



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

April 16, 1996

ASSIGNMENT NUMBER: 96-19

Mr. Brian Donnelly
Hewlett-Packard Company
2850 Centerville Road
Little Falls Site
Wilmington, DE 19808

SUBJECT: ACKNOWLEDGEMENT OF REQUEST FOR SAFETY EVALUATION

Dear Mr. Donnelly:

This letter acknowledges the receipt of your April 9, 1996 application that requested a safety evaluation and registration of the Models G2397A, G2398A, G2404A and G2405A. We have performed a cursory review of your application and determined that enough information has been provided to allow a technical reviewer to initiate the evaluation process. Applications are assigned to technical reviewers on a first-in basis. Therefore, your application will be assigned in turn. Please note that the technical reviewer may contact you to request information that was omitted from your application or to obtain clarification of technical issues concerning your application. If you have any questions concerning the status of your application, please contact me at (301) 415-7857. Please reference the assignment number listed above in your questions or correspondence.

Please be aware that your request may be subject to the NRC's application fees in accordance with 10 CFR Part 170. Therefore, a copy of your application has been forwarded to the License Fee and Debt Collection Branch for approval of the fee category and amount. If you have any questions concerning the fees associated with your application, please contact the License Fee and Debt Collection Branch at (301) 415-7544.

Sincerely,

A handwritten signature in cursive script that reads "KimBerly Randall".

KimBerly Randall, Registration Assistant
Sealed Source Safety Section
Medical, Academic, & Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

JUL 12 1993

Francis E. Roy Jr.
Du Pont Merck Pharmaceutical Co.
Radiopharmaceutical Division
331 Treble Cove Road
N. Billerica, MA 01862

Dear Mr. Roy:

Based on the information submitted in your letter dated May 4, 1993, with enclosures thereto, we have made the changes to the enclosed registration certificate NR-476-S-131-S as you have requested.

We have broadened the principle use code of these models to code (S), Foil Source. We understand that the models, NER-004 and NER-004P, designate that the Nickel-63 is either a source or is electroplated onto components. This activity can occur under principle use code (S). We have included examples of uses of the sources under the "Conditions of Normal Use" section of the registration for clarity.

Please be advised that you must manufacture and distribute the product in accordance with the statements and representations contained in your application, with enclosures thereto, and the information set out in your registration certificate. As a general rule, you must request and obtain an amendment to the certificate before you make changes or modifications to the information submitted to obtain the certificate.

Please read over the registration certificate in its entirety and notify us immediately of any errors or omissions.

You are obligated to notify us promptly in writing should you decide to no longer manufacture or offer service support for the product.

If you have any questions, please contact me at (301) 504-3336 or Mr. Steven Baggett at (301) 504-2542.

Sincerely,

Michael Russ, Co-op Engineer
Sealed Source Safety Section
Source Containment and
Devices Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosure: As stated

cc: SKimberley, LFDCB (w/enc1.)

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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-476-S-131-S

DATE: June 25, 1993

PAGE 1 OF 5

SEALED SOURCE TYPE: Beta Ionization Source

MODEL: NER-004, NER-004P

MANUFACTURER/DISTRIBUTOR:

Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Company
331 Treble Cove Road
North Billerica, MA 01862

ISOTOPE:

Nickel-63

MAXIMUM ACTIVITY:

50 millicuries (1.85 GBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPLE USE: (S) Foil Source

CUSTOM SOURCE: _____ YES _____ X _____ NO

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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-476-S-131-S

DATE: June 25, 1993

PAGE 2 OF 5

SEALED SOURCE TYPE: Beta Ionization Source

DESCRIPTION:

The sources consist of radioactive Ni-63 electroless plated or electroplated onto components fabricated from the approved materials in the following table:

Model	Approved Base Materials
NER-004	gold, platinum, nickel, copper, or monel (copper-nickel alloy)
NER-004P	gold, platinum, nickel, copper, monel, stainless steel

The NER-004 indicates a foil configuration of Du Pont design and manufacture. The NER-004P allows plating onto components of other manufacturer's design and manufacture. All sources must meet the following constraints:

maximum activity: 50 mCi (1.85 GBq)
minimum specific activity: 5 mCi/mg (0.185 GBq/mg)
radiopurity of Ni-63: > 99.9%.

