

National Veterinary Imaging, Inc.

10817 Sperry Road, Chesterland, Ohio 44026
(216) 256-8993 • (216) 291-8895 • (700) 818-1818

President: David Feiglin, MBBS, BSc, FACP, ABNM
Vice President: Lynn Tezak, RT, RT(NMT)

U. S. Nuclear Regulatory Commission
Nuclear Materials Licensing Section
Att: Robert G. Gattone, Jr.
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Mr. Gattone:

In reference to Control No. 94199 pertaining to National Veterinary Imaging Inc., the following information is submitted:

- 1.a. The mailing address and office of National Veterinary Imaging, Inc. is located at 10817 Sperry Road, Chesterland, Ohio. No radioactive materials will be used or stored at this site. Radioactive materials will only be used at 5035 Richmond Road, Cleveland, Ohio and 20600 Miles Parkway, Cleveland, Ohio. The address at 5035 Richmond Road is the small animal clinic where the small animals will be injected, and uptakes procedures performed; scanning of large and small animals will be injected and scanned at the 20600 Miles Parkway address. The addresses listed currently are used for veterinary medicine at this time.
- 1.b. The intention is to use and possess licensed material once the license has been approved.
- 1.c. The facilities are operational for veterinary medicine at this time.
- 1.d. N/A.
2. Radioactive material and purpose for which licensed material will be use:

Technetium -99m - 150 mCi per dose maximum with a total possession of 500 mCi at any given time
Purpose of use: Diagnosis

Iodine -131 - 13 mCi per dose total
Purpose: Treatment of hyperthyroidism

Cesium-137 and Barrium-133 - 500uCi each
Purpose: Instrument calibration

Information in this record was deleted
in accordance with the Freedom of Information
Act, exemptions 6
FOIA- 93-275

RECEIVED

DEC 14 1992

REGION III

9405020306 930706
PDR FOIA
CRYDERM93-275 PDR

P-32 and SR-89 - as needed for radiopharmaceutical therapy

The doses will be adjusted for weight - the guidelines from Ohio State University - Dr. Bailey, Veterinary Radiologist - will be adhered to.

The studies will be the same as those for humans with doses adjusted for veterinary use.

3. Enclosed please find Supplements A and B for both Dr. Bennet D. Fagin and Dr. Terrance A. Hamilton. Each of these Veterinarians are Board Certified by the American College of Veterinary Medicine with specialties as noted.
4. The Radiation Safety Officer will be responsible for the following:
 - a. will ensure that the use of radioactive materials is by or under the direct supervision of individuals specifically licensed on this License.
 - b. Will ensure that all users wear personnel monitoring equipment when using radioactive materials when appropriate.
 - c. will ensure that radioactive materials are properly secured against unauthorized removal at all times when not in use.
 - d. will perform routine inspections of all laboratories using or storing radioactive materials. Additionally, each of the laboratories will be visited by Universal Consultants, Inc. with a summary of findings forwarded to the Radiation Safety Officer.
 - e. will ensure that the terms and conditions of this License are met and that all required records are maintained.
 - f. will immediately halt any activity judged to be a threat to health, safety, the environment or a violation of the conditions of this License or the regulations.
- 4.b. Please refer to attached letter from Dr. David Feiglin indicating total number of hours and experience involving veterinary use of byproduct material.
5. Please delete reference for an alternate Radiation Safety Officer.

6. Enclosed are detailed diagrams of the locations of use of byproduct material located at 5035 Richmond Road and 20600 Miles Parkway.

As previously noted, the address at 5035 Richmond Road is a small animal clinic where injections for dose administrations will be performed. A thyroid uptake system will be available for thyroid assays along with personel bioassays if needed.

The address located at 20600 Miles Parkway will be for both large and small animal dose administration. This clinic has a Technicare Gamma Camera which will be used for scanning.

