING REQUIREMENTS (CONTINUED)



"Radioactive Yellow-III" Label

The upper half of the label must be bright yellow and the bottom half must be white. The three vertical bars on the lower half of the label must be bright red in color. Labels must be applied on two opposite sides of:

- (1) Each package which exceeds either of the limits for a DOT Yellow II Label.
- (2) Each Fissile Class III package.
- (3) Each package being transported under a special permit.

APPENDIX B  
ESSENTIAL INFORMATION TO PROVIDE  
WHEN REPORTING A RADIATION INCIDENT

(Post this form beside a telephone if possible)

ESSENTIAL INFORMATION TO PROVIDE  
WHEN REPORTING A RADIATION INCIDENT

1. Your name
2. Representing
3. Address where incident occurred
4. Exact location of area involved (e.g. storeroom, basement, etc.)
5. Radioactive material involved:
  - a. Chemical name
  - b. Chemical form (e.g. liquid, solid or gas)
  - c. Amount of activity (in Curies)
6. Description of Incident:
  - a. Tell briefly what happened.
  - b. When did the incident occur (date and time)
  - c. Persons injured (if any)
  - d. Status of injured persons
  - e. Identify emergency response crew(s) that have arrived (e.g. fire department, police, ambulance).

BASIC STEPS TO FOLLOW IN HANDLING A RADIOLOGICAL INCIDENT:

1. Keep all persons as far away from accident scene as is practical.
2. Perform life saving rescues and emergency first aid.
3. Avoid spreading contamination (i.e. liquid, solid or gas).
4. Do not attempt to move or clean up any material involved with the incident.
5. Stand upwind of fires.
6. Obtain names of all persons involved with incident.
7. Detain all persons involved with the incident at the scene until the Radiological Emergency Response Team arrives.
8. Eating, drinking or smoking in the area of the accident should be prohibited.
9. Remain calm and wait for arrival of qualified personnel.

## APPENDIX D

PROCEDURES TO FOLLOW IN AVOIDING  
THE SPREAD OF RADIOACTIVE CONTAMINATION

1. Know the chemical and physical form of the radioactive material you are dealing with.
2. Rope or otherwise barricade the contamination area to avoid spreading radioactive and/or toxic material.
3. If you are contaminated, shed outer clothing, including boots, prior to leaving the contamination area. Avoid spreading contamination outside the barrier or rope.
4. Be aware of possible airborne contamination.
5. Avoid touching or stepping in contaminated areas if possible.
6. Do not attempt to clean up a radioactive toxic material contamination.
7. Use soil or sand to "dam" liquids that are spilled and where run off is undesirable.
8. Keep all equipment and clothing that you suspect to be contaminated inside the contamination barrier.



APPENDIX D  
 ESSENTIAL MATERIAL TO MAINTAIN RELATIVE TO A RADIATION INCIDENT

Obtaining and storing the items listed below will provide adequate supplies necessary for use in a radiation contamination incident.

<u>ITEM</u>	<u>USE</u>
G-M Survey meter	Surveys for contamination
Dosimeters & charger (preferably 0-200 mr range)	Personnel monitoring
Spare batteries	For use in G-M Survey meter
Plastic bags of all sizes	For disposing of contaminated materials
Plastic sheet	Covering ventilation ducts, if necessary, and covering contaminated areas
Remote handling tongs or shovel	For handling contaminated objects
Radiation warning rope or ordinary rope, cord, etc.	For roping off and securing contaminated areas
Radiation caution signs and labels	For labeling contaminated areas and objects
Containers of various volumes	For collecting contaminated materials (i.e., liquids)
Masking tape	For sealing plastic bags and other containers, etc.
Soap and water	For decontamination
Cotton swabs	For decontamination
Absorbent materials	For decontamination
Waste containers (lined with removable plastic bags)	For radioactive waste disposal
Rubber gloves	For handling contaminated material
Shoe covers	For avoiding contamination of shoes
The fire department's own standard clothing, boots, gloves, and portable self-contained breathing apparatus	For avoiding personnel external and internal contamination

## APPENDIX E

INFORMATION APPLICABLE TO UNDERSTANDING RADIATION  
QUANTITIES AND UNITS

- I. Maximum permissible whole body exposure to X-ray, gamma ray or neutron radiation: 1.25 rem per quarter (3 months) or 5 rem per year.\*
- II. Recommended maximum "one time" exposure allowable in life saving emergency situations: 25 rem\*
- III. Minimum whole body X or gamma ray dose at which blood and blood forming organ changes can be detected: Approximately 50 - 100 rad.\*
- IV. Whole body dose (external X or gamma radiation) at which death may occur due to blood (i.e. bone marrow, liver and spleen) system damage: Approximately 300 to 400 rad.\*
- V. Whole body dose (X or gamma radiation) at which approximately 50% of a randomly selected population would be expected to die within 30 days following exposure: Approximately 400 to 500 rem.

\*Note: For simplification, the units rem, rad and R (roentgen), as used in this handbook, should be considered equivalent. Dose rates given are for occupationally exposed persons only.

## APPENDIX E (continued)

Gamma ray emission rates and physical half life of selected nuclides expressed in roentgens per hour per curie at a distance of one (1) foot:

<u>Radioactive nuclide and its Chemical Symbol and Atomic Mass Number:</u>	<u>R/hr./Ci at 1 foot</u>	<u>Physical Half Life</u>
Cesium 137 (Cs-137)	4.2	30 yrs.
Cobalt 60 (Co-60)	14.4	5.3 yrs.
Gold 198 (Au-198)	2.7	64.8 hrs.
Iodine 131 (I-131)	2.4	8 days
Iridium 192 (Ir-192)	5.9	74 days
Iron 59 (Fe-59)	7.3	45 days
Molybdenum 99 (Mo-99)	0.8	67 hrs.
Radium 226 (Ra-226)	9.0	1620 yrs.
Sodium 22 (Na-22)	12.4	2.6 yrs.
Technetium 99m (Tc-99m)	0.6	6 hrs.
Galium 67 (Ga-67)	1.2	78 hrs.
Xenon 133 (Xe-133)	0.55	5.2 days

## APPENDIX F:

CARE AND USE OF A GEIGER-MUELLER (G-M)  
SURVEY METER AND POCKET DOSIMETER

If possible each fire station should possess or have access to at least one (1) operable G-M survey meter. This instrument is useful in detecting areas of gamma and/or beta radiation contamination. The instrument should only be used by a qualified individual who is responsible for keeping the instrument operable and calibrated.

