



2228 South 9th Street • Ironton, Ohio 45638 • (614) 532-3231

February 25, 1994

Docket No. 030-10833  
License No. 34-16241-01  
EA 93-020

Director, Office of Enforcement  
U.S. Nuclear Regulatory Commission  
Attn: Document Control Desk  
Washington, D. C. 20555

Subject: Response to notice of violation

This response is to your letter of January 31, 1994 which summarizes the findings from your inspection of our facility on October 1, 1992 and subsequent investigations. We have been fully cooperating with the NRC since we became aware of potential violations. We have made many changes to assure compliance with NRC licensure requirements.

We trust that you will find the enclosed response satisfactory. If you have any questions please let us know.

With best regards,

Terry L. Vanderhoof  
President & CEO

TLV/ek

cc: John B. Martin  
Regional Administrator  
United States Nuclear Regulatory Commission  
Region III  
801 Warrenville Road  
Lisle, Illinois 60532-4351

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FJR ADOCK 0301083B  
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Reply to a Notice of Violation

Violation A.1.

1. Admission of violation
2. Radiation Safety Officer failed to ensure that radiation safety activities were being performed in accordance with Model Training Program (Appendix A of Regulatory Guide). Nuclear Medicine technologists were not given training when the license was renewed in its entirety on July 27, 1990, when there was a significant change in the terms of the license.

Further, the Radiation Safety Officer failed to ensure annual refresher training was given to Nuclear Medicine technologists. Radiation Safety Officer also failed to ensure annual refresher training was given to ancillary personnel in 1990, 1991, and 1992.

3. Corrective steps taken to comply with this regulation include training given to Nuclear Medicine technologists by Dr. James Kereiakes, Ph.D., Radiation Physicist, on June 14, 1993. Topics discussed were personnel monitoring; constancy checks of the dose calibrator; posting and surveying in the EKG lab; storage of radioactive material; air supplies; and action levels of surveys (see attachment).

Instruction was given to all housekeeping and security personnel working in Nuclear Medicine areas on April 7, 1993 and April 28, 1993. Additional training was given when a new employee was hired in housekeeping on June 14, 1993 (see attachment).

4. Corrective steps taken to ensure compliance: Policy was written stating Radiation Safety Officer and/or radiation physicist will provide annual refresher training for Nuclear Medicine technologists. Policy was written stating annual refresher training would be provided for ancillary personnel working in Nuclear Medicine area. Hospital education coordinator and housekeeping/security supervisors were asked to inform Nuclear Medicine Department of any new employee in order to provide training for that employee in the Nuclear Medicine area (see attachments).
5. Full compliance was achieved June, 1993.

Reply to a Notice of Violation (continued)

Violation A.2

1. Admission of violation
2. From about January 1, 1992 to April 1, 1992, Radiation Safety Officer failed to ensure radiation safety activities were being performed in accordance with Model Personnel External Exposure Monitoring Program by not having a contract service process film whole body badges or TLD finger monitors on a monthly basis. Through an oversight in accounting, payment was not made to contract company and contract service company did not provide new badges. Old badges, however, were continually worn.
3. Corrective steps to comply with this regulation: payment was made to contract service company and new badges were mailed. Upon arrival, badges were distributed to all employees.

Occupational radiation dosage based on records of daily/weekly surveys; surveys of incoming packages; no unusual events, such as radioactive spills, misadministrations, no increase in number or mix of scans allowing assumption that Nuclear Medicine technologists did not receive occupational radiation dosage in excess of acceptable values.

A letter was sent to Seimens in February, 1993, requesting the estimated occupational radiation dosage be made a part of the permanent exposure record for the Nuclear Medicine technologists (see attachment).

4. Corrective steps taken to ensure compliance: standing purchase order number for contract service company and instruction to accounting to pay the contract service bill each month.

Radiation Safety Officer designee named to collect badges and TLD finger rings during a specified time each month and to personally take them to mail room to be mailed. If badge report or badges are late in arriving to the Medical Center, a call is placed to the contract service company to assure badges have been received for reading and that all is in order with the account.

5. Full compliance achieved July, 1992.

Reply to a Notice of Violation (continued)

Violation A.3

1. Admission of violation
2. In accordance with Model Rules for Safe Use of Radiopharmaceuticals in Appendix I of Regulatory Guide, Radiation Safety Officer failed to require personnel monitoring devices to be stored in the work place in a designated low background area when device was not being worn to monitor occupational exposure. Specifically, one technologist removed the device from the hospital to be stored at home.
3. Corrective steps taken to comply with this regulation: Policy was written concerning personnel exposure monitoring which states badges must be left in the work place in a designated low background area (see attachment).
4. Corrective steps to ensure future compliance: Strict adherence to policy with revision in 1994 stating the area designated as low background is the employee's locker (see attachment).
5. Full compliance achieved July, 1993.