LABELING:

The Model NER-004 foils are serialized by scribing or laser engraving on the non-radioactive side.

The Model NER-004P sources are permanently marked on a non-radioactive surface of the component with the radiation symbol, serial number and model number (i.e. "NER-004P"). If space permits, the sources will also be labeled with the isotope, activity and the words "Caution, Radioactive Material."

DIAGRAM:

Attachment 1 shows diagrams of dose rate locations.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-476-S-131-S

DATE: June 25, 1993

PAGE 3 OF 5

SEALED SOURCE TYPE: Beta Ionization Source

CONDITIONS OF NORMAL USE:

The Models NER-004 and the NER-004P are beta ionization sources and are routinely used in gas chromatography systems, gas detection equipment, and aerosol neutralization applications. The sources shall not be subjected to temperatures which exceed 752°F (400°C).

PROTOTYPE TESTING:

The manufacturer tested prototype Models NER-004 and NER-004P sealed sources to the ANSI N542-1977 77C32211 requirements. In addition, the prototypes were subjected to 752°F (400°C) in air for 2 hours. Wipes of the inactive side of the sources after the tests revealed no removable contamination above 0.005 microcurie (185 Bq).

EXTERNAL RADIATION LEVELS:

The manufacturer reports maximum external radiation levels as follows:

Model		Dose Rate (deep/shallow)	
		mrem/hr/mCi	mSv/hr/GBq
NER-004	on contact with active side	0.15/12.3	0.04/3.32
	inactive side	1.1 /1.1	0.30/0.30
NER-004P	at mouth of cavity *	0.11/6.7	0.03/1.81

See Attachment 1 for diagrams of dose rate locations.

- * The electroplating is typically within a cavity of the component and this is the typical radiation dose when installed in the cavity.

QUALITY ASSURANCE AND CONTROL:

Du Pont Merck had previously described a quality assurance program which has been deemed acceptable for licensing purposes. The program consists of the following basic components:

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-476-S-131-S

DATE: June 25, 1993

PAGE 4 OF 5

SEALED SOURCE TYPE: Beta Ionization Source

QUALITY ASSURANCE AND CONTROL (Cont.):

- Design control
- Procurement control
- Process quality control including content activity measurement, leak tests, physical dimensions and visual inspection
- Final acceptance and records

A copy of the program is on file with the Source Containment and Devices Branch.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The maximum activity concentration shall be 15 millicuries (0.555 GBq) per square centimeter.
- The source, when used in the United States, shall be distributed only to those persons specifically licensed by the NRC or an Agreement State. Distribution outside the United States should be to persons authorized by a regulatory authority, as appropriate.
- The source shall not be subjected to pressures or impact which exceed the ANSI N542-1977 classification of 77C32211.
- The sources shall not be subjected to temperatures which exceed 758°F (400°C).
- The model NER-004P shall only be used in devices which are registered with the NRC or an Agreement State.
- The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination. Removable contamination from the inactive side shall not exceed 0.005 microcurie and the active side shall not exceed 0.5 microcurie (18.5 kBq).

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-476-S-131-S

DATE: June 25, 1993

PAGE 5 OF 5

SEALED SOURCE TYPE: Beta Ionization Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont'd):

- Handling, Storage, Use, Transfer, and Disposal: To be determined by the licensing authority.
- This registration sheet and the information contained with the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data cited below, we continue to conclude that the Du Pont Merck Models NER-004 and NER-004P sealed sources are acceptable for licensing purposes.

Furthermore, we continue to conclude that the sources would be expected to maintain their containment integrity for normal conditions of use which might occur during the uses specified in this registration sheet.

REFERENCES:


The following supporting documents are hereby incorporated by reference and are made part of this registry document.

- Du Pont Merck letters dated December 9, 1991, May 15, 1992, June 11, 1992, and July 31, 1992, and May 4, 1993, with enclosures thereto.
- NEN Products letter dated October 1, 1984, with enclosures thereto.

