



U. S. Department of Justice

Civil Division

SES:DMC:BMSIMKIN:jyd
DJ No. 154-01-434

Telephone: (202) 305-7562

Washington, D.C. 20530

August 23, 2001

Ms. Karen D. Cyr
General Counsel
Nuclear Regulatory Commission
11555 Rockville Pike
Mail Stop 015D21
Rockville, MD 20852

Re: Massachusetts General Hospital v. United States
Federal Claims No. 01-434C

Dear Ms. Cyr:

Enclosed is a copy of the complaint filed in this case. Pursuant to 28 U.S.C. § 520, we request that you provide us with a litigation report as soon as possible. Your report should include information as to any set-off or counterclaim which may be available. Our response to the complaint is due 60 days from the date the complaint was filed. If you will not be able to provide us with a litigation report by a week prior to the date our response is due, please notify us as soon as this becomes apparent so that we may prepare an appropriate motion for an enlargement of time.

In addition, please advise this office as soon as possible of the name and telephone number of the attorney in your office responsible for drafting the required report. In our office, this case is assigned to Assistant Director Brian M. Simkin, who may be reached at (202) 305-7562.

Thank you with your assistance with this case.

Sincerely,

Stuart E. Schiffer
Acting Assistant Attorney General
Civil Division

By:

David M. Cohen / sgt

DAVID M. COHEN
Director

Commercial Litigation Branch

Enclosure

Template 060 002

ERIDS 0600



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 22, 2000

CHIEF FINANCIAL
OFFICER

Electric Power Research Institute
Attn: Dr. Robin L. Jones
Vice President, Science & Technology Division
and Chief Nuclear Officer
3412 Hillview Avenue
Palo Alto, CA 94304-1395

Dear Dr. Jones:

I am responding to your December 20, 1999, letter requesting that the Nuclear Regulatory Commission (NRC) reconsider its decision to deny the Electric Power Research Institute's (EPRI) April 22, 1999, request for a waiver of the 10 CFR Part 170 fees for the review of EPRI's reactor safety analysis code, RETRAN-3D. In my August 27, 1999, letter, I informed you that your fee waiver request was denied because it did not meet the waiver requirement in Footnote 4 to 10 CFR 170.21. Your letter provides additional information that you believe shows that RETRAN-3D review meets the NRC fee waiver requirements.

The bases for your appeal are: (1) your assessment of likely future use is that the RETRAN-3D code will be used in a substantial way by EPRI, EPRI contractors, and others to address generic issues and support regulatory reform activities, including efforts toward risk-informed regulation; and (2) in your opinion, the requirement for the fee waiver does not stipulate that NRC must request the information. In addition, in an August 16, 2000, letter to Ashok Thadani, Director, Office of Nuclear Regulatory Research, you committed to perform analysis in support of risk-informing the 10 CFR Part 50 technical requirements under the Option 3 study and referenced your fee exemption request. That analysis would be applicable to planned efforts to risk-inform requirements associated with the PWR rod ejection accident.

In conjunction with the Offices of Nuclear Reactor Regulation (NRR) and Regulatory Research (RES), we have carefully reviewed the additional information you submitted. As explained below, we have determined that the additional information does not support a waiver of the fee for NRC's review of the RETRAN-3D computer code.

Footnote 4 to 10 CFR Part 170.21 states that:

Fees will not be assessed for requests/reports submitted to the NRC: ... (2.) In response to an NRC request (at the Associate Office Director level or above) to resolve an identified safety, safeguards, or environmental issues, or to assist NRC in developing a rule, regulatory guide, policy statement, generic letter or bulletin, or (3.) As a means of exchanging information between industry organizations and the NRC for the purpose of supporting generic regulatory improvements or efforts.

As indicated by the above, the waiver criteria relate to the purpose for which the report is submitted and reviewed, not to the eventual use of the topical report. This is supported by the history associated with the development of the waiver provision. In the FY 1994 proposed fee rule (May 10, 1974; 59 FR 24067), the NRC solicited public comment on its proposal to waive the Part 170 review fees for certain requests or reports submitted to the NRC. In the statement of considerations for the proposed rule, the NRC stated:

These reports, although submitted by a specific organization, support NRC's development of generic guidance and regulations (e.g., rules, regulations, guides and policy statements), and resolution of safety issues applicable to a class of licensee such as those addressed in generic letters.

After evaluating the public comments received on the proposed rule, in the final FY 1994 fee rule the NRC revised Part 170 to include the provision that review fees will not be assessed for certain requests/reports (June 20, 1994; 59 FR 36895). The statement of considerations for the final rule reiterated that the NRC believes that the costs for review of such requests/reports are more appropriately recovered through Part 171 fees because they support NRC's generic regulatory improvements or efforts. For your convenience, copies of the proposed and final FY 1994 fee rules are enclosed.

The RETRAN-3D reactor safety analysis code was not submitted to the NRC or reviewed by the NRC as a means of exchanging information between EPRI and the NRC for the purpose of supporting generic regulatory improvement or efforts. Nor was the RETRAN-3D code submitted or reviewed in response to an NRC request to develop a regulatory document or resolve an issue. EPRI requested that NRC review and approve the code, presumably so that the code could be used in the future. Use of the code by EPRI or other organizations to support their positions in the resolution of generic issues is not a basis to waive the 10 CFR Part 170 fee for review and approval of the code. We appreciate your offer to use the code to perform analysis in support of risk-informing the 10 CFR Part 50 technical requirements. However, that effort is not a basis to grant a fee waiver for the review of the RETRAN-3D computer code, since it occurred after the code was reviewed and does not affect the purpose for which the code was submitted and reviewed. While we are not able to waive the review fees, the Office of RES has indicated that they will continue to work cooperatively with you to determine whether other arrangements can be made to use the code in support of risk-informing 10 CFR Part 50.

For the above reasons, your request for a fee waiver under Footnote 4 to 10 CFR 170.21 is denied. Currently, there are 40 unpaid invoices related to NRC's review of the RETRAN-3D code for a total amount of \$350,530. These invoices are: RL0078-99, RL0335-99, RL0378-99, RL0384-99, RL0385-99, RL0386-99, RL0388-99, RL0576-99, RL0577-99, RL0578-99, RL0579-99, RL0580-99, RL0581-99, RL0584-99, RL0593-99, RL0027-00, RL0028-00, RL0029-00, RL0030-00, RL0031-00, RL0032-00, RL0035-00, RL0049-00, RL0186-00, RL0187-00, RL0188-00, RL0189-00, RL0190-00, RL0193-00, RL0363-00, RL0364-00, RL0365-00, RL0430-00, RL0529-00, RL0530-00, RL0531-00, RL0532-00, RL0533-00, RL0011-01, and RL0014-01. The invoices are due and payable. All late charges that have accrued on these invoices will be waived if payment is received within 30 days from the date of this letter. If payment is not received within 30 days, all late charges will be accrued from the date of the invoices.

R. L. Jones

-3-

If you have any question about the invoices, please contact Ellen Poteat of my staff at 301-415-6392.

Sincerely,

A handwritten signature in black ink, appearing to read "Jesse L. Funches". The signature is fluid and cursive, with a long horizontal stroke at the end.

Jesse L. Funches
Chief Financial Officer

Enclosure: FY 1994 Proposed
and Final Fee Rules

cc: Mr. Gary Vine

R. L. Jones

-3-

If you have any question about the invoices, please contact Ellen Poteat of my staff at 301-415-6392.

Sincerely,

/RA/

Jesse L. Funches
Chief Financial Officer

Enclosure: FY 1994 Proposed
and Final Fee Rules

Distribution:

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Invoice Files RL0078-99, RL0335-99, RL0378-99, RL0384-99, RL0385-99, RL0386-99, RL0388-99, RL0576-99, RL0577-99, RL0578-99, RL0579-99, RL0580-99, RL0581-99, RL0584-99, RL0593-99, RL0027-00, RL0028-00, RL0029-00, RL0030-00, RL0031-00, RL0032-00, RL0035-00, RL0049-00, RL0186-00, RL0187-00, RL0188-00, RL0189-00, RL0190-00, RL0193-00, RL0430-00, RL0363-00, RL0364-00, RL0365-00, RL0529-00, RL0530-00, RL0531-00, RL0532-00, RL0533-00, RL0011-01, and RL0014-01.

Project File 00669 PDR
LFARB (LF0-000)
OCFO RF
OCFO-2000-05

Document Name: G:\DAF-0-006glenda-redline version 12-4 jlf.wpd

*Previously concurred.

ADAMS - Yes/No

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NAME	EPoteat/DWeiss*		GCJackson/DBDandois*		ATHadani		SCollins:BWS /for/	
DATE	12/13/00		12/14/00		12/21/00		12/08/00	

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NAME	TRothschild		JTurdici		PRabideau		JLFunches	
DATE	08/16/00		12/21/00		1/1/00		12/22/00	

OFFICIAL RECORD COPY

R. L. Jones

If you have any question about the invoices, please contact Ellen Poteat of my staff at 301-415-6392.

Sincerely,

Jesse L. Funches
Chief Financial Officer

Enclosure: FY 1994 proposed
and final fee rules

Distribution:

L. Tremper, OCFO/DAF/LFARB
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Project File 00669 PDR
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NAME	<i>R. L. Jones</i> EPoteat/DWeiss		GCJackson/DBoyd		ATHadani		SCollins <i>B. Sheron</i>
DATE	12/13/00		12/14/00		1 / 00		12/8/00

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OFFICE	OGC <i>e-mail</i>	OCFO/D/DAF	DCFO	CFO
NAME	TRothschild <i>attached</i>	JTurdici	PRabideau	JLFunches
DATE	8/16/00	1 / 00	1 / 00	1 / 00

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UNITED STATES COURT OF FEDERAL CLAIMS

MASSACHUSETTS GENERAL)
HOSPITAL,)
Plaintiff,)
v.)
UNITED STATES OF AMERICA,)
Defendant.)

01 - 434 C

Case No.

FILED JUL 27 2001

COMPLAINT

As and for its Complaint, plaintiff, Massachusetts General Hospital ("MGH"), says as follows.

PARTIES AND JURISDICTION

1. The plaintiff, MGH, was at all times material hereto a charitable corporation pursuant to Massachusetts law, with a principal place of business in Boston, Massachusetts.
2. The late William H. Sweet, M.D. was at all times material hereto on the faculty of the Harvard Medical School and the medical staff at MGH.
3. This action is founded on an indemnity agreement (the "MIT Indemnity Agreement") entered into between the Massachusetts Institute of Technology ("MIT"), and the Atomic Energy Commission (the "AEC"), an agency of defendant United States of America duly authorized by act of Congress to bind the United States, and on a second indemnity agreement believed to exist between Associated Universities, Inc. ("AUI") and the AEC (the "Brookhaven Indemnity Agreement"). Under the MIT Indemnity Agreement and, on information and belief, the Brookhaven Indemnity Agreement, MGH is entitled to indemnity by the United States from certain liabilities, as discussed more fully below. MGH further seeks a declaration that United States is obligated to indemnify them against future claims falling under the Brookhaven and MIT Indemnity Agreements.
4. The Nuclear Regulatory Commission has succeeded to the responsibilities of the AEC under 42 U.S.C. §2210 and under indemnity agreements of the type at issue in this case.

5. This Court has jurisdiction under 28 U.S.C. §1491, in that this action is founded upon an express contract with the United States. This Court has jurisdiction to award declaratory relief under 28 U.S.C. §2201.

FACTS

A. The MIT Indemnity Agreement.

6. In 1958, MIT, a nonprofit educational institution, completed the construction of a research nuclear reactor, known as "MITR-I." The reactor is powered by uranium enriched in the isotope 235. It was constructed with facilities – including an operating room – designed to facilitate its use in medical research and treatment.

7. Under the Atomic Energy Act of 1954, as periodically amended and now codified, in part, at 42 U.S.C. §2210, the AEC was authorized to enter into indemnity agreements with persons licensed to operate nuclear reactors. Such agreements were to bind the AEC, and through it the United States, to indemnify and hold harmless the licensee and other persons indemnified, as their interests may appear, from "public liability" resulting from "nuclear incidents."

8. On or about June 9, 1958, the AEC issued to MIT license no. R-37 to possess and operate MITR-I. The license has been in place, subject to periodic amendments, continuously from 1958 to the present. Copies of the license, and amendments through 1962, are attached hereto as Exhibit A.

9. On or about May 25, 1959 the AEC issued to MIT an interim indemnity agreement, a true and correct copy of which is attached as Exhibit B. MIT accepted and signed the interim indemnity agreement on or about August 1, 1959. By it, the AEC agreed to indemnify MIT, and other persons indemnified as their interests may appear, from public liability in excess of \$250,000 other persons indemnified as their interests may appear, from public liability in excess of \$250,000 arising from nuclear incidents, to a limit of \$500,000,000, including the reasonable costs of investigating and settling claims and defending suits for damage. The Interim Indemnity Agreement recited that it would be superseded in due course by the execution and issuance of a formal indemnity agreement.

10. Subsequently, the AEC issued and MIT accepted Indemnity Agreement No. E-39 (the MIT Indemnity Agreement), a true and correct copy of which is attached as Exhibit C hereto. By the terms of the MIT Indemnity Agreement:

- a. The Agreement was effective from 12:01 A.M., June 9, 1958 forward, and superseded the interim indemnity agreement. (Art. 1, §5 and Attachment, Item 4)
- b. “The Commission undertakes and agrees to indemnify and hold harmless the licensee and other persons indemnified, as their interests may appear, from public liability.” (Art. II, §1)
- c. “Persons indemnified’ means the licensee [MIT] and any other person who may be liable for public liability.” (Art.I, §4)
- d. “Public liability’ means legal liability arising out of or resulting from a nuclear incident,” with certain exceptions not here relevant. (Art. I, §5)
- e. “Nuclear incident’ means any occurrence or series of occurrences at the location or in the course of transportation causing bodily injury, sickness, disease, death, or loss of or damage to property, or loss of use of property, arising out of or resulting from the radioactive, toxic, explosive, or other hazardous properties of the radioactive material,” as well as other occurrences not here relevant. (Art. I, §2(a))
- f. The “location” means the MIT reactor building and the area immediately around it. (Attachment, Item 3)

11. “Persons indemnified,” “public liability,” and “nuclear incident” are statutory terms taken from the Atomic Energy Act, and more particularly 42 U.S.C. §§2014 and 2210(c). These terms are used in the MIT Indemnity Agreement consistently with their statutory meanings, and with the purpose and intent of the Atomic Energy Act.