The following procedures should be followed when using a G-M survey meter to detect contamination.

1. Be certain the instrument's batteries are good before using.\*
2. Be certain the instrument is properly calibrated before using.\*
3. Enclose the instrument and probe in a thin transparent plastic bag when surveying areas where airborne contamination is possible.
4. Be certain that the beta shield is removed when surveying for beta radiation.
5. Avoid touching the G-M detector probe to contaminated material.
6. Move the probe slowly over areas of suspected contamination.
7. Keep a written record of all surveys and their locations.
8. G-M survey meters will not adequately detect alpha or neutron radiation. Low energy beta emitters (i.e. tritium and carbon 14) are not normally detectable unless a special thin window is utilized.

\*Note: The establishment of a regular maintenance and calibration schedule is vital to the proper operation of the instrument.

## APPENDIX F (continued)

The following procedures should be followed when using a pocket dosimeter and charger:

1. Periodically (e.g., every 6 months) check batteries in the charger.
2. If possible, dosimeters should be charged to zero prior to use.
3. If charging is not possible, be sure to note the dosimeter reading prior to entering the radiation area.
4. It is recommended that the dosimeter's range be 0.200mr.



GLOSSARY OF TERMS

Alpha Particle: A type of radiation consisting of a positively charged particle emitted by certain radioactive materials. The alpha particle is made up of two neutrons and two protons bound together which duplicates the constituents of the nucleus of a helium atom. It is the least penetrating of the three common types of radiation (alpha, beta, gamma) emitted by radioactive material, being stopped by a sheet of paper. It is not hazardous to man unless the alpha emitting substance has entered the body.

Beta Particle: A type of radiation emitted from the nucleus of atoms during radioactive decay. This particle has a single electrical charge and a mass equal to  $1/1837$  that of a proton. A negatively charged beta particle is identical to an electron. A positively charged beta particle is called a positron. Beta radiation may cause skin burns and beta-emitters may be harmful if they enter the body. Beta particles are easily stopped by a thin sheet of metal and normally give rise to some x-radiation.

Dosimetry: The measurement of the amount of radiation delivered to a specific place or the amount of radiation that was absorbed there.





Exothermally: Being characterized by evolving or emitting heat or fire.

Fissile: A synonym for fissionable material.

Gamma Ray: High energy electromagnetic radiation that is emitted from the nucleus of various "excited" or unstable atoms. Heavy shielding is required to attenuate gamma rays.

X-ray: A penetrating form of electromagnetic radiation emitted when electrons change energy levels or direction near an atom.

Enclosure 4,a  
Facilities and Equipment  
Diagram

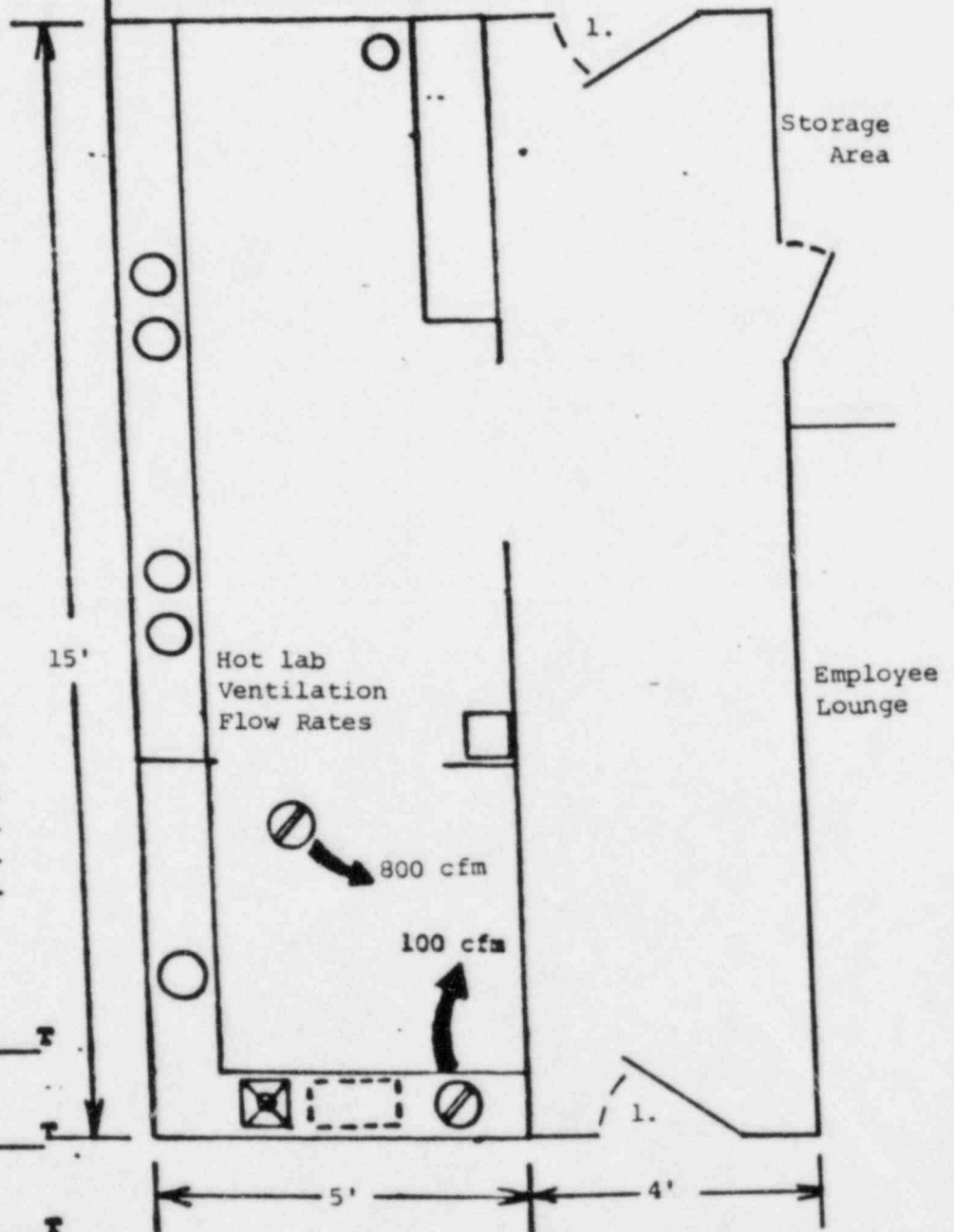
-  Air Supply
-  Air Exhaust
-  Sink
-  Lead Castle

