NRC Form 374
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 75

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

Licensee	
1. Veterans Administration Medical Center	In accordance with letter dated December 2, 1987,
2. Tremont Avenue & South Center Street East Orange, New Jersey 07019	3. License number 29-04481-01 is amended in its entirety to read as follows:
	4. Expiration date April 30, 1991
	5. Docket or Reference No. 030-02477

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. As necessary for uses authorized in Subitem 9.A.
B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. 3 curies of each byproduct material authorized in Subitem 6.B.
C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. Any radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. As necessary for uses authorized in Subitem 9.C.
D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. Any radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. As necessary for uses authorized in Subitem 9.D.
E. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. 1000 millicuries total for sources authorized in Subitem 6.E.
F. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	F. Prepackaged kits	F. 10 millicuries of each byproduct material authorized in Subitem 6.F.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 29-04481-01

Docket or Reference number: 030-02477

Amendment No. 75

(Items 6., 7., & 8. continued)

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
G. Xenon 133	G. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	G. 200 millicuries
H. Americium 241	H. Sealed Source (Amersham Model No. AMC.24)	H. 14 millicuries
I. Hydrogen 3	I. Any	I. 10 millicuries
J. Carbon 14	J. Any	J. 10 millicuries
K. Cadmium 109	K. Sealed source (Dupont (NEN) Model NER 465)	K. Two sources of 50 millicuries each
L. Any byproduct material listed in Schedule A, Column II, Section 33.100, 10 CFR 33	L. Any	L. As specified in Section 33.11(c) of 10 CFR 33 for a Type C License of Broad Scope
M. Cerium 141	M. Microspheres	M. 25 millicuries
N. Strontium 85	N. Microspheres	N. 25 millicuries
O. Chromium 51	O. Microspheres	O. 25 millicuries
P. Iodine 125	P. Microspheres	P. 25 millicuries
Q. Iodine 125	Q. Any	Q. 75 millicuries
R. Cesium 137	R. Sealed source (Nuclear Associates)	R. 10 millicuries

9. Authorized use

A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100, Title 10, Code of Federal Regulations.

B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

C. Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

D. Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

E. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

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SUPPLEMENTARY SHEET

License number 29-04481-01

Docket or Reference number 030-02477

Amendment No. 75

(Item 9. continued)

F. In vitro studies.
G. Blood flow and pulmonary function studies.
H. For use in Searle Analytic Model SS-10244 Anatomical Marker.
I. and J. Tracer studies in humans as approved by a Radioactive Drug Research Committee established with the Food and Drug Administration (FDA).
K. Human research on 50 patients in accordance with protocol "Renal Sequelae of Excessive Lead Stores" as described in the licensee's letter dated June 28, 1982. The Licensee shall file a report no later than December 1, of each calendar year discussing the results of the research.
L. through Q. Research and development as defined in Section 30.4(q) of 10 CFR 30; Animal studies.
R. For use as a calibration source.

CONDITIONS

10. Licensed material shall be used only at V. A. Medical Center, East Orange, New Jersey.

11. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Gerald Salen, M.D.	Tracer Studies in humans as approved by a Radioactive Drug Research Committee.
Maimu Ohanian, M.D.	Group VI
Ralph Lilienfeld, M.D.	Groups I, II, and III In vitro studies Xenon 133
Robert Modlinger, M.D.	Group I
Richard P. Weedeen, M.D.	Groups I, II, III, IV, and V In vitro studies Xenon 133 Cadmium 109 sealed source as listed in Subitem 6.K
John R. Mathew, M.D.	Groups I, II, and III In vitro studies Xenon 133 Iodine 131 for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma
Melvin A. Freundlich, M.D.	Groups I, II, III, IV, and V In vitro studies Xenon 133

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 29-04481-01

Docket or Reference number: 030-02477

Amendment No. 75

(11. continued)

	CONDITIONS
Candido Quinones, M.D.	Groups I, II, and III In vitro studies Xenon 133 Iodine 131 for treatment of hyperthyroidism and cardiac dysfunction
Bodh Das, M.D.	Technetium 99m radiopharmaceuticals in Groups II for cardiac imaging and diagnosis of cardiac function
Jayant N. Barai, M.D.	Groups I, II and III
Julianna Pisch, M.D.	Group VI Phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases Iodine 131 for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma

12. Licensed material listed in Items 6.L. through 6.R. shall be used by, or under the supervision of, individuals who meet the requirements set forth in Section 33.15(b) of 10 CFR Part 33 and have been designated by the V.A. Medical Center, Radiation Safety Committee.

13. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

    A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

    B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

14. For a period not to exceed 60 days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

    A. Has the prior written permission of the hospital's Administrator and Radiation Safety Committee, and

    B. Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 29-04481-01

Docket or Reference number 030-02477

Amendment No. 75

(14. continued) CONDITIONS

C. Performs only those procedures which the physician is specifically authorized to perform pursuant to a license issued by the Nuclear Regulatory Commission.

The licensee shall maintain for inspection by the Commission copies of the written permission specified in A. above and of the license(s) specified in B. and C. above for a period of 5 years from the date permission is granted under A. above.

15. The licensee may use the Calicheck device for doing linearity tests of its dose calibrator provided it follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.

16. Patients containing Iodine-131 for the treatment of thyroid carcinoma (or patients containing therapeutic quantities of Gold 198) shall remain hospitalized until the residual activity is 30 millicuries or less.

17. Experimental animals administered licensed materials or their products shall not be used for human consumption.

18. A(1) The sources specified in Items 7H, 7K, 7L, 7Q, and 7R shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch, 631 Park Avenue, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 29-04481-01

Docket or Reference number 030-02477

Amendment No. 75

(18. continued) CONDITIONS

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

19. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from detector cells by the licensee.

20. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices listed in items 7.H., 7.K., 7.L., 7.Q. and 7.R.. Records of inventories shall be maintained for 2 years from the date of each inventory.

21. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Item 3 of letter dated May 28, 1980
B. ALARA Program dated November 3, 1980
C. Letter dated June 28, 1982
D. Application dated May 25, 1985
E. Letter dated March 17, 1986
F. Letter dated March 12, 1986
G. Letter dated May 2, 1986
H. Letter dated September 15, 1986
I. Letter dated April 15, 1987
J. Letter dated December 2, 1987
K. Letter dated December 24, 1987

Date 31 DEC 1987

For the U.S. Nuclear Regulatory Commission
Original Signed By:
John R. Olson

By _____
Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406

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U.S. NUCLEAR REGULATORY COMMISSION

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MATERIALS LICENSE

Amendment No. 75

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

Licensee	
1. Veterans Administration Medical Center	In accordance with letter dated December 2, 1987,
2. Tremont Avenue & South Center Street East Orange, New Jersey 07019	3. License number 29-04481-01 is amended in its entirety to read as follows:
	4. Expiration date April 30, 1991
	5. Docket or Reference No. 030-02477

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. As necessary for uses authorized in Subitem 9.A.
B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. 3 curies of each byproduct material authorized in Subitem 6.B.
C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. Any radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. As necessary for uses authorized in Subitem 9.C.
D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. Any radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. As necessary for uses authorized in Subitem 9.D.
E. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. 1000 millicuries total for sources authorized in Subitem 6.E.
F. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	F. Prepackaged kits	F. 10 millicuries of each byproduct material authorized in Subitem 6.F.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 29-04481-01

Docket or Reference number: 030-02477

Amendment No. 75

(Items 6., 7., & 8. continued)

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
G. Xenon 133	G. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	G. 200 millicuries
H. Americium 241	H. Sealed Source (Amersham Model No. AMC.24)	H. 14 millicuries
I. Hydrogen 3	I. Any	I. 10 millicuries
J. Carbon 14	J. Any	J. 10 millicuries
K. Cadmium 109	K. Sealed source (Dupont (NEN) Model NER 465)	K. Two sources of 50 millicuries each
L. Any byproduct material listed in Schedule A, Column II, Section 33.100, 10 CFR 33	L. Any	L. As specified in Section 33.11(c) of 10 CFR 33 for a Type C License of Broad Scope
M. Cerium 141	M. Microspheres	M. 25 millicuries
N. Strontium 85	N. Microspheres	N. 25 millicuries
O. Chromium 51	O. Microspheres	O. 25 millicuries
P. Iodine 125	P. Microspheres	P. 25 millicuries
Q. Iodine 125	Q. Any	Q. 75 millicuries
R. Cesium 137	R. Sealed source (Nuclear Associates)	R. 10 millicuries

9. Authorized use

A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100, Title 10, Code of Federal Regulations.