ISSUING AGENCY:

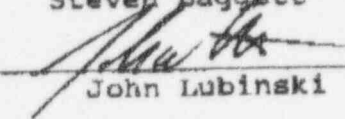
U.S. Nuclear Regulatory Commission

Date June 25, 1993

Reviewer: 

Steven Baggett

Date June 25, 1993

Concurrence: 

John Lubinski

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

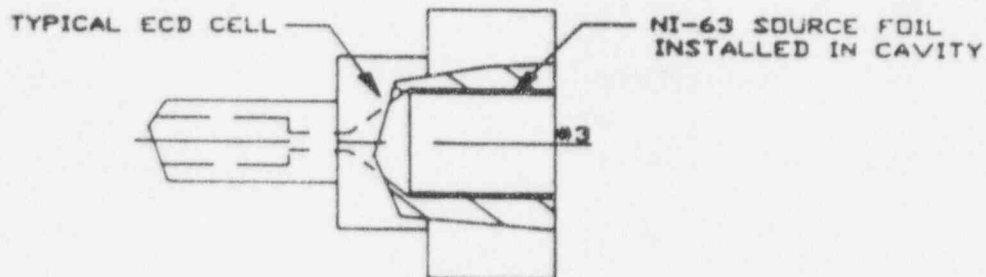
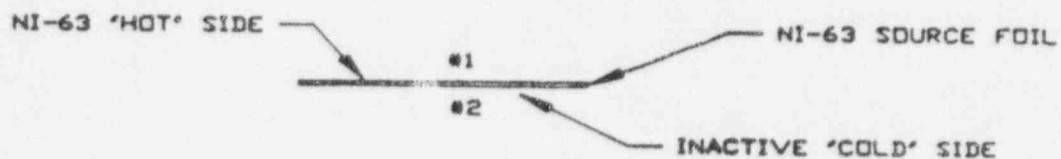
NO.: NR-476-S-131-S

DATE: June 25, 1993

ATTACHMENT 1

SEALED SOURCE TYPE: Beta Ionization Source

NER-004 DOSE RATE REPORT



LOCATION NO.	DOSE RATE mREM/HR/MCI DEEP / SHALLOW
#1	0.15 / 12.3
#2	1.1 / 1.1
#3	0.11 / 6.7

NOTES

1. THE 'LANDAUER' DOSE REPORT IS THE DOSIMETRY DATA FOR THE DURATION OF THE SURVEY (6 HOURS) USING A 15 MCI NI-63 SOURCE FOIL.

2. TLD BADGES ARE 'LANDAUER' TYPE K.

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		
1. Hewlett-Packard Company	3. License number 07-28762-01	
2. Little Falls Center 2850 Centerville Road Wilmington, Delaware 19808	4. Expiration date October 31, 1997	
	5. Docket or Reference No 030-32792 (37-07002-02)	
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Hydrogen 3	A. Titanium Tritide Foils	A. 5 curies total
B. Nickel 63	B. Plated sources and parts	B. 50 curies
C. Nickel 63	C. Foils	C. 1 curie
D. Nickel 63	D. Any	D. 1 millicurie
9. Authorized use		
A. through C. For use in the development, testing, production and assembly of detector cells; repair and maintenance of detector cells; demonstration of use of detector cells; and for distribution in detector cells to persons authorized to receive the licensed material pursuant to terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or any Agreement State.		
D. For use in the development, testing, production, assembly, repair and maintenance of detection cells, and for storage of waste materials.		

CONDITIONS

10. Licensed material may be used at the licensee's facilities at Little Falls Center, 2850 Centerville Road, Wilmington, Delaware 19808, and at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.
11. A. Licensed material shall be used by, or under the supervision of Brian Donnelly, Irv Maiorano, Rick Phillips, Paul Larson, Vernon Garner, John V. Wisniewski, Marvin Welsh, James Peters, William Howell and Richard H. Kolloff.
- B. The Radiation Safety Office for this license is Brian Donnelly.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

07-28762-01

Docket or Reference number

030-32792 (37-07002-02)

(Continued)

CONDITIONS

12. This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR 31 or to persons exempt from licensing pursuant to 10 CFR 30.18.
13. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
- (i) they contain only hydrogen 3; or
 - (ii) they contain only a gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

07-28762-01

Docket or Reference number

030-32792 (37-07002-02)

(13. continued)

