NOV 17 1992

National Veterinary Imaging, Inc.
ATTN: D. Feiglin
President & Radiation
Safety Officer
10817 Sperry Road
Chesterland, OH 44026

Dear Dr. Feiglin:

We have reviewed your application dated October 20, 1992 requesting a new NRC License and find that we will need additional information as follows:

1. Locations of Use

a. Confirm the proposed locations of use (10817 Sperry Road, Chesterland, Ohio; 5035 Richmond Road, Cleveland, Ohio and 20600 Miles Parkway, Cleveland, Ohio) are not private residences.

b. Indicate your plans to possess and use licensed material in the proposed facilities. There must be an intent to construct and use the proposed facility as described in the license application.

c. Confirm that you will notify the Commission, in writing, promptly from the date of a decision not to complete the facility, acquire equipment, or possess and use authorized material.

d. If you do not intend to possess and use licensed material in the proposed facility within 12 months after receiving authorization, respond to the following:

i. Justify why it is necessary for the Commission to authorize the locations at this time.

ii. Clarify if you intend to propose another facility or location of use not described in the application.

The Commission will not renew a license under which authorized material has never been possessed or used unless the licensee provides sufficient evidence that future use is needed.

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2. Intended Use

Please be advised that 10 CFR Part 35 does not apply to veterinary use of byproduct material (reference 10 CFR 35.2). Therefore, it is necessary for you to specify the radionuclide, the physical form, maximum activity possessed at any one time and the purpose for which the material will be used for each radionuclide requested.

3. Authorized Users

Individuals authorized to use byproduct material for veterinary use should be licensed to practice veterinary medicine and have training and experience with veterinary use of byproduct material. Therefore, submit the following information for each proposed authorized user:

a. Documentation verifying the individual is licensed to practice veterinary medicine.

b. Letter from the preceptor who supervised the individual's experience involving veterinary use of byproduct material. The letter should discuss the supervised clinical experience obtained by the proposed user including:

- o examining patients and reviewing their case histories to determine their suitability for radioisotope diagnoses, limitations, or contraindications;
- o selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
- o administering dosages to patients and using syringe radiation shields;
- o collaborating with the authorized user in the interpretation of radioisotope test results;
- o patient follow up;
- o use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction; and

- o use of iodine-131 for treatment of thyroid carcinoma.

Additionally, the letter should discuss supervised work experience obtained by the proposed user including:

- o ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- o calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
- o calculating and safely preparing patient dosages;
- o using administrative controls to prevent the misadministration of byproduct material;
- o using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
- o eluting technetium-99m from generator systems.

Indicate the locations, dates and number of hours spent obtaining the training and experience.

State the license number which authorized the preceptor for veterinary use of byproduct material during the dates he supervised the proposed user.

c. Submit documentation of the proposed user's classroom and laboratory training including;

- o radiation physics and instrumentation;
- o radiation protection;
- o mathematics pertaining to the use and measurement of radioactivity;
- o radiopharmaceutical chemistry; and
- o radiation biology.

Supplement A forms may be used to outline the training referenced in Item c. above.

4. Radiation Safety Officer (RSO)

a. Please verify your RSO will be responsible for the following:

- To ensure that the use of radioactive materials is by or under the direct supervision of individuals specifically listed on your license.
- To ensure that all users (where appropriate) wear personnel monitoring equipment when using radioactive materials.
- To ensure that radioactive materials are properly secured against unauthorized removal at all times when not in use.
- To perform routine inspections of all laboratories using or storing radioactive materials.
- To ensure that the terms and conditions of your license are met, and that all required records are maintained.
- To immediately halt any activity judged to be a threat to health, safety, the environment or a violation of the conditions of your license or the regulations.

b. In order for us to authorize Dr. Feiglin as RSO, you will need to submit documentation of his training and experience involving veterinary use of byproduct material. Include a discussion of the scope of experience (e.g., animal handling, etc.) and include the locations, dates and hours spent obtaining the experience.

