

**NEW YORK STATE DEPARTMENT OF HEALTH
BUREAU OF ENVIRONMENTAL RADIATION PROTECTION
RADIATION GUIDE 10.20
GUIDE FOR THE PREPARATION OF APPLICATIONS
FOR VETERINARY USE OF
THERAPEUTIC RADIOPHARMACEUTICALS**

PURPOSE OF GUIDE

This guide describes the information needed by the New York State Department of Health staff to evaluate an application for a specific license for veterinarians to possess and use radioactive materials for therapeutic procedures in animals. This type of license is provided for under Sections 16.100 and 16.103 of 10 NYCRR 16, "Ionizing Radiation." It is meant to serve as a supplement to Radiation Guide 10.1, revision 2, Guide for the Preparation of Applications for Medical Programs. Since Radiation Guide 10.1 is designed for human use, you do not need to address all items listed in this guide, you must only submit the information required under items 1 through 7, 8a, 9e, 10 through 17, 21 through 23, and 26.

The applicant should carefully study the regulations and these guides, and should submit all information requested. The Department will request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation safety program. Such requests will delay final action on the application.

APPLICABLE REGULATIONS

All regulations pertaining to this type of license are found in Title 10, Chapter 1, Part 16 of the New York Code of Rules and Regulations (10 NYCRR 16). Chapter 1 is entitled "State Sanitary Code" and Part 16 is entitled "Ionizing Radiation." The statutory authority for the rules and Regulations is found in the New York State Public Health Law, Section 225.

AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)

Paragraph (a) of 10 NYCRR 16.5 requires that persons who operate or permit the operation of radiation installations shall make every effort to maintain radiation exposures and releases of radioactive material as far below the limits of Part 16 as is reasonably achievable.

Each individual who is authorized to use radioactive material should provide appropriate instruction to all individuals who work with or in the vicinity of radioactive material, and should ensure that the facility and equipment are adequate for safe use. Each worker should follow procedures developed to ensure safety and should promptly report incidents and potential problems to the authorized user or Radiation Safety Officer (RSO).

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Release criteria for cats who are treated with iodine-131 have been set at 0.5 millirem/hour at one foot from the surface of the body closest to the thyroid. This would involve confining the cats at the veterinary facility until the dose rate falls to that level. This will ensure that persons caring for the cat after discharge will not be exposed to more than about 100 millirem [see 10 NYCRR 16.7(a)(1)] as long as direct contact with the cat is restricted to less than 2 hours a day. If minor children or a pregnant woman reside(s) in a home where a cat is proposed for treatment, serious consideration should be given to confining the animal until the measurement at the thyroid is less than 2 millirem/hour. As a margin of safety pet owners should be instructed to minimize direct contact, and not to exceed one hour a day.

RADIOACTIVE EFFLUENTS

The NYS Department of Environmental Conservation regulates releases of radioactive materials to the environment, and may require you to obtain a permit for the release of radioactive iodine through the ventilation system of the waste storage area and animal housing area. Please contact the Department of Environmental Conservation at (518) 457-2225, for information on what type of evaluation is required for your radioactive emissions.

PURPOSE OF APPENDICES TO THIS GUIDE

Appendix A describes acceptable training and experience requirements for veterinarians who wish to be authorized to use radioactive materials for therapy in animals. This professional (or professionals) would be responsible for patient selection; evaluating owner acceptance of, and owner cooperation with, the therapy to be administered and required home care procedures; dose calculation and administration; animal care and waste handling; application of patient discharge criteria; owner instruction; patient follow-up; and development of modifications to procedures based on experience. Submit a copy of the veterinarian's curriculum vitae, NYS veterinary license/registration, and documentation indicating that the veterinarian has met the training and experience criteria listed in Appendix A.

Appendix B describes the responsibilities of veterinarians for the requested use of iodine-131 in cats. Confirm that veterinarians will be required to discharge these responsibilities.

Appendix C contains selection criteria for cats to be treated for hyperthyroidism. Confirm that authorized veterinarians will include these in their selection criteria and will perform and document the required counseling and consideration of extended confinement when minor children or a pregnant woman resides in the home.

