

30 June 1981

Mr. Glen D. Brown, Chief
Technical Inspection Branch
Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Dear Mr. Brown:

Ref: Docket No. 70-14553
License 43-01884-20

1. License Condition 12 requires that licensed material be used by or under the direct supervision of certain specified individuals.

In addition to the notification of all users of irradiators regarding limiting use of these units to specified individuals, we have had direct contact with the operators and have rechecked the safety provisions of the units and have also revised procedures regarding safety and limitations of use and written these into the Radiological Safety Manual. These specify that only authorized personnel may use or supervise the use of radioactive materials contained in the irradiators. These revised procedures will be posted near or on the irradiators to serve as both notification and radiation safety procedures.

We have applied for an amendment to our licenses to add additional users based on determination of qualifications by the Radiological Health Committee of the University of Utah. This is designed to reduce the time required for adding authorized individuals by license amendment application for each change. We are not allowing personnel not named on the licenses to use radioactive materials until our licenses have been amended by the Nuclear Regulatory Commission.

2. Item 10 of the application dated 10 May 1978 lists the portable survey instruments to be used for surveys of the irradiator.

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We have notified the operators of the need for survey instruments to be readily available at the irradiator sites and have supplied a calibrated survey instrument (Eberline E-510) to Dr. Joseph Roti Roti until his newly ordered instrument can be delivered.

We have completed all the corrective actions noted above as of 25 June 1981. Further corrective action to increase radiation safety with this unit has been taken as follows:

1. We have requested that an added 1/2" of lead be applied to an area on this irradiator where a leakage of approximately 12 mR exists.
2. We have directed that personnel stand clear of the unit during operation and are recommending that the unit be repaired by the manufacturer to correct failure of the unit to respond to the control rod without undue effort on the part of the operator.

Ref: Docket No. 30-10707
License 43-01884-17MD

1. 10 CFR 71.5 requires that shipments of licensed materials be made in compliance with applicable regulations of the Department of Transportation.
 - (a) To correct this part of the violation, the Radiopharmacy has obtained new certified shipping containers on the front of which appear the words "Caution Radioactive Materials Type A" and/or "Type B" as appropriate. The inscription is written on the container in letters 1/2 or more inches high.
 - (b) In response to requirements given in 49 CFR 173.395(a)(1), a certification and supporting safety analysis has been obtained from the supplier and the adequacy of the material has been checked by the Department of Transportation, and a letter specifying that the construction methods, packing design and materials of construction meet D.O.T. requirements for this unit. Such records will be maintained for the new containers and the corrugated packages used for Type A shipments hereafter.

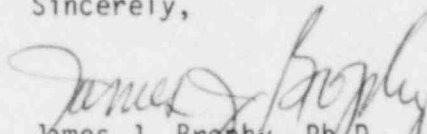
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2. 49 CFR 173.393(n)(6) requires that each closure valve and any other opening of the containment system through which the radioactive content might escape is properly closed and sealed.

To preclude a repetition of the shipment for which this violation was received, that is, shipping a ⁹⁹Tc generator which was not properly closed and sealed, a checklist has been written up which will make sure that each shipper follows step by step the procedures needed for assuring proper safety of the material.

Full compliance in all these corrective actions was achieved as of 26 June 1981. Close surveillance of this laboratory will be maintained by the Radiological Health Department to assure adherence to all applicable regulations.

Sincerely,


James J. Brophy, Ph.D.
Vice President for Research

JJB/dh

Enclosures (3)

"I certify that all information contained in this letter, including any supplements attached thereto, is true and correct to the best of my knowledge and belief."

2 July 1981
Date

Ronald Puz
Signature

Assoc. Vice Pres. for Research
Title

NOTARY:

Subscribed and sworn to before me on the date of 2 July 1981

Theresa M. Minnis
Notary Public

5. Research Irradiator (6,000 Curies Cesium-137, Shepard Mark 1, Model 25)

This unit is housed in Room BC-104 of the Medical Center and occupies the same room with a 200 KVP X-ray machine. All radiation safety procedures relative to high energy X-ray machines and irradiators must be observed.