5. Alternate RSO

It is not NRC policy to authorize "Assistant Radiation Safety Officers". However, you may request an alternate RSO (ARSO). Name the individual you wish to designate as ARSO. The ARSO must be equally qualified as the RSO.

Define the responsibilities of the ARSO and describe the parameters in which he can act for the RSO (e.g., periods when the RSO is absent).

6. Facilities

a. Submit detailed diagrams of your proposed facilities which include all of the following:

- o Scope of activities to be conducted in each room.
- o Room or rooms and adjacent areas where byproduct material will be used.
- o The direction of north.
- o Room numbers and principle use of each room or area (e.g., in-vitro, office, storage, etc.).
- o Any shielding available.
- o Additional safety equipment.

b. Describe the animal housing facilities and submit diagrams which include the information requested above.

c. Submit your procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material.

7. Personnel Training

a. If licensed material will be used by an individual under the supervision of an authorized user, please so state.

b. Confirm training of all supervised individuals will include:

- o The Model Training Program that was published in Appendix A to Regulatory Guide 10.8, Revision 2; and
- o Instruction, given by an authorized user, in the principles of radiation safety appropriate to that individual's use of byproduct material.

c. Confirm supervised individuals will be required to follow the instructions (e.g., prescriptions, etc.) of the supervising authorized user, follow the established radiation safety procedures, and comply with the license conditions respect to the use of byproduct material.

d. Confirm authorized users will periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.

e. Confirm the licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

f. Confirm that you will document all personnel training to minimally include dates, topics discussed and attendees.

g. Submit a copy of the instructions provided to animal caretakers for handling animals, animal waste carcasses, and cleaning and decontamination of animal cages.

8. Survey Instrument Calibration

a. If survey instrument calibrations will be performed by Universal Consultants, Inc., please so state. Otherwise, submit your proposed procedure for our review.

b. Confirm survey instrument calibrations will be performed before first use, annually, and following repair.

9. Leak Tests

a. If survey leak tests will be performed by Universal Consultants, Inc., please so state. Otherwise, submit your proposed procedure for our review.

b. Confirm you will perform leak tests of sealed sources before first use (unless you have a certificate from the supplier indicating that the source was tested within six months before transfer) and at intervals not to exceed six months.

10. Prescriptions

Describe the procedures and associated record keeping involving authorized user generation of a prescription to use byproduct material and the implementation of the prescription.

11. Radiopharmaceutical Therapy

Several portions of Appendix P to Regulatory Guide 10.8, Revision 2 (e.g., Items 2., 3. 6. and 12.) do not apply to veterinary use. Resubmit procedures that are specific to veterinary use (e.g., no visitors, cage contamination control, disposal of radioactive excreta (Note: animal excreta is not exempt from 10 CFR 20.303), etc.).

12. Release Criteria

a. The release criteria outlined in Appendix P to Regulatory Guide 10.8, Revision 2 and 10 CFR 35.75 do not apply to veterinary use. Therefore, submit your release criteria/procedure for animals that have been administered specific radionuclides (e.g., iodine, technetium, etc.). Include a discussion of the calculations, surveys and assumptions used to ensure the procedure will comply with 10 CFR 20.105.

b. Provide a copy of the specific written instructions provided to the owner regarding care and handling of radioactive animal patients. Confirm the owner will document his understanding of the instructions via signature prior to release of radioactive animal patients.

13. Bioassays

Submit data which demonstrates that you have assessed the need for bioassay procedures and that, if warranted, they are in place.

If a bioassay program is warranted, submit the following:

a. The qualifications and experience of all individuals responsible for performing bioassays, and describe how their competency will be evaluated prior to using the equipment involved.

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b. Describe the method used for performing analysis of bioassay samples.

c. List the equipment that will be used for bioassays.

d. If a commercial bioassay service is used, provide the name and address of the firm.

Regulatory Guide 8.20 is enclosed for assistance.

