

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 minimum 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.

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

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.
- Pre-administration acceptance screening and subsequent post-administration evaluation of indicators (such as cat/owner interaction, the owner's degree of compliance with instructions, and other behaviors) that will provide the licensee with high confidence of compliance with 10 CFR 20.1301 may be used in establishing release criteria for individual cats.
- Licensees should provide NRC with their release criteria for each category (or group of cats/owners) fitting a defined profile. 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.

[NOTE: While the licensee may establish other release criteria, the following are examples of the appropriate degree of cat/human interaction/isolation for the three most frequently proposed release criteria (i.e., 0.25 mR/hr at 1 foot, 0.5 mR/hr at 1 foot, and 0.5 mR/hr at 1 meter):

0.25 mR/hr at 1 foot	restricted very close contact; isolation usually not required
0.5 mR/hr at 1 foot	limited human interaction; isolation for 1-2 days; later restricted very close contact
0.5 mR/hr at 1 meter	licensee pre-administration acceptance screening; subsequent post-administration licensee evaluations; isolation; very limited human interaction for several weeks

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

DECEMBER 2002 UPDATED REVIEWER NOTES

These reviewer notes were updated for clarity and to include new information obtained from Radiocat® and other stakeholders subsequent to the December 21, 2001 TAR response. The bolded text is used to identify additions to the original 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." **These are common close approach or contact distances.**

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.

The December 2001 reviewer notes advised that 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 exceed 1 meter if the cat was in the back of a van, or station wagon.

These approximations are being revised to recognize that: the one foot distance should have been specified for the front seat of a small car; the 1-2 feet for the back seat of a small car or front seat of a larger car; and a cat located in the back of a large car may exceed a meter from the driver.

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 of the December 21, 2001 TAR response).

Radiocat® has since indicated that there were data collection problems, in addition to the data processing errors noted below. Since the validity and accuracy of the data cannot be verified, the data was not relied upon in the revision to the December 21, 2001 TAR response. The following analysis is included in these notes to document the problems.

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. **However, since Radiocat® representatives indicated the data that these calculations were based on was flawed, the effective half-life values cannot be relied upon.**

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 **of the December 21, 2001 TAR response**). Dose estimates 6 inches from the patient's thyroid area were used to approximate close contact.

Radiocat® - 2002 Radiation measurements and retention calculations

Radiocat® representatives provided radiation measurement data from 100 cats. The cats were identified sequentially within a group; the I-131 activity administered was recorded for each cat; an radiation measurements were made 1 meter from each cat. Radiocat®'s consultant clarified that radiation measurements were made 72 hour post I-131 administration. Because this data was collected at 1 meter, small variations in the probe position were not thought to have made significant differences in the measurement values. The consultant believed this was an intrinsic problem with making any radiation measurements at 1 foot.

The data was reordered (Table 1 of the revised guidance) in order of decreasing radiation measurements and within each radiation measurement by decreasing I-131 activity administered. The percent I-131 retained at 72 hours was calculated from the data provided. The table shows the variability of radiation measurements with I-131 activity administered to individual cats and the wide range of I-131 retained by the cats.

These results show that radiation measurement and the corresponding I-131 retention at 72 hours cannot be predicted in advance from the I-131 activity administered. No additional information was provided to see if other predictive factors existed.

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 **of the**

December 21, 2001 TAR response) and to estimate the retained I-131 activities for the 100 cats included in the 2002 data.

The first data point evaluated was the exposure rate expected at 6 inches from 500 microcuries of retained activity (Attachment 4 **of the December 21, 2001 TAR response**, 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 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 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 **of the December 21, 2001 TAR response**).

Radiocat® release analysis based upon ALI

In Attachment 7 **of the December 21, 2001 TAR response**, 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 (**of the December 21, 2001 TAR response**) based upon ALI considerations should not be used in determining when a cat can be released.

In 2002, the licensee's consultant indicated that the amount of I-131 retained by the cat could be approximated by the human model. Based on the human model, a cat would be expected to retain approximately 20 percent of the I-131 after approximately 48 hours and the free iodine was excreted. However, the retention calculations in Table 1 of the revised guidance shows that a significant number of cats did not fit the estimated 20 percent retention even at 72 hours (the values ranged from 15 to 69 percent I-131 retention with 20 cats below 30 percent and 21 above 50 percent). Personal communications with other veterinarians indicates that the effective half-life of I-131 in the cat does not reach the physical half-life of I-131 within the first week. This indicates

that additional I-131 is excreted from the cat for longer periods than estimated by the human model.

