UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 5, 2019

MEMORANDUM TO: File

FROM: Donna-Beth Howe, Ph.D. ***/RA/***
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State and Tribal Programs
Office of Nuclear Material Safety and Safeguards

SUBJECT: FOIA NRC-2019-000187 REQUEST FOR DECEMBER 21, 2001 RESPONSE TO TECHNICAL ASSISTANCE REQUEST DATED MAY 18, 2001, RELEASE CRITERIA FOR CATS TREATED WITH RADIOACTIVE IODINE

In 2001, a licensee in Region II, Radiocat LLC, submitted an amendment requesting earlier release of its radioactive cats to members of the public (i.e., their owners). The licensee provided analyzed measurement data and calculations to support this request. The region submitted a technical assistance request (TAR) to U.S. Nuclear Regulatory Commission (NRC) for guidance on the licensee's proposed release criteria and whether credit could be given for verbal instructions. The attached NRC December 21, 2001, response to the May 18, 2001, TAR request from Region II was based on information supplied by the licensee and was not intended to serve as a precedent for anyone other than the licensee.

Subsequent to the TAR response, NRC was informed by the licensee that there were errors in the data collection, assumptions, calculations and conclusions provided to support the amendment request and the TAR response. The data presented as Attachment 2 to the original TAR response had data collection and analysis errors resulting in flawed conclusions. Further, the data presented in Attachment 5 also had fundamental analysis errors and also could not be used to estimate exposure rates for members of the public.

This memorandum documents that there were errors in the information provided by the licensee and the licensee's conclusions based on this information that were referenced in the attached December 21, 2001 TAR response. This information was not used in not used as the basis for NRC's position to release radioactive cats into the public.

CONTACT: Donna-Beth Howe, NMSS/MSST
301-415-5441

The company then provided new information and measurement data from 100 cats. The NRC reviewed the new information and on February 24, 2003 revised the TAR response.

Attachment:
Memo: J. Hickey, December 21, 2001

File

SUBJECT: FOIA NRC-2019-000187 REQUEST FOR DECEMBER 21, 2001 RESPONSE TO TECHNICAL ASSISTANCE REQUEST DATED MAY 18, 2001, RELEASE CRITERIA FOR CATS TREATED WITH RADIOACTIVE IODINE **DATE June 5, 2019**

ADAMS ML19156A167

Office	MSST	MSST
Name	DBHowe	CEinberg
Date	6/5/19	6/5/19

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 21, 2001

MEMORANDUM TO: Douglas M. Collins, Director
Division of Nuclear Materials Safety, RII

FROM: John W.N. Hickey, Chief
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety, NMSS

SUBJECT: TECHNICAL ASSISTANCE REQUEST DATED MAY 18, 2001, RELEASE CRITERIA FOR CATS TREATED WITH RADIOACTIVE IODINE

ISSUE:

In a technical assistance request (TAR) dated May 18, 2001, Region II requested guidance on veterinary patient release criterion for cats treated with radioactive iodine and clarification of whether the licensee can take credit for specific verbal instructions in developing the release criteria. The veterinary patient release criterion is governed by the 100 millirem (mrem) public, yearly dose limit in 10 CFR 20.1301, "Dose limits for individual members of the public."

ACTION:

The licensee must assure the dose from a I-131 treated cat to individual members of the public (including members of the family) does not exceed the 100 mrem annual public dose limit in 10 CFR 20.1301. The licensee can provide the owner with written instructions (to avoid confusion) as a means of reducing dose to members of the public. Because compliance with these written instructions by the owner cannot be guaranteed, the instructions can provide a margin for dose reduction but should not be relied upon as the primary means to keep the dose to members of the public below the 100 mrem public dose limit.

Sample owner instructions should include how to handle contaminated litter, bedding and other objects the cat comes into contact with, and the permitted extent and duration of contact by individuals with the cat. These instructions should be evaluated with respect to the ease with which the owner can comply with them and the degree and duration of compliance needed to assure the maximum dose to a member of the public does not exceed 100 mrem.

CONTACT: Donna-Beth Howe, Ph.D., NMSS/IMNS
(301) 415-7848

Because neither the reviewer nor the licensee should expect the owner's strict compliance with the instructions, the licensee should include a sufficient safety margin in the instructions to account for this uncertainty.

The license reviewer may accept a proposed veterinary cat release criteria based upon a minimum number of days after I-131 treatment (not less than 4 complete days after treatment) and maximum dose rate (normally 0.25 milliRoentgen/hour (mR/hr) at 1 foot). This does not relieve the licensee from providing written instructions and assurance that each release will be in compliance with 10 CFR 20.1301. If the instructions pertaining to the extent and duration of contact permitted with the cat are easy for the owner to comply with, and it appears that the potential dose would be well below 100 mrem, it may be acceptable, on a case-by-case basis, to release a cat with a radiation dose measurement as high as 0.5 mR/hr at 1 foot. Regardless of the release level used, the licensee should have records to document that the veterinary patient release criterion used for an individual patient will result in compliance with 10 CFR 20.1301.

Since the I-131 effective half-life, radiation profile, typical behavior pattern, and living situation for each cat are different, the actual release date needs to be established for each individual cat. This determination should be based upon the radiation measurement and effective half-life of I-131 for the patient at the time of release. As a minimum, two consecutive daily radiation measurements made at the same time of day and same distance from the cat are needed to calculate the effective half-life of I-131 for the treated cat. When cats are released, the licensee should assume that over time there will probably be diminishing compliance by the owner with the licensee's instructions. Additional consideration may be necessary when establishing the release date for an I-131 treated cat to a home with small children.