12. On information and belief, MIT has maintained private liability insurance relative to its operation of MITR-I in an amount of at least \$250,000, continuously since operations began in 1958 to the present.

B. The Brookhaven Indemnity Agreement.

13. AUI, a nonprofit educational and research institution, operated Brookhaven National Laboratory (“BNL”) in Upton, New York from 1947 until 1998. Among the facilities at BNL are the AEC-licensed Brookhaven Graphite Research Reactor, which went into operation in 1950, and two other AEC-licensed reactors. On information and belief, each of these reactors was, like MITR-I, the subject of an indemnity agreement (collectively, the “Brookhaven

Indemnity Agreement”) between the AEC and AUI, whose terms were substantially similar to those of the MIT Indemnity Agreement.

C. The Heinrich Civil Action.

14. On or about September 21, 1995, MGH was named as a defendant in a complaint filed in the United States District Court for the Eastern District of New York. Subsequently, the action was transferred to the District of Massachusetts. The Heinrich Civil Action is pending in the United States Court of Appeals for the First Circuit, Docket Numbers 00-2553, 00-2554, and 00-2555. The Complaint has been amended several times since the action was filed. A true and correct copy of the Second Amended Complaint is attached as Exhibit D hereto.

15. The Second Amended Complaint in the Heinrich Civil Action, purports to state claims against which, under the MIT Indemnity Agreement and the Brookhaven Indemnity Agreement, the United States is obligated to indemnify MGH. The Second Amended Complaint claims that MGH is vicariously liable for the conduct of Dr. Sweet, and that MGH is liable for conduct which occurred at BNL under the theory of civil conspiracy. (Ex. D, ¶24). More particularly, the Complaint alleges:

- a. That on June 14, 1951 Joseph Mayne, underwent boron neutron capture therapy (“BNCT”) at BNL. BNCT was a treatment for brain cancer that involved intravenous injection of a boron compound, followed by exposure to neutron radiation at a reactor. (Second Amended Complaint, ¶3, 14)
- b. That on March 6, 1957 a patient named Walter Carmen Van Dyke underwent BNCT in “an operating nuclear reactor” at BNL. (Id., ¶16)
- c. That on January 18, 1961 BNCT was administered to a patient named George Heinrich at the MITR-I reactor. (Id., ¶9)
- d. That on November 13, 1960 a patient named Eileen Sienkewicz received BNCT at MITR-I. (Id., ¶11)

16. The Second Amended Complaint further alleges that the administration of BNCT to the plaintiffs’ decedents caused those decedents radiation-related injury and death, and that Dr. Sweet, MGH and others are liable to their estates and their survivors under a variety of legal theories.

17. The Mayne and Van Dyke claims were dismissed just prior to trial. The Heinrich and Sienkewicz claims were tried in September-October, 1999, and resulted in jury verdicts against Dr. Sweet and MGH for negligence, wrongful death, and punitive damages for wrongful death, as follows:

<u>Plaintiff</u>	<u>Count</u>	<u>Sweet</u>	<u>MGH</u>
Heinrich	Negligence	\$250,000	\$250,000 (joint and several)
	Wrongful Death	\$250,000	\$250,000 (joint and several)
	Death Punitives	\$750,000	\$1,250,000
Sienkewicz	Negligence	\$500,000	\$500,000 (joint and several)
	Wrongful Death	\$2,000,000	\$2,000,000 (joint and several)
	Death Punitives	\$1,000,000	\$2,000,000
TOTALS		\$4,750,000	\$6,250,000

The trial court granted Dr. Sweet/MGH's motion to reduce the jury award. This ruling reduced the compensatory and punitive damages for wrongful death to \$20,000 per plaintiff per defendant. The remaining portions of the judgment remained intact. MGH and Dr. Sweet have appealed the judgment to the United States Court of Appeals for the First Circuit.

D. The Joseph Civil Action.

18. On or about May 23, 2000, Edward A. Joseph, individually and on behalf of the Estate of his father, Nassef Joseph, filed a Complaint in the United States District Court for the District of Massachusetts as *Edward A. Joseph, et al v. Massachusetts General Hospital, Civil Action No. 00-CV-11026-WGY* (hereinafter the "Joseph Civil Action"), raising similar allegations against MGH to those set forth in the Heinrich Civil Action. A true and correct copy of the Joseph Complaint is attached hereto as Exhibit E. More particularly, the Complaint alleges:

- a. That on April 16, 1961, a patient named Nassef Joseph received BNCT at MITR-I. (Joseph Complaint, ¶10).

25. The United States is liable, under the MIT Indemnity Agreement, to indemnify MGH against its costs in defending the Heinrich, Sienkewicz and Joseph claims, and against any liability it may have on those claims upon the entry of judgment.

26. The United States' failure to indemnify MGH under the MIT Indemnity Agreement has caused and continues to cause it great damage.

COUNT II: CONTRACTUAL INDEMNITY; BROOKHAVEN INDEMNITY
AGREEMENT

27. MGH hereby repeats and re-alleges the matters set forth in paragraphs 1 through 26, inclusive, as if fully set forth herein.

28. The United States is liable, under the Brookhaven Indemnity Agreement, to indemnify MGH against its costs in defending the Mayne and Van Dyke claims, and against any liability it may have on those claims upon the entry of judgment.

29. The United States' failure to indemnify MGH under the Brookhaven Indemnity Agreement has caused and continues to cause it great damage.

COUNT III: DECLARATORY JUDGMENT

30. MGH hereby repeats and re-alleges the matters set forth in paragraphs 1 through 29, inclusive, as if fully set forth herein.

31. The Complaints in the Heinrich and Joseph Civil Actions allege that patients Mayne, Van Dyke, Heinrich, Sienkewicz, and Joseph were part of larger series of clinical trials of BNCT using the Brookhaven and MIT reactors, and involving "at least 66 patients." (Second Amended Complaint, ¶2) They have sought, and been denied, class action status, and permission to "notify" putative class members' of the pendency of the action. There is a possibility that other plaintiffs, some or all of whose claims may be subject to the indemnity obligations under the Brookhaven Indemnity Agreement, the MIT Indemnity Agreement, and possible other indemnity agreements, may join in the future or may commence separate actions against MGH.

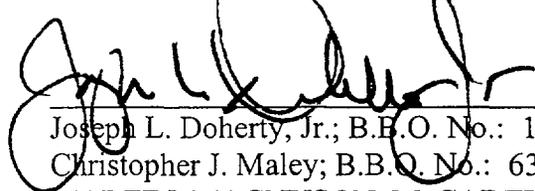
32. An actual controversy has arisen between MGH and the United States as to the United States' obligations to indemnify MGH against defense costs and potential liability in the case of claims brought by or on behalf of patients and/or their families.

WHEREFORE, MGH prays that this Court enter judgment:

- A. Awarding them as damages the amount of their defense costs in the Heinrich Civil Action, in an amount not less than \$669,667.93;

- B. Awarding them as damages the amount of their defense costs in the Joseph Civil Action, in an amount not less than approximately \$9,500.00;
- C. Awarding them as damages any amount for which they may be, or may become, liable in the Heinrich Civil Action;
- D. Awarding them as damages any amount for which they may be, or may become liable in the Joseph Civil Action;
- E. Declaring the rights and liabilities of the parties under the Brookhaven and MIT Indemnity Agreements, and more particularly, declaring that the United States is obligated to indemnify MGH against their defense costs and any potential liability in the case (at least) of any claim brought by or on behalf of any patient who received BNCT at Brookhaven or MIT, and/or their families; and
- F. Awarding MGH such other and further relief as is lawful and proper.

Massachusetts General Hospital, By Its Attorneys:



Joseph L. Doherty, Jr.; B.B.O. No.: 127280

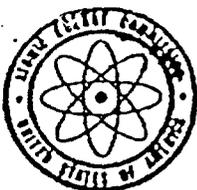
Christopher J. Maley; B.B.O. No.: 633074

MARTIN, MAGNUSON, McCARTHY
& KENNEY

101 Merrimac Street, 7th Floor

Boston, MA 02114-4716

(617) 227-3240



UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON 25, D. C.

EXHIBIT

A

DOCKET NO. 50-20
MASSACHUSETTS INSTITUTE OF TECHNOLOGY

L I C E N S E

License No. R-37

1. Subject to the conditions and requirements incorporated herein, the Commission hereby licenses Massachusetts Institute of Technology (hereinafter referred to as "MIT"):
 - a. Pursuant to Section 104a. and c. of the Atomic Energy Act of 1954 as amended, and Title 10, CFR, Chapter 1, Part 50, "Licensing of Production and Utilization Facilities", to possess and operate as a utilization facility the nuclear research reactor facility (hereinafter "the facility") designated below;
 - b. Pursuant to the Act and Title 10, CFR, Chapter 1, Part 70, "Special Nuclear Material", to receive, possess and use 12 kilograms of uranium enriched to approximately 93% in the uranium 235 isotope as fuel for operation of the facility.
 - c. Pursuant to the Act and Title 10, CFR, Chapter 1, Part 30, "Licensing of Byproduct Material", to possess, but not to separate, such byproduct material as may be produced in the operation of the facility.
2. This license applies to the facility which is owned by MIT and located in Cambridge, Massachusetts, and described in MIT's application filed on February 20, 1956, and amendments to the application, filed on May 13, 1957, September 16, 1957, November 27, 1957, January 2, 1958, January 9, 1958, January 27, 1958, February 24, 1958, and March 25, 1958, (hereinafter "the application"). The reactor is a one megawatt (thermal) heavy water-cooled and -moderated, heterogeneous, enriched uranium reactor. Experimental facilities are provided for use in neutron diffraction work, horizontal beam experiments, neutron beam therapy experiments, exponential assembly experiments, and neutron irradiation studies.
3. This license shall be deemed to contain and be subject to the conditions specified in Section 50.54 of Part 50 and Section 70.32 of Part 70; is subject to all applicable provisions of the Act and rules, regulations and orders of the Commission now or hereafter in effect; and is subject to the additional conditions specified or incorporated below.

a. Operating Restrictions

- (1) MIT shall operate the facility in accordance with the procedures and limitations described in the application.
- (2) MIT shall not operate the facility at a power level in excess of 1000 kilowatts (thermal).
- (3) No experiment shall be introduced into or permitted to remain in the reactor if more than one per cent excess reactivity would be introduced into the reactor by the withdrawal or loss of that experiment.
- (4) The reactor shall not be operated at a power level in excess of that necessary to measure the temperature and void coefficients until MIT has measured these coefficients and found them to be of the sign, and substantially of the magnitude, calculated in its application.

b. Records

In addition to those otherwise required under this license and applicable regulations, MIT shall keep the following records:

- (1) Facility operating records, including power levels.
- (2) Records showing radioactivity released or discharged into the air or water beyond the effective control of MIT as measured at the point of such release or discharge.
- (3) Records of emergency scrams, including reasons for emergency shutdowns.

c. Reports

- (1) MIT shall immediately report to the Commission any indication or occurrence of a possible unsafe condition relating to the operation of the facility.
- (2) MIT shall, upon completion of the start-up experiments described in its application, submit a report to the Commission describing such experiments and the results thereof.

4. Pursuant to Section 50.60 of the regulations in Title 10, Chapter 1, CFR, Part 50, the Commission has allocated to MIT, for use in the operation of the reactor, 11.63 kilograms of uranium 235 contained in uranium (enriched to approximately 93% in the isotope uranium 235). Estimated schedules of special nuclear material transfers to MIT and returns to the Commission are contained in Appendix "A" which is attached hereto. Shipments by the Commission to MIT in accordance with column 2 in Appendix "A" will be conditioned upon MIT's return to the Commission of material substantially in accordance with column 3 of Appendix "A".

3 -
This license is effective as of the date of issuance and shall expire at midnight, May 7, 1996, unless sooner terminated.

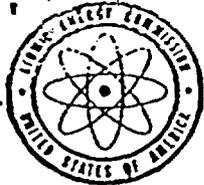
FOR THE ATOMIC ENERGY COMMISSION



H. L. Price
Director
Division of Licensing and Regulation

Date of Issuance: JUN 9 1958

JUN 9 - 1958



UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON 25, D. C.

MASSACHUSETTS INSTITUTE OF TECHNOLOGY
DOCKET NO. 50-20
AMENDMENT OF UTILIZATION FACILITY LICENSE

License No. R-37
Amendment No. 1

The first sentence of Paragraph 2 of License No. R-37 issued on June 9, 1958 to Massachusetts Institute of Technology is hereby amended to read as follows:

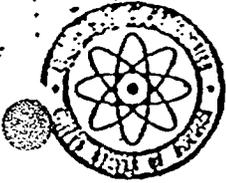
This license applies to the facility which is owned by MIT and located in Cambridge, Massachusetts, and described in MIT's application filed on February 20, 1956 and amendments to the application filed on May 13, 1957, September 16, 1957, November 27, 1957, January 2, 1958, January 9, 1958, January 27, 1958, February 24, 1958, March 25, 1958, and September 12, 1958, (hereinafter "the Application").

This amendment is effective as of the date of issuance.

FOR THE ATOMIC ENERGY COMMISSION

Eber R. Price
Eber R. Price
Acting Director
Division of Licensing and Regulation

Date of Issuance: OCT 6 1958



UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON 25, D. C.

R-37

UNITED STATES ATOMIC ENERGY COMMISSION

AMENDMENTS TO UTILIZATION FACILITY LICENSES

UNIVERSITY OF MICHIGAN, DOCKET NO. 50-2

PENNSYLVANIA STATE UNIVERSITY, DOCKET NO. 50-5

|| MASSACHUSETTS INSTITUTE OF TECHNOLOGY, DOCKET NO. 50-20 ||

OKLAHOMA STATE UNIVERSITY OF AGRICULTURE AND

APPLIED SCIENCE, DOCKET NO. 50-58

TEXAS AGRICULTURAL AND MECHANICAL

COLLEGE SYSTEM, DOCKET NO. 50-59

UNIVERSITY OF AKRON, DOCKET NO. 50-64

UNIVERSITY OF UTAH, DOCKET NO. 50-72

COLORADO STATE UNIVERSITY, DOCKET NO. 50-80

Amendment No. 3 to License No. R-28
Amendment No. 5 to License No. R-2
Amendment No. 2 to License No. R-37// ←
Amendment No. 2 to License No. R-22
Amendment No. 2 to License No. R-23
Amendment No. 1 to License No. R-24
Amendment No. 1 to License No. R-25
Amendment No. 1 to License No. R-26

Licenses numbered R-28, R-2, R-37, R-22, R-23, R-24, R-25 and R-26 issued to University of Michigan, Pennsylvania State University, Massachusetts Institute of Technology, Oklahoma State University of Agriculture and Applied Science, Texas Agricultural and Mechanical College System, University of Akron, University of Utah and Colorado State University, respectively, are hereby amended to add the following finding by the Commission:

RO
PY

XERO
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XERO
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XERO
COPY

"This license is issued for the conduct of educational activities by the licensee, a nonprofit educational institution, and the licensee is therefore exempt from the financial protection requirement of subsection 170a of the Act."