CONDITIONS

- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material in the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
14. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory.
15. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(a)(1), the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols.
16. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding that specified by the manufacturer.
17. Any proposed changes in packaging, labelling, shielding, or instructions for use and storage shall be submitted for review to the Nuclear Materials Safety Branch, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406 and approval of the changes shall be received by the licensee prior to implementing the changes.
18. The licensee may transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material".
19. The licensee shall not store licensed material contained in waste for more than two (2) years from the date the waste is put into storage or November 1, 1992, whichever is later. The licensee shall maintain records which indicate the date that licensed material contained in waste is put into storage. This condition does not apply to licensed material intended for disposal by decay-in-storage pursuant to 10 CFR 35.92 or other conditions of this license.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

07-28762-01

Docket or Reference number

030-32792 (37-07002-02)

(Continued)

CONDITIONS

20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Drawings attached to original application dated September 16, 1992
 - B. Revised application dated September 16, 1992 that was attached to a letter dated October 19, 1992
 - C. Letter dated October 19, 1992
 - D. Two Telefaxes dated October 23, 1992

For the U.S. Nuclear Regulatory Commission

Date NOV 06 1992

By

Elizabeth Ullrich
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

MATERIALS LICENSE

Amendment No. 01

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with the letter dated January 10, 1995 3. License number 07-28762-02G is amended in its entirety to read as follows:
1. Hewlett-Packard Company Little Falls Center 2. 2850 Centerville Road Wilmington, Delaware 19808		
		4. Expiration date November 30, 1997
		5. Docket or Reference No 030-32988/37-07002-03G
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. As specified in Condition 10	A. As specified in Condition 10	A. Not applicable
9. Authorized use		
A. Pursuant to 10 CFR 32.51, the licensee is authorized to distribute the devices containing sealed sources specified in Condition 10 of this license to persons generally licensed pursuant to 10 CFR 31.5 or equivalent provisions of the regulations of any Agreement State.		

CONDITIONS

10. Each device distributed pursuant to the terms and conditions of this license shall be in accordance with the following table:

Device Model Numbers (s)	Source	Isotope	Maximum Activity Per Source (Millicuries)
Model 19312 Detector Cell	Plated source	Nickel 63	15
Model 19282 Detector Cell	Plated source	Nickel 63	15
Model 19233 Detector Cell	Plated source	Nickel 63	15
Model G1223A Detector Cell	Plated source	Nickel 63	15
Model G1533A Detector Cell	Plated source	Nickel 63	15

suppl 1-2
see attached (Page 1A)

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amendments to License 07-28762-02G

10. (continued)

<u>Device Model Numbers (s)</u>	<u>Source</u>	<u>Isotope</u>	<u>Maximum Activity Per Source (Millicuries)</u>
*Model G2310A Detector Cell	Plated source	Nickel 63	5
*Model G2330A Detector Cell	Plated source	Nickel 63	5
#Model G2397A Detector Cell	Plated cylinder	Nickel 63	15
#Model G2398A Detector Cell	Plated cylinder	Nickel 63	15
#Model G2404A Detector Cell	Plated cylinder	Nickel 63	15
#Model G2405A Detector Cell	Plated cylinder	Nickel 63	15

* - My letter dated Aug. 4, 1995 (See Certificate of Registry NR-348-D-111-B)

#- New, per this request.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

07-28762-02G

Docket or Reference number

030-32988

Amendment 01

(Continued)

CONDITIONS

11. The licensee is authorized to distribute the devices specified in Condition 10 from facilities located at Little Falls Center, 2850 Centerville Road, Wilmington, Delaware.
12. This license does not authorize possession or use of licensed material.
13. Any proposed changes in packaging, labelling, shielding, or instructions for use and storage shall be submitted for review to the Nuclear Materials Safety Branch, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406 and approval of the changes shall be received by the licensee prior to implementing the changes.
14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Letter dated September 9, 1980
 - B. Letter dated February 25, 1981
 - C. Letter dated August 24, 1981
 - D. Letter dated October 28, 1981
 - E. Letter dated July 19, 1983
 - F. Letter dated November 30, 1983
 - G. Letter dated January 30, 1990
 - H. Letter dated January 10, 1995