BACKGROUND:

NRC originally authorized release of cats treated with I-131 when: the dose rate was less than 1 mR/hr at 6 inches (0.25 mR/hr at 1 foot); instructions were provided to the owners; and the licensee could demonstrate that the limits of 10 CFR 20.1301 would not be exceeded (see Attachment 1, Health Physics Position 286). This guidance continues to be a good bench mark that can be used to estimate when the patient may be released. Its use, however, must also be combined with patient specific information and radiation data. The 0.25 mR/hr at 1 foot is a conservative release criteria. If the owner follows the instructions to limit interaction with the cat for the first few days, it is unlikely that a person would receive a 100 mrem dose even considering diminishing compliance with the instructions after the first few days.

Applying the 0.25 mR/hr at 1 ft criterion to measurements provided by one licensee, shows that only a few cats could be released 4 days after treatment (Attachment 2, day 5 of the table) and some cats would have to be held beyond 8 days. Holding these cats longer than the 4 to 8 days may not be necessary to assure compliance with 10 CFR 20.1301. Higher release levels may be appropriate for specific situations, but each higher release level will require a greater degree of compliance by the owner with the licensee's instructions over longer periods of time.

Applying the 0.25 mR/hr at 1 ft criterion to measurements provided by one licensee, shows that only a few cats could be released 4 days after treatment (Attachment 2, day 5 of the table) and some cats would have to be held beyond 8 days. Holding these cats longer than the 4 to 8 days may not be necessary to assure compliance with 10 CFR 20.1301. Higher release levels may be appropriate for specific situations, but each higher release level will require a greater degree of compliance by the owner with the licensee's instructions over longer periods of time.

On a case specific basis, a radiation release measurement as high as 0.5 mR/hr at 1 foot may be acceptable provided it is easy for the owner to comply with the instructions pertaining to the extent and duration of contact permitted with the cat and difficult for an individual to receive a dose of 100 mrem. Attachment 3 demonstrates the potential doses to the owners when a cat is released, and the owners do not comply with instructions. The patient release criterion associated with the incident reported in Attachment 3 was less than 2 mR/hr at 1 meter, and the owners ignored all instructions.

Release criteria above 0.5 mR/hr at one foot are not recommended because strict compliance by owners with the licensee's instructions for extended periods is unlikely, and therefore compliance with the public dose limits cannot be assured.

REVIEWER NOTES:

See Attachment 4.

Attachments:
1. Health Physics Position 286
2. Effective Half-life of I-131 Table submitted for License No. 37-3037-01
3. NMED Report 010664
4. Reviewer notes
5. Items 10.11 and 10.12 submitted for License No. 37-3037-01
6. MicroShield Calculations
7. Release Criteria RadioCat License No. 45-25330-01

Technical Assistance Request, Angell Memorial Animal Hospital, Boston, MA; Release to Unrestricted Area of Animals Containing Iodine-131
HPPOS-286 PDR-9306180040

Title: Technical Assistance Request, Angell Memorial Animal Hospital, Boston, MA; Release to Unrestricted Area of Animals Containing Iodine-131

See memorandum from J. E. Glenn to R. E. Bellamy dated March 11, 1993. This memo responds to a technical request from Region I, dated November 25, 1992, regarding Angell Memorial Hospital's request to release animals treated with iodine-131 (I-131) when the dose rate is less than 1 mR/hr at 6 inches.

The licensee was previously authorized to perform radionuclide therapy on animals with iodine-131 (I-131) and phosphorus-32 (P-32). In a previous application for a material license, the licensee provided an "Instruction to Owners" sheet, which appears to have provided adequate care and handling instructions to the owners. Authorization was granted, with the reasoning that human patients are allowed to be released at a level twenty times greater than the limit requested. If the animal had to be held until it reached background levels, the procedure would become prohibitively expensive, and the stress on the animal would also be increased. The dose that the owner would receive should be minimal if they are given instruction and the animal is handled as little as possible.

Therefore, provided that the licensee provides and commits to distribute a similar "Instructions to Owners" sheet to owners of animals undergoing radioiodine therapy, and provides a demonstration that the limits in 10 CFR 20.1301 will not be exceeded for any member of the public, licensee's request was approved.

Regulatory References: 10 CFR 20.1301, 10 CFR 35, License Conditions

Subject codes: 3.6, 11.2, 11.5

Applicability: Byproduct Material

Attachment 1
06/01/2001 1:02 PM

...D-ATLANTIC RADIATION PHYSICS, IN
7253-D HANOVER PARKWAY • (301) 345-6803 • GREENBELT, MD 20770

EFFECTIVE HALF-LIFE FOR SODIUM IODIDE IODINE-131 INJECTED IN FELINES, DETERMINED BY OBSERVED EXPOSURE RATE FROM 04/12/99 THROUGH 05/03/99

Robert S. Kutchi, B.S.

Radiocat, L.L.C.
32A Mellor Avenue
Catonsville, MD 21228

SET 1		Observed Exposure Rate (mR/hr) Reading at 1 foot from Thyroid-region of Feline						
		Day 1	Day 2	Day 4	Day 5	Day 6	Day 7	Day 8
Cat's Name	Activity Injected (mCi)	4/12/99 14:00	4/13/99 14:00	4/15/99 10:00	4/16/99 12:00	4/17/99 12:00	4/18/99 12:00	4/19/99 12:00
Zoey W.	3.0	1.8	1.3	0.5	0.3			
Sammy W.	5.0	3.5	2.5	1.0			0.2	
Rollie C.	4.0	3.0	2.0	0.6	0.4			
Beauty S.	3.5	2.5	2.0	0.8	0.4			
Pearl H.	4.0	3.0	3.0	0.4	0.2			
Nikki L.	3.5	3.0	2.0	1.5				0.4
Sam H.	5.0	4.0	3.0	0.8		0.3		
Tawny B.	3.0	1.5	1.1	0.6	0.3			
Hannibal H.	4.5	3.5	3.0	1.7			0.3	
Susie K.	3.0	1.8	1.5	0.4	0.2			
Noel M.	4.5	3.0	2.0	1.4			0.4	
Sabeau L.	3.0	1.9	1.6	0.9			0.3	