Violation A.4

1. Admission of violation
2. In accordance with Model Rules for Area Surveys in Appendix N of Regulatory Guide, Radiation Safety Officer failed to review and initial area survey records.
3. Corrective steps taken to comply with this regulation: Review of all survey records was done and each page signed and dated by the Radiation Safety Officer.
4. Corrective steps taken to ensure future compliance: Policy written stating each survey record must be reviewed and signed by the Radiation Safety Officer monthly (see attachment).
5. Full compliance achieved July, 1993.

Reply to a Notice of Violation (continued)

Violation B

1. Admission of violation
2. In accordance with 10 CFR 35.22 (b)(6), Radiation Safety Committee failed to review the Radiation Safety Program with the Radiation Safety Officer annually.
3. Corrective steps taken to comply with this regulation: Radiation Safety Program was reviewed by the Radiation Safety Officer and Dr. James Kereiakes, Ph.D., Radiation Physicist, on December 14, 1993 during the meeting of the RSC.
4. Corrective steps taken to ensure future compliance: Policy was written stating annual review of the Radiation Safety Program by the Radiation Safety Officer will take place each year in December. Review by the Radiation Safety Committee will take place during the first quarter after the review by the RSO. (see attachment).
5. Full compliance will be achieved in February, 1994.

Violation C

1. Admission of violation
2. In accordance with 10 CFR 35.20 (c), Radiation Safety Committee failed to review the ALARA program. Meeting minutes did not document review summaries of types and quantities of by-product material used or the continuing education and training for all personnel who work with or in vicinity of by-product material.
3. Corrective steps taken to comply with this regulation: The ALARA program was reviewed by the Radiation Safety Committee on April 27, 1993. Continuing education and training was given to the Nuclear Medicine technologists via General Electric Tip-TV programs (see attachment), videotapes (see attachment), and lectures (see attachment).

Reply to a Notice of Violation (continued)

Violation C (continued)

4. Corrective steps taken to ensure future compliance:  
We have subscribed to General Electric Tip-TV and will continue to subscribe to receive all Nuclear Medicine broadcasts and/or will make seminars readily available to Nuclear Medicine technologists for continuing education and training.

Radiation Safety Committee will begin in February, 1994, to review documentation of types and quantities of by-product materials used.

5. Full compliance achieved in February, 1994.

Violation D

1. Admission of violation
2. In accordance with 10 CFR 20.207 (a)(b), Nuclear Medicine Lab was not secured against unauthorized removal because door was unlocked and the area was not under constant surveillance and immediate control of the Nuclear Medicine technologist.
3. Corrective steps taken to comply with this regulation: The existing policy was reviewed and reinforced with the Nuclear Medicine technologists.
4. Corrective steps taken to ensure future compliance: The key to the Hot Lab was put on a wrist band to be kept with the Nuclear Medicine technologist at all times. Disciplinary action will be taken if procedure is not followed.
5. Full compliance achieved October, 1992.

Violation E

1. Admission of violation
2. In accordance with 10 CFR 35.70 (a), Nuclear Medicine technologists failed to survey with a radiation detection instrument at the end of the day those areas where radiopharmaceuticals were routinely prepared for use of administration, specifically, on at least four weekends.

Reply to a Notice of Violation (continued)

Violation E (continued)

3. Corrective steps taken to comply with this regulation: Review of policy concerning surveys was done clarifying this survey included weekend call-outs and holiday call-outs. Survey of all areas was commenced immediately when called out on weekends or holidays and at the end of each work day.
4. Corrective steps taken to ensure future compliance: This policy will be strictly enforced and disciplinary action will take place for any infractions.
5. Full compliance achieved January, 1993.

Violation F

1. Admission of violation
2. In accordance with 10 CFR 35.220, Nuclear Medicine department did not possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 mR/hour to 100 mR/hour. Nuclear Medicine department also did not possess a portable radiation survey instrument during two periods that occurred from January, 1991 to April, 1991 and from April, 1992 to June, 1992.
3. Corrective steps taken to comply with this regulation: Purchase of a Ludlum Model 3 survey instrument which measures the range of 0.1 mR/hour to 100 mR/hour.
4. Corrective steps taken to ensure future compliance: We will have in our possession a properly calibrated portable radiation survey instrument at all times. If the Ludlum Model 3 survey instrument is not available (in times of calibration off-site), a rental of like instrument will be made.
5. Full compliance achieved March, 1993.

