

MAR 2 1988

License: 17-09273-01  
Docket: 30-01755/87-01

Veterans Administration Medical Center  
ATTN: Charles C. Freeman, Director  
Alexandria, Louisiana 71301

Gentlemen:

Thank you for your letter of February 2, 1988, in response to our letter and the attached Notice of Violation dated December 18, 1987. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation. We will review the implementation of your corrective actions during a future inspection to determine that full compliance has been achieved and will be maintained.

Sincerely,

William L. Fisher, Chief  
Nuclear Materials and Emergency  
Preparedness Branch

cc:  
Louisiana Radiation Control Program Director

bcc w/letter from licensee:  
DMB - Original (IE-07)  
R. Martin  
R. Bangart  
R. E. Hall  
W. Fisher  
B. Spitzberg  
RIV Files  
NMEPB  
RSTS Operator (close report)

RIV:NMIS *WLF*  
DBSpitzberg;ap  
3/2/88

C:NMEPB *WLF*  
WLFisher  
3/2/88

8803080097 880302  
REG4 LIC30  
17-09273-01 PDR

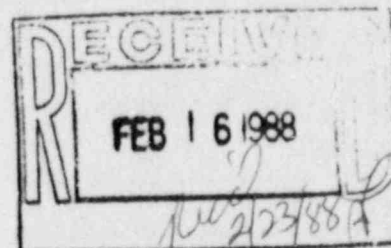
IE-07  
1/1

**Veterans  
Administration**

February 2, 1988

In Reply Refer To: 502/114/5  
License No. 17-09273-01  
Docket: 30-01755/87-01

Nuclear Regulatory Commission  
Region IV  
ATTN: William L. Fisher, Chief  
Nuclear Materials and Emergency  
Preparedness Branch  
611 Ryan Plaza Drive, Suite 1000  
Arlington, Texas 76011



Dear Sir:

This is a response in reference to the notice of violation following a routine unannounced radiation safety inspection conducted by Mr. D. B. Spitzberg of your office on November 23, 1987. The time to respond to these violations was extended by your office to February 18, 1988.

1. The Medical Center intends to completely comply with License Condition 14, statements, representations and procedures contained in the letter dated January 29, 1980, application dated April 15, 1985 and letter dated September 3, 1986.

- a. To comply with item 5 of the license application dated April 15, 1985, Dr. Jo Ann Bowers, Chief, Imaging Service has been designated as the Radiation Safety Officer. This information was conveyed to your office on December 1, 1987.
- b. The Medical Center has for many years utilized the services of John U. Hidalgo, Consulting Physicist to perform quarterly review of radiation safety program. This includes the review of operating procedures, radiation exposure records, equipment calibration and quality control on all imaging procedures. Copies of the last years surveys are enclosed.
- c. To comply with Appendix J.2 of license application dated April 15, 1985, the Mo-99/Tc99m generators. The expired generator will be brought to decay in Room 8, Building 1 basement and stored intact for a period of at least six months. The generators will then be disassembled, the columns monitored and if the activity is not measurable the remains will be discarded as normal trash.

2. The generators will no longer be returned to the supplier. The expired generator will be stored, brought to decay and disposed in the manner stated in 1-C of this letter.

IC-88/046-880303013/

3. The Radiation Safety Committee as stated in the Medical Center Memorandum 11-48 will meet quarterly to comply with 10 CFR 35.22(a)(2).

4. To comply with 10 CFR 35.92(a) all byproduct material will be allowed to decay in storage for at least 10 half lives before disposal.

a. A new record keeping system has been instituted. The form specifically specifies the date the expired generator was placed in storage and the date at which the generator or other radionuclide was disposed.

b. Records will also be kept of the background dose rate and the dose rate at the surface of each container. The technologist responsible for the disposal is now required to sign the disposal record.