This amendment is effective as of the date of issuance.

FOR THE ATOMIC ENERGY COMMISSION

H. L. ...
Director
Division of Licensing and Regulation

Date of Issuance: APR 16 1950

V-cc. Prof. Maxine Benedict - 4/13/49

UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON 25, D. C.

MASSACHUSETTS INSTITUTE OF TECHNOLOGY
DOCKET NO. 50-20
AMENDMENT OF UTILIZATION FACILITY LICENSE

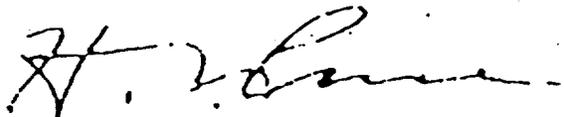
License No. R-37
Amendment No. 3

The first sentence of Paragraph 2 of License No. R-37 issued on June 9, 1958 to Massachusetts Institute of Technology is hereby amended to read as follows:

This license applies to the facility which is owned by MIT and located in Cambridge, Massachusetts, and described in MIT's application filed on February 20, 1956 and amendments to the application filed on May 13, 1957, September 16, 1957, November 27, 1957, January 2, 1958, January 9, 1958, January 27, 1958, February 24, 1958, March 25, 1958, September 12, 1958, and April 24, 1959 (hereinafter "this application").

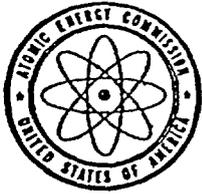
This amendment is effective as of the date of issuance.

FOR THE ATOMIC ENERGY COMMISSION



H. L. Price
Director
Division of Licensing and Regulation

Date of Issuance: MAY 2 1959



UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON 25, D. C.

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

DOCKET NO. 50-20

AMENDMENT TO UTILIZATION FACILITY LICENSE

License No. R-37
Amendment No. 4

License No. R-37 issued to Massachusetts Institute of Technology is hereby amended in the following respects:

1. Paragraph 2. is amended to read as follows:

"2. This license applies to the heavy water-cooled and-moderated reactor (herein referred to as 'the facility') which is owned by Massachusetts Institute of Technology and located on the Institute's site in Cambridge, Massachusetts, and described in the Institute's application for license dated February 20, 1956 and amendments thereto dated April 29, 1957, September 10, 1957, November 22, 1957, December 26, 1957, January 7, 1958, January 24, 1958, February 19, 1958, March 21, 1958, September 12, 1958, April 24, 1959, October 7, 1960 and March 8, 1961, (herein collectively referred to as 'the application')."

2. Paragraph 3.a.(1) is amended to read as follows:

"3.a.(1) MIT shall operate the facility in accordance with the procedures and limitations described in the application, in this license, and in Item 8 of MIT's report entitled 'MITR Operating Experience' dated January 27, 1961."

3. Paragraph 3.a.(2) is amended to read as follows:

"3.a.(2) MIT shall not operate the facility at a steady state power level in excess of two megawatts (thermal)."

4. A new paragraph 3.c.(3) is added as follows:

"3.c.(3) MIT shall promptly submit a written report to the Commission whenever, during operation of the facility, any of the operating conditions or characteristics of the facility which might affect nuclear safety varies significantly from its predicted value."

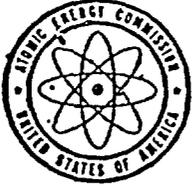
This amendment is effective as of the date of issuance.

FOR THE ATOMIC ENERGY COMMISSION

R L Kirk

R. L. Kirk
Deputy Director
Division of Licensing & Regulation

Dated at Germantown, Maryland
this *20th* day of *June*, 1961.



UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON 25, D.C.

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

DOCKET NO. 50-20

AMENDMENT TO UTILIZATION FACILITY LICENSE

License No. R-37
Amendment No. 5

License No. R-37 issued to Massachusetts Institute of Technology is hereby amended in the following respects:

1. Paragraph 1.b. is amended in its entirety to read as follows:

"1.b. Pursuant to the Act and Title 10, CFR, Chapter 1, Part 70, 'Special Nuclear Material', to receive, possess and use 14.0 kilograms of contained uranium-235 in connection with operation of the facility. These activities shall be conducted in accordance with the applicable procedures and conditions in License No. R-37, as amended, 'the application' as defined in Amendment No. 4 to License No. R-37 and the application for amendment dated April 20, 1962 and supplement thereto dated October 1, 1962."

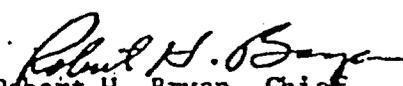
2. Paragraph 4. is revised in its entirety to read as follows:

"4. Pursuant to Section 50.60 of the regulations in Chapter 1, CFR, Part 50, the Commission has allocated to MIT, for use in connection with operation of the facility, 30.5 kilograms of contained uranium 235. Estimated schedules of special nuclear material transfers to MIT and returns to the Commission are contained in Appendix 'A' which is attached hereto. Shipments by the Commission to MIT in accordance with column 2 in Appendix 'A' will be conditioned upon MIT's return to the Commission of material substantially in accordance with column 3 of Appendix 'A'."

3. Appendix "A" to Facility License No. R-37 is revised in its entirety to read as the new Appendix "A" attached hereto.

4. This amendment is effective as of the date of issuance.

FOR THE ATOMIC ENERGY COMMISSION


Robert H. Bryan, Chief
Research & Power Reactor Safety Branch
Division of Licensing and Regulation

Attachment:
Appendix "A"

Date of Issuance: NOV 13 1962

APPENDIX "A"

TO

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

FACILITY LICENSE NO. R-37

Estimated Schedule of Transfers of Special Nuclear Material from the Commission to Massachusetts Institute of Technology and to the Commission from MIT:

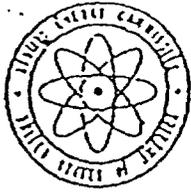
(1)	(2)	(3)	(4)	(5)
Date of Transfer (Fiscal year)	Transfers from AEC to MIT (A) Kgs. U-235	Returns by MIT to AEC Irrad. (B) Kgs. U-235	Net yearly Distribution Kgs. U-235	Cumulative Distribution Kgs. U-235
Thru-62	10.0	1.6 (C)	8.4	8.4
1963	5.9	3.5	2.4	10.8
1964	-0-	2.7	(2.7)	8.1
1965	4.1	2.7	1.4	9.5
1966	3.4	2.7	0.7	10.2
1967	3.4	2.7	0.7	10.9
1968	3.4	2.7	0.7	11.6
1969	3.4	2.7	0.7	12.3
1970	3.4	2.7	0.7	13.0
1971	3.4	2.7	0.7	13.7
1972	3.4	2.7	0.7	14.4
1973	3.4	2.7	0.7	15.1
1974	3.4	2.7	0.7	15.8
1975	3.4	2.7	0.7	16.5
1976	3.4	2.7	0.7	17.2
1977	3.4	2.7	0.7	17.9
1978	3.4	2.7	0.7	18.6
1979	3.4	2.7	0.7	19.3
1980	3.4	2.7	0.7	20.0
1981	3.4	2.7	0.7	20.7
1982	3.4	2.7	0.7	21.4
1983	3.4	2.7	0.7	22.1
1984	3.4	2.7	0.7	22.8
1985	3.4	2.7	0.7	23.5
1986	3.4	2.7	0.7	24.2
1987	3.4	2.7	0.7	24.9
1988	3.4	2.7	0.7	25.6
1989	3.4	2.7	0.7	26.3
1990	3.4	2.7	0.7	27.0
1991	3.4	2.7	0.7	27.7
1992	3.4	2.7	0.7	28.4
1993	3.4	2.7	0.7	29.1

(1)	(2)	(3)	(4)	(5)
Date of Transfer (Fiscal year)	Transfers from AEC to MIT (A) Kgs. U-235	Returns by MIT to AEC Irrad. (B) Kgs. U-235	Net yearly Distribution Kgs. U-235	Cumulative Distribution Kgs. U-235
1994	3.4	2.7	0.7	29.8
1995	3.4	2.7	0.7	30.5
1996	-0-	2.7	(2.7)	27.8
1997	-0-	3.0	(3.0)	24.8
	<u>122.0</u>	<u>97.2</u>	<u>24.8</u>	

(A) 93%

(B) Approximately 88%

(C) Recoverable cold scrap @ 93% for Thru-62 only



UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON 25, D. C.

EXHIBIT

B

Docket No. 50-20

JUN 25 1959

Massachusetts Institute of Technology
Cambridge 30, Massachusetts

Attention: Mr. James McCormack
Vice President

Gentlemen:

The Commission hereby agrees to indemnify and hold harmless

Massachusetts Institute of Technology

and other persons indemnified as their interests may appear, from public liability in excess of \$250,000 arising from nuclear incidents provided that with respect to any nuclear incident occurring between 12:01 a.m. June 9, 1958 and 12:01 a.m. August 23, 1958 inclusive the level of financial protection required of you under License No. R-37 shall be \$250,000. The aggregate indemnity for all persons indemnified in connection with each nuclear incident shall not exceed \$500,000,000 including the reasonable costs of investigating and settling claims and defending suits for damage. The obligations of the Commission under this agreement shall apply only with respect to such public liability as arises out of or in connection with the activity licensed under AEC License No. R-37. The terms "persons indemnified," "public liability," and "nuclear incident," as used in this paragraph have the meanings defined in Section 11 of the Atomic Energy Act of 1954, as amended. This agreement is effective as of June 9, 1958.

This agreement will be superseded, in due course, by the execution and issuance of a formal indemnity agreement between you and the Commission containing such provisions as are required by law and such additional provisions as may be incorporated therein by the Commission pursuant to its regulations, which formal agreement will be effective, and will supersede this agreement, as of the effective date referred to above. Until this agreement has been so superseded, it is understood that this agreement constitutes the agreement of indemnification contemplated by subsection 170k of the Atomic Energy Act of 1954, as amended.

M 25 1959

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By your acceptance of this agreement, you agree to pay to the Commission the fee provided for by Section 140.17 (b) of the Commission's regulations, in accordance with billing instructions received by the Commission.

U. S. ATOMIC ENERGY COMMISSION



By H. L. Price

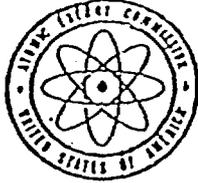
Director

Division of Licensing and Regulation

Accepted: Aug. 18, 1959

By [Handwritten Signature]

Exhibit C



UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON 25, D.C.

EXHIBIT

C

Indemnity
Agreement E-39
No.

This indemnity agreement No. E-39 is entered into by and
between Massachusetts Institute of Technology

(hereinafter referred to as the "licensee") and the United States Atomic
Energy Commission (hereinafter referred to as the "Commission") pursuant
to subsection 170k of the Atomic Energy Act of 1954, as amended (herein-
after referred to as "the Act").

ARTICLE I

As used in this agreement,

1. "Nuclear reactor", "byproduct material", "person", "source
material", and "special nuclear material" shall have the meanings given
them in the Atomic Energy Act of 1954, as amended, and the regulations
issued by the Commission.

2(a) "Nuclear incident" means any occurrence or series of occurrences
at the location or in the course of transportation causing bodily injury,
sickness, disease, or death, or loss of or damage to property, or loss of
use of property, arising out of or resulting from the radioactive, toxic,
explosive, or other hazardous properties of the radioactive material.

(b) Any occurrence or series of occurrences causing bodily injury,
sickness, disease or death, or loss of or damage to property, or loss of
use of property, arising out of or resulting from the radioactive, toxic
explosive, or other hazardous properties of

i. The radioactive material discharged or dispersed from
the location over a period of days, weeks, months or longer and
also arising out of such properties of other material defined as
"the radioactive material" in any other agreement or agreement
entered into by the Commission under subsection 170 c or k of
the Act and so discharged or dispersed from "the location" as
defined in any such other agreement; or

ii. The radioactive material in the course of transportation
and also arising out of such properties of other material defined
in any other agreement entered into by the Commission pursuant to
subsection 170 c or k of the Act as "the radioactive material" and
which is in the course of transportation

Original

shall be deemed to be a common occurrence. A common occurrence shall be deemed to constitute a single nuclear incident.

3. "In the course of transportation" means in the course of transportation within the United States, including handling or temporary storage incidental thereto, of the radioactive material to the location or from the location provided that:

(a) With respect to transportation of the radioactive material to the location, such transportation is not by pre-determination to be interrupted by the removal of the material from the transporting conveyance for any purpose other than the continuation of such transportation to the location or temporary storage incidental thereto;

(b) The transportation of the radioactive material from the location shall be deemed to end when the radioactive material is removed from the transporting conveyance for any purpose other than the continuation of transportation or temporary storage incidental thereto;

(c) "In the course of transportation" as used in this agreement shall not include transportation of the radioactive material to the location if the material is also "in the course of transportation" from any other "location" as defined in any other agreement entered into by the Commission pursuant to subsection 170 c or k of the Act.

4. "Person indemnified" means the licensee and any other person who may be liable for public liability.

5. During the period 12:01 A.M., June 9, 1958 to 12:01 A.M., September 6, 1961, inclusive:

"Public liability" means any legal liability arising out of or resulting from a nuclear incident, except (1) claims under state or Federal Workmen's Compensation Acts of employees of persons indemnified who are employed (a) at the location or, if the nuclear incident occurs in the course of transportation of the radioactive material, on the transporting vehicle, and (b) in connection with the licensee's possession, use, or transfer of the radioactive material; and (2) claims arising out of an act of war.

