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.

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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.

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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
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

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Attachment 2

MID-ATLANTIC RADIATION PHYSICS, L.
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
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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

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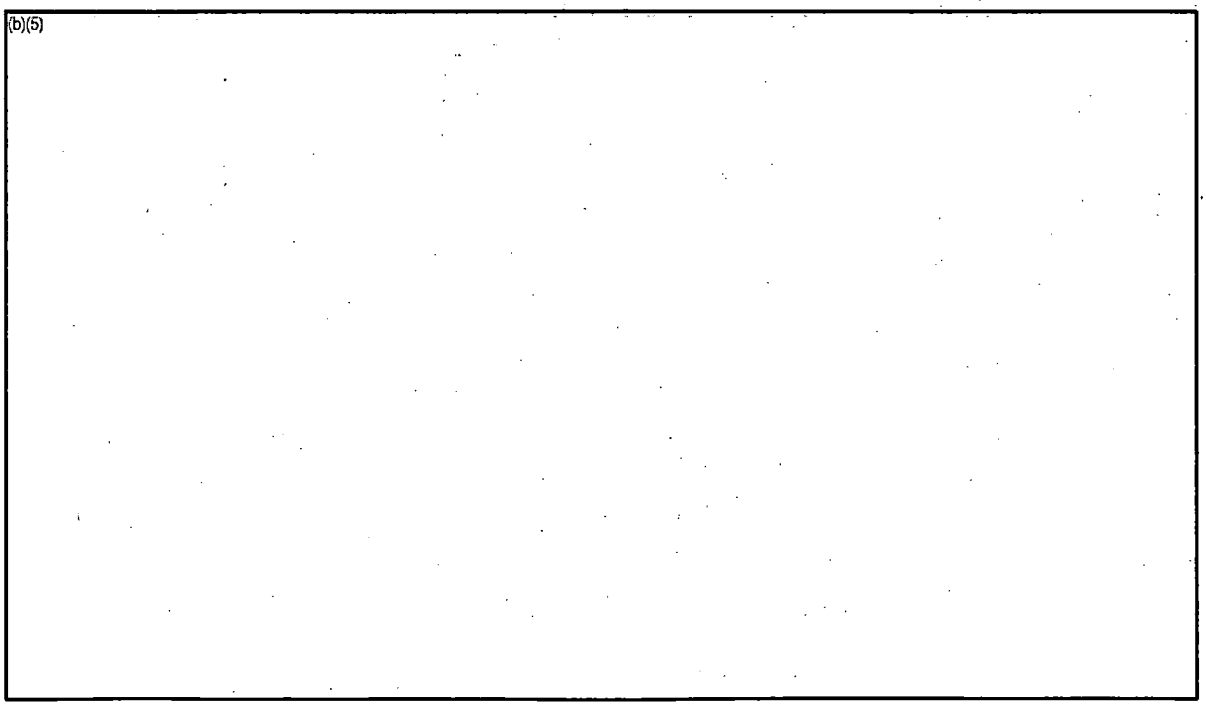

Attachment 4

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

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Best release estimate

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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 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.

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).

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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".

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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.

February 24, 2003

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

FROM: Thomas H. Essig, Chief **/RA/**
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety, NMSS

SUBJECT: REVISED TECHNICAL ASSISTANCE REQUEST RESPONSE DATED DECEMBER 21, 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 criteria for cats treated with radioactive iodine and clarification of whether the licensee can take credit for specific verbal instructions in developing a release criteria. A Memorandum dated December 21, 2001 was issued in response to the TAR. The guidance provided in that response advised, among other things, that the license reviewer may accept a proposed veterinary cat release criteria based upon a minium number of days after I-131 treatment (not less than 4 complete days) and maximum dose rate (normally 0.25 milliRoentgen/hour (mR/hr) at 1 foot), and if the licensee provides the cat owner with instructions as a means of reducing dose to members of the public, the instructions had to be in writing.

Subsequently, new information and data has been submitted to the NRC staff regarding this matter. As a result of our evaluation of this new information, we are revising in part the guidance provided in the December 21, 2001 Memorandum and are issuing this revised response to the May 18, 2001 TAR.

ACTION:

The licensee must assure that the dose to individual members of the public (including family members) from a cat treated with I-131 does not exceed the 100 millirem (mrem) annual public dose limit in 10 CFR 20.1301. Licensees may use different methods, or a combination of methods, to ensure compliance with this requirement and each must be evaluated on a case-by-case basis.