Appropriate shielding will be available so that levels of radiation are less than those specified in 10 CFR 20.105 for permissible levels of radiation in unrestricted areas. Each of the animal rooms will be secured at all times unless attended by authorized users of radioactive materials or an individual supervised by an authorized user.

- 7.a. Licenced material will only be used by an individual under the supervision of an authorized user.

- 7.b. Training of all supervised individuals will include:

the model training program that was published in Appendix A to Regulatory Guide 10.8, Rev. 2; and

be given instruction by an authorized user in the principles of radiation safety appropriate so that the individual's use of byproduct material will coincide with the conditions of this license along with appropriate rules and regulations.

- 7.c. Supervised individuals will be required to follow the instructions of the supervising authorized user, and follow the established radiation safety procedures along with complying with the licensed conditions with respect to the use of byproduct material.

- 7.d. Authorized users will periodically review the supervised individual's use of byproduct material and maintain records to indicate as such.

- 7.e. The licensee that supervises an individual will be responsible for the acts and omissions of the supervised individual.

- 7.f. Documentation of all personnel training will include dates, topics discussed and attendees.
- 7.g. Normal handling techniques for animal caretakers will be implemented. Specific instruction as to animal waste, cleaning, and decontamination of animal cages will be performed by either an authorized user or the Radiation Safety Officer. Animal waste if found to be contaminated will be stored for a time period of ten half lives or until the readings are the same as background.
- 8.a. Survey instrument calibrations will be performed by Universal Consultants, Inc., in accordance with NRC License No. 34-20327-01.
- 8.b. Survey instruments will be calibrated prior to the first use, annually thereafter, and following repair.
- 9.a. Leak tests will be performed by Universal Consultants, Inc., in accordance with NRC License No. 34-20327-01.
- 9.b. Leak tests of sealed sources will be performed prior to the first use unless a certificate from the supplier indicates that the source was tested within the previous six months and at intervals not to exceed six months.
- 10. Authorized users will generate a prescription for the use of byproduct material listing the species of animal along with the owner's last name. The doses will be adjusted for weight at approximately 500 uCi per kilogram. An average bone scan for a horse would be in the range of 100 to 150 mCi of Tc99m. For small animals, the pediatric dose schedule as printed in the MIRD pamphlets will be adhered to. For treatment of hyperthyroidism of small animals, a dose of 6 mCi of I 131 will be administered.
- 11. No visitors will be allowed to come in contact with the animals until the levels are 5MR per hour at one meter. Gloves, etc., will be used when handling all animals. All of the gloves will be monitored for contamination and retained for ten half lives or until background. All of the animal excreta will be collected and saved for 10 half lives or until the levels are the same as background. Each of the cages will be checked for ambient radiation levels along with removeable contamination once the animals have been removed.

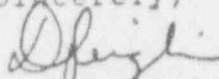
- 12.a. Animals will be released when an exposure rate from the animal is less than 5MR per hour at one meter. This will be measured with a radiation measurement survey meter at a distance of one meter from the animal.
- 12.b. Enclosed are instructions for Family of Released Patients. This form will be used with precautions discussed and with the signature obtained indicating that they have received this instruction.
- 13.a. Bioassays will be performed in accordance with Regulatory Guide 8.20. The bioassays will be performed by or under the supervision of an authorized user, the Radiation Safety Officer or a certified nuclear medicine technologist. Competency will be evaluated prior to the use of equipment involved.
- 13.b. Bioassays will be performed on the uptake system at the small animal clinic located at 5035 Richmond Road.
- 14.a. Ambient dose rates will be performed daily on each of the animal housing facilities when radioactive byproduct materials are used. Appropriate postings will be displayed in accordance with 10 CFR 20.203.

Removeable contamination surveys will be performed in the injection area at the conclusion of each day when radioactive materials are used.

- 14.b. Ambient dose rate surveys will be performed in the injection area at the conclusion of each day when radioactive materials are used.