A. Access: (This unit is under NRC License No. 43-01884-20 and cannot be used except under direct supervision of a licensed individual.)

1. Room BC-104 must be locked when unattended.
2. Key control: Keys must be controlled by a log system.
3. The keys will be kept in the Principal Investigator's office.
4. The log record must include the name of the authorized user, the time the key is checked out, the time of operation of the machine, and the time when the keys were logged back in.

B. Personnel Monitoring

All personnel entering this room or working with the irradiator must wear TLD badges.

C. Warning System

Check the condition of the console of the X-ray machine before attempting to enter, and check to be sure that the irradiator door is closed at the time you enter the room. Keep the door to the X-ray unit open while using the irradiator to preclude X-ray use.

D. Special Procedures

1. Check the radiation level in the room with a beta-gamma survey meter before entering the X-ray-irradiator room.
2. Levels above 1 mR/hr. at the door contraindicate entrance. Call the Radiological Health Department at x6141.

E. Work Procedures

1. Be sure you follow the standard operation for this machine as posted on the machine.
2. Always stand behind the yellow line on the floor and limit the time you must be in the room.
3. Keep hands free of the surface when opening and closing the unit to the extent possible.
4. Every operator must read and follow the procedures as given in this manual.

Section 3, Part 9

F. Potential Hazard

This unit has a potential hazard during use. If the rotating door does not close completely, a radiation beam can emerge at the point where the door and the upper housing intersect. It is possible that this unit can fail to close completely, allowing a beam of gamma rays to come out the front for a considerable period of time. Careful checks with a beta-gamma survey meter must be made to assure proper functioning of the unit.

G. Leak Tests

Leak tests will be done on a quarterly basis by the Radiological Health Department and will follow the procedures outlined in this manual.

H. Safety Checks

Because this unit can fail, it is essential that safety checks be performed to determine whether or not high level radiation beams are being released from the front of the unit.

I. Special Considerations

1. Careful checks of the radiation dose from this machine both in the room where it is housed and in the room behind it must be carried out with instrumental surveys and with control TLD badges. These must be made on a monthly basis and records kept.
2. This unit is deficient in shielding, and has one location accessible to personnel that reads between 10 and 13 mR/hr. It is essential that any work done on this machine be done by qualified experts, and no repairs should be attempted by the operators.

APPENDIX B

PROCEDURE FOR SHIPPING UNION CARBIDE GENERATORS:

1. Prior to shipping, elute the generator.
2. Rotate fluid path shut off valve clockwise until it is tight. Valve is located on left side of generator.
3. Lift hinged cover exposing the dispenser end. Remove needle. Remove protective cap from accompanying envelope and attach to the dispenser end of the generator.
4. Place generator in shipping carton making sure that the generator is secure and will not be disturbed during shipping.
5. Include any elution vials that may be shipped with generator, and the prescription form.
6. Place protective styrofoam over generator and seal carton shut tightly.
7. Take a reading at three feet for transport index and also check surface reading of carton for unusually high reading.
8. Prepare and attach shippers certificates for radioactive materials.
9. Affix radioactive yellow-III label to two opposite sides of the carton and fill in the necessary information.
10. Attach address and return address label to carton. Package is ready for shipping.

ENTRY NUMBER	49. C.F.R. SECTION NUMBER	NUMBER DISCOVERED	NUMBER CHECKED	NO. DRIVERS/VEHICLES IN VIOLATION
11	1.	2.	3.	4.

No violations discovered.

ENTRY NUMBER	49. C.F.R. SECTION NUMBER	NUMBER DISCOVERED	NUMBER CHECKED	NO. DRIVERS/VEHICLES IN VIOLATION
11	1.	2.	3.	4.