Date

MAR 13 1995

For the U.S. Nuclear Regulatory Commission

By

Lara White
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-348-D-111-B

DATE: August 31, 1995

PAGE 1 OF 8

DEVICE TYPE: Electron Capture Detector

G2397A, G2398A, G2404A, G2405A

MODELS: G1223A, G1533A, G2310A, G2330A (Generally Licensed)
G1224A, G1536A (Specifically Licensed)

MANUFACTURER/DISTRIBUTOR:

Hewlett-Packard Company
Little Falls Site
2850 Centerville Road
Wilmington, DE 19808

SEALED SOURCE MODEL DESIGNATION: Amersham Corporation Model NBCD

ISOTOPE:

MAXIMUM ACTIVITY:

MODELS

Nickel-63

15 millicuries (0.56 GBq)

G1223A, G1533A
G1224A, G1536A

5 millicuries (185 MBq)

G2310A, G2330A

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (N) Ion Generator, Chromatography

CUSTOM DEVICE: _____ YES _____ X _____ NO

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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-348-D-111-B

DATE: August 31, 1995

PAGE 2 OF 8

DEVICE TYPE: Electron Capture Detector

DESCRIPTION:

The Models G1223A and G1224A electron capture detector (ECD) assemblies are similar to the previously approved Models 19233 and 19235. The Model G1223A will be distributed to persons generally licensed and the Model G1224A will be distributed to persons specifically licensed. The two detectors are the same except that the detector label plate is different for general licenses versus specific licenses. The Models G1223A and G1224A ECDs are for use on the Hewlett-Packard Model 5890 Series gas chromatographs.

The specific differences of the Models G1223A and G1224A relative to the Models 19223 and 19235 are as follows:

1. The detector heat sink is made of aluminum rather than stainless steel. The new heat sink allows Hewlett-Packard to down rate their heater from 70 watts to 60 watts. This also limits the maximum temperature of the detector. In the event of a catastrophic failure mode, the 5890 gas chromatograph instrument's main processor would detect a shorted sensor fault, and turn off all heaters to devices on the gas chromatograph.
2. A 17-4 PH stainless steel will be used rather than 303 stainless steel. The supplier of the lower plated block, Amersham Corporation, has indicated that the plating quality of Ni-63 is better with 17-4 PH stainless steel. A 17-4 PH stainless steel lower block is currently being used on Models 19303 and 19312 ECD's. The inside of the lower block will be plated with non-radioactive nickel prior to plating of the Ni-63 radionuclide.
3. A metal seal will be used between the lower block (cathode) and the upper block (anode) that is currently used on other ECDs being distributed (for example, Models 18713A, 19282 and 18803-60520). This particular seal uses a silver crushable O-ring. The same tamper proof screws now used on all of Hewlett-Packard's distributed ECDs will be used.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-348-D-111-B

DATE: August 31, 1995

PAGE 3 OF 8

DEVICE TYPE: Electron Capture Detector

DESCRIPTION (Cont.):

4. The upper anode block design has been redesigned. The non-plated part has reduced mass, a purged anode which has been raised (withdrawn) from the region of the nickel-63 plating within the lower block (cathode). The purged anode remains cleaner and is retained with a special nut and seal removable only with the manufacturer's anode wrench.
5. The outer cover and insulation are different than the 19233 and 19235 merely to accommodate the new gas chromatograph. The detector label plates will have the same information as our current detectors and will remain permanently attached to a tamper proof screw.

The Models G1533A and G1536A ECD assemblies are same as the Models G1223A and G1224A with the exception of modifications to the mounting hardware and the outer cover and insulation for use with a different gas chromatograph. The Model G1533A will be distributed to persons generally licensed and the Model G1536A will be distributed to persons specifically licensed. The two detectors are the same except that the detector label plate is different for general licenses versus specific licenses. The Models G1533A and G1536A ECDs are for use on the Hewlett-Packard Model 6890 gas chromatographs.

The Models G2310A and G2330A are identical to the Models G1533A and G1223A respectively, except that the G2310A and G2330A will only contain up to 5 mCi of Ni-63. The sources will be plated in the same manner as those in the Models G1533A and G1223A.