Should you have any further questions regarding this application, please feel free to contact me.

Sincerely,



David Feiglin, M. D.
President and Radiation Safety Officer

Enclosures:

Supplement A & B - Dr. Bennet D. Fagin
Supplement A & B - Dr. Terrance A. Hamilton
Facility Diagram - 5035 Richmond Road
Facility Diagram - 20600 Miles Parkway
Instructions for Family of Released Patient
Appendum Letter - Dr. David Feiglin

SUPPLEMENT A

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

Veterinarian!

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

Dr. Bennett B. Fagin

2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED

OH

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American College of Veterinary Radiology	—	October 1991

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

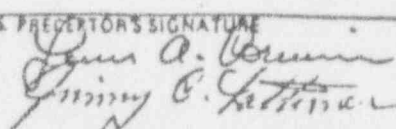
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	University of Missouri, 1987-1990 "Physics of Diagnostic Imaging" - course directed for the Pathology Residents - Vet Missouri Medical Center - taught by staff physicist	32	45
b. RADIATION PROTECTION	University of Missouri 1987-1990 Formal coursework - Vet Med & Surgery #488 "Radiation Safety"	48	45
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	See b. above	same as b. above	45
d. RADIATION BIOLOGY	University of Missouri 1987-1990, formal coursework Vet Med & Surgery #328 "Radiation Biology"	40	—
e. RADIOPHARMACEUTICAL CHEMISTRY	University of Missouri 1987-1990 formal coursework Vet Med & Surgery #487 "Nuclear Medicine"	48	—

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

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
Tc 99m	up to 100 mCi (equine dose of Tc-MDP for bone scan)	University of Missouri College of Veterinary Medicine Veterinary Teaching Hospital	Estimate ~100 hours total	Diagnostic & Therapeutic
I-131	5-10 mCi			

PROPOSED PHYSICIAN USER			
PRECEPTOR STATEMENT (Continued)			
2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)			
ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
P-32 (Colloid)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	—	<p>Co-60 performed at the University of Missouri Medical Center</p> <p>Under instruction of Dr. W. Volker - Univ. of Missouri Medical Center</p>
P-32 (Colloid)	INTRACAVITARY TREATMENT	—	
I-131	TREATMENT OF THYROID CARCINOMA	6	
	TREATMENT OF HYPERTHYROIDISM	11	
Au-198	INTRACAVITARY TREATMENT	—	
Co-60 or Co-137	INTERSTITIAL TREATMENT	—	
	INTRACAVITARY TREATMENT	—	
I-125 or Ir-192 Co-60 or Co-137	INTERSTITIAL TREATMENT	—	
	TELETHERAPY TREATMENT	27	
Sr-90	TREATMENT OF EYE DISEASE	—	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	1	
Sr-113/ In-113m	GENERATOR	—	
Tc-99m	REAGENT KITS	1	
Other	—	—	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING		
LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
University of Missouri Medical Center & Veterinary Teaching Hospital	1987-90	125

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:		5. PRECEPTOR'S SIGNATURE	
a. NAME OF SUPERVISOR DR. LOUIS CORWIN & Jimmy Lattimer			
b. NAME OF INSTITUTION 1600 E. Rollins Veterinary Teaching Hospital			
c. MAILING ADDRESS Columbia, MO		7. PRECEPTOR'S NAME (Please type or print)	
d. CITY 65211		LOUIS A. CORWIN Jimmy C. Lattimer	
6. MATERIALS LICENSE NUMBER(S) 24-00513-32		8. DATE 11-9-92	

SUPPLEMENT A

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

Terrance A. Hamilton, DVM, Dipl. ACVIM (Oncology)