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11	1.	2.	3.	4.

DATE(S) OF SURVEY:
 7, 11, 12, 1961

REPORTED BY:
George ...

COPY RECEIVED BY:
William ...

FEDERAL HIGHWAY ADMINISTRATION BUREAU OF MOTOR CARRIER SAFETY SAFETY COMPLIANCE REPORT		PRINCIPAL OFFICE ADDRESS FACILITY	5
1) NEW RECORD 2) UPDATE		NAME OF CARRIER/SHIPPER	
PRINCIPAL OFFICE STREET ADDRESS, CITY, STATE, AND ZIP CODE			
17) "OTHER FACILITY" SURVEY, ENTER CITY, STATE, ZIP, AND TELEPHONE NUMBER OF FACILITY			13) DATE SURVEY COMPLETED
6	7	8	9 AC NO
(CITY)	(STATE)	(ZIP)	(TELEPHONE NUMBER)

Violations of Title 49 C.F.R., parts 390 to 399, The Federal Motor Carrier Safety Regulations, may subject the offender to the criminal penalties provided by 49 U.S.C. 322(a) or 49 U.S.C. 11914(b), which provides for a fine of not less than \$100 nor more than \$500 for the first offense and a higher fine for subsequent offenses, or the assessment of civil penalties of up to \$500 for each offense and \$250 for each additional day such offense shall continue under the provisions of 49 U.S.C. 322(h) or 49 U.S.C. 11901(g).

Violations of Title 49 C.F.R., parts 100 to 179, The Federal Hazardous Materials Regulations, may subject motor carriers and/or shippers of hazardous materials to the penalty provisions of 49 U.S.C. 1809, which provides for the assessment of civil penalties of not more than \$10,000 for each violation, or criminal penalties of not more than \$25,000 or imprisonment for not more than five years, or both.

Violations of Title 49 C.F.R. 325, The Interstate Motor Carrier Noise Emission Standards, may subject motor carriers to the penalty provisions of the Noise Control Act of 1972, 42 U.S.C. 4910, which provides for a fine of not more than \$25,000 per day, imprisonment for one year, or both, in the case of first offenders, and a fine of \$50,000 per day, imprisonment for two years, or both, in the case of subsequent offenders.

Failure to comply with Department of Transportation regulations by motor carriers operating under a certificate or permit issued by the Interstate Commerce Commission may result in a report that a motor carrier is not in satisfactory compliance with DOT regulatory requirements, and may result in the initiation of, or participation in, proceedings before the Interstate Commerce Commission by the Department of Transportation.

PERSONS INTERVIEWED DURING THIS SURVEY

NAME <u>William Parker</u>	TITLE <u>Director of Compliance</u>
NAME <u>Robert [unclear]</u>	TITLE <u>[unclear]</u>
NAME _____	TITLE _____
NAME _____	TITLE _____
NAME _____	TITLE _____

RECOMMENDATIONS TO IMPROVE SAFETY COMPLIANCE

We are shipping packages of liquid radioactive substances in extra packages, marked "this side up" in the "End up" (49 CFR 172.312b).

Shipper is essentially in compliance with the Hazardous Materials regulations.

REPORTED BY: Charles [unclear] TITLE City Inspector DATE(S) OF SURVEY: 11/14/74

RECEIPT FOR COPY OF REPORT

THIS IS TO ACKNOWLEDGE THAT A COPY OF THIS PART, TOGETHER WITH 1 PAGE(S) OF THE CONTINUATION SHEET, VIOLATIONS AND EXAMPLES, HAVE BEEN FURNISHED TO ME ON THE DATE APPEARING BELOW. IT IS UNDERSTOOD THAT MY SIGNATURE CONSTITUTES ONLY AN ACKNOWLEDGEMENT OF RECEIPT OF A COPY OF THIS REPORT.

RECEIVED BY: William Parker TITLE Director DATE COPY RECEIVED: 11/14/74