Appendix D contains an information sheet and consent form for the owners of cats to be treated. Confirm that the information will be included in counseling given to cat owners and that a copy of the consent form will be signed by each owner or submit your own documents for review.

Appendix E contains facility design considerations for hot lab, confinement and waste storage areas. Please describe the areas you will use for these purposes. See Item 11 of Radiation Guide 10.1, revision 2, for additional requirements.

Appendix F describes waste management criteria. Confirm that your protocol for waste management will incorporate these criteria. See Appendix J of Radiation Guide 10.1, revision 2, for additional requirements.

APPENDIX A-1

TRAINING AND EXPERIENCE REQUIREMENTS FOR THERAPEUTIC VETERINARY USE OF RADIOACTIVE MATERIALS

Applicants for licenses authorizing the use of radioactive materials in therapy procedures for animals must be licensed and registered as a veterinarian in New York State and have the following qualifications:

1. (a) Certification in veterinary radiology from a recognized professional certification board;

AND

- (b) Be in the active practice of veterinary radiology;

OR

2. (a) Supervised clinical experience under the supervision of an authorized user in the use of radioactive materials for therapy in at least 10 cases.

This experience must include study and discussion with preceptor of case histories to establish appropriate therapeutic procedures, limitations, contraindications, etc.; supervised examination of patients to determine the suitability for radiopharmaceutical therapy and the appropriate dosage to be prescribed; the selection and administration of radioactive materials and the evaluation of therapy results. These cases must involve personal participation and be representative of the type of animal and type and quantity of radioactive materials for which the applicant is seeking authorization;

AND

- (b) Two hundred contact hours of classroom and laboratory instruction.

The classroom and laboratory training must be obtained as planned instruction outlined in a syllabus, which includes the topics contained in Appendix A-2 to this guide and is approved by this Bureau. The training must be comprised of lectures, demonstrations, hands-on laboratory exercises, homework assignments, quizzes and tests. The hours of training submitted in satisfaction of this requirement must be given in a classroom/ laboratory setting in the presence of instructors whose credentials qualify them to give such training, and are acceptable to the Department. No home-study or take-home work can be used to satisfy the hours required, nor are take-home tests or quizzes acceptable as evidence of adequate knowledge of subjects covered. Successful completion of this training must be evidenced by passing an examination indicating satisfactory knowledge of the subject matter presented, and documented by the provider of the instruction.

Please note that this training and experience must have been obtained within a 5-year period preceding the date of the license application or must be supplemented by continuing education or experience.

APPENDIX A-2

GUIDE FOR BASIC RADIATION SAFETY TRAINING FOR VETERINARIANS APPLYING TO BE AUTHORIZED FOR RADIOPHARMACEUTICAL THERAPY

- I. Basic Math and Science Review - logs, exponentials, powers, trigonometry, force laws, energy-mass, units and dimensional analysis, electronics, electromagnetic spectrum.
- II. Radioactivity - Atomic structure, Bohr atom, quantization, Pauli exclusion principle, nuclear structure, nuclear stability, binding energy, chart of the nuclides, decay models, decay law, half-life, decay constant, equilibrium.
- III. Interaction with Matter - particles, primary vs. secondary ionization, LET, range, shielding, photons, photoelectric effect, Compton scattering, pair production, absorption, attenuation, shielding.
- IV. Biological Effects - ionization, free radicals, stochastic vs. non-stochastic, acute vs. delayed.
- V. Dosimetry Fundamentals - activity, exposure, absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, total effective dose equivalent, dose calculations, gamma sources (point, line, area), gamma constant.
- VI. Internal Dosimetry - biological half-life, effective half-life, retention curves, compartment models, cumulative activity, absorbed fraction, bioassay.
- VII. Health Physics Instrumentation - gas filled detectors (ion chamber, GM, proportional counter), resolving time, efficiency, sensitivity, dead time, scintillators (solid, liquid), photomultiplier tubes, spectrometry, detection vs. measurement, thermoluminescent dosimeters, film badges.
- VIII. Counting Statistics - Poisson and Gaussian distributions, mean, variance, standard deviation, error propagation, LLD, MDA, background, counting times, chi-squared.
- IX. Gamma Spectrometry - pulse height analysis, SCA, MCA.
- XI. Counting Systems - NaI well Counter, dose calibrators, uptake probes, QA for measurement systems.
- XII. Radionuclides Used in Therapy - desired characteristics and nuclides commonly used, indications for use in animals, dosimetry for radiopharmaceuticals, dosimetry for sealed sources.
- XIII. Radiation Protection Guides - organizations that set standards, philosophy of radiation protection, exposure of individuals (occupational, non-occupational), applicability to veterinary use program, Part 16, license requirements, Radiation Safety Officer, ALARA, personnel training.

