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Department of Energy
Savannah River Operations Office
P.O. Box A
Aiken, South Carolina 29802

712432

FEB 03 1988

Sylvia Jane Wolfe, Isotopes Program Manager, Energy Program Division, Oak Ridge
CF-252 MEDICAL SOURCES (YOUR MEMO TO RICHARDSON, 12/18/87)

The following information is provided in response to questions in the subject memo.

Savannah River Plant's (SRP's) cost for fabrication of Cf-252 Sources for Medical Loans has been totally funded from Materials Production Program, Separations (GE0221010) for several years. A very small subsidy received for Californium Program from Office of Environmental Research was discontinued some years ago.

Savannah River Operations Office (SR) has very little written procedure and guidance.

Attached is a copy of a memo dated January 25, 1988, from Mary Lee Toole, SR, to Dick Yates, HQ-NMP, requesting HQ update their guidance on Cf-252 Medical Source Loans. The 1984 correspondence regarding DOE's continued support of the Cf-252 medical source fabrication attached to Mary Lee's memo are also attached for your information.

If additional information is needed, you may call Carolyn Garner, FTS 239-2809, Budget Branch, Financial Management and Program Support Division, or Mary Lee Toole, FTS 239-5547, Process and Weapons Division.

H. A. Booth

H. A. Booth
Deputy Director for Budget
Financial Management and Program
Support Division

AFBB:CFG:s1

Attachment

REPOSITORY Oak Ridge Operations
COLLECTION Records Holding area
BOX No. Documents 1944-94
FOLDER B-144-17 Bldg. 2714-H
N/A

1081430

Y-556

DON'T SAY IT - WRITE IT

TO Dick Yates LOCATION NMP (DP133.2), USDOE-HQ DATE 1/25/88
FROM Mary Lee Toole PHONE NO. 239-5547 LOCATION P&W Div., USDOE-SRO

Per our telecon this morning, attached for your info is some old correspondence on the subject of DOE's continued support of the Cf-252 medical source fabrication business. Our last guidance, though several years old, was that DOE would continue to support loan of Cf-252 medical sources, free of charge, for research and development and clinical trials. It is hard to do otherwise if there is a possibility that Cf-252 might play a significant role in cancer treatment.

My present problem is funding. Cf-252 source fabrication has historically been funded from the big Separations pot at SR. Now that the sales and loan program are being transferred to ORNL, we are told by SRL that it will require a minimum of \$500,000/yr to maintain the capability to produce medical sources at SR (ORNL's facility does not currently have the capacity to produce medical sources). I would appreciate some guidance from you regarding how we can fund this work in the future.

Preventive Safety - Prevents Injuries

KL

1081431

memorandum

DATE NOV 30 1984

REPLY TO
ATTN OF DP-132

SUBJECT: Recommendation Regarding Need to Continue Californium-252 Loan Program

TO: Charles W. Edington, Associate Director
Office of Health and Environmental Research, ER-70

I appreciated receiving your memorandum of November 14, 1984 regarding this matter. I would like to clarify my request. The Department has fostered a program to provide Californium-252 sources to the medical research community on a loan basis [free] for the last 20 years. I would appreciate a recommendation from your office regarding a firm need to continue the loan program or is it time to charge the medical community for this service.

Please reply by December 15, 1984.


Roger K. Heusser, Director
Materials Processing Division

→ CC:
M.S. Sires, SR
J.L. Meinhardt, DP-13
R.J. Galbo, DP-133
J.A. Ford, DP-131.2

1081432

2/0 Weapons Division

memorandum

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| WEAPONS | BRANCH |
| RLC | <u>RLC</u> |
| WAR | <u>WAR</u> |
| MLT | <u>MLT</u> |
| WBW | <u>WBW</u> |
| CMR | <u>CMR</u> |
| ALL | <u>ALL</u> |

DATE: FEB 8 1984

REPLY TO
ATTN OF: DP-132

SUBJECT: Request for Loan of Californium-252 Medical Sources

TO: C. G. Halsted, Director
Process and Weapons Division, SR

We have reviewed the proposal and protocol prepared by Dr. Peter A. Fleming of the University of Wisconsin Hospital and Clinics that includes a request for the loan of californium-252 (Cf-252) seed-assembly sources. We support the use of Cf-252 for medical purposes. We understand from your letter that you are determining the feasibility of producing the sources requested by the University of Wisconsin. Please keep us informed of your findings as to the feasibility of producing these sources.

Our staffs have been in communication on this subject, and we have sent you a copy of procedures established by the Food and Drug Administration for an investigational device exemption. Please ensure that Dr. Fleming and the University of Wisconsin are aware of these procedures.