All six ECDs are approximately 4" (10 cm) long and 1-1/8" (2.86 cm) in diameter at their widest location. General licensees never receive the tamper proof screws wrench or solvent cleaning/disassembly instructions.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-348-D-111-B

DATE: August 31, 1995

PAGE 4 OF 8

DEVICE TYPE: Electron Capture Detector

LABELING:

Each cell is stamped with the radiation symbol, the words, "Caution-Radioactive Material," the isotope and activity. Label plates are attached by cable to a tamper proof screw on the detector body. Users are instructed not to remove these plates. The plate contains the radiation symbol, the words, "Caution-Radioactive Material," the isotope, activity, model number, serial number, date, the words, "Electron Capture Detector," and the manufacturer name and logo. Additionally, for the Models G1223A, G1533A, G2310A, and G2330A, the generally licensed versions, the plate contains the labeling requirements of Section 32.51, and refers the user to an instruction manual that tells them not to open or chemically clean the cell.

DIAGRAM:

See attachment 1.

CONDITIONS OF NORMAL USE:

Each ECD is designed to be used in conjunction with gas chromatographs in analytical laboratories. Each ECD will be used in laboratory environs and by persons trained in the use of gas chromatography equipment. The ECD will normally be operated at temperatures up to 410°C (770°F).

PROTOTYPE TESTING:

Hewlett-Packard tested the detector cells to the criteria used on their presently licensed detector cells. The tests consisted of:

- Pressure test to 60 psi (414 kPa).
- Drop test from 1.5 meters (59").
- Vibration test to 55 Hz with an amplitude of 0.015" (0.38 mm).
- Freeze test to -40°C (-40°F).
- Loss of Nickel-63 in carrier gas during normal use.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
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DEVICE TYPE: Electron Capture Detector

PROTOTYPE TESTING (Cont.):

- Loss of Nickel-63 from detector is all heat control systems fail.
- Loss of Nickel-63 during solvent cleaning of the detector.
- Loss of Nickel-63 at abnormality high temperatures (625°C [1157°F] and 800°C [1472°F]).

The ECD's met the above tests and exceeded the minimum ANSI N542 classification of 77C32211 for ion generators, chromatography.

EXTERNAL RADIATION LEVELS:

The manufacturer has reported that radiation levels do not exceed background levels for measurements taken from a detector with 15 millicuries of Ni-63 at the surface and at distances of 5 cm (2") and 30 cm (12") from the surface.

QUALITY ASSURANCE AND CONTROL:

The following tests are performed on each detector cell by the manufacturer prior to shipment:

- A visual inspection of the area of radioactive plating using a stereo-optic microscope.
- Measurements of the radioactivity levels by use of ionization current.
- Wipe tests of the non-radioactive surfaces to ensure non-contamination.

A copy of the Hewlett-Packard's Quality Manual is on file with NRC.

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DEVICE TYPE: Electron Capture Detector

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The Models G1224A and G1536A shall be distributed to persons specifically licensed by the NRC or an Agreement State.
- The Models G1223A, G1533A, G2310A and G2330A shall be distributed to persons generally licensed by the NRC or an Agreement State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority or as required by 10 CFR 31.5 or Agreement State equivalent.
- The devices shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.
- The user may install the device into gas chromatographs. However, the device may not be dismantled in any way by the user unless he obtains a specific license from NRC or an Agreement State to perform such activities.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Hewlett-Packard has submitted sufficient information to provide reasonable assurance that:

- The device can be safely operated by persons not having training in radiological protection.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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DEVICE TYPE: Electron Capture Detector

SAFETY ANALYSIS SUMMARY (Cont.):

- Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the source housing, and it is unlikely that any person will receive in any period of one year a dose in excess of 10 percent of the limits specified in Section 20.1201(a), 10 CFR Part 20.
- Under accident conditions associated with handling, storage, and use of the source housing, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in the following chart:

PART OF BODY

DOSE

Whole body; head and trunk;
active blood-forming organs;
gonads; or lens of eye

15 rem (0.15 Sv)

Hands and forearms; feet and
ankles; localized areas of skin
averaged over areas no larger
than 1 square centimeter

200 rem (2.0 Sv)

Other organs

50 rem (0.50 Sv)

Based on review of the Models G1223A, G1533A, G1224A, G1536A, G2310A and G2330A ECDs, and the information and test data cited below, we continue to conclude that the devices are acceptable for licensing purposes.