SET 2		Day 1	Day 2	Day 4	Day 5	Day 6	Day 7
Cat's Name	Activity Injected (mCi)	4/19/99 14:00	4/20/99 14:00	4/22/99 14:00	4/23/99 14:00	4/24/99 14:00	4/25/99 14:00
Pickles S.	5.0	7.0	4.0	1.2			0.4
Maurice G.	3.0	3.0	2.0	0.6	0.3		
Laverne K.	3.5	3.0	3.0	0.4	0.2		
Whiskers E.	4.0	5.0	4.0	0.8		0.3	
Samantha S.	4.0	4.0	4.0	0.8		0.2	
Newton D.	5.0	5.0	3.0	1.3			0.4
Maggie E.	4.5	5.0	3.0	0.9		0.3	
Mittens B.	3.0	4.0	2.0	0.6		0.2	
Toby O.	4.0	5.0	3.0	0.8		0.2	
Kellie E.	4.0	4.0	3.0	0.6	0.3		
Megan D.	3.0	3.0	2.0	0.6	0.3		
Halston F.	3.0	3.0	3.0	0.6	0.3		

SET 3		Day 1	Day 2	Day 4	Day 5	Day 6	Day 7	Day 8
Cat's Name	Activity Injected (mCi)	4/26/99 14:00	4/27/99 14:00	4/29/99 14:00	4/30/99 14:00	5/1/99 14:00	5/2/99 14:00	5/3/99 14:00
Eddie D.	3.0	3.0	2.0	0.4				0.1
Stevie H.	3.0	3.0	2.0	0.6				0.1
Tigger S.	5.0	5.0	4.0	1.0			0.1	
Rebel B.	3.0	3.0	2.0	0.4			0.05	
Shell B.	4.0	4.0	3.0	1.5			0.4	
Sable S.	3.5	3.0	3.0	1.0		0.4		
Zak L.	3.5	3.0	2.0	1.0		0.4		
Moss A.	3.0	3.0	2.0	0.5	0.4			
Leo R.	3.5	4.0	2.0	0.5		0.2		
Sheba N.	3.0	3.0	3.0	1.2			0.4	
Cassandra R.	3.5	3.0	3.0	1.0		0.3		
Dusty R.	4.5	5.0	4.0	1.2			0.4	

Combined Analysis of Set 1, Set 2, & Set 3

	'Day 1'	'Day 2'	'Day 4'	'Day 5'	'Day 6'	'Day 7'	'Day 8'
Average Observed Exposure Rate (mR/hr):	3.5	2.6	0.8	0.3	0.3	0.3	0.2
Std. Dev.:	1.2	0.8	0.4	0.1	0.1	0.1	0.2
Ave. + Std. Dev.:	4.7	3.4	1.2	0.4	0.4	0.4	0.4
Ave. - Std. Dev.:	2.3	1.8	0.5	0.2	0.2	0.2	0.0
Max. Observed:	7.0	4.0	1.7	0.4	0.4	0.4	0.4
Min. Observed:	1.5	1.1	0.4	0.2	0.2	0.1	0.1

Average Activity Used per Set:	44.8 mCi						
Average Activity per Injection:	3.7 mCi		Average Activity + Std. Dev.:	4.5 mCi		Max. Activity per Injection:	5.0 mCi
Std. Dev.:	0.7 mCi		Average Activity - Std. Dev.:	3.0 mCi		Min. Activity per Injection:	3.0 mCi

Attachment 2

MID-ATLANTIC RADIATION PHYSICS, I.
7233-D HANOVER PARKWAY • (301) 345-6803 • GREENBELT, MD 20770

EFFECTIVE HALF-LIFE FOR SODIUM IODIDE IODINE-131 INJECTED IN FELINES, DETERMINED BY OBSERVED EXPOSURE RATE FROM 04/12/99 THROUGH 05/03/99

Robert S. Kutchi, B.S.

Radiocat, L.L.C.
32A Mellor Avenue
Catonsville, MD 21228

SET 1	Observed Effective Half-Life (days)					
Cat's Name	4/13/99 Day 2	4/15/99 Day 4	4/16/99 Day 5	4/17/99 Day 6	4/18/99 Day 7	4/19/99 Day 8
Zoey W.	2.1	1.3	1.5			
Sammy W.	2.1	1.4			1.3	
Rollie C.	1.7	1.1	1.9			
Beauty S.	3.1	1.4	1.1			
Pearl H.	0.0	0.6	1.1			
Nikki L.	1.7	4.4				2.1
Sam H.	2.4	1.0		1.5		
Tawny B.	2.2	2.1	1.1			
Hannibal H.	4.5	2.2			1.2	
Susie K.	3.8	1.0	1.1			
Noel M.	1.7	3.6			1.7	
Sabeau L.	4.0	2.2			1.9	

SET 2	Observed Effective Half-Life (days)				
Cat's Name	4/20/99 Day 2	4/22/99 Day 4	4/23/99 Day 5	4/24/99 Day 6	4/25/99 Day 7
Pickles S.	1.2	1.2			1.9
Maurice G.	1.7	1.2	1.0		
Laverne K.	0.0	0.7	1.0		
Whiskers E.	1.7	0.9		1.4	
Samantha S.	0.0	0.9		1.0	
Newton D.	1.4	1.7			1.8
Maggie E.	1.4	1.2		1.3	
Mittens B.	1.0	1.5		1.0	
Toby O.	1.4	1.0		1.0	
Kellie E.	2.4	0.9	1.0		
Megan D.	1.7	1.2	1.0		
Halston F.	0.0	0.9	1.0		