From 12:01 A.M., September 6, 1961:

"Public liability" means any legal liability arising out of or resulting from a nuclear incident, except (1) claims under state or Federal Workmen's Compensation Acts of employees of persons indemnified who are employed (a) at the location or, if the nuclear incident occurs in the course of transportation of the radioactive material, on the transporting vehicle, and (b) in connection with the licensee's possession, use, or transfer of the radioactive material; (2) claims arising out of an act of war; and (3) claims for loss of, or damage to, or loss of use of (a) property which is located at the location and used in connection with the licensee's possession, use, or transfer of the radioactive material, and (b), if the nuclear incident occurs in the course of transportation of the radioactive material, the transporting vehicle, containers used in such transportation, and the radioactive material.

6. "The location" means the location described in Item 3 of the Attachment hereto.

7. "The radioactive material" means source, special nuclear, and byproduct material which (1) is used or to be used in, or is irradiated or to be irradiated by, the nuclear reactor or reactors subject to the license or licenses designated in the Attachment hereto, or (2) is produced as the result of operation of said reactor(s).

8. "United States" when used in a geographical sense includes all Territories and possessions of the United States, the Canal Zone, and Puerto Rico.

ARTICLE II

Any obligations of the licensee under subsection 53a(8) of the Act to indemnify the United States and the Commission from public liability shall not in the aggregate exceed \$250,000 with respect to any nuclear incident.

ARTICLE III

1. The Commission undertakes and agrees to indemnify and hold harmless the licensee and other persons indemnified, as their interest may appear, from public liability.

2. With respect to damage caused by a nuclear incident to property of any person legally liable for the nuclear incident, the Commission agrees to pay to such person those sums which such person would have been obligated to pay if such property had belonged to another; provided, that the obligation of the Commission under this paragraph 2 does not apply with respect to:

(a) Property which is located at the location and used in connection with the licensee's possession, use, or transfer of the radioactive material;

(b) Property damage due to the neglect of the person indemnified to use all reasonable means to save and preserve the property after knowledge of a nuclear incident;

(c) If the nuclear incident occurs in the course of transportation of the radioactive material, the transporting vehicle and containers used in such transportation;

(d) The radioactive material.

3. The Commission agrees to indemnify and hold harmless the licensee and other persons indemnified, as their interest may appear, from the reasonable costs of investigating, settling and defending claims for public liability.

4. (a) The obligations of the Commission under this Article shall apply only with respect to such public liability, such damage to property of persons legally liable for the nuclear incident (other than such property described in the proviso to paragraph 2 of this Article) and such reasonable costs described in paragraph 3 of this Article as in the aggregate exceed \$250,000.

(b) With respect to a common occurrence, the obligations of the Commission under this Article shall apply only with respect to such public liability, such damage to property of persons legally liable for the nuclear incident (other than such property described in the proviso to paragraph 2 of this Article) and to such reasonable costs described in paragraph 3 of this Article as in the aggregate exceed whichever of the following is lower: (1) the sum of the amounts of financial protection established under all applicable agreements; or (2) \$60,000,000. As used in this paragraph, "applicable agreements" means each agreement entered into by the Commission pursuant to subsection 170c of the Act in which agreement the nuclear incident is defined as a "common occurrence."

5. The obligations of the Commission under this agreement shall apply only with respect to nuclear incidents occurring during the term of this agreement.

6. The obligations of the Commission under this and all other agreements and contracts to which the Commission is a party shall not in the aggregate exceed \$500,000,000 with respect to any nuclear incident.

7. If the licensee is immune from public liability because it is a state agency, the Commission shall make payments under this agreement in the same manner and to the same extent as the Commission would be required to do if the licensee were not such a state agency.

8. The obligations of the Commission under this Article, except to the licensee for damage to property of the licensee, shall not be affected by any failure on the part of the licensee to fulfill its obligations under this agreement. Bankruptcy or insolvency of the licensee or any other person indemnified or of the estate of the licensee or any other person indemnified shall not relieve the Commission of any of its obligations hereunder.

ARTICLE IV

1. When the Commission determines that the United States will probably be required to make indemnity payments under the provisions of this agreement, the Commission shall have the right to collaborate with the licensee and other persons indemnified in the settlement and defense of any claim and shall have the right (a) to require the prior approval of the Commission for the settlement or payment of any claim or action asserted against the licensee or other person indemnified for public liability or damage to property of persons legally liable for the nuclear incident which claim or action the licensee or the Commission may be required to indemnify under this agreement; and (b) to appear through the Attorney General of the United States on behalf of the licensee or other person indemnified, take charge of such action and settle or defend any such action. If the settlement or defense of any such action or claim is undertaken by the Commission, the licensee shall furnish all reasonable assistance in effecting a settlement or asserting a defense.

2. Neither this agreement nor any interest therein nor claim thereunder may be assigned or transferred without the approval of the Commission.

ARTICLE V

The parties agree that they will enter into appropriate amendments of this agreement to the extent that such amendments are required pursuant to the Atomic Energy Act of 1954, as amended, or licenses, regulations or orders of the Commission.

ARTICLE VI

The licensee agrees to pay to the Commission such fees as are established by the Commission pursuant to regulations or orders of the Commission.

ARTICLE VII

The term of this agreement shall commence as of the date and time specified in Item 4 of the Attachment and shall terminate at the time of expiration of that license specified in Item 2 of the Attachment, which is the last to expire; provided that, except as may otherwise be provided in applicable regulations or orders of the Commission, the term of this

agreement shall not terminate until all the radioactive material has been removed from the location and transportation of the radioactive material from the location has ended as defined in subparagraph 3(b), Article I. Termination of the term of this agreement shall not affect any obligation of the licensee or any obligation of the Commission under this agreement with respect to any nuclear incident occurring during the term of this agreement.

UNITED STATES ATOMIC ENERGY COMMISSION

Indemnity Agreement No. E-39

ATTACHMENT

Item 1 - Licensee Massachusetts Institute of Technology
Address Cambridge 39, Massachusetts

Item 2 - License number or numbers
R-37

Item 3 - Location

The Reactor Building with stack and cooling towers including the area circumscribed by a chain link fence on the north and south sides of said building; a concrete wall and chain link fence on the east side of said building; and a line coinciding with the east wall of the Nuclear Engineering Building (Room NW12). Also, that portion of the Nuclear Engineering Building north of the partition extending from the southeast corner of the Transformer Vault (Room 123) to the southwest corner of the Spectrometer Set-up Room (Room 119); and, the fuel storage vault rooms identified as NW12-127, NW12-213 and NW12-313 and the connecting corridors and the elevator when nuclear fuels are being moved to and from the vaults and the areas first mentioned. The location is further depicted on the two prints, "Building NW12 and Reactor," dated May 1, 1964 and transmitted with the Institute's letter of May 7, 1964. Said prints are made part of this indemnity agreement by reference.

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The above location is a portion of the facilities commonly known as 120 through 138 Albany Street, Cambridge, Massachusetts.

Item 4 - The indemnity agreement designated above, of which this Attachment is a part, is effective as of 12:01 A.M., on the 9th day of June, 1958 and supersedes the interim indemnity agreement between the licensee and the Atomic Energy Commission dated May 25, 1959.

FOR THE UNITED STATES ATOMIC ENERGY COMMISSION

By Eber R. Price
Eber R. Price, Director
Division of State and Licensee Relations

For the MASSACHUSETTS INSTITUTE OF TECHNOLOGY
(Name of Licensee)

By Paul V. Cusick
Paul V. Cusick COMPTROLLER

Dated at Bethesda, Maryland, the 13th
day of May, 1964.

AMENDMENT TO INDEMNITY AGREEMENT NO. E-39

AMENDMENT NO. 1

Effective January 1, 1966, Indemnity Agreement No. E-39, between Massachusetts Institute of Technology and the Atomic Energy Commission dated May 13, 1964, is hereby amended as follows:

Paragraph 4(b) of Article III is amended to read as follows:

(b) With respect to a common occurrence, the obligations of the Commission under this Article shall apply only with respect to such public liability, such damage to property of persons legally liable for the nuclear incident (other than such property described in the proviso to paragraph 2 of this Article) and to such reasonable costs described in paragraph 3 of this Article as in the aggregate exceed whichever of the following is lower: (1) the sum of the amounts of financial protection established under all applicable agreements; or (2) \$74,000,000. As used in this Article, "applicable agreements" means each agreement entered into by the Commission pursuant to subsection 170c of the Act in which agreement the nuclear incident is defined as a "common occurrence."

Paragraph 6 of Article III is amended to read as follows:

6. The obligations of the Commission under this and all other agreements and contracts to which the Commission is a party shall not, with respect to any nuclear incident, in the aggregate exceed whichever of the following is the lower: (a) \$500,000,000 or (b) with respect to a common occurrence, \$560,000,000 less the sum of the amounts of financial protection established under all applicable agreements.

FOR THE UNITED STATES ATOMIC ENERGY COMMISSION

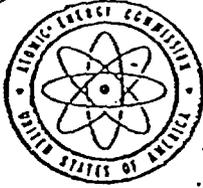
Eber R. Price

Eber R. Price, Director
Division of State and Licensee Relations

Accepted: 7 SEP 6 1966, 19

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

By Paul V. Cusick
Paul V. Cusick, Comptroller



UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

AMENDMENT NO. 2 TO INDEMNITY AGREEMENT NO. E-39

Effective NOV 30 1968, Indemnity Agreement No. E-39, dated May 13, 1964, as amended, is hereby further amended in its entirety, and the following substituted therefor:

This Indemnity Agreement No. E-39 is entered into by and between the

Massachusetts Institute of Technology

(hereinafter referred to as the "licensee") and the United States Atomic Energy Commission (hereinafter referred to as the "Commission") pursuant to subsection 170k of the Atomic Energy Act of 1954, as amended (hereinafter referred to as "the Act").

ARTICLE I

As used in this agreement:

1. "Nuclear reactor," "byproduct material," "person," "source material," and "special nuclear material" shall have the meanings given them in the Atomic Energy Act of 1954, as amended, and the regulations issued by the Commission.

2.(a) "Nuclear incident" means any occurrence, including an extraordinary nuclear occurrence, or series of occurrences at the location or in the course of transportation causing bodily injury, sickness, disease, or death, or loss of or damage to property, or loss of use of property, arising out of or resulting from the radioactive, toxic, explosive, or other hazardous properties of the radioactive material.

(b) Any occurrence, including an extraordinary nuclear occurrence, or series of occurrences causing bodily injury, sickness, disease or death, or loss of or damage to property, or loss of use of property, arising out of or resulting from the radioactive, toxic, explosive, or other hazardous properties of

1. The radioactive material discharged or dispersed from the location over a period of days, weeks, months or longer and also arising out of such properties of other material

defined as "the radioactive material" in any other agreement or agreements entered into by the Commission under subsection 170c or k of the Act and so discharged or dispersed from "the location" as defined in any such other agreement; or

ii. The radioactive material in the course of transportation and also arising out of such properties of other material defined in any other agreement entered into by the Commission pursuant to subsection 170c or k of the Act as "the radioactive material" and which is in the course of transportation

shall be deemed to be a common occurrence. A common occurrence shall be deemed to constitute a single nuclear incident.

3. "Extraordinary nuclear occurrence" means an event which the Commission has determined to be an extraordinary nuclear occurrence as defined in the Atomic Energy Act of 1954, as amended.

4. "In the course of transportation" means in the course of transportation within the United States, including handling or temporary storage incidental thereto, of the radioactive material to the location or from the location provided that:

(a) With respect to transportation of the radioactive material to the location, such transportation is not by predetermination to be interrupted by the removal of the material from the transporting conveyance for any purpose other than the continuation of such transportation to the location or temporary storage incidental thereto;

(b) The transportation of the radioactive material from the location shall be deemed to end when the radioactive material is removed from the transporting conveyance for any purpose other than the continuation of transportation or temporary storage incidental thereto;

(c) "In the course of transportation" as used in this agreement shall not include transportation of the radioactive material to the location if the material is also "in the course of transportation" from any other "location" as defined in any other agreement entered into by the Commission pursuant to subsection 170c or k of the Act.

5. "Person indemnified" means the licensee and any other person who may be liable for public liability.

6. "Public liability" means any legal liability arising out of or resulting from a nuclear incident, except (1) claims under State or Federal Workmen's Compensation Acts of employees of persons indemnified who are employed (a) at the location or, if the nuclear incident occurs in the course of transportation of the radioactive material, on the transporting vehicle, and (b) in connection with the licensee's possession, use, or transfer of the radioactive material; (2) claims arising out of an act of war; and (3) claims for loss of, or damage to, or loss of use of (a) property which is located at the location and used in connection with the licensee's possession, use, or transfer of the radioactive material, and (b) if the nuclear incident occurs in the course of transportation of the radioactive material, the transporting vehicle, containers used in such transportation, and the radioactive material.

7. "The location" means the location described in Item 3 of the Attachment hereto.

8. "The radioactive material" means source, special nuclear, and byproduct material which (1) is used or to be used in, or is irradiated or to be irradiated by, the nuclear reactor or reactors subject to the license or licenses designated in the Attachment hereto, or (2) is produced as the result of operation of said reactor(s).

9. "United States" when used in a geographical sense includes all Territories and possessions of the United States, the Canal Zone and Puerto Rico.

ARTICLE II

1. Any obligations of the licensee under subsection 53e(8) of the Act to indemnify the United States and the Commission from public liability shall not in the aggregate exceed \$250,000 with respect to any nuclear incident.

2. With respect to any extraordinary nuclear occurrence to which this agreement applies, the Commission, and the licensee on behalf of itself and other persons indemnified, insofar as their interests appear, each agree to waive

(a) any issue or defense as to the conduct of the claimant or fault of persons indemnified, including, but not limited to

- (1) negligence;
- (2) contributory negligence;
- (3) assumption of the risk;
- (4) unforeseeable intervening causes, whether involving the conduct of a third person or an act of God.

As used herein, "conduct of the claimant" includes conduct of persons through whom the claimant derives his cause of action;

(b) any issue or defense as to charitable or governmental immunity;

(c) any issue or defense based on any statute of limitations if suit is instituted within three years from the date on which the claimant first knew, or reasonably could have known, of his injury or damage and the cause thereof, but in no event more than ten years after the date of the nuclear incident.