Best release estimate

Discussion of Common Radiation Measurements:

0.25 mR/hr at 1 foot

As seen in the MicroShield calculations in the original TAR response, the radiation measurement of 0.25 mR/hr at 1 foot is a conservative release criterion. **Because it would be possible that a person sleeping near the cat at a very close distance (3 inches or less) for 8 hr per day for 3 days could approach the 100 millirem level, very close contact needs to be restricted.** 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 20.1301 limit.

Additionally, good compliance with the contamination control instructions provided to the owner should result in minimal uptake 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

The December 2001 reviewer notes included consideration of the effective half-life when making the following observations: 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.

Since Radiocat® representatives indicated that there were data collection problems with the measurements that formed the basis for the effective half-life calculations and discussions, specific effective half-life calculations are no longer considered. Because it would be possible that a person sleeping near the cat at a very close distance (3 inches or less) for 12 hours could approach the 100 millirem level, very close contact must be restricted. Limited human interaction at the 1-3 foot distance after isolation for 1-2 days to permit further reduction in I-131 burden should provide reasonable assurances of compliance with the 10 CFR Part 20 dose requirements. Very close contact (3 inches or less) should continue to be restricted beyond the 1-2 days.

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

The December 2001 reviewer notes did not consider licensee pre-administration screening of potential clients to determine the normal level of human interaction or the owner's probability of complying with licensee instructions to severely limit contact when making the following observations: Releasing a cat with a dose measurement of 0.5 mR/hr at one meter could easily result in a dose in excess 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. **However, because of data collection problems associated with the effective half-life calculations and discussions, effective half-life considerations are no longer considered.**

Cats that do not seek human companionship and that have owners that are capable of isolating the treated cat from human contact for the periods of time needed to assure that no one receives a dose in excess of 100 millirem can be released with higher I-131 burdens. A veterinary practice that uses effective pre-administration screening to identify the cat that does not seek human companionship and post administration evaluations of the human-cat interaction and owner's ability and willingness to effectively isolate the cat from others and close contact with the owner for several weeks may be able to release certain cats with radiation measurements of 0.5 mR/hr at 1 meter with confidence that the dose requirements in 10 CFR Part 20 will be met.

Days post treatment

As seen in the 1999 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.

Since Radiocat® indicated that there were data collection problems with radiation measurements made in the 1999 data, the data can no longer be used. However, the new data Radiocat® submitted in 2002 continues to show wide variability among cats administered the same I-131 activity and the radiation measurements made 72 hour post administration. This variability indicates that radiation level cannot be predicted based upon activity administered and each cat needs to be evaluated on a case-by case basis.

Conclusion

The December 2001 reviewer notes concluded essentially that while the licensee can take credit for 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 assured. 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 **and** 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 **dose rate and** an I-131 effective half-life of 1 to 1.5 **days** could be released to an adult-only home. Age, mobility, and attachment of a child to the cat would need to be considered before releasing a treated cat to a home with children.

Based upon the new information, the staff has modified its original conclusions in the December 21, 2001 TAR as follows: Although, many of the factors discussed above are still valid, stakeholder information indicated that requiring licensees to calculate effective half-lives is too great a burden and it is no longer included in the revised recommendations. The revised guidance also takes a performance-based approach to conforming with the 10 CFR Part 20 public dose limits, and recognizes that licensees may use different methods or combination of methods to achieve this goal and each must be evaluated on a case-by-case basis. Pre-administration acceptance screening and subsequent post-administration evaluation of indicators (such as cat/owner interaction, the owner's degree of compliance, and other behaviors) that will provide the licensee with high confidence of compliance with 10 CFR 20.1301 should be the key factors used to set the release criteria.

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

DISTRIBUTION: IMNS-8083

ADAMS Accession#: **ML030560258**

DOCUMENT NAME: G:\howe\cats\RevisedRadiocat.WPD *SEE PREVIOUS CONCURRENCE

OFC	MSIB*		MSIB*		OGC		MSIB*	
NAME	DBHowe		MBailey		STreby		TEssig	
DATE	12/23/02		12/23 /02		2/24/03		1/10/03	

OFFICIAL RECORD COPY