Reply to a Notice of Violation (continued)

Violation G

1. Admission of violation
2. In accordance with 10 CFR 35.50 (e), Nuclear Medicine department failed to retain records of dose calibrator accuracy, linearity, and geometry that included the signature of the Radiation Safety Officer.
3. Corrective steps taken to comply with this regulation: Each pre-existing record of dose calibrator accuracy, linearity, and geometry was reviewed and signed by the Radiation Safety Officer.
4. Corrective steps taken to ensure future compliance: Policy was written stating that review and signature of the Radiation Safety Officer is required on all dose calibrator accuracy, linearity, and geometry records (see attachment).
5. Full compliance in March, 1993.

Violation H

1. Admission of violation
2. In accordance with 10 CFR 35.59 (d), records of leakage test results did not contain the signature of the Radiation Safety Officer.
3. Corrective steps taken to comply with this regulation: All pre-existing leakage test records were reviewed and signed by the Radiation Safety Officer.
4. Corrective steps taken to ensure future compliance: Policy written requiring the review and signature of the Radiation Safety Officer on all leak test records (see attachment).
5. Full compliance achieved March, 1993.



Reply to a Notice of Violation (continued)

Violation I

1. Admission of violation
2. In accordance with 10 CFR 35.59 (g), Records of quarterly physical inventories of the sealed sources failed to include the signature of the Radiation Safety Officer.
3. Corrective steps taken to comply with this regulation: Records of the quarterly physical inventories of the sealed sources were reviewed and signed by the Radiation Safety Officer.
4. Corrective steps taken to ensure future compliance: Policy was written requiring the signature of the Radiation Safety Officer on all quarterly physical inventories of sealed sources (see attachment).
5. Full compliance achieved March, 1993.

Violation J

1. Admission of violation
2. In accordance with 49 CFR 173.415 (a), Medical Center shipped material package marked DOT Specification 7A-Type A and did not maintain documentation of tests and an engineering evaluation or comparative data showing the package complied with applicable DOT specifications for a period of at least one year following that shipment.
3. Corrective steps taken to comply with this regulation: DOT Specification 7A-Type A Certificate of Compliance was obtained and will be kept for a period of at least one year.
4. Corrective steps taken to ensure future compliance: Policy stating there will be safe keeping of the record of Certificate of Compliance DOT Specification 7A -Type A for a period of at least one year (see attachment).
5. Full compliance achieved November, 1992.

LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

INSERVICE EDUCATION

DEPARTMENT: Nuclear Medicine  
TOPIC: Radiation Safety Inservice  
LECTURE: yes  
PLACE HELD: Hot Lab - Nuclear Medicine  
INSTRUCTOR: James Kereiakes, PhD

DATE: 6-14-93

ATTENDANCE:

Barbie Zornes, RT

Lisa Hairston, RT

SIGNATURE:

Barbie Zornes R.T.

Lisa Hairston

TOPICS DISCUSSED:

1. Personnel monitoring

A policy has been adapted that all personnel working in Nuclear Medicine will monitor themselves before leaving duty and will record results.

2. Constancy checks of dose calibrator

The Co57 source checks should be carried out two digits.  
Example: 0.91

3. Posting and surveying in EKG lab

The door to the EKG lab will be posted "Caution - Radioactive Material" during injection times and there will be daily surveys and weekly wipe tests performed in the EKG lab.

4. All radioactive material to be stored in one area

Discussed rearranging office area to include collimators and crane. Will move refrigerator where radioactive material is stored into the hot lab.

5. Air supplies

Discussed the importance of having adequate air supplies where ventilation studies are being performed and radioactive gases are stored.

6. Action levels of surveys

Discussed the action levels of all surveys performed. 1.5 mR/hr in restricted areas and 0.25 mR/hr in unrestricted areas.

LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

DATE: April 7, 1993

TITLE: Safety & Instruction Training in Nuclear Medicine Hot  
Lab for Ancillary Personnel

SPEAKER: BARBIE ZORNES, R.T.  
Administrative Director Radiology/Nuclear Medicine

PLACE: Nuclear Medicine Hot Lab - Second Floor

TYPE: Lecture/Demonstration

LENGTH: 30 minutes

TIMES PRESENTED: As necessary

MANDATORY: Yes

INSTRUCTION: Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

TOPICS COVERED:

1. Presence of a restricted area: what is it and where is it located?
2. Occurrence of radiation sources: what are the radiation sources and where are they located?
3. Precautions or procedures to minimize exposure: how can exposure be controlled or minimized in your duties?
4. Applicable regulations and license conditions.
5. Areas where radioactive material is used or stored.
6. Potential hazards associated with radioactive material in each area where the employees will work.
7. Licensee's in-house rules.
8. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
9. Appropriate response to emergencies or unsafe conditions.
10. Worker's right to be informed of occupational radiation exposure and bioassay results.