5. To comply with 10 CFR 71.5(a) no byproduct material will be transported or shipped outside the confines of the Medical Center. The Mo-99/Tc99m generator will be brought to decay as specified in 1-C and disposed in a manner Appendix J.2 of license application dated April 15, 1985.

a. The Medical Center had taken the following steps to ensure a total compliance with NRC regulations pertaining to our radioactive materials license. The Medical Center has, effective December 6, 1987, appointed a physician Board Certified in Nuclear Medicine to serve as Section Chief of Nuclear Medicine.

b. The technologist in Nuclear Medicine Service have received inservice training in regards to proper record keeping and radionuclide disposal.


c. The scope of the duties of the consulting physicist have been expanded to include quarterly review of NRC requirements including proper record keeping, byproduct material disposal and safety requirements including compliance with ALARA.

d. As stated in item 3 of this letter, Medical Center Memorandum 11-48 has been revised to include the listing of the Radiation Safety Officer, the members of the Radiation Safety Committee and requires quarterly meetings be scheduled for the Radiation Safety Committee.

e. The record keeping system has been revised and improved as previously stated in item 4 of this letter.

Please do not hesitate to contact me if any questions remain unanswered.

Sincerely yours,

  
CHARLES C. FREEMAN  
Director

Enclosure

DATE \_\_\_\_\_ BKGD \_\_\_\_\_ DATE GENERATOR  
SURFACE \_\_\_\_\_ DISPOSED OF \_\_\_\_\_

WELL \_\_\_\_\_ Date Generator Sent 137  
To Decay Room \_\_\_\_\_ Cs Std \_\_\_\_\_ mCi \_\_\_\_\_

[illegible]

VETERANS ADMINISTRATION MEDICAL CENTER  
Alexandria, Louisiana

January 22, 1988

MEDICAL CENTER MEMORANDUM  
NO.....11-48

RADIATION SAFETY COMMITTEE

- I. PURPOSE. To designate membership and functions of the Radiation Safety Committee.
- II. POLICY. The Committee will function in accordance with VA and Nuclear Regulatory Commission (NRC) directives.
- III. ACTION.
  - A. Membership.

Chief, Imaging Service- Chairman  
and Radiation Safety Officer

Chief, Nuclear Medicine Section

Infection Control Nurse, Nursing Service

Safety Technician- Engineering Service

AA/COS- Representative of Institution Management
  - B. Committee Functions. The Radiation Safety Committee shall coordinate and supervise the Medical Center Radiation Safety Program and shall:
    1. Ensure that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.
    2. Ensure that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations, and the conditions of the license.
    3. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.




4. Review the training and experience of an individual who uses radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.
5. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by Para. 19.12 of 10 CFR Part 19.
6. Review and approve all proposed diagnostic, therapeutic and research issues of radionuclides. The Committee responsibilities include compliance with regulations contained in Title 10, CFR Part A, "Notices, Instructions and Reports to Workers; Inspections", and 10-CFR Part 20, "Standards for Protection Against Radiation."
7. Review and approve all requests for use of radioactive material within the institution.
8. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.
9. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures, and management control system.
10. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
11. Maintain written records of all committee meetings actions, recommendations, and decisions.
12. Ensure that the by-product material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel.

C. Meetings

1. The Committee will meet quarterly and as needed at the call of the Chairman.
2. Minutes of the meeting will be prepared by the Chairman and forwarded to the Chief of Staff and Clinical Executive Board.

IV. REFERENCES. M-2, Part XX  
M-1, Part 1, Chapter 1  
NRC Regulatory Guide, Section 10.8  
DM&S Circular 10-86-72

V. RESCISSION. Medical Center Memorandum 11-48, dated  
June 27, 1985.



CHARLES C. FREEMAN  
Director

DIST. A  
All wards

RADIATION SAFETY COMMITTEE  
VAMC, ALEXANDRIA, LOUISIANA

CONVENED: 2:00 P.M.  
ADJOURNED: 3:00 P.M.

Date: January 29, 1988

MEMBERS: J. BOWERS, M.D., Chief, Imaging Service, Chairman (114/5)  
M. YUNUS, M.D., Chief, Nuclear Medicine Section (114/5)  
R. LOVE, Engineering Safety Technician (138)  
S. TUDOR, R.M., Infection Control Nurse (118)  
C. PARVIN, AA/COS (11D)  
B. HAY, CMT, Secretary/Recorder (114/5)

1. APPROVAL OF PREVIOUS MINUTES:

The minutes of September 30, 1987 stand approved.