- Scanner
- Uptake
- Well
- Scaler
- Camera
- File
- 1. Lockable Door
- Isotope Receipt Area
- Generator
- Kit preparation
- Isotope Storage
- Dose Preparation
- Waste Storage
- Dose Calibrator
- Refrigerator

Adjacent Areas


Lead Shielding

	L	x		W	x		H	x		T
	L	x		W	x		H	x		T
	L	x		W	x		H	x		T
	L	x		W	x		H	x		T



Enclosure 4,b  
Facilities and Equipment  
Diagram

- ☒ Air Supply
- ☒ Air Exhaust
- ☒ Sink
- ☒ Lead Castle
- N/A Scanner
- N/A Uptake
- 1. Well
- Scaler
- N/A Camera
- 2. File/Desk
- 3. Lockable Door
- 4. Isotope Receipt Area
- 5. Generator
- 6. Kit preparation
- 7. Isotope Storage
- 6. Dose Preparation
- 8. Waste Storage
- 9. Dose Calibrator
- 10. Refrigerator

Adjacent Areas

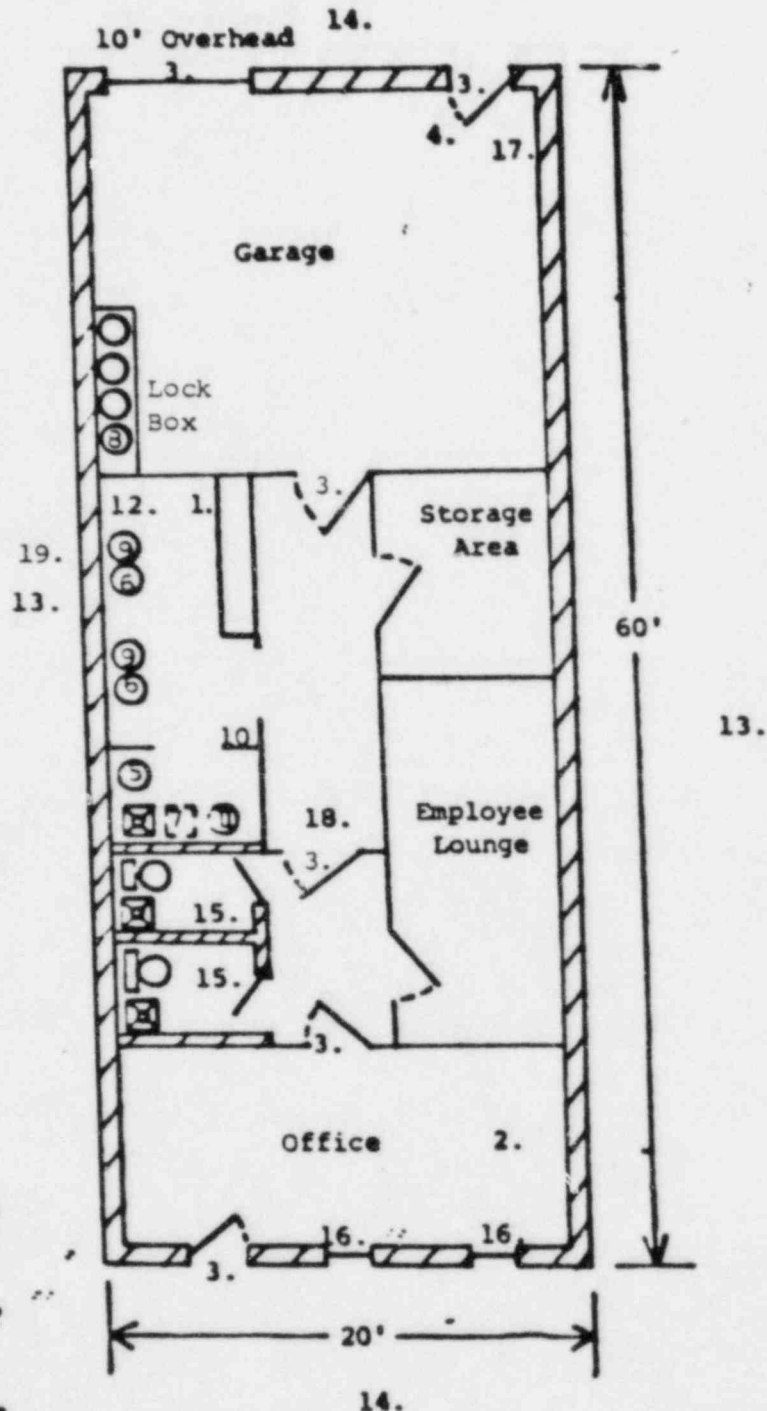
- 11. Exhaust Hood
  - 12. Monitoring Equipment
  - 13. Unoccupied unit
  - 14. Exterior
  - 15. Restroom
  - 16. Window
  - 17. Propane Heater
  - 18. Hallway
  - 19. Courier Service
- Lead Shielding