*B. R. Galambos*



Nuc Med 1

LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street    Ironton, OH    45638

DATE: 4-28-93

TITLE: Safety & Instruction Training in Nuclear Medicine Hot  
Lab for Ancillary Personnel

SPEAKER: Lisa D. Hairston, RT(R)

PLACE: Nuclear Medicine Hot Lab - Second Floor

TYPE: Lecture/Demonstration

LENGTH: 30 minutes

TIMES PRESENTED: As necessary

MANDATORY: Yes

INSTRUCTION: Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

TOPICS COVERED:

1. Presence of a restricted area: what is it and where is it located?
2. Occurrence of radiation sources: what are the radiation sources and where are they located?
3. Precautions or procedures to minimize exposure: how can exposure be controlled or minimized in your duties?
4. Applicable regulations and license conditions.
5. Areas where radioactive material is used or stored.
6. Potential hazards associated with radioactive material in each area where the employees will work.
7. Licensee's in-house rules.
8. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
9. Appropriate response to emergencies or unsafe conditions.
10. Worker's right to be informed of occupational radiation exposure and bioassay results.

LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

11. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.
12. Question and answer period.

EMPLOYEE NAME

DEPARTMENT

William Lewis

House Keeping

Ruby Dean

Housekeeping - Security

Aunt Nell

House Keeping

Suzie Rault

House Keeping

Virginia Pittman

House Keeping

Dorothy Davis

House Keeping

Betty Clark

House Keeping

Robert Leck

House Keeping

Keith Thompson

House Keeping

Jonda Kennedy (6-14-93) 62

House Keeping

LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

DOCUMENTATION

I have asked Mary Janet Medinger, RN, Education Coordinator, to please inform the Nuclear Medicine Department of any new employees hired in order for the employee to receive training for working in Nuclear Medicine areas.

I have also asked Gary Wilson, Supervisor, Housekeeping and Everett Reeves, Supervisor, Security to inform the Nuclear Medicine Department of any new employees hired in order for the employee to receive training for working in Nuclear Medicine areas.

Refresher training will be given annually for all ancillary department personnel working in Nuclear Medicine areas.

  
\_\_\_\_\_  
Acting Radiology Manager

6-14-93  
\_\_\_\_\_  
Date

# SIEMENS

APR 01, 1993

CUSTOMER NUMBER 47505

LAWRENCE CO GENERAL  
HOSPITAL  
X-RAY DEPT  
2212 SOUTH 9TH ST  
INDIANAPOLIS OH 45638

LAWRENCE CO GENERAL  
HOSPITAL  
2212 SOUTH 9TH ST  
INDIANAPOLIS OH 45638

## RADIATION EXPOSURE RECORD CHANGES MAR 1993

THIS REPORT LISTS CHANGES TO YOUR RADIATION EXPOSURE RECORDS.  
YOU SHOULD KEEP THIS REPORT FOR FUTURE REFERENCE.

WEARER NUMBER	EXPOSURE TYPE	PENETRATING	NON-PEN	NEUTRON	EXPOSURE PERIOD CHANGED	DATE OF CHANGE
012	11	+0.030	+0.000	+0.000	1ST QTR 1992	03/02/93
073	11	+0.030		+0.000	1ST QTR 1992	03/02/93

*Bo R. Galbraith*

*Bo R. Galbraith*  
*APR 1993*

Siemens Gammasonics, Inc.

Health Physics Services • 2801 Barrington Road • Hoffman Estates, IL 60195-7372 • Telephone (800) 888-1936



LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

POLICY: Radiation Safety  
EFFECTIVE: March, 1993  
REVIEWED:  
REVISED:

PERSONNEL RADIATION MONITORING

1. A film badge will be furnished by the Medical Center to all persons working in areas where ionizing radiation is in use, in accordance with the judgment of the Radiation Safety Officer.
2. An individual's film badge will be processed immediately when it is suspected that he/she might have received a single exposure greater than 100 mRem or an accumulated exposure greater than 300 mRem in one week.
3. A record of the individual's radiation exposure status will be kept by the Radiation Safety Officer. These records will comply with 10CFR 19 and 20 and the State Radiation Protection Code. The personnel exposure readings will be posted monthly in the Radiology Department. Yearly totals of an individual's exposure are available from the Radiation Safety Officer.
4. At no time will a film badge be exposed to radiation unless worn by the individual to whom it is issued. Any infraction of this rule may result in the loss of that person's privilege to work with radioactive material and/or ionizing radiation at the Medical Center.
5. Collection and distribution of the film badges for routine processing will be the responsibility of the Radiation Safety Officer, however, it is the responsibility of the authorized user, physician, or department manager to insure the cooperation of personnel under his/her supervision.
6. At the discretion of the Radiation Safety Officer, a finger TLD badge will be assigned in addition to whole body film badges by persons preparing radioisotopes or injecting radioisotopes for imaging or therapeutic purposes.
7. Pregnant workers are urged to declare their pregnancy to the Radiation Safety Officer so that a separate waist-level badge can be provided to estimate the fetal exposure.


LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

Personnel Radiation Monitoring - continued

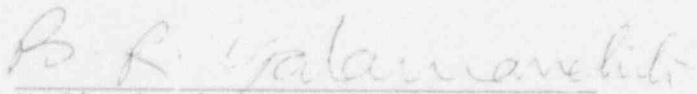
8. The estimate of radiation exposure made from the monitoring devices will only be correct if these rules regarding the wearing of the badges are observed.
  - a. The film badge shall be worn at all times while working at the Medical Center.
  - b. Wear the badge at collar level outside the lead apron. Pregnant workers should request an additional badge to be worn at waist level inside any lead aprons.
  - c. Leave the film badge in a safe place in your work area when not on duty. Do not take it out of the Medical Center.
  - d. Never wear a film badge issued to another person.
  - e. The film badge issued to you is your responsibility. Turn it in at the right time in exchange for a like one and take care of it.
  - f. Do not tamper with the film badge (by removing the film, for example).
  - g. Report loss of badge immediately to your supervisor or the Radiation Safety Officer.
  - h. Report any other incident relative to the wearing of the film badge (such as possible accidental exposure when badge is not worn) to your supervisor or the Radiation Safety Officer.
  - i. The Medical Center's film badge is not to be worn while on duty at another facility. The badge is the property of the Medical Center and meant to indicate the efficiency of this Medical Center's radiation safety program.
  - j. It is the responsibility of the supervisory personnel to see that the above rules are observed and to report radiation protection problems to the Radiation Safety Officer.

Personnel Radiation Monitoring - continued

- k. Flagrant violations of this policy may result in reprimand, suspension, or termination.

  
\_\_\_\_\_  
Acting Radiology Manager

8-26-93  
Date

  
\_\_\_\_\_  
Medical Director Radiology *RSO*

8-26-93  
Date

LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

POLICY: Radiation Safety  
EFFECTIVE: March, 1993  
REVIEWED: 1994  
REVISED: 1994

PERSONNEL RADIATION MONITORING

1. A film badge will be furnished by the Medical Center to all persons working in areas where ionizing radiation is in use, in accordance with the judgment of the Radiation Safety Officer.
2. An individual's film badge will be processed immediately when it is suspected that he/she might have received a single exposure greater than 100 mRem or an accumulated exposure greater than 300 mRem in one week.
3. A record of the individual's radiation exposure status will be kept by the Radiation Safety Officer. These records will comply with 10 CFR 19 and 20 and the State Radiation Protection Code. The personnel exposure readings will be posted monthly in the Radiology Department and Surgery Department where each employee is required check their exposure, sign and date the accompanying sheet. Yearly totals of an individual's exposure are available from the Radiation Safety Officer.
4. At no time will a film badge be exposed to radiation unless worn by the individual to whom it is issued. Any infraction of this rule may result in the loss of that person's privilege to work with radioactive material and/or ionizing radiation at the Medical Center.
5. Collection and distribution of the film badges for routine processing will be the responsibility of the Radiation Safety Officer, however, it is the responsibility of the authorized user, physician, or department manager to insure the cooperation of personnel under his/her supervision.
6. At the discretion of the Radiation Safety Officer, a finger TLD badge will be assigned in addition to whole body film badges by persons preparing radioisotopes or injecting radioisotopes for imaging or therapeutic purposes.
7. Pregnant workers are urged to declare their pregnancy to the Radiation Safety Officer so that a separate waist-level badge can be provided to estimate the fetal exposure.

Personnel Radiation Monitoring - continued

8. The estimate of radiation exposure made from the monitoring devices will only be correct if these rules regarding the wearing of the badges are observed.
  - a. The film badge shall be worn at all times while working at the Medical Center.
  - b. Wear the badge at collar level outside the lead apron. Pregnant workers should request an additional badge to be worn at waist level inside any lead aprons.
  - c. Leave the film badge in your locker when not on duty. DO NOT take it out of the Medical Center.
  - d. Never wear a film badge issued to another person.
  - e. The film badge issued to you is your responsibility. Turn it in at the right time in exchange for a like one and take care of it.
  - f. Do not tamper with the film badge (by removing the film, for example).
  - g. Report loss of badge immediately to your supervisor or the Radiation Safety Officer.
  - h. Report any other incident relative to the wearing of the film badge (such as possible accidental exposure when badge is not worn) to your supervisor or the Radiation Safety Officer.
  - i. The Medical Center's film badge is not to be worn while on duty at another facility. The badge is the property of the Medical Center and meant to indicate the efficiency of this Medical Center's radiation safety program.
  - j. It is the responsibility of the supervisory personnel to see that the above rules are observed and to report radiation protection problems to the Radiation Safety Officer.