*Transmitted to
William 229
Dr. Fleming
mkt*


Roger K. Heusser, Director
Division of Materials Processing

memorandum

DATE: OCT 15 1984

REPLY TO
ATTN OF DP-132

SUBJECT: Review of Use of Californium-252 in Medical Research

TO: Charles W. Edington, Associate Director, Office of Health and
Environmental Research, ER-70

For a number of years the Nuclear Materials Production Program and the Savannah River Plant have been engaged in the fabrication of the californium-252 medical sources in a variety of forms. These sources have been made available on a loan basis to the medical research community and have been used by researchers at a large number of medical institutions.

The number of institutions using this material has declined and currently we are only aware of the University of Kentucky, the University of Wisconsin, and several Japanese medical institutions that are using californium-252 in clinical trials. However, we have no way of judging the medical effectiveness of the use of californium in cancer treatment, other medical uses, or the need to continue the loan program.

We request your assistance in evaluating the use of californium in medical research and its use in medical treatments to determine the effectiveness of this treatment. We suggest that your office assist in forming an evaluation team with a charter to draw upon the appropriate expertise necessary to make an informed judgment of the effectiveness of californium-252 in its medical uses, and to determine if there is a need to continue the loan program.

Please let me know if you have any questions about this matter.

Louis R. Willett, for
Roger K. Heusser, Director
Materials Processing Division

cc:

M. S. Sires, SR 
J. L. Meinhardt, DP-13
R. J. Galbo, DP-133
J. A. Ford, DP-131.2

1081434

3-8-84

WEAPONS

3/8/84

PSW DIV

3/ /84

Roger K. Hausser, Director
Division of Materials Processing
Office of Nuclear Materials (DP-132), EQ

CALIFORNIUM-252 MEDICAL SOURCES

Du Pont has evaluated the most recently submitted protocol/proposal for loan of Cf-252 medical sources. This proposal came from the University of Wisconsin who has requested 148 micrograms of Cf-252 as seed assembly sources.

We have not made any seed assembly type sources since 1979 and upon examination of equipment it became apparent that some of it will have to be repaired/replaced due to deterioration from the radioactive and corrosive environment within the cells. Estimated cost for equipment repair/replacement is about \$75,000. We do not currently have an operator trained to make seed assembly sources and predict it will take 3-4 months to train someone to do this job. The manual dexterity required to fabricate this type source makes it as much an art as a science and to retain a skilled operator requires a great deal more activity than one order every five years.

Before we are committed to provide medical sources to the University of Wisconsin, it may be prudent to reevaluate DOE's position regarding the loan of Cf-252 for medical research. We would recommend that investigators from the University of Kentucky, the University of Wisconsin, and the Japanese medical institutions using Cf-252 in clinical trials be invited to make presentations to a DOE evaluation team so they can personally relate their experiences, their progress, and their opinions concerning the value of Cf-252 in cancer treatment. Do their investigations continue simply because Cf-252 is relatively easy to obtain from DOE on a loan basis or do they predict a breakthrough in treatment which will significantly increase the demand for medical sources? We would further recommend that the DOE evaluation team consist of DOE-affiliated medical advisors; DOE-HQ, ER, OR personnel; and personnel from Savannah River Laboratory/Oak Ridge National Laboratory.

1081435

Roger K. Hausser

- 2 -

With the pending transfer of industrial source fabrication to Oak Ridge National Laboratory, we feel it is timely to consider this matter and establish DOE policy relevant to fabrication of medical sources.

ONW:MLT:cmr

C. G. Haisted, Director
Process & Weapons Division

cc: L. King, ORNL
C. Smith, Du Pont, S&L

bc: SR Rdg File

1081436

ROUTE SLIP

ASSISTANT MANAGER FOR ENERGY RESEARCH AND DEVELOPMENT

FROM: AMERD MAIL ROOM

DATE: FEBRUARY 8, 1988

COPY TO: AM DD's BC's ALL

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| | Phillips | |

| CHECK | NATIONAL MATERIALS PROGRAMS | INITIAL |
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| | EP-10 | |
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| ENERGY PROGRAMS DIVISION | | ER-11 |
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| OFFICE OF DIRECTOR | | |
| | Price | |
| | Young | |

| RESEARCH & WASTE MANAGEMENT DIVISION | | ER-12 |
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| OFFICE OF DIRECTOR | | |
| | Adams | |
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| MRS OFFICE | | ER- |
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| ENERGY TECHNOLOGY BRANCH | | ER-111 |
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| MAIL AND FILE ROOM | | ER-1 |
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| FUSION AND BASIC SCIENCES BRANCH | | ER-112 |
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| RESEARCH MANAGEMENT BRANCH | | ER-122 |
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OUTSIDE CONCURRENCE

MAIL

1081437

X-554