7  
24" L x 12" W x 12" H x 1/2" T

\_\_\_ L x \_\_\_ W x \_\_\_ H x \_\_\_ T

\_\_\_ L x \_\_\_ W x \_\_\_ H x \_\_\_ T

\_\_\_ L x \_\_\_ W x \_\_\_ H x \_\_\_ T



## SHIPPER:

## CONSIGNEE:

SHIPPER CERTIFICATE  
RADIOACTIVE MATERIAL, N.O.S., NORMAL FORM  
NATURE AND QUANTITY OF CONTENT

OHIO ISOTOPES, INC.  
2937 Switzer Road  
Columbus, Ohio 43219  
(614) 253-3020

ITEM	TIME	PRESCRIPTION #

Order for (date):

Purchase Order No.

Proper Shipping Name	Radio-Nuclide	Chemical Form	Physical State	Activity (mCi)	
				SEND	RETURN
Radioactive Material, N.O.S.	99m Tc	Salt	Liquid		
Radioactive Material, N.O.S.	201 Tl	Salt	Liquid		
Radioactive Material, N.O.S.	133 Xe	Gas-Inert	Uncompressed Gas Liquid		
Radioactive Material, N.O.S.	131 I	Salt	Liquid Solid		
Radioactive Material, N.O.S.	125 I	Salt	Liquid Solid		
Radioactive Material, N.O.S.	67 Ga	Salt	Liquid		
Radioactive Material, N.O.S.	75 Se	Amorphous Acid	Liquid		
Radioactive Material, N.O.S.					
Radioactive Material, N.O.S.					

## Swipe Test

Sample      BKG

SEND

## Survey (mR/hr)

Surface      3 Feet

PHARMACY

HOSPITAL

RETURN

PACKAGE QUANTITY: ONE

PACKAGE TYPE: A

ID# UN 2982

D.O.T.  
LABELTOTAL  
ACTIVITY

mCi

WHITE I

YELLOW II

YELLOW III  
Placard Vehicle

SEND      RETURN

TRANSPORT  
INDEX

This is to certify that the above named materials are properly classified, described, packaged, marked, and labeled for transportation according to the applicable regulations of the Department of Transportation (D.O.T.).

Rec'd by / time

Shipper

Date

WHITE COPY: Pharmacy Ship    YELLOW COPY: Hospital Receipt    PINK COPY: Hospital Return    GOLD COPY: Pharmacy Receipt

Enclosure 4c

PROCEDURES FOR:

Bioassay Record

A. Discussion

Bioassay must be performed in accordance with NRC Regulatory Guide 8.20. This Guide should be used as a reference should thyroid burden action levels be exceeded. Urine bioassay will be performed monthly as a backup procedure to assess the need for further in vivo procedures.

B. In Vivo Thyroid Bioassay to be completed monthly at Riverside Methodist Hospital, Columbus, Ohio.

Equipment Necessary:

1. Thyroid scintillation counting system with flat field collimator
2. Thyroid neck phantom
3. 10" spacer device
4.  $^{131}\text{I}$  capsule

Procedure:  $^{131}\text{I}$  energy = 364 Kev

Analyzer window = 100 Kev

With the  $^{131}\text{I}$  capsule, peak the analyzer by adjusting the detector voltage until maximum count rate is achieved.

1. Obtain background of counting system (Bg cpm)
2. Obtain standard count by placing neck phantom containing capsule 10" and centered from detector face (Capsule cpm)
3. Obtain thyroid count by placing your neck 10" and centered from the detector face (Neck cpm)

Calculate thyroid activity from:

$$\begin{array}{l} \text{Thyroid activity} = \frac{(\text{Neck cpm} - \text{Bg cpm})(\text{uCi of capsule})}{\text{Capsule cpm} - \text{Bg cpm}} = \text{uCi in thyroid} \end{array}$$

Comment: Since NRC Guide 8.20 specifies an action level with respect to thyroid burden of 0.04 uCi, it will be necessary to determine the sensitivity of the equipment, and the thyroid counting time necessary to demonstrate a level of 0.04 uCi in the thyroid. This may be done in the following manner:



1. From the data obtained when counting the <sup>131</sup>I capsule for thyroid bioassay, express the sensitivity of the counting system in cpm per uCi. Example: a 5.0 uCi <sup>131</sup>I capsule is counted in the thyroid neck phantom at 10" from the detector face and counts 20,000 cpm then:

$$\frac{20,000 \text{ cpm}}{5 \text{ uCi}} = 4000 \text{ cpm/uCi}$$

2. Since the action level for thyroid burden is 0.04 uCi then:

$$4000 \text{ cpm/uCi} \times 0.04 \text{ uCi} = 160 \text{ cpm}$$

Therefore, for this particular counting system, a thyroid burden of 0.04 uCi would represent 160 cpm above background (action level).

C. Urine Bioassay Procedure to be completed at radiopharmacy.

1. Well counting system is the Nucleus, Inc. Model 2560 well detector listed on page 1 of Item 9 of application dated October 10, 1983.

2. Test tubes

3. Urine collection cups

Procedure: <sup>131</sup>I energy = 364 Kev

Analyzer window = 100 Kev

1. Obtain monthly urine sample. Additionally, a urine bioassay procedure will be performed within 24 hours of dispensation of liquid I-<sup>131</sup> therapy dose, on the radiopharmacist who performed the dispensing.

2. Place known ml quantity in well counting test tube

3. Obtain background of counting system (Bg cpm)

4. Obtain urine sample activity cpm

5. Calculate uCi activity in urine from:

$$\text{I-131 urine activity} = \frac{(\text{Urine sample cpm} - \text{Bg cpm}) \times \text{CF}}{2.2 \times 10^6 \text{ dpm/uCi}} = \text{uCi}$$

6. Calculate uCi/ml of urine sample.

If any <sup>131</sup>I activity above background is detected in the urine, then a vivo thyroid bioassay will be performed.