The waiver of any such issue or defense shall be effective regardless of whether such issue or defense may otherwise be deemed jurisdictional or relating to an element in the cause of action. The waivers shall be judicially enforceable in accordance with their terms by the claimant against the person indemnified.

3. The waivers set forth in paragraph 2 of this Article:

(a) shall not preclude a defense based upon a failure to take reasonable steps to mitigate damages;

(b) shall not apply to injury or damage to a claimant or to a claimant's property which is intentionally sustained by the claimant or which results from a nuclear incident intentionally and wrongfully caused by the claimant;

(c) shall not apply to injury to a claimant who is employed at the site of and in connection with the activity, where the extraordinary nuclear occurrence takes place if benefits therefor are either payable or required to be provided under any workmen's compensation or occupational disease law;

(d) shall not apply to any claim for punitive or exemplary damages, provided, with respect to any claim for wrongful death under any State law which provides for damages only punitive in nature, this exclusion does not apply to the extent that the claimant has sustained actual damages, measured by the pecuniary injuries resulting from such death but not to exceed the maximum amount otherwise recoverable under such law;

(e) shall be effective only with respect to those obligations set forth in this agreement;

(f) shall not apply to, or prejudice the prosecution or defense of, any claim or portion of claim which is not within the protection afforded under (1) the limit of liability provisions under subsection 170e of the Atomic Energy Act of 1954, as amended, and (b) the terms of this agreement.

ARTICLE III

1. The Commission undertakes and agrees to indemnify and hold harmless the licensee and other persons indemnified, as their interest may appear, from public liability.

2. With respect to damage caused by a nuclear incident to property of any person legally liable for the nuclear incident, the Commission agrees to pay to such person those sums which such person would have been obligated to pay if such property had belonged to another; provided, that the obligation of the Commission under this paragraph 2 does not apply with respect to:

(a) Property which is located at the location and used in connection with the licensee's possession, use, or transfer of the radioactive material;

(b) Property damage due to the neglect of the person indemnified to use all reasonable means to save and preserve the property after knowledge of a nuclear incident;

(c) If the nuclear incident occurs in the course of transportation of the radioactive material, the transporting vehicle and containers used in such transportation;

(d) The radioactive material.

3. The Commission agrees to indemnify and hold harmless the licensee and other persons indemnified, as their interest may appear, from the reasonable costs of investigating, settling and defending claims for public liability.

4.(a) The obligations of the Commission under this agreement shall apply only with respect to such public liability, such damage to property of persons legally liable for the nuclear incident (other than such property described in the proviso to paragraph 2 of this Article) and such reasonable costs described in paragraph 3 of this Article as in the aggregate exceed \$250,000.

(b) With respect to a common occurrence, the obligations of the Commission under this agreement shall apply only with respect to such public liability, such damage to property of persons legally liable for the nuclear incident (other than such property described in the proviso to paragraph 2 of this Article) and to such reasonable costs described in paragraph 3 of this Article as in the aggregate exceed whichever of the following is lower: (1) the sum of the amounts of financial protection established under all applicable agreements; or (2) \$74,000,000. As used in this Article, "applicable agreements" means each agreement entered into by the Commission pursuant to subsection 170c of the Act in which agreement the nuclear incident is defined as a "common occurrence."

47,000,000
140,000,000

5. The obligations of the Commission under this agreement shall apply only with respect to nuclear incidents occurring during the term of this agreement.

6. The obligations of the Commission under this and all other agreements and contracts to which the Commission is a party shall not, with respect to any nuclear incident, in the aggregate exceed whichever of the following is the lower: (a) \$500,000,000 or (b) with respect to a common occurrence, \$560,000,000 less the sum of the amounts of financial protection established under all applicable agreements.

7. If the licensee is immune from public liability because it is a State agency, the Commission shall make payments under this agreement in the same manner and to the same extent as the Commission would be required to do if the licensee were not such a State agency.

8. The obligations of the Commission under this agreement, except to the licensee for damage to property of the licensee, shall not be affected by any failure on the part of the licensee to fulfill its obligations under this agreement. Bankruptcy or insolvency of the licensee or any other person indemnified or of the estate of the licensee or any other person indemnified shall not relieve the Commission of any of its obligations hereunder.

ARTICLE IV

1. When the Commission determines that the United States will probably be required to make indemnity payments under the provisions of this agreement, the Commission shall have the right to collaborate with the licensee and other persons indemnified in the settlement and defense of any claim and shall have the right (a) to require the prior approval of the Commission for the settlement or payment of any claim or action asserted against the licensee or other person indemnified for public liability or damage to property of persons legally liable for the nuclear incident which claim or action the licensee or the Commission may be required to indemnify under this agreement; and (b) to appear through the Attorney General of the United States on behalf of the licensee or other person indemnified, take charge of such action and settle or defend any such action. If the settlement or defense of any such action or claim is undertaken by the Commission, the licensee shall furnish all reasonable assistance in effecting a settlement or asserting a defense.

2. Neither this agreement nor any interest therein nor claim thereunder may be assigned or transferred without the approval of the Commission.

ARTICLE V

The parties agree that they will enter into appropriate amendments of this agreement to the extent that such amendments are required pursuant to the Atomic Energy Act of 1954, as amended, or licenses, regulations or orders of the Commission.

ARTICLE VI

The licensee agrees to pay to the Commission such fees as are established by the Commission pursuant to regulations or orders of the Commission.

ARTICLE VII

The term of this agreement shall commence as of the date and time specified in Item 4 of the Attachment and shall terminate at the time of expiration of that license specified in Item 2 of the Attachment, which is the last to expire; provided that, except as may otherwise be provided in applicable regulations or orders of the Commission, the term of this agreement shall not terminate until all the radioactive material has been removed from the location and transportation of the radioactive material from the location has ended as defined in subparagraph 4(b), Article I. Termination of the term of this agreement shall not affect any obligation of the licensee or any obligation of the Commission under this agreement with respect to any nuclear incident occurring during the term of this agreement.

UNITED STATES DISTRICT COURT
FOR MASSACHUSETTS

-----X

EVELYN HEINRICH on behalf of her	:	Civ. Action No.
husband, GEORGE HEINRICH, HENRY M.	:	97-CIV-12134-MLW
SIENKEWICZ, JR., on behalf of his	:	
mother, EILEEN ROSE SIENKEWICZ,	:	Wolf, J
ROSEMARY GUALTIERI, on behalf of	:	
her father JOSEPH MAYNE, WALTER	:	
CARL VAN DYKE on behalf of his	:	<u>SECOND AMENDED</u>
father WALTER CARMEN VAN DYKE and	:	<u>COMPLAINT</u>
all others similarly situated,	:	

Plaintiffs,

-against-

WILLIAM H. SWEET, M.D., Trustee of	:	
the Lee Edward Farr Trust dated	:	
1/11/71, as amended, THE ESTATE OF	:	
LEE EDWARD FARR, M.D., ASSOCIATED	:	
UNIVERSITIES, INC., MASSACHUSETTS	:	
GENERAL HOSPITAL, MASSACHUSETTS	:	
INSTITUTE OF TECHNOLOGY, THE UNITED	:	
STATES OF AMERICA	:	

Defendants.

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INTRODUCTION

REASON FOR AMENDMENT TO COMPLAINT

1. (a) This Second Amended Complaint is filed to add as a plaintiff Walter Carl Van Dyke as the representative of the Estate of his father, Walter Carmen Van Dyke, to substitute as a defendant the Trustee of the Lee Edward Farr Trust dated 1/11/71, as amended of Lee Edward Farr, M.D. for Lee Edward Farr, M.D., to

formalize the previously approved substitution of the United States of America for defendants Estates of Warren and Dunham, former employees of the United States and to modify the remainder of the Complaint to reflect these amendments. At this time Mr. Van Dyke is not asserting any claims against the United States pending a response to his administrative claim filed with the United States. Should that claim be denied, Mr. Van Dyke will seek to amend the complaint to assert his claims against the United States in this action.

BACKGROUND

(b) This action is brought to seek redress from the defendants who were responsible for using the decedents of plaintiffs and the class they represent as human guinea pigs, without their consent, in a series of extremely dangerous, painful and unproven medical experiments for which there was no reasonable basis to believe that the decedents would receive any therapeutic value. These experiments were the product of a common scheme devised by defendants and were conducted on patients under the care of the Massachusetts General Hospital ("MGH") and other hospitals at reactor facilities at the Brookhaven National Laboratory ("BNL") which was operated by

Associated Universities, Inc. ("AUI") in Upton, New York, an Atomic Energy Commission ("AEC") owned nuclear research center, and the Massachusetts Institute of Technology ("MIT") in Cambridge, Massachusetts. The principal doctors who, working in concert, devised and implemented these experiments were defendants Dr. Lee E. Farr, Chairman of the Medical Department at BNL during all times relevant here and Dr. William H. Sweet, a neurosurgeon at MGH. Defendants Shields Warren and Charles Dunham were the federal officials at the AEC responsible for funding and overseeing the experiments.

2. The defendants acting in concert and as part of a common scheme, with substantial funding provided by the AEC, conducted extensive, unproven and dangerous medical experiments on over 140 terminally ill patients, without their knowledge or consent. The experiments ranged from injecting patients who suffered from brain tumors with toxic compounds of boron, uranium, or other substances solely to see where the substances would concentrate in the brain and what other biologic consequences the patients would suffer (at least 75 patients), to injecting brain tumor patients with one of the toxic substances and exposing them to the neutrons emanating from operating nuclear reactors where there was no reasonable basis to believe

such radiation would provide any therapeutic benefit to the patient (at least 66 patients). Some of these patients had their skulls opened solely for the purpose of better exposing their brains to radiation.

3. This suit is brought as a class action by the survivors and heirs of four of the unfortunate victims of these medical experiments, filed on behalf of all similarly situated survivors and heirs. One of the victims, George Heinrich, was subjected to non-therapeutic injections of boron to see what would happen to the boron in his body. Later, he was subjected to a separate injection of boron plus neutron irradiation from the MIT reactor. This experiment was known as boron neutron capture therapy ("BNCT"). The second named victim, Eileen Sienkewicz, was subjected to a single boron injection followed by BNCT at MIT. The third named victim, Joseph Mayne, was a patient at MGH but was transported to BNL by Dr. Sweet where, under the supervision of Drs. Sweet and Farr, he received a boron injection and BNCT. The fourth named victim, Walter Van Dkye, a resident of New York, was part of a BNCT experiment at BNL which, from the outset, the doctors knew and acknowledged, to themselves, would provide no therapeutic benefit to Mr. Van Dyke. Defendants never obtained the consent of the plaintiffs' or the class' decedents

or of the class members for these radiation and injection experiments. None of these named victims nor the remainder of the class were advised of the true nature of the experiments, the lack of any reasonable medical basis for such experiments or the excruciating pain and likely death which would occur as a result of such experiments. Defendants affirmatively misled the plaintiffs' and class' decedents by exploiting the decedents' desperate health condition, downplaying the risk of BNCT and grossly overstating the possible health benefits and, in the case of the injectees who did not receive BNCT, by failing to advise them that they were injected with toxic substances. This misconduct was made worse by the deliberate decision of defendants, acting in concert, never to advise the decedents during their lifetime or the class, even to this day, of the true facts of what occurred.

4. The first public glimpse of the true nature of the experiments conducted on the class members was not revealed until 1995 when the President's Advisory Committee on Human Radiation Experiments uncovered and made public documents which disclosed for the first time that (a) the experiments were conducted on unwitting patients, (b) the experiments either had no therapeutic value or were of such unlikely therapeutic value that no

reasonable medical professional would conduct them, (c) the patients or their families had never been fully advised by the defendants of the true nature of the experiments or the lack of scientific or medical basis for such experiments, (d) the defendants had never obtained the consent of the class' decedents or the class, and (e) the persons principally responsible for the misconduct are the persons identified in this complaint. Given the misinformation generated by the defendants at the time of the experiments and subsequently, the members of the proposed class did not know, and could not reasonably have determined by diligent inquiry, that illegal experiments had been conducted on the decedents until the documents uncovered by the President's Advisory Committee, some of which documents were only recently declassified, had been made public and until they had seen the medical records of the decedents.

5. Plaintiffs and the class seek compensation for pain, suffering and wrongful death of their decedents, for their own pain and suffering, and for punitive damages to deter defendants from ever again using any human beings, particularly the terminally ill, as guinea pigs for scientifically untested and unproven experimental procedures and to deter defendants from ever using any person for any medical experiment without first

obtaining their informed consent after full and accurate disclosure. Plaintiffs and the class also seek injunctive relief to halt the institutional defendants from continuing the practices complained of here and to compel them to institute safeguards to prevent any recurrence of these practices.

JURISDICTION AND VENUE

6. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§1331 and 1367. Venue is proper in this Court pursuant to 28 U.S.C. §1391(b) because a substantial portion of the events giving rise to these claims occurred in this district. This action was transferred to this Court from the United States District Court for the Eastern District of New York.

PARTIES

7. Plaintiff Evelyn Heinrich, the surviving spouse of the named decedent George Heinrich, is a resident of Massachusetts. Mrs. Heinrich is the executrix of the estate of George Heinrich. She brings this action on behalf of the estate of George Heinrich, individually on her own behalf and on behalf of all similarly situated estates and individuals.

8. George Heinrich was first admitted to MGH in October 1960 and diagnosed with glioblastoma multiforme (a brain tumor) at age 35. An operation was performed on October 25 and

as much tumor as possible was removed. Mr. Heinrich then received daily cobalt radiation therapy during the month of November (a total of 4000 rads). On December 4, he was readmitted for further tests which showed regrowth of the tumor. He was discharged on December 8 for follow up after the holidays. He was readmitted on December 11 because of progressive swelling and other symptoms and another craniotomy was performed on December 15, at which defendant Dr. William H. Sweet presided. Dr. Sweet's report of the operation discloses that during this operation he was given an intravenous boron injection in the form of 13 cc (3 mg/kg) sodium decaborate. Dr. Sweet then took samples of tumor and normal tissue for analysis. Forty-five minutes to an hour after the intravenous injection, Mr. Heinrich received a second identical dose of the boron compound via the carotid artery and more samples were taken. These injections were given without Mr. Heinrich's consent and had no conceivable therapeutic value. Then Dr. Sweet removed all tissue that he could identify by sight as tumor although he reported that "there may be many remnants behind." Mr. Heinrich was discharged on December 24 with the recommendation to return for BNCT. Mrs. Heinrich recalls being told by Dr. Sweet that there was an excellent chance for survival with the use of BNCT.