APPENDIX A-2

BASIC RADIATION SAFETY TRAINING - continued

XIV. Safe Use of Radioactive Materials - Operating and Emergency Procedures

- reducing radiation exposure (sources, time, distance, shielding, surveys, protective clothing, volatility, decontamination, air sampling, package opening, syringe handling)
- storage of radioactive materials (security, monitoring)
- personnel monitoring (external, internal)
- exposure rates from typical dosages and sources (gamma constant, inverse square)
- workup and animal preparation for treatment
- exposure rate from animals
- elimination rate; effective half-life
- safe handling practices (radioactive materials and animals containing radioactivity)
- safe release of animal (criteria, instructions to owners)
- waste handling and disposal (excreta and bedding, decay-in-storage)
- decontamination of use and holding areas
- surveys, wipe tests, and bioassay
- spills (major and minor)
- record keeping (receipt, use and disposal of radioactive materials, surveys, wipe tests, personnel monitoring, personnel instruction, air sampling)

XV. Suggested References

- A. Cember, H. *Introduction to Health Physics*. Pergamon Press, New York. 1983.
- B. Gollnick, D.A. *Basic Radiation Technology*. Pacific Radiation Corporation, Altadena, California. 1988.
- C. Kirk. *Current Veterinary Therapy IX*. W.B. Saunders Company, Philadelphia. 1986.
- D. Shapiro, J. *Radiation Protection: A Guide for Scientists and Physicians*. Harvard University Press, Cambridge, Massachusetts. 1990.
- E. Sorenson, J. A., and Phelps, M.E. *Physics in Nuclear Medicine*. Grune and Stratton, New York 1980.
- F. United States Nuclear Regulatory Commission. *Regulatory Guide 8.9: Acceptable Concepts, Models Equations and Assumptions for a Bioassay Program*, Revision 1. July 1993.
- G. United States Nuclear Regulatory Commission. *Regulatory Guide 8.20: Applications of Bioassay for I-125 and I-131*, Revision 1. September 1979.
- H. United States Nuclear Regulatory Commission. *Regulatory Guide 8.25: Air Sampling in the Workplace*, Revision 1. June 1992.
- I. United States Nuclear Regulatory Commission. *Regulatory Guide 8.29: Instruction Concerning Risks from Occupational Radiation Exposure*, Revision 1. February 1996.

APPENDIX B

AUTHORIZED VETERINARIAN RESPONSIBILITIES

- Patient selection
- Evaluation of owner cooperation
- Dose estimate
- Dose administration
- Patient confinement during therapy
- Waste handling during confinement
- Applying patient discharge criteria
- Owner instruction for post-discharge care
- Patient follow-up

APPENDIX C

CRITERIA FOR PATIENT SELECTION PRIOR TO RADIOIODINE ADMINISTRATION FOR VETERINARY FELINE THERAPY

- Cats must be referred by a practitioner who has clinically documented hyperthyroidism.
- Cats must be in otherwise good health - no congestive heart failure, chronic renal failure, or other serious health problems.
- Cats belonging to owners who exhibit anxiety about radioactive material will not be accepted for treatment.
- Owners must agree to be separated from the cat for up to two weeks during therapy confinement.
- Owners must sign a consent form confirming that post-therapeutic procedures will be followed.
- Owners with minor children or pregnant women living in the home will be carefully evaluated before a cat is selected for treatment. If a decision is made to treat, detailed counseling will be given about avoiding contact between the treated animal and these individuals. Consideration should be given to extending the confinement of the animal until the exposure rate at the body surface closest to the thyroid is less than 2 millirem per hour. Such counseling and consideration must be documented.

