NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved by OMB 3150-0041 Expires 9-30-83

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to : Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Naval Hospital
Camp Lejeune, N.C.
28542

TELEPHONE NO.: AREA CODE 919 451 4670

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

Same as 1a.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

HMC J. T. Cusick

TELEPHONE NO.: AREA CODE 919 451 4670

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 32-00189-03
c. ☐ RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

LTjg R. W. Huseman

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100,SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. 1 Date: October 1980

7. MEDICAL ISOTOPES COMMITTEE	15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*
☐ Names and Specialties Attached; and	☐ Appendix G Rules Followed; or
☐ Duties as in Appendix B; or *(Check One)*	☐ Equivalent Rules Attached
☐ Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*
8. TRAINING AND EXPERIENCE	☐ Appendix H Procedures Followed; or
☐ Supplements A & B Attached for Each Individual User; and	☐ Equivalent Procedures Attached
X Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*
9. INSTRUMENTATION *(Check One)*	☐ Appendix I Procedures Followed; or
☐ Appendix C Form Attached; or	☐ Equivalent Procedures Attached
☐ List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*
10. CALIBRATION OF INSTRUMENTS	☐ Appendix J Form Attached; or
☐ Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	☐ Equivalent Information Attached
☐ Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*
☐ Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	☐ Appendix K Procedures Followed; or
☐ Equivalent Procedures Attached	☐ Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	20. THERAPEUTIC USE OF SEALED SOURCES
☐ Description and Diagram Attached	☐ Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	☐ Appendix L Procedures Followed; or *(Check One)*
☐ Description of Training Attached	☐ Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)
☐ Detailed Information Attached	☐ Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS
	☐ Detailed Information Attached
☐ Appendix F Procedures Followed; or	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b
☐ Equivalent Procedures Attached	☐ Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM		
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD		
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY:

(2) LICENSE FEE ENCLOSED: $

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*
J. D. MARRIOTT, CAPT, MC, USN

(2) TITLE
Commanding Officer, Naval Hospital
Camp Lejeune, N.C.
28542

c. DATE
30 Jan 1984

NRC FORM 313M (9-81)

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
LTjg William F. Huseman, USN, RSO	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
State Board of Pharmacy of Colorada	Registered Pharmacist Nuclear Pharmacist	April 1982 July 1982

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	SEE ATTACHED ENCLOSURE		
b. RADIATION PROTECTION	"		
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"		
d. RADIATION BIOLOGY	"		
e. RADIOPHARMACEUTICAL CHEMISTRY	"		

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Various	Various	Western Diagnostic Services, Denver, Colorado	1979 to Febuary 1982	Radiopharma-ceuticals

ciriculum vitea for :

William F. Huseman
LTJG MSC USNR
575-62-5541

This circulum vitea is submitted with supplement A of NRC-313M for location, dates of training, past experience and qualifications as a Nuclear Pharmacist.

A. Courses at the University of Colorado School of Pharmacy

1. CNPH-437 Nuclear Pharmacy Externship 96 contact hours 2 semester hours
I worked with Ron Gonzales, BS Pharmacy and a certified Nuclear Pharmacist, at Nuclear Pharmacy Inc. Denver, Colorado. This course explained the regional and unit dose concepts of a Nuclear Pharmacy, its use of various nuclear-pharmaceuticals with regard to their physical and chemical properties, and clinical applications, radiologic laboratory procedures and safety techniques, dose calculation, preparation and calibration, thin layer chromotography to assure quality control of kit preparations, receipt and shipment of radio-active material, radioactive waste storage and disposal.

2. CNPH-428 Institutional Pharmacy Externship-Nuclear Pharmacy 96 contact hours 2 semester hours
This externship took place at the University of Colorado Health Sciences Center where I worked for Dennis Eshima BS-Pharmacy, MS-Nuclear Pharmacy, and a certified Nuclear Pharmacist. This course was an introduction to the hospital Nuclear Medicine Department with heavy emphasis on several aspects of nuclearpharmaceutical practice including radiation properties, chemical properties and biological properties. I did continual monitoring of calculations for volume-activity, dosage-activity, decay factors and rate of generation of daughter nuclides from the mother for a wide variety of nuclearpharmaceuticals including many investigational ones. I also worked closely with the Radiation Safety Unit and took part in their safety inspection, waste monitoring and waste disposal.