2. OLD BUSINESS:

- A. Up to date film badge reports have been received for Nuclear Medicine, Radiology and Engineering. The last film badge report for Nursing Service is dated for October 1987. Dr. Bowers and Dr. Yunus have reviewed the reports and no excessive radiation reported.
- B. Medical Center Memorandum 115-1, dated June 15, 1983, titled Radiation Safety Program was reviewed and will be revised to reflect the new rules and regulations of the Nuclear Regulatory Commission.

3. NEW BUSINESS:

- A. The letter from the Nuclear Regulatory Commission dated 12/18/87 was addressed pertaining to the violations listed from the unannounced radiation inspection conducted by Mr. D. B. Spitzberg on November 23, 1987. Dr. Yunus has done an excellent job in answering this letter for the Director's signature.
- B. The standardization of Nuclear Medicine report forms with radiology report forms was discussed. On January 8, 1988, a Memorandum was sent to all services requesting the use of SF 519A for all Radiologic exams and Nuclear Medicine Exams.
- C. In answer to SERP, all patients will be received in Radiology Section for registration. This will keep the noninjected patients separated from the injected patients.
- D. The Radiation Survey report was reviewed. It was noted that Mr. Hidalgo performs duties the technologists and service representatives perform. Investigation will be done regarding a contract for the physicist, if so, what are his key responsibilities.
- E. Dr. Mohammed Yunus, Chief, Nuclear Medicine Section was introduced to the committee members and welcomed to the Radiation Safety Committee.



- F. A discussion ensued pertaining to over exposure of radiation. The monitors for each service are checked monthly. The ALARA (As Low As Is Reasonably Achievable) Nuclear Regulatory Commission rules pertaining to dosage levels will be followed closely with briefings and educational sessions to insure this Medical Center stays below the minimum levels as listed below:

	Investigational Levels (mrems per calendar quarter)	
	Level I	Level II
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

\*Not normally applicable to medical use operations except those using significant quantities of beta-emitting isotopes.

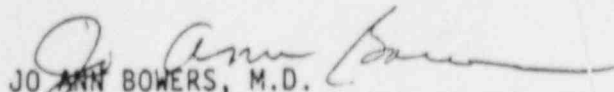
4. IDENTIFIED PROBLEMS:

- A. Monthly film badge reporting for Nursing Service.
- B. Outdated Medical Center Memorandum 115-1, dated June 15, 1983, Radiation Safety Program.
- C. Contract for physicist performing radiation surveys.

5. SOLUTIONS TO PROBLEMS:

- A. It is a ruling of the Nuclear Regulatory Commission Society that film badge reporting will be turned in on a monthly basis. These monitors will be reviewed by the Radiation Safety Officer, or designee.
  - B. MCM 115-1, dated 6/15/83, Radiation Safety Program is in the process of being rewritten.
  - C. Check is being done to see if a contract exists for the present physicist, and if so what his duties entail. If no contract exists, then will get with Supply Service regarding the drafting of a contract.
6. There were no reported reactions to a medication, no report of a wrong dosage of medication being given, and no report of a wrong medication being given.

7. RECOMMENDATIONS TO CEB: None.

  
JO ANN BOWERS, M.D.  
Chairman, Radiation Safety Committee



John U. Hidalgo  
Consulting Physicist

January 15, 1988

Jo Ann Bowers, M.D.  
Nuclear Medicine Service  
Veterans Administration Medical Center  
Alexandria, LA 71301

Dear Dr. Bowers:

This is to report to you on my visit of January 13, 1988 to your institution.

The Ludlum 14C and the two CDV 700 Survey Meters have been recalibrated. None of the units required adjustment. All three units are functioning correctly and well.

The CRC-17 Dosage Calibrator has been recalibrated. No adjustment was necessary. The unit is functioning accurately and well.

The NC SCA Thyroid Uptake unit is functioning correctly. Calibration required some adjustment. Gain is linear.

General inspection of the LFOV Camera showed no indication of mechanical or system failure. Review of the routine flood studies showed acceptable field uniformity. Bar phantom studies showed acceptable field linearity. Special flood studies showed acceptable field uniformity. Off peak floods with Co 57 showed no indication of crystal fault. The camera is in acceptable alignment.