2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED

Ohio, Illinois

SPECIALTY BOARD
A

CERTIFICATION
CATEGORY
B

MONTH AND YEAR CERTIFIED
C

American College of
Veterinary Internal Medicine
with a subspecialty of
Oncology

May, 1992

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

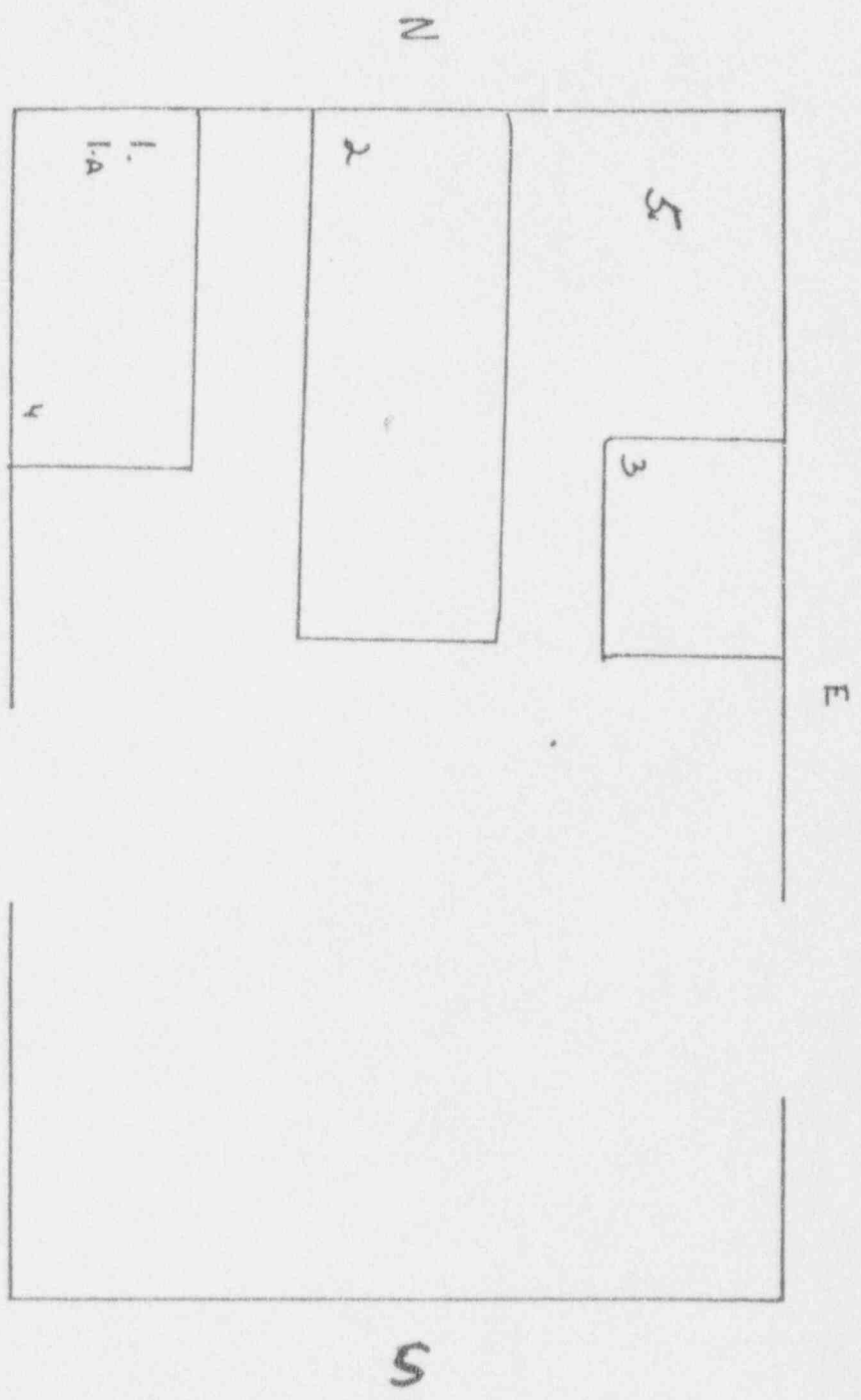
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	University of Illinois - 1986	3	120
	Purdue University - 1988-1991	1	5
b. RADIATION PROTECTION	University of Illinois - 1986	1	120
	Purdue University - 1988-1991	1	5
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Purdue University - 1988-1991	0	4
d. RADIATION BIOLOGY	University of Illinois - 1986	1	0
	Purdue University - 1988-1991	2	25
e. RADIOPHARMACEUTICAL CHEMISTRY	Purdue University - 1988-1991	1	36