9. Mr. Heinrich was readmitted on January 2, 1961 with a very persistent infection at the site of his previous operation. For two weeks he received aggressive treatment for the infection. Nonetheless the infection persisted. On January 16, 1961, Mr. Heinrich's treating physician, Dr. J.C. White recommended that a further operation in the face of such continued infection not be undertaken. On January 18, 1961, despite this clear medical warning and without the consent of Mr or Mrs. Heinrich, Mr. Heinrich was operated on at the MIT reactor site by Dr. Sweet. His skull was opened, he received an intravenous injection of para-carboxyphenylboronic acid, and his exposed brain was irradiated. Mr. Heinrich's condition gradually worsened post-BNCT. He was removed to a nursing home on May 15, 1961, while in a coma and he died on May 27, 1961. At the autopsy it was discovered that he had no residual tumor but his brain showed "Massive radiation necrosis with swelling; herniation of left hemisphere." The cause of death was "extensive radiation necrosis of brain" which was caused by the BNCT. The boron injections in 1960 and the BNCT in 1961 also caused Mr. Heinrich to suffer excruciating pain which he would not have suffered had he not been subjected to these procedures. Mrs. Heinrich observed the pain her husband suffered as a result

of the procedures employed by the defendants and suffered great emotional distress, distress made manifestly more severe when she learned in the last year that her husband's pain and suffering were unnecessary and were the result of unauthorized injections and unconsented and dangerous and unproven medical procedures.

10. Plaintiff Henry M. Sienkewicz, Jr., the oldest surviving son of the named decedent, Eileen Rose Sienkewicz, is a resident of Massachusetts. Mr. Sienkewicz is the administrator of the estate of Eileen Sienkewicz. He brings this action on behalf of the estate of Eileen Sienkewicz, individually on his own behalf and on behalf of all similarly situated estates and individuals.

11. Eileen Sienkewicz was first admitted to MGH on June 10, 1960, at age 39, and diagnosed with glioblastoma multiforme. The tumor was removed by Dr. Sweet, who noted in the record, "I think this lady is an excellent candidate for boron slow neutron capture therapy and hope to carry this out in August." She returned for office examinations in July, August, September, and October, during which she suffered severe depression. She was readmitted to MGH on November 13, 1960, and taken to MIT on November 15 for BNCT. BNCT was performed without her consent and without the consent of any members of her family.

During the BNCT procedure she was given a boron injection in the form of 20 mg of paracarboxy phenylboronic acid and subjected to neutron irradiation from the MIT reactor. Following the operation she remained depressed. She was discharged on December 3, 1960. On December 8 she was seen by Dr. Sweet to whom she reiterated that she wanted to die. Dr. Sweet referred her to Dr. Jackson Thomas at Deaconess Hospital where she underwent electroconvulsive therapy (shock treatments). She was readmitted on February 27, 1961, to MGH complaining of speech difficulties, but no definite diagnosis of recurrent tumor could be made and she was discharged on March 4. She continued to see Dr. Sweet. Her depression gradually returned, and she also showed continuing symptoms of brain dysfunction. On August 13, 1961, she was again admitted to MGH with depression, insomnia, nausea, headaches, and some aphasia. An eye exam showed total lack of vision in the right field, and an EEG was markedly abnormal. She was discharged on August 19. She was again admitted on September 27, 1961, after taking an overdose of Dilantin. She remained severely depressed for several days, gradually became more lethargic, then comatose, and died on October 31, 1961 at the age of 40.

12. The findings at autopsy of Mrs. Sienkewicz reported by Asbury were "Definite tumor nests in left hemisphere, one directly in op. site," and "Widespread necrosis of left hemisphere spreading into corpus callosum. Extreme vessel changes." The cause of death was "extensive radiation necrosis of brain" which was caused by the BNCT. The BNCT also caused Mrs. Sienkewicz to suffer excruciating pain which she would not have suffered had she not been subjected to it. Her family, including her oldest son, Henry, observed the pain she suffered as a result of the procedures employed by the defendants and suffered great emotional distress, distress made manifestly more severe when they learned in the last year that Mrs. Sienkewicz's pain and suffering were unnecessary and were the result of unconsented and dangerous and unproven medical procedures.

13. Plaintiff Rosemary Gualtieri, the daughter of the named decedent Joseph Mayne, is a resident of Massachusetts. She brings this action on behalf of the estate of Joseph Mayne, individually on her own behalf, and on behalf of all similarly situated estates and individuals.

14. Joseph Mayne was diagnosed with glioblastoma multiforme by Dr. Sweet at MGH and initially operated on in February 1951 at MGH. Thereafter Dr. Sweet had Mr. Mayne

admitted to Brookhaven under the care of Dr. Farr where he underwent BNCT on June 14, 1951. According to an article authored by Dr. Farr and others, Joseph Mayne and other patients at BNL who underwent BNCT, suffered severe acute reactions to the injections of boron which preceded the irradiation. According to an article by Farr, Sweet, and others published in February 1954, the dose of B¹⁰ was 1.69 grams given intravenously in the form of borax. On the fourth day after irradiation, Mr. Mayne became lethargic and the lethargy rapidly increased thereafter. Repeated spinal taps were necessary to control the increased cerebrospinal fluid pressure. Following the experiment at Brookhaven, Mr. Mayne's condition became progressively worse. He was transferred from Brookhaven to his home and eventually to Chelsea Old Soldiers Home in Chelsea, Massachusetts, where he died on November 3, 1951.

15. Plaintiff Walter Carl Van Dyke the son of the named decedent Walter Carmen Van Dyke, is a resident of New York. Mr. Walter Carl Van Dyke, is the legal representative of the estate of Walter Carmen Van Dyke. He brings this action on behalf of the estate of Walter Carmen Van Dyke, individually on his own behalf, and on behalf of all similarly situated estates and individuals.

16. On March 4, 1957, Walter Carmen Van Dyke, who was awake and alert at the time although somewhat confused, was admitted to Brookhaven National Laboratory Hospital. He was 50 years old. Approximately a year before that, on March 8, 1956, he had been admitted to a local hospital and undergone a left frontal craniotomy with removal of a tumor diagnosed as glioblastoma multiforme. After the operation he underwent standard radiation treatments. He was discharged in April 1956 and continued reasonably well until February 1957 when he was readmitted to the hospital and then transferred to Brookhaven on March 4, 1957.

17. On February 28, 1957, Walter Carmen Van Dyke's wife signed a document prepared by Brookhaven National Laboratory Hospital entitled Application for Admission on Research Service. Mr. Van Dyke never signed the document. The document provided, inter alia,

To the patients admitted free of charge for study of improved methods of treatment, the hospital gives at all times the most complete care possible. No treatments are employed except those which are designed for [sic] benefit of the patient and of other patients who suffer from similar conditions. No treatment is used in which the probable benefit is not believed to outweigh the possibility of untoward effects.

18. At Brookhaven, on March 6, 1957, Walter Carmen Van Dyke was injected in his carotid artery with approximately 17.9 grams of pentaborate, containing approximately 3.1 grams of boron¹⁰. Almost immediately thereafter he was laid on the top of an operating nuclear reactor and his head was placed inside the reactor where it was exposed to neutron radiation. This process is called BNCT. Mr. Van Dyke was under the care of Howard J. Bagnall, MD. The discharge summary signed by Dr. Bagnall notes in its description of the process of injecting boron and then exposing Mr. Van Dyke to neutron radiation, that there was "slight retching towards the end of treatment. He had a right facial seizure about 15-20 minutes after cessation of radiation followed by right facial paralysis and severe dysphasia. He vomited several times during the first night"

19. After the BNCT, Mr. Van Dyke never improved enough to be discharged. In fact, his condition deteriorated steadily and he died on June 10, 1957. From and after the use of BNCT, Mr. Van Dyke had severe bouts of nausea and vomiting. There is no evidence of such conditions prior to the use of BNCT. An autopsy was done on Mr. Van Dyke's body and his brain was examined for effects of the treatment. The dorsal half of the left frontal lobe having been removed, the remaining basal

portion of the frontal lobe was found to have been replaced by tumor. Microscopic examination of the tumor showed it to be "extremely vascular with active endothelial proliferation and hyalinization of walls of many vessels. There are vast areas of coagulation necrosis."

20. Contrary to the representation made to Mrs. Van Dyke in the above cited Application for Admission, Brookhaven knew that the use of BNCT on Mr. Van Dyke would be of no therapeutic benefit and he was chosen for BNCT precisely because he was terminal with no hope for benefit from the BNCT. The date of Mr. Van Dyke's treatment places him in the third round of BNCT patients at Brookhaven. According to a Conference paper published in *Progress in Nuclear Energy Series VII Vol. 2 (Recent Advances in Neutron Capture Therapy, by L.E. Farr, J.S. Robertson, E.E. Stickley, H.J. Bagnall, O.D. Easterday, and W. Kahle (1959))*,

[b]ecause of the previous frequency of harassing skin complications, patients in the current [third] series were selected for treatment initially only when believed to be near terminal status although the latest patients were treated in an earlier state. This was done, however, only after gaining confidence in the safety of the procedure. It must be emphasized that the third series of patients were treated to evaluate procedural changes alone and therefore cannot properly be compared with the patients of series one and two for longevity following treatment.

21. Dr. L.E. Farr was the principal supervisor and instigator of the BNCT experiments at Brookhaven. Dr. H.J. Bagnall was Mr. Van Dyke's principal doctor at Brookhaven and the witness to Mrs. Van Dyke's signature on the Application for Admission.

22. Defendant William Henry Sweet, M.D., is a neurosurgeon who continues to maintain an office at MGH. He is a resident of Massachusetts. During the relevant years in this case he was a member of the neurosurgery staff and then chief of neurosurgery at MGH. He directly conducted and supervised many of the experiments which are the subject of this litigation.

23. Lee E. Farr, M.D., was the head of Medical Department at BNL during all years relevant here and was personally involved in carrying out many of the experiments which are the subject of this litigation. Dr. Farr, as head of the Medical Department at BNL, was directly responsible for and supervised all BNCT experiments conducted at BNL, including any experiments involving injections without radiation therapy. Dr. Farr is now deceased and his Trust, which on information and belief holds his assets, is being administered in the County of Contra Costa, California.

24. Defendant MGH is a private hospital corporation incorporated under the laws of Massachusetts with its principal place of business in Boston, Massachusetts. It had direct supervisory responsibility for the treatment of patients under the care of Dr. Sweet, many of which patients were subjected to the experiments involved in this litigation.

25. Defendant MIT is a private educational institution incorporated under the laws of Massachusetts with its principal place of business in Cambridge, Massachusetts. MIT was responsible for supervision of the uses to which its nuclear reactors were put and in particular to the use of such reactors to conduct experiments on humans.

26. Defendant Associated Universities, Inc. ("AUI") is a scientific and educational institution incorporated under the laws of New York. It's founding institutions are Harvard, Yale, Columbia, Cornell, Princeton, MIT, Rochester University, Johns Hopkins, and University of Pennsylvania. It operated BNL which has its principal place of business in Upton, New York, during all the years relevant here. AUI, as the operator of BNL, was directly responsible for the conduct of medical experiments on patients admitted to its facility and on any persons who were brought to its facility for the purpose of carrying out medical

experiments on the BNL nuclear reactors. AUI was also directly responsible for the supervision of the conduct of Dr. Farr, particularly the use by Dr. Farr of the BNL facilities to conduct radiation and other experiments on humans.

27. Shields Warren, M.D. was Director of the AEC's Division of Biology and Medicine ("DBM") from 1947 to 1952. In that capacity he had direct responsibility for the development, implementation and supervision of AEC policy, programs, contracts and funding pertaining to biological and medical effects of radiation, radiation safety, and radiation-related research including human radiation research and experimentation and including the experiments involved in this case. During the period of his directorship, defendant Warren was also responsible for ensuring that AEC and other relevant guidelines and standards on human experimentation, including informed consent for, and adequacy of research and therapeutic merit of, human experiments were implemented and followed. He was also responsible for seeing to it that appropriate remedial action was taken in cases where human experiments violated, or were discovered to have violated, applicable guidelines and standards. He delegated the responsibility to assure compliance with the applicable medical, ethical and AEC standards to the private defendants and failed to

properly supervise their implementation of that responsibility. The United States of America is sued to answer for the tortious conduct of Shields Warren, M.D.

28. Defendant United States of America is responsible for the acts of Shields Warren, M.D. The United States has determined that Dr. Warren was acting within the scope of his employment when he engaged in the omissions and commissions which are the subject of this complaint and with its consent has been substituted for Dr. Warren as a defendant in this action.

29. Charles Dunham, M.D. was Director of the AEC's Division of Biology and Medicine ("DBM") from approximately 1954 to 1967. In that capacity he had direct responsibility for the development, implementation and supervision of AEC policy, programs, contracts and funding pertaining to biological and medical effects of radiation, radiation safety, and radiation-related research including human radiation research and experimentation and including the experiments involved in this case. During the period of his directorship, defendant Dunham was also responsible for ensuring that AEC and other relevant guidelines and standards on human experimentation, including informed consent for, and adequacy of research and therapeutic merit of, human experiments were implemented and followed. He

was also responsible for seeing to it that appropriate remedial action was taken in cases where human experiments violated, or were discovered to have violated, applicable guidelines and standards. He delegated the responsibility to assure compliance with the applicable medical, ethical and AEC standards to the private defendants and failed to properly supervise their implementation of that responsibility. The United States of America is sued to answer for the tortious conduct of Charles L. Dunham, M.D.

30. Defendant United States of America is responsible for the acts of Charles L. Dunham, M.D. The United States has determined that Dr. Dunham was acting within the scope of his employment when he engaged in the omissions and commissions which are the subject of this complaint and with its consent has been substituted for Dr. Dunham as a defendant in this action.

31. The United States of America, in addition to being included by the term "defendants" may also be referred to as "federal defendant." However, references to the conduct of defendants or the federal defendant does not include conduct of the former United States employees, Drs. Dunham and Warren, relating to the claims of Mr. Van Dyke until and unless this Complaint is amended to assert Mr. Van Dyke's claims against the

United States except for purposes of the First and Ninth Causes of Action which are not asserted against the United States and for which reference to the conduct of defendant's includes the conduct of Drs. Warren and Dunham.