General inspection of the ZLC 750 Camera showed no indication of mechanical or system failure. Review of the routine flood studies showed acceptable field uniformity. Bar phantom studies showed acceptable field linearity. Special flood studies showed acceptable uniformity. Off peak floods showed no indication of crystal fault. The camera is in acceptable alignment.

Review of the personnel monitor reports through November 30, 1987 showed no unusual or remarkable exposure.

I have reviewed the waste storage areas and all is in order. Surveys are correct. Waste record procedures have been modified to improve completeness.

I am pleased to be of service.

Sincerely,

John U. Hidalgo

## ORDER FOR SUPPLIES OR SERVICES

(CONTINUATION)

PAGE NO. 2 OF 2 PAGES

DATE  
10/1/87ORDER NO.  
502-C80005

ISSUING OFFICE

Veterans Administration

Medical Center

Alexandria, LA 71301

VENDOR

JOHN U. HILDALGO, Physicist

ITEM NO.	DESCRIPTION	QUANTITY ORDERED	UNIT	UNIT PRICE	AMOUNT	QUANTITY SHIPPED	AMOUNT BILLED
	SERVICE: NUCLEAR Physicist to visit the Nuclear Medicine Service, VAMC Alexandria, LA 71301 four (4) times during FY 88 and perform the following:	4	visits	485.00	1940.00		
1.	Review of license provisions						
2.	Complete review of all health physics and safety programs with recommended changes, if needed.						
3.	Complete review of dosage control system with recommendations						
4.	Detailed calibration of all survey meters.						
5.	Detailed calibration of all wells and probes.						
6.	Detailed calibration of dose calibrators.						
7.	Quality control study on all imaging.						
8.	Review and/or establish day of use quality controls of all instruments.						
	DELIVERY: October, 1987 January, 1988 April, 1988 July, 1988						
TOTALS CARRIED FORWARD TO FIRST SHEET					1940.00		



John U. Hidalgo  
Consulting Physicist

October 9, 1987

Jo Ann Bowers, M.D.  
Nuclear Medicine Service  
Veterans Administration Medical Center  
Alexandria, LA 71301

Dear Dr. Bowers:

This is to report to you on my visit of October 7, 1987 to your institution.

The Ludlum 14C and the two CDV 700 Survey Meters have been recalibrated. None of the units required adjustment. All three units are functioning correctly and well.

The CRC-17 Dosage Calibrator has been recalibrated. No adjustment was necessary. The unit is functioning accurately and well.

The NC SCA Thyroid Uptake unit is functioning correctly. Calibration required some adjustment. Gain is linear.

General inspection of the LPOV Camera showed no indication of mechanical or system failure. Review of the routine flood studies showed acceptable field uniformity. Bar phantom studies showed acceptable field linearity. Special flood studies with Cs 137 showed acceptable field uniformity. Off peak floods with Co 57 showed no indication of crystal fault. Flow flood studies showed correct function of the Micro Dot multiformatter in dynamic mode. The camera is in acceptable alignment.

General inspection of the ZLC 750 Camera showed no indication of mechanical or system failure. Review of the routine flood studies showed some deterioration in field uniformity. Bar phantom studies showed acceptable field linearity. Special flood studies with Co 57 showed several PM assemblies running high in pulse height output even with % correction. Off peak floods showed no indication of crystal fault. The camera needs realignment.

Review of the personnel monitor reports through August 31, 1987 showed no unusual or remarkable exposure.

I am pleased to be of service.

Sincerely,

John U. Hidalgo

## CERTIFICATE OF INSPECTION

Jo Ann Bowers, M.D.  
Nuclear Medicine Service  
Veterans Administration Medical Center  
Alexandria, LA 71301

THIS IS TO CERTIFY THAT THE SOURCE OR SOURCES LISTED BELOW WERE  
WIPE/LEAK TESTED AND FOUND TO HAVE LESS THAN .005 MICROCURIES  
OF REMOVABLE CONTAMINATION.