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

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
I-131	6 mCi	Purdue University	6 hours	hyperthyroid treatment
Tc-99m	5-20mCi	Purdue University	46 hours	bone scans thyroid scans liver scans

PROPOSED PHYSICIAN USER <i>Terrance A Hamilton, DVM, Dipl. ACVIM (oncology)</i>			
PRECEPTOR STATEMENT (Continued)			
2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)			
ISOTOPE	CONDITIONS DIAGNOSED OR TREATED	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION	COMMENTS <small>(Additional information or comments may be submitted in duplicate on separate sheets.)</small>
A	B	C	D
<i>P-32 (Soluble)</i>	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	<i>0</i>	
<i>P-32 (Colloidal)</i>	INTRACAVITARY TREATMENT	<i>0</i>	
<i>I-131</i>	TREATMENT OF THYROID CARCINOMA	<i>1</i>	
	TREATMENT OF HYPERTHYROIDISM	<i>5</i>	
<i>Au-198</i>	INTRACAVITARY TREATMENT	<i>0</i>	
<i>Co-60</i> or <i>Cs-137</i>	INTERSTITIAL TREATMENT	<i>0</i>	
	INTRACAVITARY TREATMENT	<i>0</i>	
<i>I-125</i> or <i>Ir-192</i>	INTERSTITIAL TREATMENT	<i>0</i>	
	TELE THERAPY TREATMENT	<i>0</i>	
<i>Co-60</i> or <i>Cs-137</i>	TELE THERAPY TREATMENT	<i>0</i>	
	TREATMENT OF EYE DISEASE	<i>0</i>	
	RADIOPHARMACEUTICAL PREPARATION		
<i>Mo-99/ Tc-99m</i>	GENERATOR	<i>0</i>	
<i>Sn-113/ In-113m</i>	GENERATOR	<i>0</i>	
<i>Tc-99m</i>	REAGENT KITS	<i>0</i>	
Other			
3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING			
LOCATION	DATES	CLOCK HOURS OF EXPERIENCE	
<i>Purdue University</i>	<i>7/88-6/91</i>	<i>46 hours</i>	
4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:			
a. NAME OF SUPERVISOR <i>X William E. Blevins</i> <i>W.E. Blevins</i>	5. PRECEPTOR'S SIGNATURE <i>X Terrance A Hamilton, DVM</i>		
b. NAME OF INSTITUTION <i>X Purdue University</i>	7. PRECEPTOR'S NAME (Print name type or print) <i>X Terrance A Hamilton, DVM</i>		
c. MAILING ADDRESS <i>X School of Veterinary Medicine</i>	8. DATE <i>X 11/23/90</i>		
d. CITY <i>X W. LaFayette, IN 47907</i>			
6. MATERIALS LICENSE NUMBER(S) <i>X 13-02812-04</i>			