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In summary, we recommend the following:

- The licensee may establish different release criteria for different groups of cats based upon behavioral groupings and confidence in owner compliance with instructions.
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- Licensees should provide NRC with their release criteria (b)(5) (b)(5). The criteria should, as a minimum, be in terms of maximum radiation measurement in milliRoentgen per hour (mR/hr) at a specified distance and minimum hours post treatment.
- If screening programs, subsequent evaluations, and instructions are used by licensees to ensure that the annual public dose limit is not exceeded, they must be described to NRC.
- If the licensee administers the I-131 treatments at temporary sites, a description of the licensee's care for those cats which cannot be released during the normal occupancy period at that site must be provided.
- Regardless of the release level used, the licensee should maintain records to document that the veterinary patient release criterion used for an individual cat will ensure compliance with 10 CFR 20.1301.
- Regardless of the release criterion used, it is recommended that no cat be released prior to at least 96 hours following administration.
- Each release must be accompanied with written instructions addressing as a minimum (1) waste handling, (2) contamination, and (3) appropriate human interaction/isolation instructions.

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These examples are provided for information only.]

DISCUSSION:

Background.

In our December 21, 2001, response to the May 18, 2001 TAR from Region II, we provided guidance with regard to release of cats treated with I-131. In that response, we advised, among other things, that a license reviewer may accept a proposed cat release criteria based upon a minimum number of 4 complete days after treatment and maximum dose rate of normally 0.25 milliRoentgen/hour (mR/hour) at one foot. We further advised that since the I-131 effective half-life, radiation profile, behavior pattern, and living situation for each cat differ, the actual release date needs to be established for each individual cat, and that this determination should be based upon the radiation measurement and effective half-life of I-131 for each cat. The reviewer notes provided as an attachment to the December 21, 2001 TAR response also addressed the three radiation measurement release criteria (0.25 mR/hr at 1 foot, 0.5 mR/hr at 1 foot, and 0.5 mR/hr at 1 meter) most commonly requested by licensees.

Following issuance of the TAR, Radiocat®, an NRC veterinary licensee licensed to administer I-131 to hyperthyroid cats, contested the basis for the TAR. Radiocat® informed the NRC staff that the data relied upon by the NRC staff in its response was flawed, and that Radiocat® would provide actual, more accurate data. Radiocat® also asserted that it had other factors in place in its program, such as pre-screening of individual cats, that should be considered in determining criteria for the release of cats treated with I-131. Subsequently, Radiocat® provided new radiation measurement data for 100 cats (see Attachment 1) which showed the unpredictability, variability, and high I-131 retention for individual cats. Following evaluation of the data and receipt of input from Agreement States and other stakeholders, we have concluded that the guidance provided in the December 21, 2001 response to the TAR should be revised.

Minimum holding time.

The December 2001 guidance recommended that all treated cats be held for a minimum period of time (not less than 4 days). This holding period generally allows for at least half the I-131 to be excreted and for some radiological decay to occur, both of which serve to reduce the quantity of radioactive material in a given cat. It ensures licensee control during the period that the cat contains the highest levels of byproduct material and reduces the amount of I-131 contamination in the owner's home.

The staff is not revising this recommendation. However, the staff has since become aware that there has been an inconsistency in how licensees have interpreted this requirement and released cats on the fourth calendar day and not 4 full days after the administration. To assure consistency in how licensees implement this requirement, licensees should indicate the minimum post administration time in hours that the cats will be held. License reviewers may accept a minimum release time of 96 hours. The basis for shorter release criteria should be provided and reviewed on a case-by-case basis.

Pre-administration screening and post-administration evaluation.

The December 2001 guidance did not recognize the implications of licensee pre-administration screening of potential clients to determine the normal level of cat/human interaction or the owner's probability of complying with licensee instructions to severely limit contact. Accurate pre-screening and subsequent post-administration evaluation of the cat/owner interaction, the owner's degree of compliance, and behaviors that will provide the licensee with high confidence that no members of the public (including family members) will receive in excess of 100 mrem are the determining factors the licensee should use in developing a release criterion for an individual cat. The licensee should provide NRC with the criteria used in the screening and subsequent evaluation needed to comply with 10 CFR 20.1301.

NRC's December 21, 2001 guidance recommended that the license reviewer accept I-131 cat release criteria based upon a minimum number of days after I-131 treatment (not less than 4 days) and maximum dose rate (normally 0.25 mR/hr at 1 foot) with written instructions and licensee assurance that each release will be in compliance with 10 CFR 20.1301. This recommendation was based upon the estimated retained I-131 activity of about 100 microcuries and the approximately 4 mR/hr radiation field that an affectionate lap-cat might expose its owner to at very close contact (when hugged or held in the lap) upon release. Instructions provided to the owner concerning how to handle and dispose of contaminated litter and wash bedding as well as reasonable suggested contact times should provide high confidence that doses to individuals living with a cat meeting this release criterion would not exceed 100 mrem.