Personnel Radiation Monitoring - continued

- k. Flagrant violations of this policy may result in reprimand, suspension, or termination.

Katherine Fuller, R.T.  
Radiology Manager

2/16/94  
Date

B.R. Galambos, M.D.  
Medical Director Radiology

2-16-94  
Date

Area Surveys

Procedure:

**Ambient Dose Rate Surveys**

1. Survey Areas

- a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
- b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.
- c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.
- d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.

2. Immediately notify the Radiation Safety Officer if you find unexpectedly high or low levels.

**Removable Contamination Surveys**

1. Survey areas

- a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
- b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.
- c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

Area Surveys - continued

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm<sup>2</sup> of removable contamination (200 dpm/100 cm<sup>2</sup> for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.
3. Immediately notify the Radiation Safety Officer if you find unexpectedly high levels.

Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:
  - a. The date, area surveyed, and equipment used.
  - b. The name or initials of the person who made the survey.
  - c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the Radiation Safety Officer.
  - d. Measured dose rates in mR/hr or contamination levels in dpm/100 cm<sup>2</sup>, as appropriate.
  - e. Actions taken in the case of excessive dose rates or contamination and follow-up survey information.
2. The Radiation Safety Officer will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

*R. Kirk JW*  
Radiology Manager (acting)

7-1-93  
Date

*B. R. Yodanis*  
Medical Director Radiology

7.1.93  
Date



LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

DOCUMENTATION

The Radiation Safety Program was reviewed by B. R. Yalamanchili, M.D., Radiation Safety Officer along with James Kereiakes, Ph.D., during the December meeting of the Radiation Safety Committee.

Copies of the Radiation Safety Program will be made and distributed to each member of the Radiation Safety Committee for review during the first quarter of 1994.

B. R. Yalamanchili  
Radiation Safety Officer

12-15-93  
Date

LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

Review of Radiation Safety Program

Policy:

1. Annual review of the Radiation Safety Program by the Radiation Safety Officer in December of each year.
2. Annual review of the Radiation Safety Program by the Radiation Safety Committee will take place in the first quarter following review by the Radiation Safety Officer.

\_\_\_\_\_   
Radiology Manager

12/10/73  
\_\_\_\_\_   
Date

\_\_\_\_\_   
Medical Director Radiology

12/10/73  
\_\_\_\_\_   
Date

Training in Partnership  
**CERTIFICATE OF ATTENDANCE**

presented to

LISA HAIRSTON

for participation in

**Quality Control**

by

**GE Medical Systems TIP-TV Network**

*Glan A. Costello*

Program Development Specialist

*Mary J. Medinger RN*

Broadcast Coordinator

.16

CEU Credits

*June 15, 1993*

Date



GE Medical Systems

Training in Partnership  
**CERTIFICATE OF ATTENDANCE**

presented to

BARBIE ZORNES

for participation in

**Quality Control**

by

**GE Medical Systems TIP-TV Network**

*Glan A. Costello*

Program Development Specialist

*Mary J. Medinger RN*

Broadcast Coordinator

.16

CEU Credits

*June 15, 1993*

Date



GE Medical Systems

Training in Partnership  
**CERTIFICATE OF ATTENDANCE**

presented to

BARBIE ZORNES

for participation in

**Nuclear Neurology**

by

**GE Medical Systems TIP-TV Network**

*Jean A. Costello*

Program Development Specialist

*Mary J. Medinger, PhD*

Broadcast Coordinator

.16

CEU Credits

*August 18, 1993*

Date



GE Medical Systems

Training in Partnership  
**CERTIFICATE OF ATTENDANCE**

presented to

LISA HAIRSTON

for participation in

**Nuclear Neurology**

by

**GE Medical Systems TIP-TV Network**

*Jean A. Costello*

Program Development Specialist

*Mary J. Medina, PhD*

Broadcast Coordinator

.16

CEU Credits

*August 18, 1993*

Date



GE Medical Systems

Training in Partnership  
**CERTIFICATE OF ATTENDANCE**

presented to

BARBIE ZORNES

for participation in

**Protocol Building**

by

**GE Medical Systems TIP-TV Network**

*Jan A. Costello*  
Program Development Specialist

*May J. M... ..*  
Broadcast Coordinator

.16  
CEU Credits

10-27-93  
Date



GE Medical Systems

Training in Partnership

**CERTIFICATE OF ATTENDANCE**

presented to

LISA HAIRSTON

for participation in

**Protocol Building**

by

**GE Medical Systems TIP-TV Network**

*Jean A. Costello*

Program Development Specialist

*May J. Medinger RN*

Broadcast Coordinator

.16

CEU Credits

10-27-93

Date



GE Medical Systems



LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

CONTINUING EDUCATION

DEPARTMENT: Nuclear Medicine DATE: 4/27/93

TOPIC: Quality Assurance Instrumentation

FILM: ✓ (series) VIDEO: \_\_\_\_\_ AUDIO: \_\_\_\_\_ LECTURE: \_\_\_\_\_

PLACE HELD: Rm # 101 INSTRUCTOR: L. Stephen Graham, Ph. D.