B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

C. Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

D. Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

E. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 29-04481-01

Docket or Reference number 030-02477

Amendment No. 75

(Item 9. continued)

F. In vitro studies.
G. Blood flow and pulmonary function studies.
H. For use in Searle Analytic Model SS-10244 Anatomical Marker.
I. and J. Tracer studies in humans as approved by a Radioactive Drug Research Committee established with the Food and Drug Administration (FDA).
K. Human research on 50 patients in accordance with protocol "Renal Sequelae of Excessive Lead Stores" as described in the licensee's letter dated June 28, 1982. The Licensee shall file a report no later than December 1, of each calendar year discussing the results of the research.
L. through Q. Research and development as defined in Section 30.4(q) of 10 CFR 30; Animal studies.
R. For use as a calibration source.

CONDITIONS

10. Licensed material shall be used only at V. A. Medical Center, East Orange, New Jersey.

11. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Gerald Salen, M.D.	Tracer Studies in humans as approved by a Radioactive Drug Research Committee.
Maimu Ohanian, M.D.	Group VI
Ralph Lilienfeld, M.D.	Groups I, II, and III In vitro studies Xenon 133
Robert Modlinger, M.D.	Group I
Richard P. Weedeen, M.D.	Groups I, II, III, IV, and V In vitro studies Xenon 133 Cadmium 109 sealed source as listed in Subitem 6.K
John R. Mathew, M.D.	Groups I, II, and III In vitro studies Xenon 133 Iodine 131 for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma
Melvin A. Freundlich, M.D.	Groups I, II, III, IV, and V In vitro studies Xenon 133

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 29-04481-01

Docket or Reference number: 030-02477

Amendment No. 75

(11. continued)

	CONDITIONS
Candido Quinones, M.D.	Groups I, II, and III In vitro studies Xenon 133 Iodine 131 for treatment of hyperthyroidism and cardiac dysfunction
Bodh Das, M.D.	Technetium 99m radiopharmaceuticals in Groups II for cardiac imaging and diagnosis of cardiac function
Jayant N. Barai, M.D.	Groups I, II and III
Julianna Pisch, M.D.	Group VI Phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases Iodine 131 for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma

12. Licensed material listed in Items 6.L. through 6.R. shall be used by, or under the supervision of, individuals who meet the requirements set forth in Section 33.15(b) of 10 CFR Part 33 and have been designated by the V.A. Medical Center, Radiation Safety Committee.

13. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

    A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

    B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

14. For a period not to exceed 60 days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

    A. Has the prior written permission of the hospital's Administrator and Radiation Safety Committee, and

    B. Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and

(14. continued) CONDITIONS

C. Performs only those procedures which the physician is specifically authorized to perform pursuant to a license issued by the Nuclear Regulatory Commission.

The licensee shall maintain for inspection by the Commission copies of the written permission specified in A. above and of the license(s) specified in B. and C. above for a period of 5 years from the date permission is granted under A. above.

15. The licensee may use the Calicheck device for doing linearity tests of its dose calibrator provided it follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.

16. Patients containing Iodine-131 for the treatment of thyroid carcinoma (or patients containing therapeutic quantities of Gold 198) shall remain hospitalized until the residual activity is 30 millicuries or less.

17. Experimental animals administered licensed materials or their products shall not be used for human consumption.

18. A(1) The sources specified in Items 7H, 7K, 7L, 7Q, and 7R shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch, 631 Park Avenue, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 29-04481-01

Docket or Reference number 030-02477

Amendment No. 75

(18. continued) CONDITIONS

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

19. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from detector cells by the licensee.

20. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices listed in items 7.H., 7.K., 7.L., 7.Q. and 7.R.. Records of inventories shall be maintained for 2 years from the date of each inventory.

21. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Item 3 of letter dated May 28, 1980
B. ALARA Program dated November 3, 1980
C. Letter dated June 28, 1982
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F. Letter dated March 12, 1986
G. Letter dated May 2, 1986
H. Letter dated September 15, 1986
I. Letter dated April 15, 1987
J. Letter dated December 2, 1987
K. Letter dated December 24, 1987

For the U.S. Nuclear Regulatory Commission

Date 31 DEC 1987

By Original Signed By!
John E. Glenn
Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406