3. CNPH-441 Clinical Pharmacy Projects- Nuclear Pharmacy Research 96 contact hours 2 semester hours
This research project was done at the University of Colorado Health Sciences Center, Denver Colorado under Allen Fritzberg PhD and titled "The Iodination of 12(iodophenylsulfonamide)dodecanoic Acid and It's Use As a Myocardial Imaging Agent".The purpose of this project was to determine if a radio-iodinated fatty acid analog could be used to replace the potassium analog approach currently being used in myocardial imaging. A summary of this project is submitted as enclosure (1).

B. Post graduate courses attended at the University of Colorado Health Sciences Center, Denver Colorado

1. RAD-623 Radiology-Nuclear Pharmacy 3 semester hours
This course delt with radionuclide selection and production, nuclear physics, nuclear chemistry, chemistry and biological properties of routine and new nuclearpharmaceuticals, selection of appropriate agents, pharmaceutical preparation considerations, quality assurance, in vitro studies, competitive protein binding assays. Also included observation and participation in nuclear medicine hot lab and laboratory preparations from chemicals to bio-logical assay.

2. RAD-614 Radiology-Radiation Biology 3 semester hours
This course emphasized the effects of irradiation on human tissues, effects of radiation on cellular, molecular organs and whole organism levels, and late effects of ionizing radiation including mutation and carcinogenesis.

C. Intern Nuclear Pharmacist for BNPI/WDS Golden, Colorado for 2 years 1979-81

As an intern I worked for Benedict Nuclear Pharmaceutical Inc., a manufacturer of nuclearpharmaceuticals and its subsidiary, Western Diagnostic Services, a nuclear pharmacy. I had the benefit of not only learning the operation of a nuclear pharmacy but the process by which the nuclearpharmaceuticals are manufactured. While an intern I was given many lectures on radiation safety and health physics by R. Penndelton PhD. Dr. Penndelton was the company's advisor on radiation safety and health physics who monthy came from the University of Utah to Colorado to inspect our facility and teach, and continuously reminded us of the ALARA concept of nuclear safety. When I took over as supervisor of WDS I worked closely with Dr. Penndelton on the rules and regulation pertaining to radioactive materials, shipment, receiving, waste management and disposal.

D. Graduated from the University of Colorado School of Pharmacy with a BS in Pharmacy May 1981 enclosure (2)

E. Became a Registered Pharmacist in the state of Colorado April 1982 enclosure (3)

F. Became certified as a Nuclear Pharmacist by the State Board of Pharmacy of Colorado July 1982 enclosure (4)

G. Nuclear Pharmacist with Western Diagnostic Services, Denver, Colorado. Primary duties:

1. Supervisor of the nuclear pharmacy
2. Radiation Safety Officer-May 81 to Feb 82
3. Insure compliance with the rules and regulations of the
   State Board of Pharmacy
   Nuclear Regulatory Commission
   Department of Transportation
   Department of Health

William Huseman

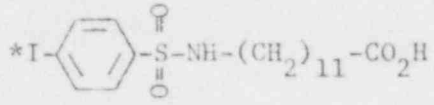
William Huseman

Bill Huseman CNPH-441 Clinical Pharmacy Projects 12-22-80

THE IODINATION OF 12(iodophenylsulfonamide)dodecanioc Acid and IT'S USE AS A MYOCARDIAL IMAGING AGENT.

With the increase of heart related deaths it becomes increasingly important that early and accurate detection be made. At this time the radiopharmaceutical Tl-201 is the most widely used myocardial imaging agent and can be used to detect ischemic tissue and coronary artery disease. Tl-201, although probably the best myocardial imaging agent on the market now, has a limited use. The fact only three percent uptake is seen and that it's gamma peaks are at 135 and 167 with a half life of 74 hours could be considered limiting. There is on-going research for a radiopharmaceutical that could be diagnostically reliable yet with fewer problems.