Note:  $*CF = \frac{1}{\text{detector efficiency}}$ ; cpm x CF = dpm

0398

OHIO STATE BOARD OF PHARMACY

65 S. FRONT ST. - RM. 504  
COLUMBUS, OHIO 43215

CATEGORY II

TERMINAL DISTR OF DANGEROUS DRUGS

Be it known that

OHIO ISOTOPES, INC.  
LEFEVRE, STEVEN R. R.P.H.  
2937 SWITZER ROAD  
COLUMBUS, OH 43219

IDENTIFICATION NUMBER 02-388600

Expiration Date 12-31-84

has given satisfactory evidence that all statutory requirements as required by the Revised Code have been met. (Wholesale—R.C. 4729.52 and 4729.53. Terminal—R.C. 4729.54 and 4729.55). In witness whereof this certificate is issued under seal.

SIGN, POST AND DISPLAY

Before change of ownership, control address or location, notify secretary of the Ohio Board of Pharmacy immediately.

SIGNED

*Steven R. Lefevre R.Ph.*  
SIGNATURE OF RESPONSIBLE PHARMACIST OR PRACTITIONER

CLASS 07

AUDIT NUMBER 006 789

*Ohio State Board of Pharmacy*

Enclosure #6

Sample #2 Color sample for proposed label.

Ohio Isotopes, Inc.  
2937 Switzer Road  
Columbus Ohio 43219

Hospital

Doctor

Radionuclide

Pharmaceutical

Procedure

Lot Number

Assay

Quantity Ordered

Volume Dispensed

Dispensed By

Patient Name

Comment:

P.O.

SPECIAL CHARGE

CAUTION

Rx

RADIOACTIVE MATERIAL

Date

as of

Dispensed

Rx #

Use as directed by physician

CAUTION

RADIOACTIVE MATERIAL

Rt #

See sample label for information proposed for actual label (Color sample only)

Sample of label information to be used - colors to be yellow/purple as per sample #2 or \* below

Ohio Isotopes, Inc.  
2937 Switzer Road  
Columbus, Ohio 43219  
614-253-3020

Warning: This radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 35.14 and 35.100 Group of 10 CFR part 35. Syringe containing drug should be kept in this container or within heavier shield.

Hospital

Doctor

Radionuclide

Pharmaceutical

Procedure

Lot #

Assay

Qty. Ordered

Dispensed

Vol. Disp

Patient Name

Comment:

P.O.

EXTRA CHARGE

CAUTION

Rx

RADIOACTIVE MATERIAL

Date

Expires

as of

Dispensed By

Rx #

Use as directed by physician

Expires

CAUTION

RADIOACTIVE MATERIAL

Except for color, this label is as we propose to print

Consolidated Business Forms, Inc. 313/792-4700

## U. S. NUCLEAR REGULATORY COMMISSION

## MATERIALS LICENSE

License Number 34-16272-4

## Supplementary Sheet

Docket or  
Reference No. \_\_\_\_\_

Amendment Number 08

Continued from page 1

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9. Authorized use

- A. For possession incident to the performance of tests for leakage/contamination on the source and devices as specified in letter dated January 9, 1981.
- B. through F. To be used for instrument calibration and testing.

---

CONDITIONS

10. Tests for leakage and/or contamination shall be performed only at temporary job sites of the licensee anywhere in the United States where the Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material. Analysis of leak test samples may be performed at the licensee's facilities at 9726 Park Heights Avenue, Cleveland, Ohio 44125 and at 5278 East 98th Street, Garfield Heights, Ohio 44125. Licensed material in Subitems 6.B. through 6.E. shall be used only at the licensee's facilities at 9726 Park Heights Avenue, Cleveland, Ohio 44125 and 5278 East 98th Street, Garfield Heights, Ohio 44125; and at temporary job sites of the licensee anywhere in the United States where the U. S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of the licensed material. Licensed material in Subitem 6.F. shall be used only at the licensee's facilities at 9726 Park Heights Avenue, Cleveland, Ohio 44125 and 5278 East 98th Street, Garfield Heights, Ohio 44125.
11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."
12. Licensed material shall be used by, or under the supervision and in the physical presence of, Paul J. Early, William H. Miller, John R. Ferrell, Michael D. Reynolds, Darlene M. Belmonte, Frank T. Bloer, Daniel A. Davis, Vincent A. Gargaro, David T. Williams, Charles A. Giomuso, Edward J. Began, or David W. Close.
13. A. (1) Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months, except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months. In the absence of a certificate from a transferor, indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.
- (2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

NAME OF AUTHORIZED USERTITLEAUTHORIZATION

Paul J. Early	Consultant	Licensed Material
William H. Miller	Consultant	Licensed Material
Frank T. Bloer	Consultant	Licensed Material
David W. Close	Consultant	Licensed Material
Charles A. Giomuso	Consultant	Licensed Material
Edward J. Began	Consultant	Licensed Material
E. DeWitt Liles	Consultant	Licensed Material
Raymond L. Kaczur	Consultant	Licensed Material
W. Christopher Wagner	Consultant	Licensed Material
Steve A. Spinosi	Consultant	Licensed Material

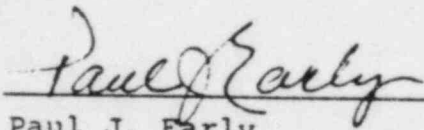
Item #8  
1 of 2 pages  
Prepared: 11-9-83  
License#34-16272-01

The following individuals have received 50 hours of supervised training in the listed areas:

1. Survey Meter
  - a) Calibration
  - b) Radiation Safety
  - c) Reporting
  
2. Wipe Sampling of Sealed Sources
  - a) Technique
  - b) Analysis
  - c) Radiation Safety
  - d) Instrument Calibration
  - e) Reporting

In addition, a review of conditions as stated in NRC License has been completed.

