UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 6, 2007

Docket No. 030-35758 License No. 31-30650-01
Control No. 140423

Barry A. Lissman, D.D.
Partner
Thyro-Cat, LLP
227 Union Avenue
Holbrook, NY 11741

SUBJECT: THYRO-CAT, LLP, LICENSE AMENDMENT, CONTROL NO. 140423

Dear Dr. Lissman:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please note that this amendment approves only the part of your amendment request regarding disposal of waste using flushable litter.

In order to approve your request to remove the restriction to hold cats for a minimum of three days, data is needed to support your request. As stated in our May 3, 2007, letter, your current release criteria (minimum holding time of three days, and a dose rate at 1 meter of less than 0.5 millirem per hour, with limited close contact by the owner for a designated period) is less restrictive than the NRC's current guidance (a minimum holding time of four days, and a dose rate at 1 meter of less than 0.5 millirem per hour, and isolation of the cat at home for the first several days followed by limited contact for a designated period, and other restrictions). Additional review will be needed of your information in order to determine if less restrictive guidance is appropriate. In addition to radiation levels from the cat, we are concerned that release of cats early after treatment may result in far more iodine-131 (I-131) contamination in the home of the cat's owner. Typically, I-131 taken into the body requires a period of time for some I-131 to be incorporated by the thyroid, followed by a relatively quick period in which the remaining free (unbound) I-131 is cleared from the body, and a longer period of time over which bound I-131 is slowly released as compounds break down again. The period of time for this to occur is not well known for cats, and appears to vary greatly based on a study provided to the NRC of 100 cats. This period of release of free iodine can result in high levels of I-131 in excreta including animal wastes and saliva, and is one of the reasons for the minimum holding time requested by the NRC.

You should provide data that addresses radiation levels and potential for contamination from the cat. The data should represent a large number of cats, and for each cat: the date, time, and dosage administered; the date(s), time(s) and dose rate(s) measured at given time intervals at a distance of 1 meter from the cat; and any other information pertinent about each cat that you believe should be considered. The study should include some method to assess the potential for I-131 contamination, such as I-131

released into animal waste for each cat at given time intervals, and provide any data collected that demonstrates the potential for spread of contamination. You should provide a description of the data collection that includes the method used to ensure that measurements are taken in a consistent manner for each animal; the method for any collection of animal waste or other assessment of I-131 in animal wastes; the model(s), serial number(s), and calibration date(s) of all instruments used to make radiation measurements; and other information as necessary.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

In accordance with NRC Regulatory Issue Summary (RIS) 2004-17: Revised Decay-In-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material (http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2004/ri200417.pdf), your license has been modified. Your license now contains a revised decay-in-storage (DIS) condition. This revised condition permits greater flexibility for DIS of waste by eliminating a specific holding period prior to disposal. Please review the RIS 2004-17, and the revised condition carefully to ensure that you understand its requirements.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

***Original signed by Elizabeth Ullrich***

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 2

cc:
Gerald W. Bennett, Ph.D., Radiation Safety Officer

DOCUMENT NAME: C:\FileNet\ML071620223.wpd

**SUNSI Review Complete:** EUllrich
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| NAME | EUllrich ***/BU/*** | | | | | | | |
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Amendment No. 2

# 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, 36, 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.

| Licensee | In accordance with the letter dated April 19, 2007, |
|---|---|
| 1. Thyro-Cat, LLP | 3. License number 31-30650-01 is amended in its entirety to read as follows |
| 2. 227 Union Avenue<br>Holbrook, New York 11741 | 4. Expiration date August 31, 2011 |
| | 5. Docket No. 030-35758<br>Reference No. |

| 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. Iodine 131 | A. Sodium iodide in solution in precalibrated unit dosages contained in syringes | A. No single unit dosage to exceed 6 millicuries , and 80 millicuries total |

9. Authorized use:

A. Treatment of feline hyperthyroidism.

## CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at the Animal Emergency Clinic of Danbury, 22 Newtown Road, Danbury, Connecticut and The Complete Cat Veterinary Clinic, 32 Old Milford Road, Brookfield, Connecticut.

11. Licensed material shall be used only by Victor Rendano, V.M.D., Barry A. Lissman, D.V.M., and Howard Camay, D.V.M.

12. The Radiation Safety Officer for this license is Gerald W. Bennett, Ph.D.

**MATERIALS LICENSE**
**SUPPLEMENTARY SHEET**

License Number
31-30650-01

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030-35758

Amendment No. 2

13. The licensee shall not use licensed material in or on human beings.

14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.

15. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

    A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

    B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

    C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE**
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17. 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. Letter dated May 21, 2001 (ML031830088)
B. Letter dated August 3, 2001 (ML012190135)
C. Letter dated December 7, 2004 (ML043560033)
D. Letter dated April 19, 2007 (ML071150205), paragraph 2 only (waste disposal)
E. Letter dated May 10, 2007 (ML071360340), Item 2 only (waste disposal and instructions)

For the U.S. Nuclear Regulatory Commission

Date June 6, 2007

By ***Original signed by Elizabeth Ullrich***

Elizabeth Ullrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406