That recommendation assumed all cats were affectionate lap-cats and the owner would not be able to totally isolate the cat from human contact for several weeks. Not all cats fit this behavior characterization and some owners can isolate their cats from all human contact for the periods of time needed to assure that no individual would receive a dose in excess of 100 mrem.

If pre-administration screening determined that a cat does not seek human companionship and could effectively be isolated from close contact with the owner for several weeks, then the 0.25 mR/hr at 1 foot release criterion would be too restrictive. In this case, a release criterion of 0.5 mR per hour at a meter would be acceptable if the owner was provided clear instructions concerning the very limited interaction he/she could have with the cat for the designated weeks and how to handle and dispose of contaminated litter and wash bedding. Table 2 (Attachment 2) shows the relationship between dose rates that could be expected from close human contact with the cat and the amount of I-131 retained by the cat. As seen in the table, a cat released at a radiation level of 0.5 mR/hr at 1 meter indicates the cat still retains an estimated I-131 activity of 2.3 millicuries in its thyroid and body and could expose its owner to approximately 86 mR/hr at release when hugged or held in the lap.

Clearly there are other situations that fall between the extremes described above. There may be cases (or group of cats/owners fitting a defined profile) for which a release criterion of 0.5 mR/hr at 1 foot would be acceptable provided the instructions pertaining to the extent and duration of contact permitted with the cat are easy for the owner to comply with, and it appeared that the potential dose to an individual would be below 100 mrem. As seen in Table 2, a cat released at a radiation field of 0.5 mR/hr at 1 foot still retains an estimated I-131 activity of

about 200 microcuries in its thyroid and body and could expose its owner to approximately 8 mR/hr at release when hugged or held in the lap.

Documentation of release criterion.

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.

Veterinary practices at temporary sites.

Because of the great variability in the I-131 retention for individual cats, permanently located veterinary practices are expected to retain cats until they reach the appropriate release level. Veterinary practices in temporary locations may treat cats that cannot be released during the normally allotted time these licensees are at the site. To meet the requirements of 10 CFR 30.33(a)(2), the applicant must have adequate facilities; therefore, the applicant with a veterinary practice at a temporary site must describe its provisions for handling cats that cannot be released during the normally allotted time at the site. This is especially important when the licensee does not have high confidence that the owner of an affectionate lap-cat will comply with the contact hour limitations needed to ensure compliance with 10 CFR 20.1301.

Written instructions.

As discussed in our December 21, 2001, response, the licensee should provide the owner with written instructions as a means of reducing dose to members of the public. These instructions should clearly state the regulatory limits and the need to keep doses ALARA, indicate the potential radiation fields surrounding the cat and potential dose with time at various distances, describe the permitted extent and duration of contact by individuals with the cat, and indicate how to handle contaminated litter, bedding and other objects with which the cat comes into contact.

The licensee should include a sufficient safety margin in the instructions to account for the fact that compliance by owners cannot be guaranteed. Since owner compliance with the written instructions is not guaranteed, licensees could use instructions to provide a margin for dose reduction, but should not rely upon them as the primary means to keep the dose to members of the public below the 100 mrem public dose limit. The consequences of owners disregarding the contact time instructions was illustrated by an incident (described in Attachment 3 to the December 21, 2001, response) that resulted in an estimated dose to the owner of 2.88 rem and 0.5 rem to the owner's spouse.

These instructions should be evaluated by licensees and license reviewers with respect to the ease with which the owner can comply with them and the degree and duration of compliance needed to ensure that the maximum dose to a member of the public does not exceed 100 mrem.

Reduction of unnecessary burden.

The December 2001 guidance recommended the use of effective half-lives as an element for establishing the release date, but stakeholders have indicated this is an unnecessary burden. Therefore, we have concluded that the release determination does not have to include effective half-lives.

REVIEWER NOTES:

See Attachment 3.