SET 3	Observed Effective Half-Life (days)					
Cat's Name	4/27/99 Day 2	4/29/99 Day 4	4/30/99 Day 5	5/1/99 Day 6	5/2/99 Day 7	5/3/99 Day 8
Eddie D.	1.7	0.9				2.0
Stevie H.	1.7	1.2				1.5
Tigger S.	3.1	1.0			0.9	
Rebel B.	1.7	0.9			1.0	
Shell B.	2.4	2.0			1.6	
Sable S.	0.0	1.3		1.5		
Zak L.	1.7	2.0		1.5		
Moss A.	1.7	1.0	3.1			
Leo R.	1.0	1.0		1.5		
Sheba N.	0.0	1.5			1.9	
Cassandra R.	0.0	1.3		1.2		
Dusty R.	3.1	1.2			1.9	

Combined Analysis of Set 1, Set 2, & Set 3

	'Day 2'	'Day 4'	'Day 5'	'Day 6'	'Day 7'	'Day 8'
Average Effective Half-life (days):	1.7	1.4	1.3	1.3	1.6	1.9
Std. Dev.:	1.2	0.8	0.6	0.2	0.4	0.3
Ave. + Std. Dev.:	2.9	2.2	1.9	1.5	1.9	2.2
Ave. - Std. Dev.:	0.5	0.6	0.7	1.1	1.2	1.6
Max. Observed:	4.5	4.4	3.1	1.5	1.9	2.1
Min. Observed:	0.0	0.6	1.0	1.0	0.9	1.5

Overall Average Effective Half-Life (days):	1.5
Std. Dev.:	0.9

NMED Report 010664

ABSTRACT: The Polk County North Central Landfill reported that a City of Lakeland garbage truck set off their radiation monitor alarm. The load was dumped and a bag of kitty litter was found to be the source of radioactivity (probably I-131). Tag J-17 was issued and the investigator impounded the bag for decay and disposal. On 5/16/2001, the State of Florida Public Health Unit stated that the landfill had discovered the residence from which the kitty litter originated and had spoken to the cat's owner. The Public Health Unit visited the residence to determine the level of contamination. The owner of the cat stated that the cat had been given a 0.19 GBq (5 mCi) I-131 treatment from the Cat Thyroid Center (Ruskin Animal Hospital & Cat Clinic) on 5/1/2001. The investigator surveyed the home on 5/18/2001 and found the following readings: Cat read 2.5 mR/hour on contact with the surface of the shoulder and 0.04 mR/hour at one meter; garbage bags read 3 mR/hour on contact; floor next to litter box read 400 cpm; spot on floor where cat spit up read 2,000 cpm; towel in bathroom where cat often naps read 3,000 cpm; owner's bed where cat sleeps read 3,000 cpm and bedding material brought home from clinic (not used since discharge) read 1,000 cpm. The actual contact readings of the cat upon discharge from the clinic on 5/3/2001 was 90 mR/hour. The owner stated that she had lost the animal hospital discharge instructions and had been sleeping with the cat. The female owner stated that the cat had actually slept on her during the first ten days touching her head or neck an average of six hours per night, one foot from her husband's head area. It was estimated that the female owner received 2.88 cSv (rem) whole body dose (gamma). The male owner was estimated to have received 0.534 cSv (rem) whole body dose (gamma). Based on calculations using the actual dose rate from this cat, it appears impossible to keep the general public below 0.1 cSv (100 mrem) following the clinic's outpatient instructions. The cat died on 6/5/2001.

Event Date	Discovery Date	Report Date
05/08/2001	05/08/2001	05/17/2001

Licensee / Reporting Party Information:
Agreement State Regulated: YES
Reciprocity: NONE
License Number: NON-LICENSEE
Licensee: PRIVATE INDIVIDUAL
Docket: NA
City: LAKELAND
Program Code: NA
State: FL
NRC Region Office: 2

REVIEWER NOTES

Distance Perspectives

The measurement distances used by several licensees include radiation measurements at 1 meter, 1 foot, and 6 inches. NRC's definition of the" whole body" in 10 CFR Part 20 is the head, trunk (including male gonads), arms above elbow, or legs above knee. The distances provided are put into perspective by relating them to distances from the highest activity measured from the cat to the center of the area of the person that NRC defines as the "whole body. "

One meter is the approximately distance from a cat lying on the floor to a standing adult. One foot is approximately an arm's distance. Thus, one foot could either be the distance from a cat to a person patting a cat when keeping the cat at arm's distance or the distance from a cat lying on the floor to an adult sitting in a chair near the cat. Although six inches would be the maximum distance from a cat to an adult holding the cat in their lap, three inches is a better estimate of this distance from a cat. All these distances should at least be halved when considering small children.

During transportation, one foot is approximately the distance between an adult driver and a cat in a carrier in the front passenger seat of a car. This distance would be between 1-2 feet if the cat were in the back seat, and may approach 1 meter if the cat was in the back of a van or station wagon.

Radiocat® - 1999 Radiation measurement and effective half-life Data

Veterinarians typically use 3- to 5-millicuries to treat feline hyperthyroidism. Radiocat®, provided data collected on 36 cats treated between April 12- 26, 1999, at the licensee's Maryland facility (Attachment 2). The data consisted of observed exposure rate measurements made 1 foot from the thyroid-region for each cat after injection and subsequently approximately 1, 3, 4, 5, and 6 days after treatment. In most cases, measurements were stopped after a reading of 0.4 mR/hr or less after day 4. This data was used to calculate I-131 effective half-lives for each cat. For 29 of the cats, the I-131 effective half-lives at day 1 ranged from a low of 1.0 to a high of 4.5 days; for the remaining 7 cats there was no decline in radiation measurements. The licensee incorrectly concluded the I-131 effective half -life for these animals was zero. This error lowered the licensee's average I-131 effective half life to 1.7 days when it should have been 2.1 days for those animals with declining measurements. Although the animals with no decline in measurements should have been assigned I-131 effective half-lives of 8 days (the physical half life of I-131), the measurement data at 3 days after injections shows a marked reduction in radiation levels to those similar to the other cats.

