

MAY 07 1985

License No. 20-06799-02
Docket No. 030-04659
Control No. 03679

Cambridge Medical Diagnostics Inc.
ATTN: Stephen H. Szczepanik
Radiation Safety Officer
575 Middlesex Turnpike
Billerica, Massachusetts 01865

Gentlemen:

This is in reference to your request in a letter dated April 4, 1985 to amend License No. 20-06799-02. In order to continue our review, we need the following additional information:

1. In Section VI.E.1. of your Radiation Safety Manual, Seventh Revision, you specify the action levels for iodine-125 thyroid uptake. You state that these action limits are based upon the maximum permissible body burden. However, Section 20.103 of 10 CFR Part 20 requires that the concentration of radioactive material in air to which individuals are exposed not exceed the values in Appendix B, Table I, Column 1. The action levels specified in your manual appear to result from exposures exceeding this limit for iodine 125. I have enclosed a copy of Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131". If you will comply with the criteria, the frequency for performing bioassays and action to be taken when positive results are obtained, please state this. If your criteria, frequency or action differ, please state your limits and explain how they will lead to compliance with 10 CFR 20, Section 20.103.
2. In Attachment B of your Amendment to Byproduct Material License No. 20-06799-02, you provided a description of the training and experience for S. Fan, S. Farbotho, S. Monahan, J. Kava, J. Davis, C. Gifford, P. Williams, and S. Savoie. It appears that these individuals do not have experience with the quantity of isotopes that you have requested. Please provide additional information concerning their training program including the topics covered, length of time to cover each topic, and the isotopes, activity and the length of time spent in gaining the on-the-job training.

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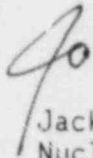
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We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 03679.

Sincerely,

 Original Signed By:
Jack Davis


Jack Davis
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

Enclosures:

1. 10 CFR Part 20
2. Regulatory Guides 8.20

RI:DRSS

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NRC FORM 218 (4-76) NRCM 0240		U.S. NUCLEAR REGULATORY COMMISSION	
TELEPHONE OR VERBAL CONVERSATION RECORD		DATE 4/25/85	
		TIME <input type="checkbox"/> A.M. <input type="checkbox"/> P.M.	
<input type="checkbox"/> INCOMING CALL		<input type="checkbox"/> OUTGOING CALL	
<input type="checkbox"/> VISIT			
PERSON CALLING <i>Jack Davis</i>	OFFICE/ADDRESS <i>KI</i>	PHONE NUMBER	EXTENSION
PERSON CALLED <i>Stephen SZCZEPANIK</i>	OFFICE/ADDRESS <i>Cambridge Med Diag Inc</i>	PHONE NUMBER <i>617-935-</i>	EXTENSION <i>4050</i>
CONVERSATION			
SUBJECT			
SUMMARY <p><i>Discussed action levels for positive thyroid analysis for I-125.</i></p> <p><i>Levels appear to be a factor of 100 too high. Will lower limits. Requested copy of Reg Guide 8.20.</i></p> <p><i>Change in authorized user do not appear to have training & experience to use or supervise the use of material. Technician will be removed from the authorized user list.</i></p>			
REFERRED TO:		<input type="checkbox"/> ADVISE ME OF ACTION TAKEN.	
ACTION REQUESTED			
		INITIALS	
		DATE	
ACTION TAKEN		INITIALS	
		DATE	
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