E. De Witt Liles  
Raymond L. Kaczur  
W. Christopher Wagner  
Steve A. Spinosi

  
Paul J. Early  
Radiation Safety Officer

Item #8  
2 of 2 pages  
Prepared: 11-9-83  
License#34-16272-01



TRAINING AND EXPERIENCE  
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1 NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER W. Christopher Wagner, B.A.		2 STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE		
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
American Registry of Radiologic Technologists	Registered - Radiologic Technology	1979		
	Registered - Nuclear Medicine Technology	1981		
Nuclear Medicine Technology Certification Board	Certified Nuclear Medicine Technology	1980		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES				
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING		
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D	
a RADIATION PHYSICS AND INSTRUMENTATION	Training accrued during 2 year Radiologic Technology at Muskingum Area	120	100	
b RADIATION PROTECTION	Technical College, Zanesville, Ohio and 1 year Nuclear Medicine Technology program at the	30	20	
c MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Ohio State University	20		
d RADIATION BIOLOGY		20		
e RADIOPHARMACEUTICAL CHEMISTRY		20	80	
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		See attached resume.		

# **V NMA STAFF CONSULTANT**

## **W. Christopher Wagner, B.A., CNMT**

Consultant, Nuclear Medicine Associates, Inc.

### **EDUCATION**

- 1975-1976 Ohio Northern University
- 1976-1977 Ohio University
- 1977-1979 Muskingum Area Technical College, Zanesville, Ohio  
Associate Degree - Applied Sciences; Major: Radiologic Technology
- 1979-1980 Ohio State University Hospitals, School of Nuclear Medicine Technology, Columbus, Ohio. Certificate in Nuclear Medicine
- 1982-1983 Otterbein College, Westerville, Ohio, B.A. Degree. Major: Nuclear Medicine

### **EXPERIENCE & QUALIFICATIONS**

- 1979 Bethesda Hospital, Zanesville, Ohio, Staff Radiologic Technologist
- 1980-1983 Doctors Hospital, Columbus, Ohio, Staff Nuclear Medicine Technologist
- 1983 Nuclear Medicine Associates, Inc., Cleveland, Ohio

### **PROFESSIONAL AFFILIATIONS**

- American Registry of Radiologic Technologists - Registered 1979 in Radiology;  
Registered 1980 in Nuclear Medicine
- Nuclear Medicine Technology Certification Board - Registered 1980
- Central Ohio Society of Nuclear Medicine (Board Member - Executive Committee 1983)
- Society on Nuclear Medicine (SNM)
- Cleveland Area Medical Physicists (CAMP)

TRAINING AND EXPERIENCE  
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER Raymond L. Kaczur	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
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3. CERTIFICATION		
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Registry of Radiologic Technologists Nuclear Medicine Technology Certification Board		A.R.R.T. 1979 Reg. #153290 C.N.M.T. 1979 Reg. #003312

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES			
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Didactic Training: Nuclear Medicine Institute 6780 Mayfield Road Cleveland, Ohio 44124	29	72
b. RADIATION PROTECTION	From 5-78 to 9-78  Clinical Training:	25	8
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	From 9-78 to 5-79 Presbyterian Hospital of Pacific Medical Center	40	8
d. RADIATION BIOLOGY	and Childrens Hospital, San Francisco, California	20	—
e. RADIOPHARMACEUTICAL CHEMISTRY		26	16

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Mo-99	3 Ci	Hillcrest Hospital	4 years	Diagnostic
Tc-99m	2 Ci	Cleveland, Ohio	"	Diagnostic
I-131	250 mCi	"	"	Diagnostic
Cs-137	1.0 mCi	"	"	Diag/Therapy
P-32	15 mCi	"	"	Calibration
Yb-169	1.0 mCi	"	"	Therapy
I-125	3 mCi	"	"	Diagnostic
Cr-51	0.5 mCi	"	"	Diagnostic

## **Raymond L. Kaczur, B.S., CNMT**

Consultant, Nuclear Medicine Associates, Inc.

### **EDUCATION:**

- 1975        B.S. University of Akron, Akron, Ohio  
1978-1979   Nuclear Medicine Institute, Cleveland, Ohio

### **QUALIFICATIONS:**

- 1978-1979   Student Nuclear Medicine Technologist, Presbyterian Hospital of Pacific Medical Center and Childrens Hospital, San Francisco, California  
1979-1981   Staff Technologist, Hillcrest Hospital, Cleveland, Ohio  
1981-1982   Assistant Technical Director, Nuclear Medicine Department, Hillcrest Hospital, Cleveland, Ohio  
1982-1983   Chief Technologist, Nuclear Medicine Department, Hillcrest Hospital, Cleveland, Ohio  
1983        Nuclear Medicine Associates, Inc., Cleveland, Ohio

### **CERTIFICATIONS:**

- 1979        R.T. (N) (ARRT) Nuclear Medicine #153290  
1979        Nuclear Medicine Technology Certification Board Certificate No. 003312

### **PUBLICATIONS:**

- 1982        Contribution to Technicare Corporation, Computer Users Disc. Program called "THALP" for Processing Thallium Studies.

### **LECTURES:**

- "Macroprogramming" Technical Computer Users Meeting, Cleveland, Ohio, 1981  
"Stress Imaging and What to Avoid", N.O.S.N.T. Meeting, October, 1981

### **SOCIETIES:**

- Board Member, Northeastern Ohio Society of Nuclear Medicine Technologists.  
Society of Nuclear Medicine (SNM)  
Member, Cleveland Area Medical Physicists (CAMP)

**TRAINING AND EXPERIENCE  
AUTHORIZED USER OR RADIATION SAFETY OFFICER**

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

Steve A. Spinosi, B.S.