In this study we evaluated the use of a radioiodinated fatty acid analog utilizing a sulfonamide as a connecting group in the fatty acid alkyl chain.(Fig.1)



Rather than try the potassium analog approach, Tl-201, we used fatty acids for two reasons. The first being that the major source of energy to the myocarium is from fatty acids so rapid uptake could be expected. The subsequent reason is the ease of using a I-123 label which not only has a 159 KeV gamma radiation but a thirteen hour half life as well.

The use of a sulfonamide in the alkyl chain is because "sulfur is well known as an isostere of CH_2 and CH=CH groups and can be inserted without significant alteration of biological behavior. The more highly oxidized forms involve a larger insertion group but it is thought that they will be far enough from the carboxy group so that uptake will not be changed by a large extent. Although the metabolism of thioethers does not appear to be well known, it is reported to involve cleavage and sulfur oxidation to the sulfonic acid level via sulfinic acids. Sulfonic acids are strong acids and would remain vertually completely ionized under physiological conditions. Thus, alkyl sulfonic acids may be expected to remain trapped in the cell in contrast to carboxylic acids which are protonated sufficiently to readily cross the cellular membrane(1)."

METHODS and MATERIALS.

The reaction mixture was 2mg of 12(iodophenylsulfonamide)dodecanioc acid, 0.01 ml $CuSO_4$ and 0.1ml I-125 in 0.4ml of the solvent dimethylformamide (DMF). The mixture was placed in an oil bath at 100-120°C for a period of one hour. After the reaction was complete it was extracted in 0.5ml of water with two drops of 6N HCl and washed with 0.5ml toluene. The organic layer was dried in an oil bath, 110°C, under a nitrogen stream. 0.5ml of propylene glycol was added to the residue and heated for 15 minutes in a 38°C water bath. The mixture was then added to 0.83ml of a twenty percent albumin solution and heated for 15 minutes in a 38°C water bath.

enclosure (1)

The study was done in mice who were injected IV through a tail vein with luCi in 0.2ml solution. Six mice were used with two each injected and sacrificed at 5, 30 and 60 minutes.

RESULTS:

	Heart	Blood	Liver	Spleen	Lungs	Kidneys	Stomach	Intestine	Urinary Bladder	Muscle	Carcass
dose uptake mouse#1 30 minutes	0.05	6.03	4.39	0.11	.256	1.06	0.83	6.43	61.3	2.45	5.17
dose uptake mouse #2 1 hour	0.04	4.40	1.44	0.09	0.14	0.69	0.73	4.95	76.4	1.62	7.8
dose uptake mouse #3 30 minutes	0.05	6.03	6.04	0.11	0.24	2.79	0.78	3.51	58.6	6.80	2.65
dose uptake mouse #4 1 hour	0.02	3.73	2.34	0.50	0.17	0.44	0.80	3.96	79.4	1.51	2.16
dose uptake mouse #5 5 minutes	0.20	17.9	20.9	0.16	0.70	16.0	0.64	3.77	7.27	15.9	17.1
dose uptake mouse #6 5 minutes	0.19	15.3	20.8	0.19	0.58	19.9	0.63	6.43	2.14	12.4	15.1

DISCUSSION:

It appears that the iodinated fatty acid is dispersed quickly in the blood and just as quickly taken up by the liver. It is then taken up by the kidneys and then collected in the urinary bladder. Heart uptake is most evident at five minutes although the amount is extremely small and and quickly cleared.

R ences;
1. Taken from the grant application tit y Acid Myocardial Imaging Agents" by Dr. Alan R. Frit 3-30

enclosure (1)

THE REGENTS OF THE

UNIVERSITY OF COLORADO

HAVE CONFERRED ON

WILLIAM F. HUSEMAN

THE DEGREE

BACHELOR OF SCIENCE

PHARMACY

WITH ALL THE RIGHTS AND PRIVILEGES THEREUNTO APPERTAINING.
IN WITNESS THEREOF THIS DIPLOMA IS AWARDED BY THE REGENTS
UPON THE RECOMMENDATION OF THE FACULTY.