NES 356, Cs 137, 209 uCi (3/11/80), Epoxy in Plastic

EQUIPMENT USED:

DATE:

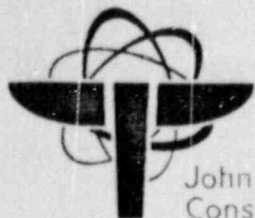
October 7, 1987



JOHN U. HIDALGO, M.S., F.A.C.R.  
C.N.M.P.

1209 LAIR AVENUE  
METAIRIE, LOUISIANA 70003





John U. Hidalgo  
Consulting Physicist

July 10, 1987

Jo Ann Bowers, M.D.  
Nuclear Medicine Service  
Veterans Administration Medical Center  
Alexandria, LA 71301

Dear Dr. Bowers:

This is to report to you on my visit of July 8, 1987 to your institution.

The Ludlum 14C and the two CDV 700 Survey Meters have been recalibrated. None of the units required adjustment. All three units are functioning correctly and well.

The CRC-17 Dosage Calibrator has been recalibrated. No adjustment was necessary. The unit is functioning accurately and well.

The NC SCA Thyroid Uptake unit is functioning correctly. Calibration required some adjustment. Gain is linear.

General inspection of the LFOV Camera showed no indication of mechanical or system failure. Review of the routine flood studies showed acceptable field uniformity. Bar phantom studies showed acceptable field linearity. Special flood studies with Cs 137 showed acceptable field uniformity. Off peak floods with Co 57 showed no indication of crystal fault. Flow flood studies showed correct function of the Micro Dot multiformatter in dynamic mode. The camera is in acceptable alignment.

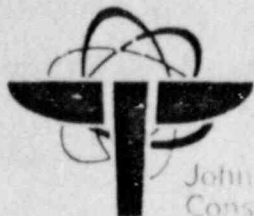
General inspection of the ZLC 750 Camera showed no indication of mechanical or system failure. Review of the routine flood studies showed acceptable field uniformity with correction. Bar phantom studies showed acceptable field linearity. Special flood studies with Co 57 showed acceptable field uniformity. Off peak floods showed no indication of crystal fault. The camera is in acceptable alignment.

Review of the personnel monitor reports through May 31, 1987 showed no unusual or remarkable exposure.

I am pleased to be of service.

Sincerely,

John U. Hidalgo



John U. Hidalgo  
Consulting Physicist

April 13, 1987

Jo Ann Bowers, M.D.  
Nuclear Medicine Service  
Veterans Administration Medical Center  
Alexandria, LA 71301

Dear Dr. Bowers:

This is to report to you on my visit of April 8, 1987 to your institution.

The Ludlum 14C and the two CDV 700 Survey Meters have been recalibrated. None of the units required adjustment. All three units are functioning correctly and well.

The CRC-17 Dosage Calibrator has been recalibrated. No adjustment was necessary. The unit is functioning accurately and well.

The NC SCA Thyroid Uptake unit is functioning correctly. Calibration required a little adjustment. Gain is linear.

General inspection of the LFOV Camera showed no indication of mechanical or system failure. Review of the routine flood studies showed acceptable field uniformity. Bar phantom studies showed acceptable field linearity. Special flood studies with Cs 137 showed acceptable field uniformity. Off peak floods with Co 57 showed no indication of crystal fault. The camera is in acceptable alignment.

General inspection of the ZLC 750 Camera showed no indication of mechanical or system failure. Review of the routine flood studies showed acceptable field uniformity. Bar phantom studies showed acceptable field linearity. Special flood studies with Co 57 showed acceptable field uniformity. Off peak floods showed no indication of crystal fault. The camera is in acceptable alignment.

Review of the personnel monitor reports through February 28, 1987 showed no unusual or remarkable exposure.

I am pleased to be of service.

Sincerely,

John U. Hidalgo

## CERTIFICATE OF INSPECTION

Jo ANN Bowers, M.D.  
Nuclear Medicine Service  
Veterans Administration Medical Center  
Alexandria, LA 71301

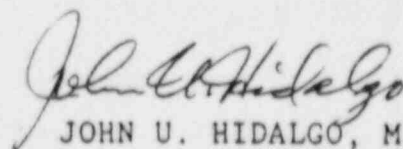
THIS IS TO CERTIFY THAT THE SOURCE OR SOURCES LISTED BELOW WERE  
WIPE/LEAK TESTED AND FOUND TO HAVE LESS THAN .005 MICROCURIES  
OF REMOVABLE CONTAMINATION.