ATTENDANCE:

Employee Signature	Date
<u>Barbie James</u>	<u>4-28-93</u>
<u>David Houston</u>	<u>4-28-93</u>
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[Signature]  
SUPERVISOR'S SIGNATURE

CONTINUING EDUCATION

DEPARTMENT: Nuclear Medicine DATE: 5-25-93

TOPIC: Radionuclide evaluation of Cardiac Function

FILM: \_\_\_\_\_ VIDEO:  AUDIO: \_\_\_\_\_ LECTURE: \_\_\_\_\_

PLACE HELD: Rm # 101 INSTRUCTOR: Robert Bonow, M.D.  
Elias Botwinick, MD

ATTENDANCE:

Employee Signature	Date
<u>Basil Zornas R.T.</u>	<u>5-25-93</u>
<u>David Hairston R.T.</u>	<u>5-26-93</u>
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[Signature]  
SUPERVISOR'S SIGNATURE

LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

CONTINUING EDUCATION

DEPARTMENT: Nuclear Medicine DATE: 7-16-93

TOPIC: Radiation Protection

FILM:      VIDEO:  AUDIO:      LECTURE:     

PLACE HELD: Nuc. Med INSTRUCTOR: Dr. Kerecikes Ph.D.

ATTENDANCE:

Employee Signature	Date
<u>Don S. Hamilton RT(R)</u>	<u>7-16-93</u>
<u>Barbie Jones RT (R)</u>	<u>Sept. 8, 1993</u>
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Steve Fuller RT 9-8-93  
SUPERVISOR'S SIGNATURE

LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

CONTINUING EDUCATION

DEPARTMENT: Nuclear Medicine DATE: 2-16-93

TOPIC: Aerosol Ventilation Studies

FILM:      VIDEO:      AUDIO:      LECTURE:

PLACE HELD: K. D. M.C. Nuc. Med. INSTRUCTOR:     

ATTENDANCE:

Employee Signature	Date
<u>Barbie James R.T.</u>	<u>2-16-93</u>
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[Signature]  
SUPERVISOR'S SIGNATURE

LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

Locking of Nuclear Medicine Hot Lab

POLICY:

The Nuclear Medicine Hot Lab will be kept locked at all times. During the times when the lab is unlocked, it must be under constant surveillance and in the immediate control of the Nuclear Medicine technologist.

Any infraction in this policy will necessitate disciplinary action.

R. K. ...  
Radiology Manager (acting)

3-23-93  
Date

B. R. ...  
Medical Director Radiology

3-23-93  
Date

Calibrating Dose Calibrator

Procedure:

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. (These recommended tolerances are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.)
  - a. Constancy at least once each day prior to assay of patient dosages (+/- 5 percent).
  - b. Linearity at installation and at least quarterly thereafter (+/- 5 percent).
  - c. Geometry dependence at installation (+/- 5 percent).
  - d. Accuracy at installation and at least annually thereafter (+/- 5 percent).
2. After repair, adjustment, or relocation of the dose calibrator, repeat the above tests as appropriate.
3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Co-57\*, or Ra-226\* using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:
  - a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
  - b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.
  - c. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
  - d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.

Calibrating Dose Calibrator - continued

- e. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technologist or authorized user of suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The regulation requires repair or replacement if the error exceeds 10 percent.
- \* Co-57 and Ra-226 are not subject to NRC licensing; the appropriate State agency should be consulted to determine its requirements for possessing this material.
4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.
5. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

Decay Method

- a. Assay the Tc99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the Dose Calibrator Linearity Test Form. This first assay should be done in the morning at a regular time, for example, 8 a.m.
- b. Repeat the assay at 6, 24, 30, 48, 54, 72, and 78 hours. Continue on subsequent days until the assayed activity is less than 10 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.
- c. Convert the time and date information you recorded to hours elapsed since the first assay.

Calibrating Dose Calibrator - continued

- d. On a sheet of semilog graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.
- e. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line ( $A - \text{observed} - A - \text{line}$ ) / ( $A - \text{line}$ ) = deviation.
- f. If the worst deviation is more than  $\pm 0.05$ , the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity".
- g. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate them.