GIVEN AT BOULDER ON THE TWENTY-SECOND DAY OF MAY, A.D.
NINETEEN HUNDRED AND EIGHTY-ONE AND IN THE
ONE HUNDRED FIFTH YEAR OF THE UNIVERSITY

Jack Kay Anderson
CHAIRMAN, BOARD OF REGENTS

Arnold R. Weber
PRESIDENT OF THE UNIVERSITY

UNIVERSITY OF COLORADO 1876

J. Russell Nelson
CHANCELLOR

V. Gene Erwin
DEAN OF THE FACULTY

16925

The State Board of Pharmacy
State of Colorado,

DOES HEREBY CERTIFY THAT

William F. Huseman

IS A REGISTERED PHARMACIST

No. 11436

as defined in an act of the General Assembly entitled "an act creating a Board of Pharmacy and defining the powers and duties thereof," approved April 18th, 1907, and as subsequently amended, and is therefore duly authorized to compound and dispense drugs, medicines and pharmaceutical preparations in a licensed pharmacy during the term ending June 30th, 1982 and thereafter upon payment of the annual renewal fee.

In Witness Whereof we have hereunto set our hands and affixed the Seal of the State Board of Pharmacy, this 3rd day of March 1982.

President

Vice President

Member

Member

Member

Member

Member

Executive Secretary

STATE OF COLORADO

STATE BOARD OF PHARMACY
D.L. Simmons
Program Administrator

128 State Services Building
1525 Sherman Street
Denver, Colorado 80203
Phone (303) 866-2526

Department of Regulatory Agencies
Wellington E. Webb
Executive Director

Division of Registrations
Bruce M. Douglas, Director

Richard D. Lamm,
Governor

July 20, 1982

Mr. William Huseman
10312 West Florida Avenue
Lakewood, CO 80226

Dear Mr. Huseman:

The Colorado State Board of Pharmacy has reviewed your qualifications as a nuclear pharmacist and find that you meet the requirements of Regulation 81-11.

FOR THE COLORADO STATE BOARD OF PHARMACY

D. L. Simmons

D. L. Simmons
Administrator

DLS/ak

enclosure (4)

0 AP 89 5

PHARMACY RULES AND REGULATIONS

81-11 Nuclear Pharmacy

It is unlawful to receive, possess or transfer radiopharmaceuticals, except in accordance with Title 12, Article 22, C.R.S. 1973. It is also unlawful for any person to provide radiopharmaceutical services unless he or she is a nuclear pharmacist or a person acting under the direct supervision of a nuclear pharmacist acting in accordance with Title 12, Article 22, C.R.S. 1973 and the State Board of Pharmacy regulations and regulations of the Colorado Department of Health with the exception of an authorized practitioner for administration to his patients. No person may receive, acquire, possess, use, transfer or dispose of any radioactive material except in accordance with the conditions of any radioactive material license required by the Colorado Department of Health pursuant to Title 25, C.R.S. 1973. The requirements of these pharmacy regulations are in addition to, and not in substitution for, other applicable provisions of regulations of the State Board of Pharmacy and the State Radiation Control Agency.

1) Definitions

A. A "nuclear pharmacy" means a specialized pharmacy which deals with the preparation and delivery of radioactive material as defined in Section 25-11-101 C.R.S. 1973.

B. "Nuclear pharmacist" means a pharmacist who has received notification by letter from the Board that, based on the evidence submitted, he or she is recognized by the Board as qualified to provide radiopharmaceutical services.

C. "Radiopharmaceutical service" shall mean, but shall not be limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals, and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of radiopharmaceuticals.

D. A "radiopharmaceutical" is any substance defined as

a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or protons and includes any such drug which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

E. "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

F. "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to insure the integrity of the test.

G. "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical.

H. "Authorized practitioner" means a practitioner authorized by law to possess, use and administer radiopharmaceuticals, acting within the scope of such authority.

2. General Requirements for Nuclear Pharmacies

A. A nuclear pharmacy shall only be managed by a nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the direct supervision of a nuclear pharmacist. A nuclear pharmacist shall be in attendance at all times that the nuclear pharmacy is open for business and shall be responsible for all operations of the licensed area.

B. Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided. The nuclear pharmacy area shall be separate from the areas for non-radioactive drugs and shall be secured from unauthorized personnel. Nuclear pharmacies shall provide a radioactive storage and product decay area, occupying at least 25 square feet of space, separate from and exclusive of the radioactive laboratory, compounding, dispensing, quality assurance and administrative area. Nuclear pharmacies handling radiopharmaceuticals exclusively may be

exempted from the general space requirements for pharmacies by obtaining a waiver from the Board. Detailed floor plans shall be submitted to the Board and the State Radiation Control Agency before approval of the license.

C. Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable standards of radiopharmaceutical quality assurances.

D. Nuclear pharmacies shall maintain records of acquisition and distribution of all radiopharmaceuticals in accordance with Titles 12 and 25, C.R.S. 1973.

E. Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing non-radioactive drugs.

F. Radiopharmaceuticals are to be dispensed only upon a prescription order from an authorized practitioner.

G. A nuclear pharmacist may distribute radiopharmaceuticals to authorized practitioners. Such distribution shall be documented in the control system.

H. A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with regulations of the State Radiation Control Agency.

I. In addition to any requirement of the Board for non-radiopharmaceutical prescription orders, the prescription order shall include: (1) address of the authorized practitioner and/or the address where the prescription is to be administered; (2) the name of the radiopharmaceutical; (3) the amount of radioactive material contained, in millicuries or microcuries; (4) if a liquid, the volume in milliliters; (5) the requested calibration time for the amount of radioactivity contained; and (6) specific concentration of radioactivity.

J. In addition to any labeling requirement of the Board for non-radiopharmaceuticals, the immediate outer container of the radiopharmaceutical to be dispensed shall also be labeled with: (1) the standard radiation symbol; (2) the words "caution-radioactive material"; (3) the name of the radiopharmaceutical; (4) the amount of radioactive material contained, in millicuries or microcuries; (5) if a liquid, the volume in milliliters; (6) the requested calibration time for the amount of radioactive material contained; (7) expiration data, if applicable; (8) specific concentration of radioactivity.

K. The immediate inner container shall be labeled with: (1) the standard radiation symbol; (2) the words "caution radioactive material"; (3) the name and address of the nuclear pharmacy; (4) the serial number of the prescription; (5) the name of the radiopharmaceutical.

L. The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

M. Nuclear pharmacies may redistribute NDA approved radiopharmaceuticals if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging.

N. Nuclear pharmacies shall maintain a library commensurate with the level of radiopharmaceutical service to be provided, and shall include state and/or federal regulations governing the use of applicable radioactive materials. A detailed library listing shall be submitted to the Board and the State Radiation Control Agency before approval of the license. The nuclear pharmacy shall maintain current editions of the publications shown on the library listing.

O. Nuclear pharmacies shall have adequate equipment commensurate with the scope of radiopharmaceutical services to be provided. A detailed list of equipment and description of use must be submitted to the State Board of Pharmacy and State Radiation Control Agency before approval of the license. The Board may, for nuclear pharmacies, for good cause shown, waive the requirements of 12-22-118(1).1.

P. General Requirements for Nuclear Pharmacists

A nuclear pharmacist shall:

1. Meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the State Radiation Control Agency;

2. Be a pharmacist licensed to practice in Colorado;

3. Submit to the Board either:

a) Certification that he or she has completed a minimum of four months on-the-job training providing radiopharmaceutical services under the supervision of a nuclear pharmacist in a nuclear pharmacy, or

b) Certification that he or she has completed a nuclear pharmacy training program in an accredited college of pharmacy, or

c) That upon application to the Board, in affidavit form, and upon the furnishing of such other information as the Board may require, the Board may grant partial or equivalent credit for education and experience gained in programs not sponsored by an accredited college of pharmacy if, in the opinion of the Board, the education and experience gained by participants in these programs would provide the same level of competence as participation in a program at an accredited college of pharmacy; and

4. Receive a letter of notification from the Board that the evidence submitted that the pharmacist meets the requirements of subsections (1), (2) and (3) above has been accepted by the Board and that, based thereon, the pharmacist is recognized as a nuclear pharmacist.

Basis: This regulation is promulgated under the authority of 12-22-120(3) and 12-22-110(1)(b) C.R.S. 1973, as amended.

Purpose: To insure that potentially dangerous radioactive pharmaceuticals are received, stored and dispensed in a safe manner and that federal and state nuclear regulatory commission standards have been met.

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