5035 Richmond Road Cleveland, Ohio



1. Counter - Receipt & Storage Radioactive material

1A. Work Counter - Decay storage Radioactive waste

2. Administration, Injection Area (Counter)

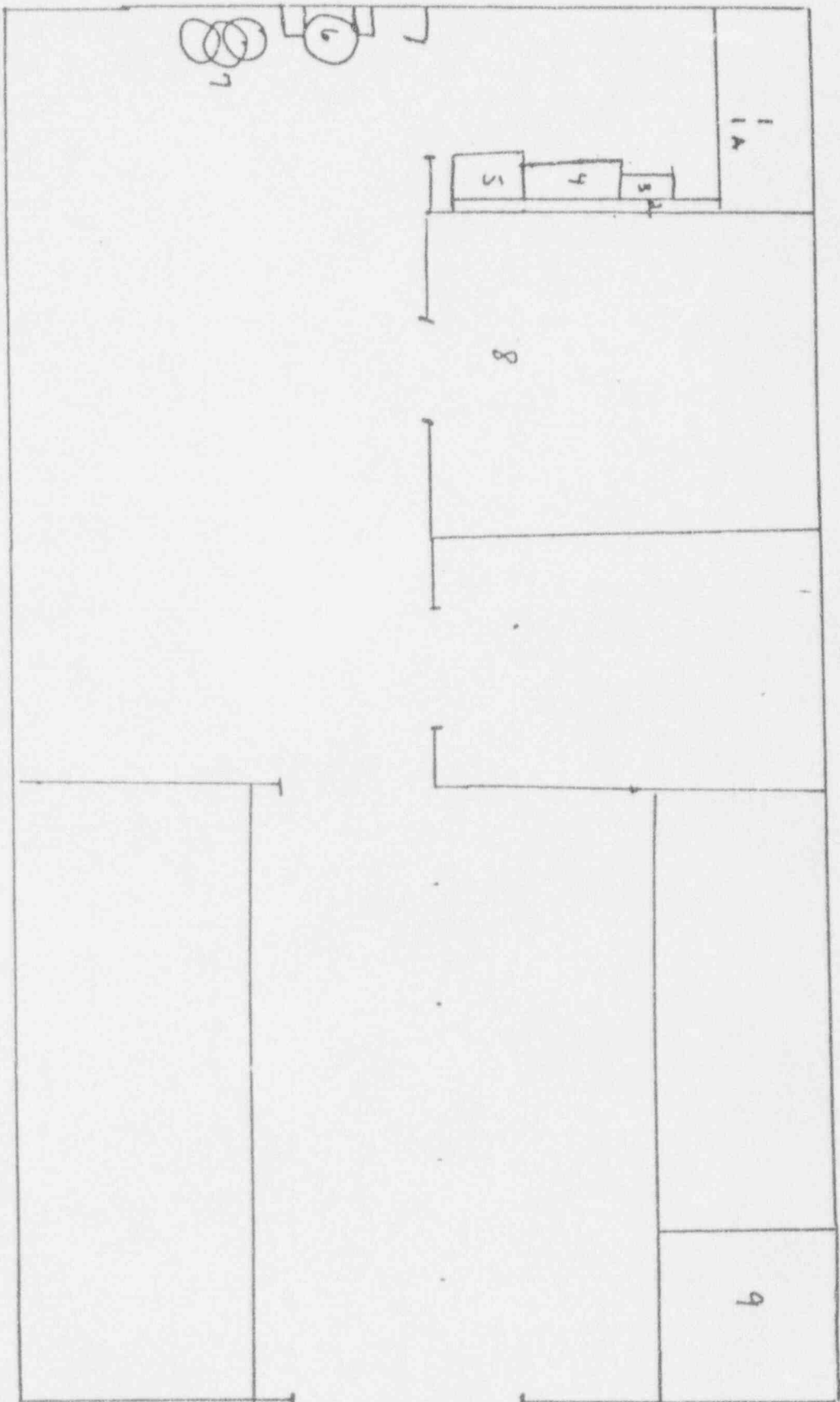
3. Counter

4. DOSE CALIBRATOR

5. Small animal housing (if necessary)

20600 Miles Parkway, Cleveland, Ohio

E



- 1. Receipt, Storage Room
- 2. Storage waste e.a.m. well
- 3. Dose calibrator
- 4. Formattor