Furthermore, we continue to conclude that the devices would be expected to maintain their containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
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DEVICE TYPE: Electron Capture Detector

REFERENCES:

The following supporting documents for the ECDs are hereby incorporated by reference and are made a part of this registry document.

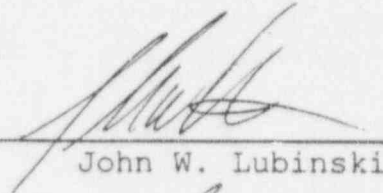
- Hewlett-Packard's letters dated January 30, 1990, February 2, 1990, May 9, 1990, September 17, 1990, October 3, 1990, and October 10, 1990, with enclosures thereto.
- Hewlett-Packard's letters dated August 4, 1995 and June 8, 1994, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

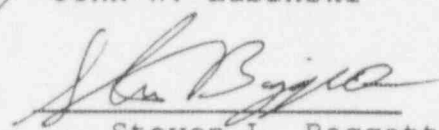
Date: August 31, 1995

Reviewer:


John W. Lubinski

Date: August 31, 1995

Concurrence:

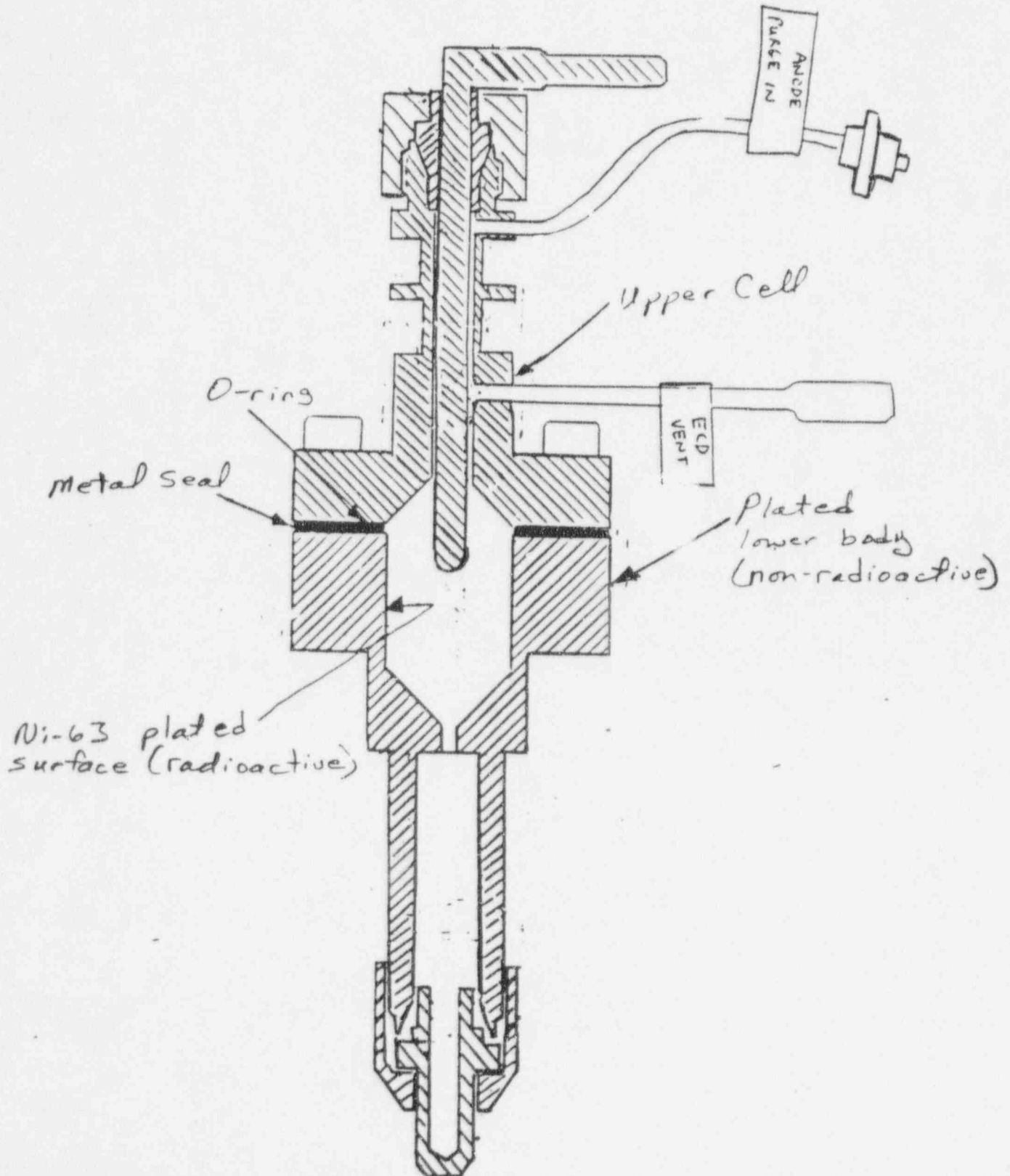

Steven L. Baggett

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

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ATTACHMENT 1



HEWLETT-PACKARD COMPANY
PACKING LIST

PAGE 1

CUSTOMER INFORMATION

SHIP TO:
US NUCLEAR REGULATORY COMMISSION
SEALED SOURCE SAFETY SECTION
DIV/INDUSTRIAL & MEDICAL NUCLEAR SAFETY
WASHINGTON, DC 20555

DELIVER TO:
MR. STEVE BAGGETT

SOLD TO:
US NUCLEAR REGULATORY COMMISSION
SEALED SOURCE SAFETY SECTION
DIV/INDUSTRIAL & MEDICAL NUCLEAR SAFETY
WASHINGTON, DC 20555

ATTENTION OF:

SHIPPER INFORMATION

SHIPPED FROM:
Hewlett-Packard CO. 2340
Little Falls Operation
2850 Centerville Road
Wilmington, DE USA 19808-1610

S/O: ORDER NO. SECT PTL
23-072663

SHIPPER
REFERENCE #: 3830601993
CARRIER: FE1

SHIP DATE: 04/09/96

SHIPMENT CONTENTS

ITEM	SI	PRODUCT NUMBER	DESCRIPTION	QTY	UM
01	00	DOCUMENTS	DOCUMENTS FOR LICENSE #07-28762-01	1	