- a. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps b through d below must be completed within 6 minutes.
- b. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
- c. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
- d. Continue for all sleeves.
- e. Complete the decay method linearity test steps b through g above.
- f. From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step b.



Calibrating Dose Calibrator - continued

- g. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step c.
- h. Continue for all sleeves.
- i. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

- a. Assay the Tc99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.
- b. Steps c through e below must be completed within 6 minutes.
- c. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
- d. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
- e. Continue for all sleeves.
- f. On a sheet of semilog graph paper, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.
- g. Plot the data using the equivalent decay time associated with each sleeve.
- h. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.  
$$(A - \text{observed} - A - \text{line}) / A - \text{line} = \text{deviation.}$$
- i. If the worst deviation is more than +/- 0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."
- j. Put a sticker on the dose calibrator that says when the next linearity test is due.

Calibrating Dose Calibrator - continued

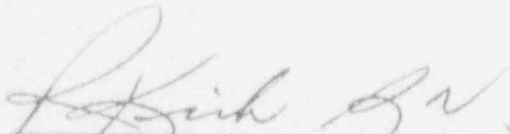
6. Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.
  - a. In a small beaker or vial, mix 2 cc of a solution of Tc99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.
  - b. Draw 0.5 cc of the Tc99m solution into the syringe and assay it. Record the volume and millicuries indicated on the Dose Calibrator Geometry and Accuracy Form.
  - c. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
  - d. Repeat the process until you have assayed a 2.0 cc volume.
  - e. Select as a standard the volume closest to that normally used for injections. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume".
  - f. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.
  - g. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

Calibrating Dose Calibrator - continued

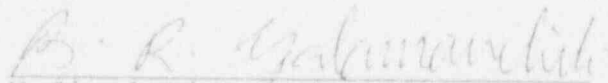
- h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
  - i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.
  - j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."
  - k. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity". If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.
7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) should be used. The regulations require that one must have a principal photon energy between 100 keV and 50 keV. The regulations also require that, if a Ra-226 source is used, it must be at least 10 microcuries; other sources must be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.
- a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source activity and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement on the Dose Calibrator Geometry and Accuracy Form. Repeat for a total of three determinations.

Calibrating Dose Calibrator - continued

- b. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference source, mathematically corrected for decay.
- c. Repeat the procedure for other calibrated reference sources.
- d. If the average value does not agree, within 5 percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.
- e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.
- f. Put a sticker on the dose calibrator that says when the next accuracy test is due.
8. The Radiation Safety Officer will review and sign the records of all geometry, linearity, and accuracy tests.

  
Radiology Manager (acting)

3-23-93  
Date

  
Medical Director Radiology

3-23-93  
Date

Leak-Testing Sealed Sources

Procedure:

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

- b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
- c. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care to touch neither field light and mirror nor crosshairs. Also wipe the primary and secondary collimators and trimmers.
- d. If you are testing radium sources at the same time you are testing NRC-licensed sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.

LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

Leak-Testing Sealed Sources - continued

4. The samples will be analyzed as follows:

- a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
- b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.
- c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
- d. Record the wipe sample counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
- e. Continue the same analysis procedure for all wipe samples.
- f. If the wipe sample activity is 0.005 microcurie or greater, notify the Radiation Safety Officer. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the NRC must be notified. (See paragraph 21.21(b) of 10 CFR Part 21 and paragraph 35.59(e)(2) of 10 CFR Part 35.)
- g. Sign and date the list of sources, data, and calculations.
- h. Radiation Safety Officer will review and sign records.

*R. Kirk RN*  
Radiology Manager (acting)  
*W. B. [unclear]*  
Medical Director Radiology

*3-23-93*  
Date

*3.23.93*  
Date

LAWRENCE COUNTY MEDICAL CENTER  
2228 South Ninth Street Ironton, OH 45638

Quarterly Physical Inventories of Sealed Sources

POLICY:

The Radiation Safety Officer will review and sign all quarterly physical inventories of sealed sources.

  
\_\_\_\_\_  
Radiology Manager (acting)

3-23-93  
Date

  
\_\_\_\_\_  
Medical Director Radiology

3.23.93  
Date

MALLINCKRODT DIAGNOSTICS  
MALLINCKRODT, INC.

Certificate of Compliance For Radioactive Materials Packages  
C.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 recommendation 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 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 requirements 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: A. Bruchdunig

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

Eluant: 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 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: Mark 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 be safety tested and approved prior to use.

Approved: [Signature]

Title : Chairman, Packaging Committee  
Diagnostic Products Group

Date : 8/15/85