- 5. Computer
- 6. Console
- 7. Detector head
- 8. Collimators

- 9. Imaging Area
- 10. Imaging Area
- 11. Imaging Area

INSTRUCTIONS FOR FAMILY OF RELEASED PATIENT

Name of Patient _____

Name of Hospital _____

Address _____

Telephone No. _____

For further information contact _____

Telephone No. _____

Please show this form to every physician consulted concerning this patient until _____

(date)

_____ was treated on _____ 19__.

(Name of Patient)

with _____ millicuries of _____ in the form of _____
NO SPECIAL RADIATION SAFETY PRECAUTIONS ARE NECESSARY AFTER

_____ (date)

UNTIL THAT DATE:

Persons under 45 years of age should not remain closer than the following distances from the patient, for the time period indicated:

a) _____ to _____
(date) (date)

Permissible distance _____ feet or more, for _____ hours per week. (At other times remain farther than 6 feet.)

b) _____ to _____
(date) (date)

Permissible distance _____ feet or more, for _____ hours per week. (At other times remain farther than 6 feet.)

Note: During the above times brief periods of closer contact (for example while shaking hands, or kissing the patient) are permissible.

SPECIAL PRECAUTIONS:

a) Spouse or other person caring for patient:

b) Children or pregnant women:

c) Sleeping Arrangements:

IF THE PATIENT IS TO BE HOSPITALIZED, OR IF DEATH SHOULD OCCUR NOTIFY THE FOLLOWING INDIVIDUAL(S) IMMEDIATELY.

A COPY OF THIS FORM SHOULD BE KEPT WITH THE PATIENT'S RECORD.

November 25, 1992.

Vincent A. Gargaro, MBA
President, Universal Consultants, Inc.,
34088 Center Ridge Road,
North Ridgeville, 44019-0223,
OHIO.

Dear Vincent,

re: License application for NATIONAL VETERINARY IMAGING, Inc.

As discussed this letter is sent as an addendum to the above application.

I have been actively in clinical and investigative nuclear practice for the past 22 years and would estimate a minimum experience in the field of at least 50,000 hours. From my CV you will see that I have experience in physics, instrumentation, radiation safety and the mathematical computational side of radionuclide and radiopharmaceutical handling. I am actively and currently qualified and board certified to practice in Nuclear Medicine in the USA, Canada and Australia.

In regard to my veterinary experience with radiopharmaceutical administration, handling and scanning this has been as part of my research activities:

In Australia I was directly involved in multiple dog studies in the evaluation of then new radiopharmaceuticals for assessment of renal transplant function and renal function using Tc-99m DMSA, DTPA as well as I-131 Hippuran and I-125 Iothalamate. These studies took place in both the animal laboratory, pathology and the Nuclear Medicine department. A number of presentations ensued as a consequence (pages 18, 21 CV). I would estimate over the course of three years that I spent at least 50-100 hours directly involved in these dog studies. In addition a limited number of studies were performed on sheep.

In USA i) at the Cleveland Clinic I was a co-investigator on an NIH grant which was directly involved in the investigation of artificial hearts implanted in calves. I was directly responsible and present for the radiopharmaceutical imaging of these animals and was responsible for the handling of the radioactive materials. (Tc-99m PYP, Albumin), (pages 7,20,31 CV)

ii) at MetroHealth Medical Center I was involved in a project involving cardiac MRI scanning which also extended to visits to the animal lab and MR suite in Indianapolis at the University of Indiana. Although this study did not involve use of radiopharmaceuticals it did involve direct presence of myself in the animal laboratory.

I would estimate my time of involvement with various animals over the course of the past nine years in the USA as at least 100 hours. In all cases I was involved directly in regard to aspects of radiopharmaceutical handling though not necessarily actually cleaning cages etc.

I hope that this information is adequate for needs of the license application.

Yours Sincerely,



David Feiglin, MBBS, B.Sc., FACP, FRCPC, ABNM.