Attachments:
1. Table 1, "Radiocat® Radiation Measurements For 100 Cats And Calculated Percent I-131 Retention"
2. Table 2, "Estimated Radiation Fields at Common Distances December 2002 Updated
3. December 2002 Updated Reviewer Notes

D. Collins February 24, 2003

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DECEMBER 2002 UPDATED REVIEWER NOTES

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Attachment 3

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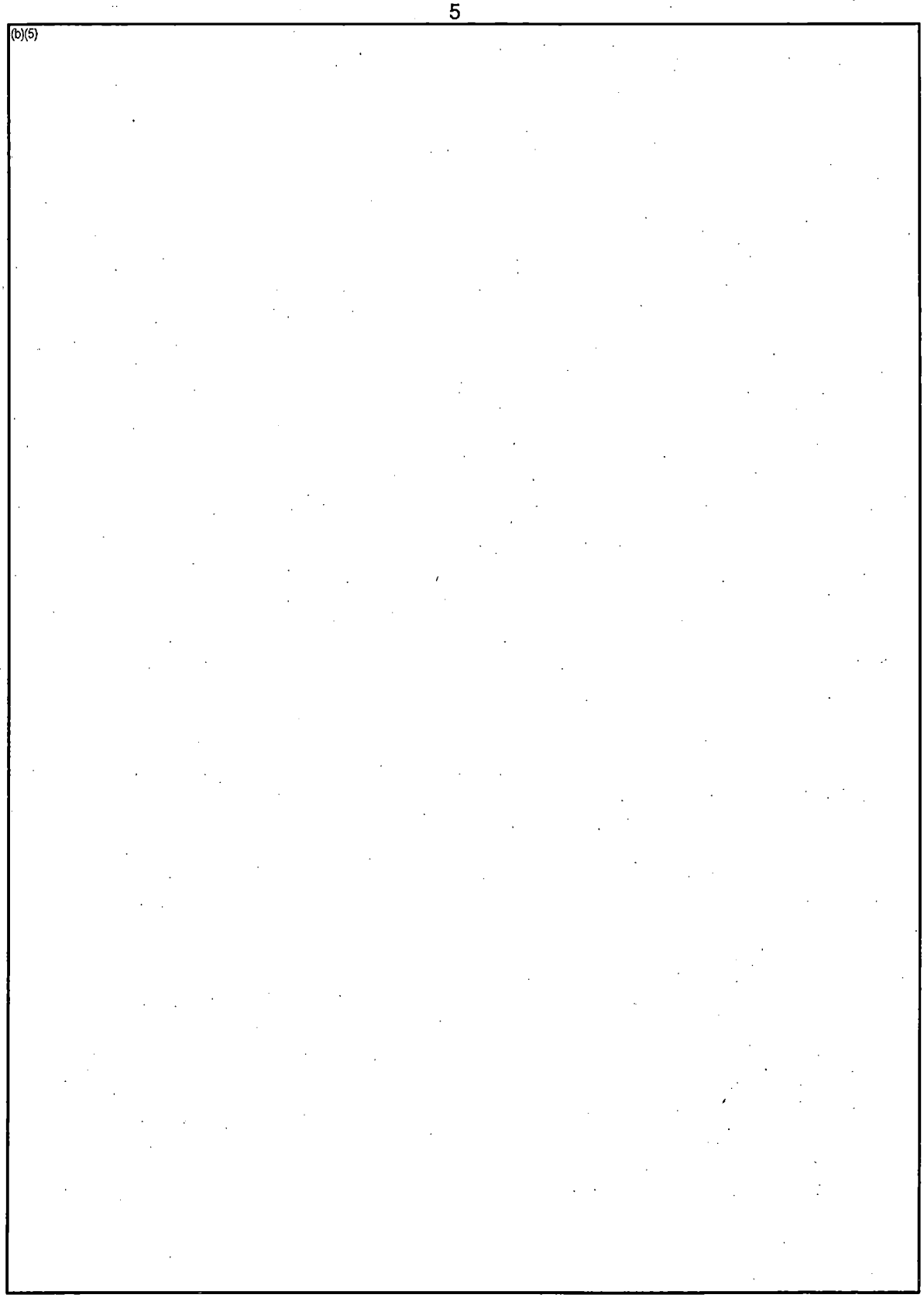

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TABLE 1

RADIOCAT® RADIATION MEASUREMENTS FOR 100 CATS[1]
AND CALCULATED PERCENT I-131 RETENTION

Cat ID	I-131 Injected mCi time =0	Calculated mR/hr at 1 m t=0	Measured mR/hr at 1 m t=69-73 hr	Calculated Activity mCi t=69-73 hr	% Retained decayed corrected t=69-73hr
G-2	3.0	0.65	0.1	0.5	20%
J-2	3.0	0.65	0.1	0.5	20%
J-6	3.0	0.65	0.1	0.5	20%
K-6	3.0	0.65	0.1	0.5	20%
L-3	3.0	0.65	0.1	0.5	20%
F-10	3.5	0.75	0.1	0.5	17%
G-5	3.5	0.75	0.1	0.5	17%
G-8	3.5	0.75	0.1	0.5	17%
G-14	3.5	0.75	0.1	0.5	17%
K-4	3.5	0.75	0.1	0.5	17%
E-5	4.0	0.86	0.1	0.5	15%
G-1	4.0	0.86	0.1	0.5	15%
H-8	4.0	0.86	0.1	0.5	15%
E-6	3.0	0.65	0.15	0.7	30%
E-11	3.0	0.65	0.15	0.7	30%
F-7	3.0	0.65	O.15	0.7	30%
H-23	3.0	0.65	0.15	0.7	30%
J-4	3.0	0.65	0.15	0.7	30%
J-5	3.0	0.65	0.15	0.7	30%