NES 356, Cs 137, 209 uCi (3/11/80), Epoxy in Plastic

EQUIPMENT USED:

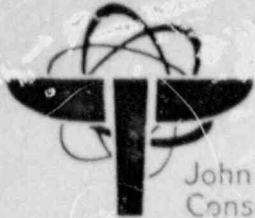
DATE:

April 8, 1987



JOHN U. HIDALGO, M.S., F.A.C.R.  
C.N.M.P.

1209 LAIR AVENUE  
METAIRIE, LOUISIANA 70003



John U. Hidalgo  
Consulting Physicist

January 20, 1987

Jo Ann Bowers, M.D.  
Nuclear Medicine Service  
Veterans Administration Medical Center  
Alexandria, Louisiana 71301

Dear Dr. Bowers:

This is to report to you on my visit of January 14, 1987 to your institution.

The Ludlum 14C and CDV-700 Survey Meters have been recalibrated. Neither unit required adjustment. Both units are functioning correctly and well.

The CRC-17 Dosage Calibrator has been recalibrated. No adjustment was required. The unit is functioning accurately and well.

General inspection of the LFOV Camera showed no indication of mechanical or system failure. Review of the routine flood studies showed acceptable field uniformity. Bar phantom studies showed acceptable field linearity. Special flood studies with Cs 137 showed acceptable field uniformity. Off peak flood studies with Co 57 showed no indication of crystal fault. Flow flood studies showed correct function of the Micro Dot multiformatter in dynamic mode. The camera is in acceptable alignment.

General inspection of the ZLC 750 Camera showed no indication of mechanical or system failure. Review of the routine flood studies showed acceptable field uniformity. Bar phantom studies showed acceptable field linearity. Special flood studies with Co 57 showed acceptable field uniformity. Off peak flood studies showed no indication of crystal fault.

Inspection of the NCSA Uptake System showed correct function. Calibration is correct and gain is linear.

Review of the personnel monitor reports through November 30, 1986 showed no unusual or remarkable exposure.

I am pleased to be of service.

Sincerely,

John U. Hidalgo

VA MEDICAL CENTER  
ALEXANDRIA, LA  
1987 JAN 22 AM 10:06  
RADIOLOGY SERVICE  
VA MEDICAL CENTER  
ALEXANDRIA, LA  
1987 JAN 22 AM 10:06



MATERIALS LICENSE

Amendment No. 44

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, 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 application dated November 27, 1985													
1. Mallinckrodt, Inc.		3. License number 24-04206-01 is amended in its entirety to read as follows:													
2. 2703 Wagner Place Maryland Heights, MO 63043		4. Expiration date January 31, 1992													
		5. Docket or Reference No. 030-00001													
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. Any byproduct material with Atomic Nos. 1 through 83,	A. Any	A. Not to exceed 100 curies of each radionuclide, except as listed below:													
		<table border="0"> <tr> <td>Strontium-90</td> <td>25 curies</td> </tr> <tr> <td>Molybdenum-99</td> <td>10,000 curies</td> </tr> <tr> <td>Technetium-99m</td> <td>10,000 curies</td> </tr> <tr> <td>Iodine-131</td> <td>500 curies</td> </tr> <tr> <td>Selenium-75</td> <td>200 curies</td> </tr> <tr> <td>Xenon-133</td> <td>200 curies</td> </tr> </table>		Strontium-90	25 curies	Molybdenum-99	10,000 curies	Technetium-99m	10,000 curies	Iodine-131	500 curies	Selenium-75	200 curies	Xenon-133	200 curies
Strontium-90	25 curies														
Molybdenum-99	10,000 curies														
Technetium-99m	10,000 curies														
Iodine-131	500 curies														
Selenium-75	200 curies														
Xenon-133	200 curies														
B. Cesium-137	B. Sealed Sources	B. Not to exceed 100 curies total													

9. Authorized Use

- A. For research and development of radiopharmaceuticals as defined in 30.4(q), 10 CFR Part 30, including animal studies. For use in manufacturing, processing and packaging of radiochemicals and radiopharmaceuticals.
- B. For use in instruction calibration and irradiation of TLD materials.