The I-131 effective half-life data presented for 3, 4, 5, 6,and 7 days after I-131 administration show variation between different days for the same cat. In some cases, the I-131 effective half-lives increased with time. There was also variation among cats. As evidenced by the large standard deviations resulting from simple averaging, the data sample is probably too small to draw statistical conclusions. At their time of release, most cats (26 of 36) had an estimated I-131 effective half-life of 1.5 days or less. The longest I-131 effective half-life was 3.1 days.

of release, most cats (26 of 36) had an estimated ^{131}I effective half-life of 1.5 days or less. The longest ^{131}I effective half-life was 3.1 days.

Attachment 4

In 1999, the licensee also provided a table estimating the dose to an individual spending 3 hours a day with a released patient with an estimated retained activity of 500 microcuries (Attachment 5). Dose estimates 6 inches from the patient's thyroid area were used to approximate close contact.

NRC MicroShield Calculations

MicroShield version 5.05 was used to perform dose rate calculations and estimate retained activity from dose rates to verify data submitted in 1999 by the licensee (Attachment 6).

The first data point evaluated was the exposure rate expected at 6 inches from 500 microcuries of retained activity (Attachment 4, Table on page labeled "page 4 of 6, Item 10"). The MicroShield variables were set at: a 0.3 centimeter diameter sphere (for an approximation of the thyroid volume), retained activity of 500 microcuries, and 6 inch distance from the source. The MicroShield result was 4.8 mR/hr compared to the licensee's value of 2 mR/hr. This indicates that the licensee's results may be a factor of 2 too low for a cat with 500 microcuries of residual activity.

However, if the cat was released with a measurement at day 5 of 0.5 mR/hr at a foot (not 500 microcuries), the licensee's table could be used since 0.5 mR/hr at 1 foot is essentially 2 mR/hr at 6 inches. Actual measurements at these close distances may vary due to geometry and effect of I-131 present on fur or in the bladder.

MicroShield was also used to estimate the retained activity expected from the licensee's release criteria of a dose reading of 0.5 mR/hr at 1 foot and the newer requested dose rate of 0.5 mR/hr at one meter. An estimated 210 microcuries curies of I-131 would result in 0.5 mR/hr at 1 foot and 2.4 millicuries was estimated to result in 0.5 mR/hr at 1 meter. A residual radioactivity of 210 microcuries is calculated to result in an estimated dose rate of 2.0 mR/hr at 6 inches, and a an estimated 22 mR/hr at 6 inches for a residual radioactivity of 2.4 millicuries. A residual activity of 100 microcuries is calculated to result in an estimated dose rate of 1.0 mR/hr at 6 inches, the maximum residual activity for the measurements cited in the 1992 TAR request and Health Physics Position 286 (Attachment 1).

Radiocat® release analysis based upon ALI

In Attachment 7, Radiocat® used calculations to demonstrate that cats could be released at 3 days based upon estimates that 95-98 percent of the free I-131 was excreted from the cat in the first 24 hours. The human uptake criteria used resulted in a calculated dose to a person of 26 mrem. One flaw in the licensee's calculations was equating "95 percent of the free I-131" that was excreted in the first 24 hours with "95 percent of the entire I-131 dosage" being excreted every 24 hours. The measurement and effective half-life data demonstrate that these are not the same for the hyper-thyroid cat. The calculations provided in Attachment 7 based upon ALI considerations should not be used in determining when a cat can be released.

Best release estimate

0.25 mR/hr at 1 foot

As seen in the MicroShield calculations, the radiation measurement of 0.25 mR/hr at 1 foot is a conservative release criteria and, if the owners follow the instructions to limit interaction with the cat for the first few days, it would be unlikely for a person to receive more than a 100 millirem dose. While compliance with the owner instructions will keep doses to the public ALARA, good compliance but not absolute compliance with the instructions even during the first day or two would probably not result in a dose in excess of the 10 CFR 20.1303 limit.

Additionally, good compliance with the contamination control instructions provided to the owner should result in minimal up take by the care givers because the cat only has an estimated I-131 retained activity of 100 microcuries at release.

0.5 mR/hr at 1 foot

Releasing an animal with a dose measurement of 0.5 mR/hr at 1 foot and an calculated effective half-life of approximately 1-1.5 days, would require stricter compliance for the first day or two but not absolute compliance with the owner's instructions after the first two or three days to assure compliance with 10 CFR Part 20 for most cats.

Further, good compliance with the contamination control instructions provided to the owner should result in minimal additional dose due to up take by the care givers because the cat only has an estimated I-131 retained activity of 200 microcuries at release.

0.5 mR/hr at one meter

Releasing a cat with a dose measurement of 0.5 mR/hr at one meter could easily result in a dose of 100 mrem unless the instructions to the owner are more rigorous and both the cat and the owner strictly comply with all the instructions. The dose estimates provided only consider external dose. A cat released at 0.5 mR/hr at one meter (or calculated retained activity of 2.4 millicuries) may contain enough I-131 that the dose contribution from contamination also has to be considered.

Days post treatment

As seen in the Radiocat® data, the release dates for cats with measurements below 0.5 mR/hr at one foot ranges from 4 to 7 days after injection and the specific day cannot be predicted based upon the initial treatment dosage. With this variability, days post injection by itself is not an appropriate release criteria.

Conclusion

While the licensee can factor in some reduction in dose to members of the public due to compliance with the owner instructions, strict compliance by the animal and the owner cannot

be guaranteed. Therefore, the instructions can provide a margin for dose reduction but should not be relied on as the primary means to keep the dose to members of the public below the 100 mrem yearly public dose limit.