APPENDIX D

OWNER INFORMATION AND CONSENT FORM

Radioactive iodine has been used to treat hyperthyroidism in people for over fifty years. The first reported use of radioactive iodine to treat hyperthyroid cats was in 1983. Radioactive iodine therapy is a safe and effective choice for treating hyperthyroidism in most cats.

The cat does not experience any adverse side effects from the radioactive iodine. Because the delivery of radiation is targeted to the overactive thyroid gland, the cat does not experience any radiation side effects at the normal therapy doses used to treat hyperthyroidism. The medicine is given as an injection, usually on the day the cat is admitted to the clinic. Following the treatment, the cat will be hospitalized for 5-14 days to allow most of the radioactive medicine to leave the thyroid gland or decay prior to discharge from the clinic. This is different from the situation in human nuclear medicine as most people treated with radioactive iodine for hyperthyroidism are discharged the same day they are treated.

You cannot visit your pet during therapy, nor can pets be removed from the ward until officially released. You cannot terminate therapy or arrange for early release once therapy has begun. Pets may not be boarded/hospitalized elsewhere until they meet the requirements for release.

After being released from therapy, your cat will still possess a very low level of radioactivity, being voided out primarily via urine and feces. You don't need to totally isolate your cat from people/pets, but you must follow safety precautions until the date listed on the next page. Due to the natural decay of radioactivity and continual loss of radioiodine through the urine and stool, your cat will contain no detectable level of radioactivity soon after that date.

During hospitalization, cats are housed in individual enclosures in an isolation room in the clinic. Bedding is changed regularly and fresh food and water are available at all times. Cats get plenty of attention while they are hospitalized. Please be sure to let us know if your cat has any special feeding requirements so that his stay can be made as comfortable as possible.

Within one to three months after therapy, 85-90% of hyperthyroid cats become normal (euthyroid), 5-7% will become hypothyroid (too little thyroid hormone in the blood) and may require oral thyroid hormone replacement therapy, and 5-7% remain somewhat hyperthyroid. Cats with persistent hyperthyroidism can be retreated three months after their initial therapy.

To be candidates for radioactive iodine therapy, all cats have screening laboratory work (CBC/Chem screen, diagnostic T4, and urinalysis) performed by the referring veterinarian within one month prior to the anticipated treatment date. We must have copies of this lab work before your cat comes for treatment. Cats with chronic renal (kidney) failure and/or advanced heart disease are not good candidates for radioactive iodine therapy.

Please let us know what medications your cat is receiving, as some medications may interfere with radioactive iodine therapy. If your cat is receiving oral anti-thyroid medication (such as Tapazole or Methimazole), it will need to be discontinued _____ days prior to therapy with radioactive iodine. If your cat requires other medication, we will continue to administer it during your cat's hospitalization.

Please read the attached radiation safety instructions and consent form. Feel free to discuss any questions or concerns. If you are unable/unwilling to comply with these precautions, you should consider surgical or medical management of your cat's condition.

APPENDIX D - continued

OWNER INFORMATION AND CONSENT FORM

Your pet was treated with ____ millicuries of radioactive iodine on _____.
When released to your care, your pet had an exposure rate of ____ millirem per hour at one foot from its thyroid gland.

NO SPECIAL SAFETY PRECAUTIONS ARE NEEDED AFTER

The medication that your cat has received is beneficial to it, but it is important that other persons not be unnecessarily exposed to radiation. With the release of the patient to your care, you are accepting responsibility for the radiation protection of your self and all other persons who come into contact with your pet. Your cooperation is needed to comply with the laws of the State of New York and allow continued availability of this type of treatment. Please feel free to contact us regarding any specific problem or questions you may have regarding your pet's treatment or these radiation safety instructions.