GENERAL ALLEGATIONS

A. The Beginning of BNCT

32. In the late 1940s a consortium of nine universities created AUI to operate BNL under contract with the AEC. Part of BNL was a research medical facility designed to do biomedical research using radiation and radio-isotopes.

33. In 1948, Dr. Lee E. Farr was offered the position of Chairman of the Medical Department at BNL. As a condition of taking the job Dr. Farr insisted that BNL be allowed to use diseased patients who would be given free hospital beds for the radiation experiments. Free hospital beds were deemed essential by Dr. Farr so that the doctors would feel justified in keeping the patients in the hospital for an extended time to observe them following the experiment and on whom the doctors could use medical techniques "whose value we as yet have no valid information."

34. The Brookhaven Graphite Research Reactor was commissioned in August 1950, and Dr. Farr was interested in use of the reactor for slow-neutron therapy.

35. In the 1940's Dr. Sweet, a neurosurgeon at MGH, devised a scheme to use a previously untested procedure on human subjects to see if he could successfully destroy brain tumors. Dr. Sweet submitted a proposal to the AEC for BNCT of brain tumors at the BNL reactor. AEC and BNL enthusiastically accepted Dr. Sweet's proposal and thus began the relationship between AEC, MGH, Sweet, Farr and BNL to use human beings as test subjects in the BNCT experiments.

36. In the early 1950s, the AEC, Dr. Sweet, Dr. Farr, AUI, and MGH undertook a joint enterprise, funded by the AEC and overseen initially by Dr. Warren and later by Dr. Dunham, to use terminally ill brain cancer patients as "test animals" for their theory that BNCT would work. The elements of the scheme included, (a) injecting terminal brain cancer patients, without their knowledge or consent, with toxic substances, including boron and uranium, which could absorb neutrons to see which would best concentrate in brain tumors, (b) performing BNCT on these and other terminally ill brain cancer patients, without their consent, when there was no evidence BNCT would provide them with

therapeutic benefit and when the available evidence demonstrated that BNCT would not work for most of them, (c) luring patients into BNCT by falsely advising them such therapy had a reasonable possibility of success and offering them free hospital beds, (d) failing to obtain the consent of the patients prior to invading their bodies with harmful chemicals and radiation, and (e) failing to ever inform the families of the patients of the true nature of the experiments performed on their decedents or the results of the autopsies performed on the decedents and deliberately hiding this information from the class members.

37. In its initial stages the BNCT experiment program was conducted using the BNL reactor with patients supplied by MGH and Dr. Sweet. Drs. Sweet and Farr were directly and jointly involved in making the decisions on which patients should receive BNCT, which patients to inject with various boron and other toxic compounds, what protocols to use in the experiments including the nature of the neutron bombardment, the timing of the irradiation after injection, the level of radiation to use, the chemical composition of the materials to be injected into the patients, the condition of the patients' skull at the time of the experiment, the length of time for the irradiation and the interpretation of the results of the experiments. These joint

activities are evident from articles written jointly by Drs. Sweet and Farr on the results of experiments with BNCT and articles written by others about the work of Drs. Farr and Sweet.

B. The Theory of BNCT

38. The concept of neutron capture as treatment for tumors is based on the idea of using radiation to kill tumor cells from the inside of the tumor, and on the use of an allegedly benign external source of energy, slow neutrons, which become lethal only when captured by substances introduced into the tissues of the tumor. Unlike conventional radiation therapy or chemotherapy, both of which can harm both tumor and healthy tissue, BNCT is supposed to produce ionizing radiation only within the tumor. Thermal, or slow neutrons alone, are presumed to not have an ionizing effect by themselves, but can be "captured" by some nuclei that have an affinity for them. If the boron (or other neutron capturing substance) could be in theory confined to the tumor cells and if the radiation could be limited to slow neutrons, then, theoretically, the radiation damage should also be confined to the tumor cells.

39. The human experiments involved in this case can be divided into two categories: (1) the experiments in which

patients underwent the full BNCT procedure, which involved the injection of boron (in some form) immediately prior to or during exposure to slow neutron radiation; and (2) the experiments where patients were injected with boron, or some other potential neutron capturing substance, but were not exposed to slow neutron radiation, solely to test the performance of the compound itself for future BNCT experiments.

C. Absence of Knowledge About BNCT

40. Although some preliminary biological and animal studies had been done prior to the first human studies, they were not adequate to answer accurately the following essential questions regarding the safety and efficacy of human experiments:

- a. What would be the acute or other effects of injecting humans with boron or the other neutron absorbing compounds being tested?
- b. What would be the distribution of the neutron absorbing compounds between the tumor tissue and healthy tissue in the vicinity of the body where the neutron bombardment would activate the substance and cause an acute radioactive reaction?
- c. Exactly how much slow neutron radiation would the patients receive? Exactly how much other radiation (fast neutron, gamma, etc.) would the patients receive?
- d. What would be the effects of all types of radiation on both healthy and tumorous tissue?

e. Exactly how far would the slow neutrons travel through the body tissues and how much of the energy of such neutrons would be lost before reaching the tumor?

f. What would the impact of the neutron irradiation be on the portion of the brain which was not cancerous but contained the neutron absorbing material or through which the neutrons had to penetrate to reach the tumor?

g. What were the facts regarding assimilation, distribution, selective localization and excretion of the neutron capturing substance being administered?

It was not until the early 1960's, after human BNCT experiments had ended at BNL, that BNL or any other researchers involved with BNL, MGH or MIT began studies designed to answer the questions above. By that time, over 140 patients had been the subject of one or both of these experimental procedures.

41. It is evident from a review of the historical documents at BNL that at no time prior to 1961 was there an adequate understanding of the toxic effects of the neutron capturing agent which was being injected into patients with brain tumors nor had adequate research been completed to find other less toxic agents. In 1959 John F. Bonner of the AEC reported on a program review at BNL and concluded, with respect to BNCT, "[t]his program could be strengthened by additional basic research in the biochemistry, pharmacology, and physiology of

boron compounds. The base of the neutron capture idea should be broadened to include a more thorough investigation of other promising radioelements and other methods of localization."

42. By 1959 BNL, MGH and Dr. Sweet had already injected over 50 people with boron compounds and inflicted BNCT on at least 25 others.

43. Not only was it the initial intent of the BNL program to use medical procedures which lacked evidence of their potential effectiveness, but documents from BNL also reveal that this intent persisted. In 1959 John C. Whitnah of the AEC reported on a visit to BNL where he learned that one of several reasons that patients were admitted at no charge to the BNL hospital was "there might be greater flexibility in the design of investigation".

44. Subsequent to the conclusion of the experiments, Dr. Sweet and several other doctors wrote articles and reports indicating that the BNCT experiments were a failure and the failure stemmed, in part, from the absence of adequate scientific evidence regarding the nature of boron distribution in the human body, absence of adequate scientific evidence regarding boron chemistry, absence of adequate scientific evidence regarding the

Fraudulent
Conclusions?

proper shape of a neutron beam for BNCT and the absence of requisite dosimetric equipment to measure radiation.

45. In 1964, Dr. Sweet delivered a paper at a conference in Venice, Italy where he discussed BNCT. He admitted it had been a failure and listed the following reasons for the failure:

1. Our lack of appreciation of the full complexity and requirements of our biological systems with regard to the boron compound, specifically to the need to clear it from the cerebral blood stream.
2. The inadequacy of the current status of knowledge regarding boron chemistry.
3. Insufficient information as to the methods of optimizing the shape of a neutron beam for capture therapy.
4. The lack of the requisite dosimetric equipment."

A. H. Soloway, G. L. Brownell, R. G. Ojemann and W. H. Sweet, "Boron-Slow Neutron Capture Therapy: Present Status" from Preparation and Bio-Medical Application of Labeled Molecules, Proceedings of a symposium sponsored by The Radiation Chemistry and Radioelements Centers of the Universities of Bologna, Padua and Rome, The Italian National Research Council (C.N.R.) and The European Atomic Energy Community (EURATOM), Venice - August 23-

29, 1964, published by the European Atomic Energy Community (EURATOM), Brussels, December 1964.

46. On September 16, 1982, Dr. Victor Bond, the successor to Dr. Farr as head of the Medical Department at BNL, gave an interview in which he stated in reference to BNCT:

The early experience was very unfortunate. . . . Then they went beyond that. It wasn't stopped until long after it became evident it wasn't working - that's the criticism of it. Damage was done to patients just as damage was done with the first external fast neutron radiations, because radiobiology wasn't that well understood.

D. The Human Experiments

(a) BNCT

47. The first trial of BNCT began in February 1951 at BNL and Drs. Sweet and Farr were jointly involved in the process. This first trial lasted 24 months and involved 10 patients brought by Dr. Sweet from MGH, all of whom had undergone craniotomy for tumor removal and 8 of whom had undergone conventional radiation therapy. These 10 patients were transferred to BNL for BNCT which conducted jointly by Drs. Farr and Sweet. Plaintiff Joseph Mayne was one of these first ten patients. The procedure involved injection of a boron compound followed as quickly as possible by exposure to the neutron flux from the reactor. Each

patient was lowered into a special room created by removing some of the shielding above the reactor. There was an aperture in the top of the reactor and the patient lay with his or her head placed over the aperture. The reactor was then powered up, which took 8-10 minutes (coinciding with Dr. Sweet's estimate of maximum concentration of boron in the tumor) and the patient was irradiated for an indefinite period of time (30-40 minutes). Radiation was administered with the skull closed. Some of the patients received multiple doses of BNCT. None of these patients gave their consent for these procedures and defendants concealed from them and their families information which would permit them to know what had really happened to them.

48. The boron dose which was given at the time of the neutron exposure was in the form of borax and had been formulated at BNL using a special boron preparation provided by Oak Ridge National Laboratory. This boron from Oak Ridge contained 96% B^{10} (commercial boron contains 19% B^{10} and 81% B^{11} , which does not work as well for capturing neutrons). The dose of borax given the 10 BNCT patients just before the neutron exposure averaged 20 grams, which gave 19 to 46 mg of B^{10} per kg of body weight.

49. Locksley and Farr wrote the only article dealing directly with the toxicology of the boron injections at the time

of the neutron exposures. The article records the severe side effects of the borax injections in the first 10 BNL patients. Reactions included: nausea, vomiting, and retching in all but 2 cases within 2 minutes after injection; urgent defecation and micturition; face flushed with a grey cast followed by pallor; grand mal seizures on several occasions; and significant respiratory depression in 2 cases. One patient who received 4 doses became very sick and died within 3.5 weeks. The authors opined:

"Whether or not this patient's interim systemic illness represented cumulative boron poisoning it is impossible to say with certainty. Circumstantially and symptomatically it was most suggestive."

50. The second round of BNCT at BNL was during 1954-55 and included nine patients. No consent was obtained from these patients and defendants have concealed from them and their families information from which they could learn what had happened to them. Slatkin says that these patients were given a "less toxic boron preparation, sodium pentaborate with D-glucose in the molar ratio 2:1 ... but at a higher [B¹⁰] dose than in the first series: 32-50 mg per kg body weight (median, 42 mg/kg)." According to Farr, the boron was given "intravenously in a

concentrated solution of 100 ml. containing 20 to 30 grams of borax. The dose ... has ranged from 32 mg B¹⁰ per kilogram body weight to 42 mg B¹⁰ per kilogram body weight." In addition, modifications to the reactor provided greatly increased neutron radiation. These patients developed severe skin and scalp lesions as a result of boron accumulating in the skin and capturing neutrons there, thus causing radiation damage.

51. The third round at BNL was during 1956-58 and included 9 patients. No consent was obtained from these patients and defendants have concealed from them and their families information from which they could learn what had happened to them. Farr et al. say that mouse studies by Easterday showed that a new boron compound, sodium pentaborate, could deliver more boron with less toxicity. Other animal studies at Brookhaven showed that the scalp lesions were directly caused by neutron capture in the skin. In an attempt to deal with this problem, it was decided to give more boron, begin the radiation more quickly, and limit the period of radiation. To accomplish this, the boron was administered directly via the carotid artery rather than intravenously (experiments had shown that the boron concentrated in the tumor faster than in the skin) and irradiation was begun during injection. The dose of B¹⁰ ranged from 25 to 60 mg/kg

body weight (median 50 mg/kg). Finally, because of the previous skin problems, "patients in the current series were selected for treatment initially only when believed to be near terminal status...." In short, these patients had no hope of recovery and were used as guinea pigs to test the new theories. "It must be emphasized that the third series of patients were treated to evaluate procedural changes alone and therefore cannot properly be compared with the patients of series one and two for longevity following treatment."

52. In 1959, the new BNL Medical Research Reactor came on line. A fourth series of 17 patients received BNCT at this reactor from 1959 to 1961. No consent was obtained from these patients and defendants have concealed from them and their families information from which they could learn what had happened to them.

53. None of the four rounds of BNCT experiments at BNL resulted in prolonging life beyond what might be expected without such experiments. Median survival times post-BNCT were 97 days, 147 days, 96 days, and 90 days.

54. Dr. Sweet and MGH were directly involved with the first two rounds of BNCT at BNL and, on information and belief, Dr. Sweet was consulted with regard to all BNCT related

experiments at BNL. He also became involved in developing a brain tumor experiment facility at MIT which was funded by the AEC and, on information and belief, with respect to which BNL was consulted. In 1960-61, 21 patients were subjected to BNCT at the MIT facility. No consent was obtained from these patients and defendants have concealed from them and their families information from which they could learn what had happened to them. All of them had had a craniotomy to remove the tumor mass at least 3 weeks prior to BNCT. According to the 1972 article by Asbury, Ojemann, Nielsen, and Sweet, 16 of the patients received paracarboxybenzene boronic acid intravenously; and two received sodium perhydrodecaborate intracarotidly. The doses ranged from 15 to 31 mg B/kg.

55. Unlike the earlier BNCT experiments at BNL, in which patients were irradiated with the skull closed, the MIT patients received the neutron radiation with the skull open and the brain exposed. The opening of the skull was additional surgery performed on these patients solely for the BNCT and unrelated to their normal medical treatment.

56. The experiments at MIT involved new surgery on each patient following their craniotomy and used the reactor at MIT which had been specifically designed by Dr. Sweet and MIT to

include an operating room directly beneath the reactor. All patients had their skull reopened at the site of their previous craniotomy. They were then injected with the boron compound.