When combined with information about the cat's behavior and the home's occupants, the radiation measurement made 1 foot from the thyroid area of the cat and the I-131 effective half-life for the cat calculated when that measurement reaches 0.5 mR/hr at one foot are probably the best parameters to use when estimating dose to the public and determining whether the patient can be released. For example, a patient with a dose rate of 0.5 mR/hr at one foot but an I-131 effective half-life of 3 or 4 days may need to be held for another day or two while another cat with the same reading but an I-131 effective half-life of 1 to 1.5 could be released to an adult only home. Age, mobility, and attachment of a child to the cat would need to be considered when considering releasing a treated cat to a home with children.

10.10 Area Radiation Survey Procedures: Area survey procedures will N to be NRC established Regulatory and

Radiation Safety Program (Continued)

10.10 Area Radiation Survey Procedures: Area survey procedures will be established and implemented according to the procedures found in Appendix N to NRC Regulatory Guide 10.8 (Revision 2, August 1987). Trigger levels for exposure rate surveys shall be 5 mR/hr and 0.2 mR/hr for restricted and unrestricted areas, respectively. Trigger levels for removable contamination shall be 200 dpm per 100 cm^2 as per Table N-1 in Appendix N to NRC Regulatory Guide 10.8 (Revision 2, August 1987). An operational check to verify proper portable survey instrument response with a dedicated check source shall be conducted each day prior to the use of the portable survey instrumentation. An exposure rate and removable contamination survey shall be conducted of the dose area following the last injection and placement of the animal in the cage.

Routine surveys shall be performed as follows:

- Exposure rate area surveys shall be performed any day radioactive materials are received, handled, and/or administered. These routine area surveys shall include package receipt area, dose injection area, waste compactor, and patient quarantine area. An exposure rate area survey shall be conducted in the area used to store radioactive waste during each week radioactive materials are used (i.e., survey will be conducted each week when radioactive materials are administered to patients). An exposure rate area survey shall be conducted, for each week radioactive materials are used, to monitor unrestricted areas adjacent to the radiation ward (restricted area), including the area directly below the animal quarantine area (see Item 10.13 of this application). Action levels for exposure rate area surveys shall be set at 5 mR/hr and 2 mR/hr for restricted and unrestricted areas, respectively.
- Personnel contamination surveys shall be performed any day radioactive materials are received, handled, and/or administered, and anytime personnel egress from any restricted area. Personnel exiting this restricted area shall monitor their hands and feet for potential contamination with a survey meter equipped with a pancake GM detector. Measurement shall be made in a low background area.
- Routine removable contamination surveys shall be performed at least weekly following the last administered dose (doses are only administered 1 day each week). These surveys shall include areas where unit doses were received and administered, the quarantine area, waste compaction area, and waste storage area.

Records of routine surveys shall be maintained in accordance with requirements of 10 CFR, Part 20.

10.11 Release of Patients Treated with I-131: Typical administered activities of 4 to 5 mCi will be given for the treatment of benign hyperthyroidism. Injected patients shall be confined to a single isolation cage at the facility for a minimum of 5 days until the residual activity is 500 µCi or less. Typically patients are confined at the facility for 5 to 7 days. Exposure rates will be measured periodically and must be less than 0.5 mR/hr at 1 foot before release. Written special care procedures will be reviewed, signed, and provided to the owner at the time of patient release.

GM detector. Measurement contamination with meter equipped shall be made in a low background area.

- Routine removable contamination are only surveys administered shall be performed **I** day each at week). least weekly These following surveys. shall the last administered dose (doses were received and administered, the quarantine area, waste include areas where unit doses compaction area, and waste storage area.

Records of routine surveys shall be maintained in accordance with requirements of 10 CFR, Part 20.

10.11 Release of the Patients treatment Treated of benign with 1-131:hyperthyroidism. a Typical minimum administered of 5Injected days until activities patients the residual shall of 4 be to confined 5 mCi will is 500to be a JlCi given for facility for activity

single isolation cage at the are confined at the facility for 5 to 7 days. Exposure rates will be or less. Typically patients and must be less than 0.5 mR/hr at 1 foot before release. Written measured periodically be the time of special care procedures will reviewed, signed, and provided to the owner at patient release.

Radiation Safety Program (Continued)

10.12 Instructions to Owner of Patient: The patient's owner has specific instructions to quarantine the animal for an additional 2 weeks following the release from the treatment facility (i.e., release from licensee's control). Patient owners shall be directed to use only scoopable cat litter during the 2-week quarantine period at home. These instructions are reviewed with the owner several times prior to release from confinement and are signed by the owner (see attached instructions to owners).

Assuming that the owner does not strictly follow the quarantine instructions, we estimated the potential whole-body exposure to the owner (or a member of the owner's family) as follows. From an evaluation performed at our Catonsville, Maryland facility (see attachment), we have determined an average effective half-life for felines injected with iodine-131 as approximately 1.5 days; and the average exposure rate at 1 foot from a patient's thyroid shortly after injection of 5.0 mCi of iodine-131 is 5.0 mR/hr. Using these assumptions and assuming release post confinement for a minimum of 5 days, the following table indicates for several days post release the estimated patient retained activity within the patient and the estimated exposure rate at 1 foot from the patient.

Days Elapsed, Post Release	Estimated Patient Retained Activity	Estimated Exposure Rate at Approximately 6" from the Patient's Thyroid
0 (i.e., on day of release)	500 µCi	2.0 mR/hr
1	310 µCi	1.3 mR/hr
2	200 µCi	0.8 mR/hr
3	120 µCi	0.5 mR/hr
4	80 µCi	0.3 mR/hr
5	50 µCi	0.2 mR/hr
6	30 µCi	0.1 mR/hr
7	20 µCi	≤ 0.1 mR/hr
8	12 µCi	< 0.1 mR/hr
9	8 µCi	< 0.1 mR/hr
10	5 µCi	< 0.1 mR/hr
11	3 µCi	< 0.1 mR/hr
12	2 µCi	< 0.1 mR/hr
13	1 µCi	< 0.1 mR/hr
14	≤1 µCi	< 0.1 mR/hr

For a single individual who may be in close contact with their pet for 3-hours each day during the 2-week quarantine period, the cumulative exposure is estimated to be 16 mR. Therefore, this estimate indicates that individual is not likely to receive in excess of 20% of the annual dose limit for members of the public (i.e., dose limit for members of the public is 100 mrem per year).