14. Survey Procedures

a. Indicate the type (e.g., ambient dose rate, removable contamination) and frequency (e.g., daily) of surveys performed in animal housing facilities.

b. Confirm an ambient dose rate survey will be performed in the injection area immediately following each injection of radioactive material.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 94199.

Upon failure to file an answer within the specified time, we will consider that you have abandoned your request and will void this action. This is without prejudice to resubmission of the application.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708)790-5625.

Sincerely,

Original Signed By
Robert G. Gattone, Jr.
Nuclear Materials Licensing Section

Enclosures:
1. 10 CFR Part 35
2. 10 CFR Part 20
3. Regulatory Guide 10.8, Revision 2
4. Regulatory Guide 8.20

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RIII (yes)
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11/16/92

NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

94199

Licensee	
1. National Veterinary Imaging, Inc.	3. License number 34-26454-01
2. 10817 Sperry Road Chesterland, OH 44026	4. Expiration date January 31, 1998
	5. Docket or Reference No. 030-32987

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Technetium-99m	A. Any	A. 500 millicuries
B. Iodine-131	B. Any	B. 30 millicuries
C. Cesium-137	C. Sealed source (registered pursuant to Section 32.210 of 10 CFR Part 32 or an Agreement State)	C. Two sources not to exceed 500 microcuries each
D. Barium-133	D. Sealed source (registered pursuant to Section 32.210 of 10 CFR Part 32 or an Agreement State)	D. Two sources not to exceed 500 microcuries each
E. Phosphorus-32	E. Any	E. 10 millicuries
F. Strontium-89	F. Any	F. 10 millicuries

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 34-26454-01

Docket or Reference number 030-32987

9. Authorized Use:

A. For veterinary diagnostic imaging studies.

B. For veterinary therapy for hyperthyroidism.

C. and D. For calibration of the licensee's survey instruments.

E. and F. For veterinary radiopharmaceutical therapy.

CONDITIONS

10. Location of Use: 5035 Richmond Road, Cleveland, Ohio and 20600 Miles Parkway, Cleveland, Ohio.

11. Radiation Safety Officer: Dr. David Feiglin

12. Licensed material shall be used by, or under the supervision of, Dr. Bennett D. Feiglin.

13. The licensee shall maintain records of information related to decommissioning at the location listed in item 2 as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.

14. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. A record of each disposal permitted under this License Condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

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MATERIALS LICENSE
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License number 34-26454-01
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15. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. Sealed sources need not be leak tested if:

(i) they contain only hydrogen-3; or

(ii) they contain only a radioactive gas; or

(iii) the half-life of the isotope is 30 days or less; or

(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission,

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MATERIALS LICENSE
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15. (Continued)

Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

G. Tests for leakage and/or contamination shall be performed by Universal Consultants, Inc. or by the persons specifically licensed by the Commission or an agreement state to perform such services.

16. Licensed material shall not be used in or on human beings.

17. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

18. The licensee shall not acquire licensed material in a sealed source or device that contains a sealed source unless the source or device has been registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

19. The licensee shall establish a bioassay program for individuals handling millicurie amounts of iodine-125 and/or iodine-131 in accordance with frequencies and procedures contained in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

20. Survey instrument calibrations shall be performed by Universal Consultants, Inc. or by other persons specifically licensed by the Commission or an agreement state to perform such services.

21. The licensee may not possess and use materials authorized in Items 6, 7, and 8 until:

1. The licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and

2. The U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Materials Licensing Section, 799 Roosevelt Road, Glen Ellyn, IL 60137 has been notified that activities authorized by the license will be initiated.

22. Within 30 days of the date of a decision not to complete the facility, acquire equipment, or possess and use authorized material, the licensee must notify the Commission in writing, of the decision.

UNITED STATES NUCLEAR REGULATORY COMMISSION

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 34-26454-01

Docket or Reference number 030-32987

23. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated October 20, 1992; and

B. Letters received December 14, 1992 and December 23, 1992 (excluding Item 9.).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JAN 0 4 1993

By Robert D. Hatten Jr.
Materials Licensing Section, Region III

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