What happened next was:

Following the administration of the boron, the patient was elevated to the beam aperture by a hydraulic lift built into the floor. Once the patient was secured, everyone left the room and the built-in shutters were opened, allowing an intense beam of thermal neutrons to irradiate the open brain. The patients were irradiated for 45 min to 90 min for a total neutron fluence of 5×10^{12} to 2×10^{13} n/cm².

Jong-Ho Richard Choi, "Development and Characterization of an Epithermal Beam for Boron Neutron Capture Therapy at the MITR-II Research Reactor," submitted to the Department of Nuclear Engineering in partial fulfillment of the requirement for the degree of Doctor of Science at the Massachusetts Institute of Technology, April 1991, p. 62. While it was hoped that this method would both solve the problem of scalp lesions and expose more of the tumor cells to the neutron radiation, none of the prior experimental animal data or other studies provided a reasonable medical basis that this hope would be realized.

57. The BNCT experiments at MIT were just as unsuccessful as the previous ones at BNL; most of the patients were dead within 6 months. The Asbury article reports on the

neuropathologic study of the brains of 14 of the subjects. Residual tumor was found in all but one. There was "extensive coagulation necrosis with attendant severe vascular damage... consistent with radiation injury." It was found that boron levels in blood at the time of irradiation were as great or greater than the level in tumor tissue. Although normal brain tissue was not greatly damaged, blood vessel walls were often destroyed. This damage, rather than tumor regrowth, was the cause of death in 10 of the 14 cases autopsied.

(b) Injections

58. In addition to these BNCT experiments, defendants also engineered a series of human experiments on patients without their consent who were injected with boron, uranium or other toxic neutron absorbers, solely for the purpose of determining where the boron concentrated in the brain and what kind of health effects would result from the injection. All of these patients had brain tumors and the injections occurred prior to or during brain surgery. Some of these patients, like George Heinrich, later also received another boron injection as part of BNCT. No consent was obtained from any of these patients and defendants have concealed from them and their families information from which they could learn what had happened to them.

59. In 1952, Dr. Sweet and Manucher Javid, MD, published an article describing "the first exploratory steps we have taken in man leading to the use of a beam of slow neutrons from a nuclear reactor in an effort to improve the treatment of neoplasms." This referred to the preliminary experiments conducted at MGH prior to the first round of BNCT at BNL, in which subjects with brain tumors were injected with borax prior to routine craniotomy but not subjected to BNCT. As to dosage, the article states:

We have given i.v. to 23 adults with brain tumor 5.0 g. of borax ($\text{Na}_2\text{B}_4\text{O}_7 \cdot 10\text{H}_2\text{O}$), containing 0.57 g. of boron. In another 35 patients the injected agent contained 6.3 g. of glycerol to each 5.0 g. of borax. At the time of operative removal of the brain tumor, specimens were taken of this and of nearby normal gray and/or white matter and frequently of scalp, muscle, bone, blood and cerebrospinal fluid.

60. The article further reports that:

One encouraging feature of these data is the relatively high concentration of boron throughout brain and tumor with such a small nontoxic dose. Since a craniotomy was either being or shortly to be performed, no effort was made in these cases to move the dose up into the maximal range consistent with recovery. But since the patient will not have to surmount an operation at the time he is being exposed to the neutron beam, the dose of boron just prior to exposure can, if necessary be pushed even to slightly dangerous levels to secure a maximal

therapeutic effect. We have given intravenously to several adults with brain tumor 15 g. borax/70 kg. body weight and have found this to be well tolerated.

61. This article also refers to previous experiments by Sweet and Selverstone involving the injection of radioactive phosphorus in the hope that it would concentrate in brain tumors where it would have a destructive effect (by itself, not as a neutron capture agent).

62. In 1958, A.J. Luessenhop, Sweet, and others published an article on their experiment with injecting hexavalent uranium into human subjects. The experiment had two purposes: (1) investigate U^{235} for possible use in neutron capture therapy, and (2) study toxicity and metabolism of U^{235} in humans. Five terminal patients with brain tumors were injected with uranyl nitrate in doses ranging from 5.5 mg to 15.8 mg (0.097-0.28 mg/kg) and then monitored for changes in bodily functions. Four out of the five were autopsied after death. There was evidence of renal toxicity, especially in the 3 patients receiving the highest doses. Other documents indicate that Luessenhop and Sweet did other experiments on humans involving injection of U^{233} and U^{238} . The patients were injected with uranium with no intent that the injection would have any therapeutic value to the patient.

63. Dr. Sweet and others were involved in other experiments, both human and non-human, to evaluate different boron compounds for use in neutron capture therapy. According to Sweet and Soloway's 1962 article, they tested three other boron compounds on "patients hopelessly ill with malignant gliomas" in order to evaluate the toxicity of the compounds for future use in BNCT. The compounds were administered both intravenously and via the carotid artery. "This latter route was included in the event that this mode of injection becomes the preferred one for use in neutron-capture therapy." The patients were then monitored for their reactions to these boron compounds but were not given radiation therapy.

64. In the Sweet/Soloway experiments, five patients were injected with 3-Amino-4-carboxybenzeneboronic acid i.v. in a dose ranging from 3 to 24 mg of boron/kg of body weight. The authors noted "transient bradycardia" and lowered blood pressure at the highest doses. Four patients were injected with m-Boronosuccinanic acid intra carotid in a solution containing 10 mg B/ml. "Doses ranged from 2.8 to 16 mg B/kg." Patients' complaints included "hyperemia of the ipsilateral side of the face" and "burning pains in the supraorbital region." Five patients were injected with Sodium perhydrodecaborate in doses

ranging from 20 to 50 mg B/kg. One patient's breathing became shallow at a dose of 55 mg B/kg and the patient received breathing assistance for 2 minutes. There was no intent that these injections would have any therapeutic value for the patients.

E. Consent

65. Neither the patients who received BNCT nor the patients who received boron or uranium injections without corresponding neutron therapy were ever informed that the medical procedures being performed upon them were wholly experimental and extremely dangerous with potentially very serious side effects including severe acute reactions and death.

66. In addition, none of these patients were advised that the procedures being performed upon them either had no conceivable therapeutic value (the boron and uranium injectees) or had no reasonable possibility of providing them with any therapeutic benefits. To the contrary all of the patients who received the BNCT were led to believe that there was a reasonable basis to expect that the neutron therapy would be beneficial. Defendants had no reasonable scientific or medical basis for such representations and in fact they knew, or should have known, that BNCT was a totally unproven therapy with no evidence of success

in either animals or humans. None of the patients or their families, either the injectees or the BNCT patients, ever gave consent to be experimented on by the defendants.

67. A review of the medical records obtained from the defendants with regard to the medical treatment of the named plaintiffs' decedents discloses no notations of any consent obtained from the patients for the particular experiments which were performed on them, nor are there any written consent forms in the medical files. In addition, a review of all of the documents provided by the defendants to the President's Advisory Committee on Human Radiation Experiments relating to BNCT fails to disclose a single form in use by any of these institutions prior to the conclusion of the BNCT experiments in 1961 which, if used in any of these cases, would have provided consent for the radiation and other experiments performed on the class' decedents.

F. The Prevailing Medical Standards

68. In 1946, even before the AEC was created, the American Medical Association had expressed its opinion on the rules for human experimentation. The AMA's Judicial Council met on December 10, 1946, to consider a report on the Nazi experiments uncovered at Nürnberg. The Chairman declared that

the Nazi experiments violated the standards that already existed in Principles of Medical Ethics of the American Medical Association. However, since the Principles did not deal explicitly with human experimentation, the Judicial Council offered the following statement:

In order to conform to the ethics of the American Medical Association, three requirements must be satisfied: (1) the voluntary consent of the person on whom the experiment is to be performed [must be obtained]; (2) the danger of each experiment must be previously investigated by animal experimentation, and (3) the experiment must be performed under proper medical protection and management.

The AMA House of Delegates approved this report. In 1946, approximately 70% of all physicians belonged to the AMA.

69. In May 1946, MGH established its own Radioactive Isotope Committee. Later, the AEC required all institutions to establish local isotope committees. MGH's committee had

the duty of passing on all work within the hospital walls in which isotopes are used, either approving or disapproving such undertakings. It should also ... satisfy itself that both patients and personnel are properly safeguarded from the deleterious effects of radiation.

Despite this charter, Dr. Sweet's 1953 Application for Approval of Use of Radioactive Isotopes (for injections of U^{233} and U^{235}) sole reference to patient safety was to note that he was not

going to be protective of the patient: "This [dose] exceeds max. permissible exposure rate of 0.3 rem/wk but pts [patients] are terminal."

70. At the March 15, 1955, meeting of the MGH Radioactive Isotope Committee, one member declared that the safety of the patient was of "paramount importance." The committee concluded that "it is not wise in any way to inhibit investigators with ideas, and yet the safety of the patient must come first."

71. The AEC, which funded the experiments performed by defendants, adopted a policy on informed consent which was expressed by its General Manager, Carroll Wilson, as early as April 1947 in a letter to Stafford Warren, Dean of the UCLA Medical School:

[T]reatment (which may involve clinical testing) will be administered to a patient only when there is expectation that it may have therapeutic effect. . . . [I]t should be susceptible of proof from official records that, prior to treatment, each individual patient, being in an understanding state of mind, was clearly informed of the nature of the treatment and its possible effects, and expressed his willingness to receive the treatment.

72. That policy was confirmed and expanded in a letter later that year from the General Manager of the AEC.

We therefore wish to record our approval of the position taken by the medical staff of the AEC in point of their studies of the substances dangerous to human life. We believe that no substances known to be, or suspected of being, poisonous or harmful should be given to human beings unless all of the following conditions be fully met: (a) that a reasonable hope exists that the administration of such a substance will improve the condition of patient, (b) that the patient give his complete and informed consent in writing, and (c) that the responsible nearest of kin give in writing a similarly complete and informed consent, revocable at any time during the course of such treatment.

November 5, 1947 letter from Carroll Wilson to Robert Stone.

73. In March 1948, the Subcommittee on Human Applications of the AEC passed a resolution stating:

Radioactive materials may be used in patients suffering from diseased conditions of such nature that there is no reasonable probability of the radioactivity employed producing manifest injury provided:

- a. Animal studies have established the assimilation, distribution, selective localization and excretion of the radioisotope or derivative in question.
- b. The subject is of sound mind, has full knowledge of the act and has given his consent to the procedure....

74. In 1953, the NIH Clinical Center required written consent from normal research subjects. NIH also began a system of group review of research proposals that became the model for today's institutional review boards.

75. In direct contradiction of all of these clear ethical standards, defendants embarked on a series of human experiments on the named plaintiffs' decedents and the class' decedents without their consent and without sufficient animal or other data to determine either the potential adverse effects of the experiments or the reasonable possibility of any benefits to the named plaintiffs' decedents or the class' decedents.

76. The conduct of defendants did not involve the practice of medicine. It involved the unauthorized use of unproven and highly dangerous experiments on the persons of the decedents of the plaintiffs and the class which fall totally outside the definition of medical practice and have nothing to do with the practice of medicine. The doctor's first and most important creed is "Do no harm." Defendants blatantly and willfully ignored that creed. Therefore, while they held the title of doctor, hospital or medical facility, they were not acting in those capacities when they committed the acts complained of here.

77. Defendants were not engaged in any charitable activities when they committed the acts complained of here. Their conduct was contrary to public policy and violative of the civil rights of the decedents of plaintiffs and the class. As such it is outside the scope of legitimate charitable activities.

78. In addition, to this day defendants or any one of them have never informed the named plaintiffs or any member of the class of the true facts surrounding the medical experiments perpetrated on their decedents and have engaged in a deliberate effort to fraudulently conceal these facts from plaintiffs and the class. In fact, from the first day of the experiments, the defendants have embarked upon a concerted effort to hide from the class' decedents and other class members the true nature of the experimental procedures to which they were subjected. Thus the class did not know, and could not have reasonably known, that the class' decedents were the victims of the tortious actions alleged in this complaint until, at the earliest, 1995 when documents were released which revealed, for the first time, the true nature of the experiments.

CLASS ALLEGATIONS

79. The class consists of the following:

All persons who were injected with boron, uranium or any other toxic substances by the defendants or any one of them as part of the BNCT experiments from 1948 to 1964 and their surviving immediate family members (spouses, siblings, parents and children).

80. Plaintiffs bring this action individually and, in their representative capacity, as a class action on behalf of all others similarly situated pursuant to and under the provisions of Rule 23 of the Federal Rules of Civil Procedure.

81. Plaintiffs are unable to state precisely the number of persons comprising the class which, upon information and belief, number in excess of one hundred and forty persons. The class is sufficiently numerous, so that the joinder of all of its members is impractical.

82. Common questions of law and fact exist with respect to the defendants' actions that are the subject matter of this Complaint and include:

a. Did defendants' medical research activities with BNCT and related toxic injections constitute battery on the members of the class?

b. Did defendants' medical research activities with BNCT and related toxic injections constitute

negligence, gross negligence and/or wanton and willful conduct?

c. Are defendants liable to the class for punitive damages and if so in what amount?

d. Did defendants negligently or intentionally cause the class to suffer emotional distress?

e. Did the defendants undertake concerted activities and a joint enterprise which caused damage to the class?

f. Did the defendants commit fraud by falsely inducing the decedents of the class and the class members to participate in untested and therapeutically worthless medical experiments?

g. Did the defendants deliberately hide from the decedents of the class and the class members the information necessary for them to make an informed decision about the nature of the experiments performed and the existence of legal claims against the defendants for their actions?

h. Did the defendants fail to obtain the consent of the class' decedents to conduct radiation and other experiments?

83. The claims of the class action plaintiffs are typical of the claims of the class.

84. The class action plaintiffs will fairly and adequately protect the interests of the class they represent. The interest of the class action plaintiffs are consistent with those of the members of the class; there is no conflict of interest in maintaining a class action; and plaintiffs have, or can acquire the financial resources to assure that there will be full protection for the interests of the class. In addition, the class action plaintiffs are represented by experienced and able counsel who have represented persons in complex tort matters and some of whom have previously represented plaintiff classes, including the prosecution of "mass tort" class actions.

85. Class action treatment provides a fair and efficient method for the adjudication of the controversy herein. The class action will provide an effective method whereby the enforcement of the rights of the class action plaintiffs and class action members can be fairly managed without unnecessary expense or duplication.