MicroShield v5.05 (5.05-00274)
US NRC
Conversion of calculated exposure in air to dose
FILE: Case1
Case Title: 500uci I-131 at 6 in
This case was run on Friday, November 2, 2001 at 3:22:25 PM
Dose Point # 1 - (15,0,0) cm

Results (Summed over energies)	Units	Without Buildup	With Buildup
Photon Fluence Rate (flux)	Photons/cm²/sec	6.765e+003	6.879e+003
Photon Energy Fluence Rate	MeV/cm²/sec	2.460e+003	2.496e+003
Exposure and Dose Rates:			
Exposure Rate in Air	mR/hr	4.822e+000	4.894e+000
Absorbed Dose Rate in Air	mGy/hr	4.210e-002	4.273e-002
"	mrad/hr	4.210e+000	4.273e+000
Deep Dose Equivalent Rate	(ICRP 51 - 1987)		
o Parallel Geometry	mSv/hr	5.320e-002	5.400e-002
o Opposed	"	3.891e-002	3.949e-002
o Rotational	"	3.884e-002	3.941e-002
o Isotropic	"	3.456e-002	3.507e-002
Shallow Dose Equivalent Rate	(ICRP 51 - 1987)		
o Parallel Geometry	mSv/hr	5.503e-002	5.586e-002
o Opposed	"	5.148e-002	5.224e-002
o Rotational	"	5.148e-002	5.224e-002
o Isotropic	"	3.712e-002	3.766e-002
Effective Dose Equivalent Rate	(ICRP 51 - 1987)		
o Anterior/Posterior Geometry	mSv/hr	4.569e-002	4.636e-002
o Posterior/Anterior	"	3.878e-002	3.934e-002
o Lateral	"	2.727e-002	2.766e-002
o Rotational	"	3.417e-002	3.467e-002
o Isotropic	"	2.869e-002	2.911e-002

MicroShield v5.05 (5.05-00274)
US NRC
Conversion of calculated exposure in air to dose
FILE: Case2
Case Title: 210uci I-131 at 1 ft
This case was run on Friday, November 2, 2001 at 3:34:19 PM
Dose Point # 1 - (30,0,0) cm

Results (Summed over energies)	Units	Without Buildup	With Buildup
Photon Fluence Rate (flux)	Photons/cm²/sec	7.089e+002	7.224e+002
Photon Energy Fluence Rate	MeV/cm²/sec	2.579e+002	2.621e+002
Exposure and Dose Rates:			
Exposure Rate in Air	mR/hr	5.054e-001	5.139e-001
Absorbed Dose Rate in Air	mGy/hr	4.412e-003	4.487e-003
"	mrad/hr	4.412e-001	4.487e-001
Deep Dose Equivalent Rate	(ICRP 51 - 1987)		
o Parallel Geometry	mSv/hr	5.576e-003	5.670e-003
o Opposed	"	4.079e-003	4.146e-003
o Rotational	"	4.071e-003	4.138e-003
o Isotropic	"	3.622e-003	3.682e-003
Shallow Dose Equivalent Rate	(ICRP 51 - 1987)		
o Parallel Geometry	mSv/hr	5.768e-003	5.865e-003
o Opposed	"	5.395e-003	5.485e-003
o Rotational	"	5.395e-003	5.485e-003
o Isotropic	"	3.890e-003	3.955e-003
Effective Dose Equivalent Rate	(ICRP 51 - 1987)		
o Anterior/Posterior Geometry	mSv/hr	4.788e-003	4.868e-003
o Posterior/Anterior	"	4.064e-003	4.131e-003
o Lateral	"	2.858e-003	2.905e-003
o Rotational	"	3.582e-003	3.641e-003
o Isotropic	"	3.007e-003	3.056e-003

MicroShield v5.05 (5.05-00274)
US NRC
Conversion of calculated exposure in air to dose
FILE: Case3
Case Title: 2.4 mci I-131 at 1 m
This case was run on Friday, November 2, 2001 at 3:37:39 PM
Dose Point # 1 - (100,0,0) cm

Results (Summed over energies)	Units	Without Buildup	With Buildup
Photon Fluence Rate (flux)	Photons/cm²/sec	7.224e+002	7.437e+002
Photon Energy Fluence Rate	MeV/cm²/sec	2.631e+002	2.697e+002
Exposure and Dose Rates:			
Exposure Rate in Air	mR/hr	5.154e-001	5.288e-001
Absorbed Dose Rate in Air	mGy/hr	4.499e-003	4.616e-003
"	mrad/hr	4.499e-001	4.616e-001
Deep Dose Equivalent Rate	(ICRP 51 - 1987)		
o Parallel Geometry	mSv/hr	5.687e-003	5.835e-003
o Opposed	"	4.160e-003	4.266e-003
o Rotational	"	4.152e-003	4.258e-003
o Isotropic	"	3.695e-003	3.789e-003
Shallow Dose Equivalent Rate	(ICRP 51 - 1987)		
o Parallel Geometry	mSv/hr	5.882e-003	6.035e-003
o Opposed	"	5.503e-003	5.644e-003
o Rotational	"	5.503e-003	5.644e-003
o Isotropic	"	3.968e-003	4.069e-003
Effective Dose Equivalent Rate	(ICRP 51 - 1987)		
o Anterior/Posterior Geometry	mSv/hr	4.884e-003	5.009e-003
o Posterior/Anterior	"	4.146e-003	4.250e-003
o Lateral	"	2.916e-003	2.989e-003
o Rotational	"	3.654e-003	3.746e-003
o Isotropic	"	3.068e-003	3.145e-003