2. STATE OR TERRITORY IN  
WHICH LICENSED TO  
PRACTICE MEDICINE

**3. CERTIFICATION**

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Registry of Radiologic Technologist	Registered - Radiologic Technology; Registered- Nuclear Medicine Tech- nology	1975 1976
Nuclear Medicine Tech- nology Certification Board	Certified Nuc. Medicine Technology	1978

**4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES**

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Training accrued during two year radiologic technology and one year	120	100
b. RADIATION PROTECTION	nuclear medicine tech- nology program at the Ohio State University	30	20
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY		20	—
d. RADIATION BIOLOGY		20	—
e. RADIOPHARMACEUTICAL CHEMISTRY		30	60

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
	See attached	resume.		



# **V NMA STAFF CONSULTANT**

## **Steve A. Spinosi, B.S.**

Consultant, Nuclear Medicine Associates, Incorporated

### **EDUCATION**

- 1970-1975 Ohio State University, Columbus, Ohio, B.S. in Allied Medicine,  
Radiologic Technology
- 1975-1976 Ohio State University Hospitals, Columbus, Ohio  
Certificate: Nuclear Medicine Technology
- 1978 James Picker School of Ultrasound, Cleveland, Ohio  
Certificate: Ultrasound Technology
- 1979 Doctors Hospital Management Training, Columbus, Ohio

### **QUALIFICATIONS**

- 1974-1976 Doctors Hospital, North, Columbus, Ohio, Radiologic Technologist
- 1976-1979 Hardin Memorial Hospital, Kenton, Ohio  
Chief Technologist Department of Nuclear Medicine and Ultrasound
- 1979-1983 Doctors Hospital, North, West and Doctors Hospital of Columbus, Ohio  
& Nelsonville, Ohio. Chief Technologist - Department of Nuclear Medicine
- 1983-Present Nuclear Medicine Associates, Incorporated

### **SOCIETIES**

- American Registry of Radiologic Technologists (ARRT)  
- 1975 Radiologic Technology  
- 1976 Nuclear Medicine Technology

American Society of Radiologic Technologists

Ohio Society of Radiologic Technologists

- Society of Nuclear Medicine  
- Faculty & Program Advisor: Central Chapter

- Past President: Local Chapter

- Nuclear Medicine Institute, Cleveland, Ohio  
- Faculty & Advisor

- Nuclear Medicine Technology Certification Board (NMTCB)  
- 1978 Nuclear Medicine Technology

### **LECTURES & PAPERS:**

- "Nuclear Medicine Imaging in Stress Fractures" Ohio Osteopath - 1982
- "Review of Current Nuclear Medicine Technology Certification"  
Central Ohio Society of Nuclear Medicine - 1982
- "Management of the Nuclear Therapy Patient"  
Central Ohio Society of Nuclear Medicine - 1982
- "Professional Ethics & Patient Communications" - Dept. of Radiology,  
Nuclear Medicine, Ultrasound & Computed Tomography - 1983
- "Camera Acceptance Testing" - Cleveland Area Medical Physicists (CAMP) - 1983



TRAINING AND EXPERIENCE  
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER  E. DeWitt Liles, M.A.	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
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3. CERTIFICATION		
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES			
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Minimally, the number of hours	62.5	37.5
b. RADIATION PROTECTION	Obtained over the course of masters	17.5	12.5
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Degree at the University of Texas of Austin	20	0
d. RADIATION BIOLOGY		20	0
e. RADIOPHARMACEUTICAL CHEMISTRY		17.5	12.5

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
See attached resume.				

# NMA STAFF CONSULTANT

## **E. DeWitt Liles, M.A.**

Consultant and Instructor, Nuclear Medicine Associates, Inc.

### **EDUCATION**

- 1959-1962 B.A. in Mathematics, The University of Texas at Austin
- 1963 B.S (equivalent) in Physics. The University of Texas at Austin
- 1962-1964 Graduate Studies, The University of Texas at Austin
- 1965-1967 Pre-Doctoral Fellow in Biophysics, University of Texas Graduate School of Biomedical Sciences, Houston, Texas
- 1968 M.A., Nuclear Physics. The University of Texas at Austin
- 1972-1974 Fellow in Medical Physics, M.A. Anderson Hospital and Cancer Institute, Houston, Texas
- 1981 Nuclear Regulatory Commission. Licensing Course, Washington, D.C.
- 1982 Hospital and Public Health Administration. Cleveland State University

### **EXPERIENCE & QUALIFICATIONS**

- 1968-1970 Human Engineering Analyst, The Boeing Co., Life Sciences Technology Division, Houston, Texas
- 1970-1972 Research Associate, NASA Medical Directorate and Physics Department, University of Texas, M.D. Anderson Hospital, Houston, Texas
- 1972-1974 Fellow in Medical Physics, M.D. Anderson Hospital and Cancer Institute, Houston, Texas
- 1974-1975 Medical Physicist, Methodist Hospital/Baylor College of Medicine System Affiliated Hospitals, Houston, Texas
- 1976-1982 Manager or Applications Engineer. EMI Therapy Systems, TOSHIBA Medical Systems, AECL and Victoreen, Inc.
- 1981 Radiation Physicist III, Alabama Department of Public Health - Radiological Health, Montgomery, Alabama
- 1983 Medical Physics Consultant and Instructor, Nuclear Medicine Associates, Inc., Cleveland, Ohio

### **SOCIETIES**

- Society of Nuclear Medicine (SNM)
- Cleveland Area Medical Physicists (CAMP)

## PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES

In accordance with the Guide for Supporting Documentation for Xenon-133 use, please accept the following information:

### I. Quantities to be received and dispensed:

The desired possession limit is two curies of Xenon-133 in gas and/or saline form. The only forms of Xenon-133 we are requesting are sealed glass vials of the New England Nuclear, Diagnostic Isotopes, Medi-Physics type of glass vial containing gas, or the Mallinckrodt cartridge or Diagnostic Isotope vial of Xenon-133 in saline. The rubber septums of these vials will not be punctured nor the contents of the vials altered in any way. These vials will be shipped from the nuclear pharmacy in the same containers and form in which they are shipped to the pharmacy, reducing the possibility of Xenon-133 leaks, spills or contamination essentially to zero.