CONDITIONS

10. Licensed material shall be used only at facilities of the licensee located at 2703 Wagner Place, Maryland Heights, Missouri.
11. A. Licensed material shall be used by or under the supervision of, individuals approved by the licensee's Radiation Safety Committee, Roy W. Brown, Chairman.



MALLINCKRODT DIAGNOSTICS  
MALLINCKRODT, INC.

Certificate of Compliance For Radioactive Materials Packages  
D.O.T. Specification 7A, Type A

---

1. Package Identification: K620-1 Common Name: UTK Generator Packaging

---

2. PREAMBLE

2a. This certificate is issued to satisfy sections 171.2, 171.12, 173.411, 173.412, 173.415, 173.431, 173.461 through 173.466 and Subpart K of Part 178 of the Department of Transportation Hazardous Materials Regulations (49 CFR), as amended.

2b. The packaging and contents described in item 4 below were found to meet the safety standards set forth in, and tested, according to the more stringent recommendations for general performance testing from:

Subpart C, 10 CFR 71.

ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air, 1985 Edition, Part 3, Chapter 9 (9.1, 9.3) and Part 7, Chapter 7 (7.1 through 7.4 and 7.9 through 7.11).

IATA Dangerous Goods Regulations, 26th Edition, Section 6 (6.3.1 through 6.3.19 and 6.4.1 through 6.4.27).

IAEA Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material: 1985 Revised Edition, Section VI (614 through 625).

ANSI, American National Standard N14.7-1975.

Canadian TDG, Transportation of Dangerous Goods Regulations and Transport Packaging of Radioactive Materials Regulations.

49 CFR as listed in item 2a above.

2c. This certificate does not release the consignor from compliance with any requirement of the regulations of the U.S. Department of Transportation or other applicable regulatory agencies, including the government of any country through or into which the package will be transported.

---

3. This certificate is issued on the basis of a safety analysis report of the package design or application (Safety Analysis Data, File # K620-1).

Prepared By: AL Bruchdun

Title : Radiation Specialist

Date : 8-13-85

4. Descriptions of Packaging and Authorized contents, Other Conditions, and References:

Authorized Contents:

Normal Form Radioactive Material in Type A quantities

Description of Outer Packaging and Components:

Box: 275# test, single wall, C flute, RSC, 15 11/16" X 15 11/16" X 16 5/16"

Foam: 1.5 # density expandable polystyrene shipping cube, SRC: K616

Description of Primary and Secondary Containment:

UTK: All plastic parts: Foster grant 840 high impact polystyrene  
(American Hoechst), light blue

Lead: Up to 33 lbs (96% lead purity)

Glass Column: Type 1 glass (Borosilicate)

Stoppers: red rubber (SRC: S87)

Brass insert: .328" long, 8/32 threaded

Bolts: Round phillips head, 8/32 thread, 3 1/4" long

Vial Support: 1.8# density, expandable polystyrene

Bottle Wrap: 1.8# density, expandable polystyrene

Eluent: 500 ml bottle, Type 1 glass (Borosilicate).

Stoppers: #1704 gray (SRC: S51)

Specifications and Restrictions:

None

Prototype Divergence from Spec. Box:

None

5. CERTIFICATION

This document is to certify that to the best of my knowledge, information and belief, the construction methods, the packaging design and the materials of construction for this specification package utilized by Mallinckrodt, Inc. comply with the standards described in items 2a., 2b., and 2c. herein.

Approved: Mal Duff

Title : Supervisor, Health Physics

Date : 8-13-85

6. This Certificate of Compliance has been reviewed by the Packaging Committee and is approved for use as described in item 4, herein. Any deviation from these conditions must be safety tested and approved prior to use.

Approved: Agulera

Title : Chairman, Packaging Committee  
Diagnostic Products Group

Date : 8/15/85