MicroShield v5.05 (5.05-00274)
US NRC
Conversion of calculated exposure in air to dose
FILE: Case4
Case Title: 2.4 mci I-131 at 6in
This case was run on Friday, November 2, 2001 at 3:40:41 PM
Dose Point # 1 - (15,0,0) cm

Results (Summed over energies)	Units	Without Buildup	With Buildup
Photon Fluence Rate (flux)	Photons/cm²/sec	3.247e+004	3.302e+004
Photon Energy Fluence Rate	MeV/cm²/sec	1.181e+004	1.198e+004
Exposure and Dose Rates:			
Exposure Rate in Air	mR/hr	2.315e+001	2.349e+001
Absorbed Dose Rate in Air	mGy/hr	2.021e-001	2.051e-001
"	mrad/hr	2.021e+001	2.051e+001
Deep Dose Equivalent Rate	(ICRP 51 - 1987)		
o Parallel Geometry	mSv/hr	2.554e-001	2.592e-001
o Opposed	"	1.868e-001	1.895e-001
o Rotational	"	1.864e-001	1.892e-001
o Isotropic	"	1.659e-001	1.683e-001
Shallow Dose Equivalent Rate	(ICRP 51 - 1987)		
o Parallel Geometry	mSv/hr	2.641e-001	2.681e-001
o Opposed	"	2.471e-001	2.507e-001
o Rotational	"	2.471e-001	2.507e-001
o Isotropic	"	1.782e-001	1.808e-001
Effective Dose Equivalent Rate	(ICRP 51 - 1987)		
o Anterior/Posterior Geometry	mSv/hr	2.193e-001	2.225e-001
o Posterior/Anterior	"	1.861e-001	1.888e-001
o Lateral	"	1.309e-001	1.328e-001
o Rotational	"	1.640e-001	1.664e-001
o Isotropic	"	1.377e-001	1.397e-001

MicroShield v5.05 (5.05-00274)
US NRC
Conversion of calculated exposure in air to dose
FILE: Case5
Case Title: 100 uci I-131 at 6in
This case was run on Friday, November 2, 2001 at 3:43:25 PM
Dose Point # 1 - (15,0,0) cm

Results (Summed over energies)	Units	Without Buildup	With Buildup
Photon Fluence Rate (flux)	Photons/cm²/sec	1.353e+003	1.376e+003
Photon Energy Fluence Rate	MeV/cm²/sec	4.921e+002	4.992e+002
Exposure and Dose Rates:			
Exposure Rate in Air	mR/hr	9.644e-001	9.789e-001
Absorbed Dose Rate in Air	mGy/hr	8.419e-003	8.545e-003
"	mrad/hr	8.419e-001	8.545e-001
Deep Dose Equivalent Rate	(ICRP 51 - 1987)		
o Parallel Geometry	mSv/hr	1.064e-002	1.080e-002
o Opposed	"	7.783e-003	7.897e-003
o Rotational	"	7.768e-003	7.882e-003
o Isotropic	"	6.912e-003	7.014e-003
Shallow Dose Equivalent Rate	(ICRP 51 - 1987)		
o Parallel Geometry	mSv/hr	1.101e-002	1.117e-002
o Opposed	"	1.030e-002	1.045e-002
o Rotational	"	1.030e-002	1.045e-002
o Isotropic	"	7.423e-003	7.533e-003
Effective Dose Equivalent Rate	(ICRP 51 - 1987)		
o Anterior/Posterior Geometry	mSv/hr	9.137e-003	9.272e-003
o Posterior/Anterior	"	7.756e-003	7.868e-003
o Lateral	"	5.454e-003	5.533e-003
o Rotational	"	6.835e-003	6.934e-003
o Isotropic	"	5.738e-003	5.822e-003

I. Procedure for the Use of Radioactive Material in Animals

A. Animal facilities containing licensed material will be locked or secured by administrative control to prevent unauthorized access to or removal of licensed material.

B. Animals, animal tissue, carcasses, animal waste and bedding materials that are or become radioactive will be kept separate from non-radioactive waste, etc.

C. Animal parts, bedding and wastes will be placed in specified containers and labeled as required. Means of preserving these wastes until disposal will be provided.

D. Measures will be taken to prevent the spread of contamination in animal quarters, and surveys will be routinely performed according to the established survey frequency schedule.

E. If necessary, animal facilities (cages, floors, etc.) will be decontaminated and surveyed prior to subsequent use.

F. Animals administered licensed material or their products shall not be used for human consumption.

G. Cages containing animals that have received licensed materials will be labeled to indicate the radionuclide administered, the date of administration, the amount administered, and the words "Caution - Radioactive Material".

Release Criteria:

Releasing the cat to its owners as early as possible has clear clinical advantages. Prolonged hospitalization unnecessarily stresses the animal and the following modeling demonstrates that release in two days produces public dose lower than the annual limits.

A. Potential uptake of I-131
For I-131, the dose conversion factor, based upon the ALI for ingestion, is 1.67 rem/μCi. 95%-98% of free iodine is excreted within a 24 hour period. Using the 95% value, a cat dosed with 5 mCi will have retained 12.5 μCi of free iodine after 48 hours. It is assumed that all free iodine will eventually be excreted.

It is also assumed that after a cat's release, a member of the public will have a maximum oral uptake of 0.1% of the iodine excreted after the cat is released. This results in an uptake of

0.0125 µCi resulting in a TEDE of 21 mrem. Cats will be retained a minimum of three days to further reduce dose by another order of magnitude. In addition the external dose rate at 1 meter must not exceed 0.5 mrem/hour.

Written special care procedures will be reviewed and signed by the owner at the time of admission and at the time of release. These procedures follow.