

July 24, 2002

MEMORANDUM TO: Thomas Essig, Chief  
Materials Safety  
and Inspection Branch  
Division of Industrial  
and Medical Nuclear Safety

FROM: N. Jeff Griffis */RA/*  
Materials Safety  
and Inspection Branch, Section A  
Division of Industrial  
and Medical Nuclear Safety

SUBJECT: SUMMARY OF JULY 9, 2002 PUBLIC MEETING WITH  
RADIOCAT, LLC, REGARDING RELEASE CRITERIA OF CATS  
TREATED WITH I-131

On July 9, 2002, the Nuclear Regulatory Commission (NRC) staff held a public meeting with Radiocat, LLC. Also present by telephone were the Texas State Department of Health, the Illinois State Department of Health, the Iowa State Department of Health, the Georgia State Department of Health, the New York State Department of Environmental Conservation, the Florida State Department of Health, a number of private veterinary practitioners and other members of the public. The purpose of the meeting was to discuss the release criteria for cats treated for hyperthyroidism with I-131 by Radiocat, LLC. The discussion included a brief chronology of licensing and guidance issues leading to the meeting, and a technical presentation of Radiocat's submitted release criteria. Participating parties added general discussion and offered questions throughout the presentation.

NRC began by briefly reviewing the use of I-131 to treat feline hyperthyroidism. NRC discussed the regulatory concerns with releasing cats containing residual I-131, and remarked on the lack of consistent release criteria. NRC stated that current guidance did not address the scope of the issues involved, and inconsistencies were evident across NRC regions and between Agreement States. NRC offered three key issues where inconsistencies were found concerning cat release criteria: (1) the maximum allowable exposure rate at a known distance from the cat, (2) the minimum duration that a treated cat should be held before considering release to the public, and (3) the format and content of instructions issued to cat owners prior to release.

After introductory comments by NRC staff, Radiocat's Radiation Safety Officer (RSO) and Health Physics consultant presented the release criteria they had proposed in current license applications and amendment requests. Radiocat noted that these proposed criteria had been denied in a recent licensing action by one State. Radiocat representatives presented technical arguments as part of their effort to justify the proposed criteria.

Radiocat representatives then presented the model they used to calculate doses to a critical member of the public (e.g. usually the cat's owner) from a cat released after I-131 treatment (See Attachment 1). Radiocat asserted that the original NRC Health Physics Position concerning unrestricted release of animals treated with I-131 (HPPOS-286, dated March 11, 1993) did not contain a technical model to show compliance with 10CFR20.1301, which limits the annual dose to a member of the public to 100 millirem (mrem).

After Radiocat's presentation, NRC staff asked for clarification of the internal dose calculations performed by Radiocat. Radiocat expanded on the metabolism of I-131 in humans, and equated the human model with other mammals, including cats. Radiocat argued that holding a cat for two days after treatment significantly reduces I-131 in cat excreta, which is the main source of potential internal dose to a member of the public. Radiocat's proposal included holding cats for an additional day as an extra margin of safety.

After collective discussion of Radiocat's internal dose calculations, participants generally agreed that the calculations followed the ICRP human model, and were technically sound from that perspective. Participants agreed that, based upon this model, the three day holding period resulted in a low internal dose contribution from I-131 to a member of the public. NRC raised the concern that the three day requirement should be measured in terms of 72 hours to avoid semantic arguments with the term "day," and participants agreed.

Radiocat next discussed the external dose contribution to a member of the public when releasing a cat having a measured radiation exposure rate of 0.5 milliroentgen/hour (mR/h) at one meter. Radiocat explained that compliance with instructions would limit doses to cat owners to values well below 100 mrem. Radiocat added that cats released from their facilities after three days typically exhibit much lower exposure rates than 0.5 mR/h.

NRC and other participants raised questions about how exposure measurements were performed. The questions involved the distance at which the measurement should be made (one foot or one meter), and sources of error in such measurements. Radiocat staff argued that exposure rate measurements should be made at one meter from the cat using a reproducible geometry such as marked tables. Radiocat claimed that errors in exposure rate measurements at one foot resulted from the cat being a mobile source.

NRC next discussed the instructions that Radiocat issued to the owners of treated patients. NRC staff raised concern that cats released at 0.5 mR/h at one meter could easily result in an overexposure of a member of the public if owners did not comply with Radiocat's instructions. Radiocat remarked that the instructions they offered included multiple sessions with the cat owner. Radiocat explained that owners are first questioned in a pre-visit telephone call about the cat's health and general behaviors. Radiocat representatives asserted that, if any cat *or* owner seem unable to comply with instructions, the cat would not be considered for treatment. Radiocat representatives explained that, if a cat is selected for treatment, the owner then comes to the office for counseling on handling the cat and the risks involved with I-131. Radiocat stated that counseling is also given upon releasing the cat, and is combined with written instructions that must be signed by the owner. The written instructions cited by Radiocat gave specific time and distance constraints for interacting with the cat each day.

July 24, 2002

3

T. Essig

The meeting was concluded with a summary by NRC staff. It was noted that the internal exposure pathway for cat owners appeared to be relatively insignificant, and that external exposures were highly dependent on the exposure scenario, i.e., the extent to which the veterinarian's post-treatment handling instructions were followed by the cat owner.

Radiocat requested that the participants provide any specific comments for Radiocat's written instructions to cat owners. Radiocat also asked NRC for a revised regulatory position on the topics discussed. Radiocat stated that this would aid their application efforts in certain Agreement States. NRC replied that a new regulatory position could not be issued at the time of the meeting, but the topics discussed in the meeting would be considered during the development of revisions to existing guidance.

Attachments:

1. Public Meeting Handouts from Radiocat, LLC

Distribution:

IMNSr/f

J. Griffis

DOCUMENT NAME: C:\ORPCheckout\FileNET\ML022110495.wpd

OFFICE	MSIB/IMNS	E	MSIB/IMNS	
NAME	JGriffis*		TEssig*	
DATE	7/24/02		7/24/02	

OFFICIAL RECORD COPY

The meeting was concluded with a summary by NRC staff. It was noted that the internal exposure pathway for cat owners appeared to be relatively insignificant, and that external exposures were highly dependent on the exposure scenario, i.e., the extent to which the veterinarian's post-treatment handling instructions were followed by the cat owner.

Radiocat requested that the participants provide any specific comments for Radiocat's written instructions to cat owners. Radiocat also asked NRC for a revised regulatory position on the topics discussed. Radiocat stated that this would aid their application efforts in certain Agreement States. NRC replied that a new regulatory position could not be issued at the time of the meeting, but the topics discussed in the meeting would be considered during the development of revisions to existing guidance.

Attachments:

1. Public Meeting Handouts from Radiocat, LLC