### II. Use and Storage Areas:

When the pharmacy receives shipments of Xenon-133, the gas or gas in saline will be in sealed glass vials which will be shipped to authorized users without being opened or without the septum being punctured by anyone in the pharmacy. The sealed vials will be stored in a fume hood, nevertheless, and will remain inside the lead containers used by the manufacturer for shipment of the Xenon-133. Please see attached floor plan diagram for the location of the fume hood.

Xenon-133 is not to be used in the pharmacy. It will be stored and dispensed in the fume hood only. The exhaust system consists of a vent in the hot lab room and the fume hood. The ducts from these two exhausts meet before reaching the roof. There is a common duct for these vents from this juncture to the roof. The exhaust rate from the hot lab vent is 800 cfm. The exhaust rate from the front of the fume hood is 100 cfm. This is a direct exhaust to the roof only, no recirculation. The nearest point of re-entry is at least 35 feet from the nearest window, door or intake vent.

These exhaust rates will be checked semi-annually with a velometer to determine if the fume hood is operating according to specifications in this license.

### III. Procedures for routine use:

The vials will be stored in the original shipping containers composed of lead, and they will be stored in the fume hood at all times. When an authorized user orders a quantity of Xenon-133 gas or gas in saline, the vials will be dispensed in their original containers to the physician. Dispensing will be preceded by an assay of the vial in the dose calibrator.

### IV. Emergency Procedures:

The worst occurrence possible will be the accidental release of the contents of a Xenon-133 unit dose vial(s). This could happen through breakage or a cracked vial.

In the event there is an accidental loss of Xenon into the room, the exhaust system will clear the room to levels less than  $1 \times 10^{-5}$  uCi/ml in less than 6 minutes:

For the Hot lab room:

$$\text{Activity per loss (A)} = 25 \text{ mCi} = 2.5 \times 10^4 \text{ uCi}$$

$$\begin{aligned} \text{Room Volume (V)} &= 15' \times 9' \times 8' \\ &= 1080 \text{ ft.}^3 \\ &= 3.06 \times 10^7 \text{ ml} \end{aligned}$$

$$\begin{aligned} \text{Clearance rates } (\lambda) &= \frac{900 \text{ cfm}}{1080 \text{ ft.}^3} \\ &= 0.83 \text{ min.}^{-1} \end{aligned}$$

$$\begin{aligned} \text{Initial Concentration (C}_0) &= \frac{2.5 \times 10^4 \text{ uCi}}{3.06 \times 10^7} \\ &= 8.17 \times 10^{-4} \text{ uCi/ml} \end{aligned}$$

$$\text{Evacuation time (t)} = 6 \text{ min.}$$

$$\begin{aligned} \text{Final concentration (C)} &= C_0 e^{-\lambda t} \\ &= 8.17 \times 10^{-4} e^{-0.83 \times 6} \\ &= 5.62 \times 10^{-6} \text{ uCi/ml} \end{aligned}$$

This value is less than  $1 \times 10^{-5}$  uCi/ml.

All unnecessary personnel will evacuate the room. Both hallway doors leading to the hot lab will be guarded against inadvertent entry during this time period.

A survey meter will be placed on the floor so it can be observed from the door. When background levels are reached, the room may be re-entered.

V. Air Concentration of Xenon-133 in Restricted Areas

- A. The maximum amount of Xenon in possession per week will be 1500 mCi (A).
- B. For storage of Xenon in the hot lab it is assumed that up to 5% of the gas may be lost due to leakage. (f)
- C. An exhaust rate of 900 cfm will be used for this calculation.

$$V = 900 \text{ cfm} \times 6.797 \times 10^7 \text{ ml/40 hr wk/cfm}$$

$$V = 6.12 \times 10^{10} \text{ ml/wk}$$

- D. The average concentration of Xenon in the hot lab is (C):

$$C = \frac{A \times f}{V}$$

$$= \frac{1500 \text{ mCi} \times 1 \times 10^3 \text{ uCi/mCi} \times 0.05}{6.12 \times 10^{10} \text{ ml/wk}}$$

$$= 1.23 \times 10^{-6}$$

This value is less than required for restricted areas ( $1 \times 10^{-5}$  uCi/ml)

VI. Methods for Xenon-133 Disposal:

- A. All Xenon acquired will be disposed by dispensing to clients, or by decay in storage. Containers and vials will be surveyed unshielded with the low level survey meter held on contact. If levels are the same as background, the containers will be disposed after defacing the labels.

All escaped Xenon will be vented through the exhaust system.

- B. It is estimated that up to 78000 mCi of Xenon-133 will have been in possession per year.
- C. Of this amount, 5% will be lost due to leakage of Xenon in storage.
- D. Therefore, 5% or 3900 mCi will be vented to the atmosphere per year.
- E. The total exhaust system of 900 cfm will be used in this calculation.
- F. Air flow per year is (V):

$$V = 900 \text{ cfm} \times 1.484 \times 10^{10} \text{ ml/yr/cfm}$$

$$V = 1.34 \times 10^{13}$$

- G. The average concentration of Xenon to the environment is (C):

$$C = \frac{A}{V}$$

$$= \frac{3.9 \text{ Ci} \times 1 \times 10^6 \text{ uCi/Ci}}{1.34 \times 10^{13} \text{ ml/yr}}$$

$$= 2.91 \times 10^{-7} \text{ uCi/ml/yr}$$

This value does not exceed the quantity  $3 \times 10^{-7} \text{ uCi/ml}$  permitted in 10 CFR 20.106 for unrestricted areas.