[1] New data provide by Radiocat® from actual patient measurements. The measurements were made approximately 72 hours after I-131 treatment and 1 meter from the cat. The data was augmented by calculations to estimate the activity of I-131 and percentage of I-131 retained by each cat at 72 hours. The variability and range of values are expected to be representative of other feline patients.

H-5	3.5	0.75	0.2	0.95	34%
H-10	3.5	0.75	0.2	0.95	34%
H-16	3.5	0.75	0.2	0.95	34%
H-17	3.5	0.75	0.2	0.95	34%
J-3	3.5	0.75	0.2	0.95	34%
K-2	3.5	0.75	0.2	0.95	34%
K-8	3.5	0.75	0.2	0.95	34%
K-16	3.5	0.75	0.2	0.95	34%
K-18	3.5	0.75	0.2	0.95	34%
L-7	3.5	0.75	0.2	0.95	34%
G-13	4.0	0.86	0.2	0.95	30%
H-14	4.0	0.86	0.2	0.95	30%
H-15	4.0	0.86	0.2	0.95	30%
J-1	4.0	0.86	0.2	0.95	30%
K-7	4.0	0.86	0.2	0.95	30%
G-3	4.5	0.97	0.2	0.95	27%
G-3	4.5	0.97	0.2	0.95	27%
F-5	3.0	0.65	0.3	1.4	60%
H-2	3.0	0.65	0.3	1.4	60%
H-11	3.0	0.65	0.3	1.4	60%
J-7	3.0	0.65	0.3	1.4	60%
K-1	3.0	0.65	0.3	1.4	60%
E-2	3.5	0.75	0.3	1.4	52%
F-2	3.5	0.75	0.3	1.4	52%
H-3	3.5	0.75	0.3	1.4	52%
H-9	3.5	0.75	0.3	1.4	52%
H-12	3.5	0.75	0.3	1.4	52%
H-19	3.5	0.75	0.3	1.4	52%
H-22	3.5	0.75	0.3	1.4	52%

TABLE 2

ESTIMATED RADIATION FIELDS AT COMMON DISTANCES[1]

Radiation Measurement	Estimated Radiation Field at Distance to Cat			
at 1 meter	3 inches	6 inches	12 inches	3 feet
0.5 mR/hr (2.3 mCi)	86 mR/hr	22 mR/hr	5.4 mR/hr	0.6 mR/hr
0.4 mR/hr (1.85mCi)	69 mR/hr	17 mR/hr	4.3 mR/hr	0.5 mR/hr
0.3 mR/hr (1.4 mCi)	52 mR/hr	13 mR/hr	3.2 mR/hr	0.35 mR/hr
0.25 mR/hr (1.15 mCi)	43 mR/hr	11 mR/hr	2.7 mR/hr	0.3 mR/hr
0.2 mR/hr (0.95 mCi)	35 mR/hr	9 mR/hr	2.2 mR/hr	0.25 mR/hr
0.15 mR/hr (0.7 mCi)	26 mR/hr	6.5 mR/hr	1.6 mR/hr	0.18 mR/hr
0.1 mR/hr (0.5 mCi)	19 mR/hr	4.7 mR/hr	1.2 mR/hr	0.13 mR/hr
0.05 mR/hr (0.215mCi)	8 mR/hr	2 mR/hr	0.5 mR/hr	0.06 mR/hr
0.025 mR/hr (0.1mCi)	4 mR/hr	1 mR/hr	0.25 mR/hr	0.03 mR/hr

[1]This table relates estimated radiation fields at frequently cited close cat-human contact distances for different I-131 activities. The calculations were based on the I-131 contained in a 0.3 centimeter diameter sphere. Three feet approximates the distance from a cat rubbing against an ankle and the center of the torso of an adult (for determining the whole body dose). One foot to 6 inches approximates the distance from a cat being fed on an elevated surface to the center of the torso of an adult. Three inches approximates the distance from the cat lying in the lap to the center of the torso of the adult.