

Bruce Mallett

APR 30 1987

MEMORANDUM FOR: Vandy L. Miller, Chief, Medical, Academic and Commercial  
Use Safety Branch, NMSS

FROM: W. L. Axelson, Chief, Nuclear Materials Safety and  
Safeguards Branch, Region III

SUBJECT: 3M - UPDATE ON CUSTOMER INSTRUCTIONS FOR REUSABLE I-125  
BRACHYTHERAPY SEEDS

*4th of the*

*June 1  
int  
copy*

The purpose of this memorandum is to provide you with a progress report on 3M providing specific instructions recommended by the Office for Analysis and Evaluation of Operational Data (AEOD) to customers reusing high intensity iodine-125 brachytherapy seeds. At the time of our last memorandum to you, dated January 30, 1987, we were awaiting a response to a request for 3M to adopt AEOD's recommendations. Since that time, we discussed the recommendations with 3M's management during a February 12, 1987 site visit. In a letter dated March 16, 1987, 3M responded to our request and committed to revising the product labeling and instructions for these seeds as requested. A copy of the letter is attached. We have discussed the March 16 response with 3M management and asked them to submit actual samples of the labels and instructions when they are complete. Upon receipt, we will amend 3M's license (No. 22-00057-59MD) to incorporate the commitments in the March 16 letter and the actual instructions and labels.

As of this date, 3M has the following in place:

1. An internal procedure to identify and review precautions with each new customer for the reusable iodine-125 seeds. Attached is a copy of a January 30, 1987 letter from 3M which lists customers using the iodine-125 seeds as of that date. This list could be used to send an NRC notice to all users regarding precautions.
2. A warning notice that is included with each shipment of reusable seeds. The notice has been utilized since August 12, 1985 and is described in the attached August 12, 1985 3M letter.
3. Instructions to customers which discuss precautions for ruptured seeds. The instructions currently include recommendations for decontamination surveys and bioassays for individuals handling the seeds. We have attached a January 17, 1985 letter which includes the instructions.

*Technical representatives go over  
H.P. reports*

*1. proceed on seeds  
2.*

*9105210323*


9105210323 880108  
REG3 LIC30  
22-00057-59MD PDR

Vandy L. Miller

2

As you recall during our meeting with the Commissioners' technical assistants on this subject, Margaret Federline, Commissioner Carr's technical assistant, requested that we follow up with her on this matter. Accordingly, you may wish to inform her and the other assistants regarding 3M's actions.

This should close out our response to your December 12, 1986 technical assistance request. If you have any questions, please contact Bruce Mallett at FTS 388-5742.

  
W. L. Axelson, Chief  
Nuclear Materials Safety  
and Safeguards Branch

Attachments: As stated

cc w/o attachments:  
K. Black, AEOD

RIII  
AS 9/29/87  
Mallett/jl  
04/29/87

RIII  
Axelson  
4/29/87

DRAFT  
To AX  
on 4/28/87

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W. L. Axelson, Chief  
Nuclear Materials Safety  
and Safeguards Branch

Attachments: As stated

# CONVERSATION RECORD

TIME

DATE

4/27/87

TYPE

VISIT

CONFERENCE

TELEPHONE

INCOMING

OUTGOING

ROUTING

NAME/SYMBOL INT

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

Jacquelyn D. Bush

ORGANIZATION (Office, dept., bureau, etc.)

3M

TELEPHONE NO.

612-733-6421

SUBJECT

Re: Lic. No. 22-00057-59MD; NRC request

to include warnings in labeling for reusable I-125 high intensity seeds.

SUMMARY

1. She will supply to us the exact labeling in short term. B. Mattatt told her, NRC will send license to incorporate wording when they submit. NRC will allow flexibility in changing as long as it does not change AEOD recommendations.

2. Discussed fact that 3M reviews use of seeds with each potential user prior to shipping as indicated in AEOD study. 3M does not wish to commit to this procedure due to potential legal problems and FDA concerns.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

Bruce Mattatt

DATE

4/27/87

ACTION TAKEN

SIGNATURE

TITLE

DATE

CONVERSATION RECORD

TIME

DATE

6/1/87

TYPE

VISIT

CONFERENCE

TELEPHONE

INCOMING

OUTGOING

ROUTING

NAME/SYMBOL

INT

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

ORGANIZATION (Office, dept., bureau, etc.)

TELEPHONE NO.

Jackie D. Bush

3M

612-733-6421

SUBJECT

B Mallett called to get update on revisions to warning card & package inserts for reusable I-125 seeds.

SUMMARY

- possible may not get back material from printer until the end of this week.

- from time text is developed, key lines prepared, revisions made and to printer - takes 90 days. They have group to go through. - takes 30 more days from that time to get back from printer. She is through with her revisions.

- revised texts have been drafted. At best they are talking about 10/1/87. They will check into speeding process, but they have other changes they wanted to make at same time.

- the warning card is placed over packing material. you have to see warning card to get to seeds.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

B Mallett

6/1/87

ACTION TAKEN

called & briefed V. Miller in HR on 6/1/87

SIGNATURE

TITLE

DATE