		ENR NSN	IN BOX: 2340-24821	WT:	1.00 LB
		TOTAL BOX COUNT:	1	TOTAL WT:	1.00 LB

ATTENTION RECEIVING PERSONNEL : IN CASE OF CONCEALED OR OBVIOUS DAMAGE:

- 1) SAVE ALL PACKAGING MATERIAL
- 2) CONTACT THE DELIVERING CARRIER FOR INSPECTION
- 3) CONTACT THE NEAREST HEWLETT-PACKARD SALES OFFICE

*** END OF PACKING LIST ***

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ATTN: S. Kimberley, T-9E10

TYPE OF ACTION

- ☐ NEW LICENSE
- ☐ RENEWAL OF LICENSE
- ☒ AMENDMENT TO LICENSE

REQUESTED DATE

4-9-96

LICENSE NUMBER

NR0348D111B

CONTROL NUMBER

96-19

Hewlett-Packard Company
Little Falls Site
ATTN: Brian Donnelly
2850 Centerville Road
Wilmington, DE 19808

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
9A	\$ 3,200.00	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE \$ 3,200.00

PAYMENT RECEIVED \$

AMOUNT DUE \$ 3,200.00

☒ Your request was received without the prescribed application fee.

☐ We received your Check No. _____ in the amount of \$ _____. Payment of the additional fee noted above is required.

☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:

☐ We received your Check No. _____ in payment of the fee.

☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____.

Control No. _____

☐ Your request was combined, prior to review, with your request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:

- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. _____ Amendment No. _____, issued on _____.

_____ was issued without the required fee being collected. The fee required is noted in Section I of this form.

☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE - LICENSE FEE ANALYST

Sandra Kimberley

LFDCB

4/16/96

LFDCB

4/16/96

Distribution: Pending File

OC/DAF/LFARB (LK-3.2.7) S/F
OC/DAF/LFARB R/F
cc: S. Kimberley, NRC

DATE

4-16-96