1. Keep the cat confined to your home. Area wildlife, neighbors, their children and pets, are unaware of the radioactivity in its urine or feces.
2. Limit close contact (closer than one foot) to less than 10 minutes per day. Avoid prolonged face-to-face snuggling, and face/hand contact with your cat's saliva & footpads.
3. Wash your hands thoroughly after handling your cat, its food dishes, or litter pan.
4. Do not allow your cat to sleep on your bed. Keep your cat in an unoccupied room at night.
5. Put a plastic liner in box before adding litter (if cat shreds liner, don't use it but discard box after date listed above). Keep box out of occupied areas and away from unsupervised dogs and children.
 - A. FOR PUBLIC SEWER: Add flushable litter to box, scoop soiled litter into toilet and flush. After the date listed above, discard any remaining soiled litter into the trash. Hold all soiled litter for an additional two weeks after the release date listed above, then send to a landfill.
 - B. FOR SEPTIC SYSTEM: Scoop soiled litter into a ziploc bag and seal. Place this bag into a second ziploc bag and seal. Discard into a covered trash can outside of your home. After the date listed above, discard any remaining soiled litter into the trash. Hold all soiled litter for an additional two weeks after the release date listed above, then send to a landfill.
 - C. IF YOU DO NOT USE SCOOPABLE LITTER: Change the litter at least every other day by removing it in the liner. Seal the liner and discard into a covered trash can outside of your home. After the date listed above, discard any remaining soiled litter into the trash. Hold all soiled litter for an additional two weeks after the release date listed above, then send to a landfill.

APPENDIX D - continued

OWNER INFORMATION AND CONSENT FORM

Most landfills do not allow the disposal of low-level radioactive waste until the radioactivity has decayed to nearly background levels. Therefore, it is important that you hold the litter for the recommended period of time in order to satisfy this requirement.

6. If your cat vomits/soils outside the litter box, use normal cleaning procedures. Seal all soiled paper cleaning materials in a ziploc bag. Place this bag into a second ziploc bag, seal and put in outside trash with soiled litter. Wash hands thoroughly.
7. Anyone pregnant or younger than 18 should not handle the soiled litter.
8. Keep your cat from food preparation areas.
9. Instruct children to avoid the cat, and wash their hands if they touch it. Small children may not remember or understand these rules, so take extra precautions by having them wash their hands often, especially before eating.
10. If your pet must be seen by a veterinarian prior to the release date listed on this form, please inform the doctor of the type of treatment that your cat received and the date it was treated. show this form to the doctor prior to the examination.
11. If you pet should die prior to the release date listed on this form, please notify

Dr. _____ at _____.
(veterinarian) (phone)

I have read this form and the information contained in it has been explained to me. I understand the radiation safety precautions that I must follow until the date listed above.

Owner's Signature _____ Date _____

Veterinarian's Signature _____ Date _____

APPENDIX E
FACILITY DESIGN

(See also Item 11 of Radiation Guide 10.1, revision 2)

- **Restricted access to hot lab, waste storage, and confinement areas**
- **Hot lab near confinement area**
- **Confinement area with dedicated ventilation**
- **Stainless steel metabolic cages (easily decontaminated) will be used**
- **Shielding will be provided as needed**
- **Concrete floors, no drains, in confinement area**
- **Continuous negative pressure ventilation in confinement area**
- **Evaluation of air concentration of radioactive materials in confinement area**

APPENDIX F

WASTE MANAGEMENT

(See also Appendix J of Radiation Guide 10.1, revision 2)

- **Cat urine and feces will be collected and disposed of as radioactive waste**
- **Decay-in-storage will be done in a secure, well ventilated area**
- **Waste will be stored in secure heavy double plastic bags**
- **Continuous negative pressure ventilation will be provided in waste storage area**
- **Wipe and meter surveys of waste storage area will be performed on a weekly basis**