03009049

ABANDONED
[redacted] SHEET

TO: License Fee Management Branch

FROM: Region I

SUBJECT: [redacted] APPLICATION
ABANDONED

Sept 6
122207

Control Number: 122207

Applicant: George Washington University Medical Center

Date [redacted] Abandoned: 5/19/97

Reason for [redacted] Abandonment: Licensee failed to respond to Region I deficiency letter dated 4/4/97 for license no. 08-00216-22 (030-09049). After review.

M. A. Perkins 5/19/97
Signature Date

Attachment:
Official Record Copy of
[redacted] Action
Abandoned

FOR LFMB USE ONLY

ABANDONMENT
Final Review of [redacted] Completed:

Refund Authorized and processed

No Refund Due

Fee Exempt or Fee Not Required

Comments:

Log completed

Processed by: BJ

030113

MAY 19 1997

Mr. Astra Bain-Dowell
Acting Director, Office of Research
George Washington University
Medical Center
2300 Eye Street, NW
Washington, D.C. 20037

SUBJECT: APPLICATION FOR MATERIAL LICENSE AMENDMENT DATED AUGUST 15, 1995, AND OUR REQUEST FOR ADDITIONAL INFORMATION DATED APRIL 4, 1997

Dear Mr. Bain-Dowell:

This concerns the subject application for a material license amendment and our letter in which we notified you that the application was deficient and that certain additional information was required.

You are hereby notified that since the additional information that was requested in our April 4, 1997 letter has not been received within thirty (30) days from the date of the letter, we consider that you have abandoned your application. This action is without prejudice to the resubmission of an application.

Sincerely,

ORIGINAL SIGNED BY:
STEVEN R. COURTEMANCHE

Steven R. Courtemanche
Division of Nuclear Materials Safety

License No. 08-00216-22
Docket No. 030-09049
Control No. 122207

Enclosure:
Letter dated April 4, 1997
DOCUMENT NAME: R:\WPS\MISC\L0800216.22

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	SCourtemanche/s							
DATE	05/19/97		05/ /97		05/ /97		05/ /97	

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APR - 4 1997

License No. 08-00216-22
Docket No. 030-09049
Control No. 122207

Mr. Terry Johnson
Radiation Safety Officer
George Washington University
Medical Center
2300 Eye Street, NW
Room 712
Washington, DC 20037

Dear Mr. Johnson:

This is in reference to your application dated March 24, 1995 enclosed with your letter dated August 15, 1995 requesting to amend Nuclear Regulatory Commission License No. 08-00216-22. In order to continue our review, we need the following additional information:

1. In order for the NRC to exempt a licensee from a regulation, it is necessary that there be adequate justification. In your August 15, 1995 letter, you did not provide justification for your amendment request. Please submit a justification as to why the exemption from 10 CFR 35.315(a)(4) and 415(a)(4) is needed.

2. Items 10.11/10.14/10.15 G of the application states, in part, that surveys in adjacent patient rooms may be omitted when the administered activity does not exceed 200 millicuries (mCi), plus or minus 10 percent for dosage calibration. If the dosage received exceeds 200 mCi, surveys in contiguous areas must be reperformed since a percent difference in the dosage calibration cannot be used as a factor for determining the maximum dosage rates in contiguous areas. Confirm that surveys will be performed in contiguous areas if the administered activity exceeds 200 mCi.

3. Items 10.11/10.14/10.15 G of the application states, in part, that nursing personnel and visitors in adjacent patient rooms will not receive a dose exceeding 5 millirem and visitors in [illegible] rooms will not receive a dose exceeding 10 [illegible] Please describe procedures for verifying that doses to individuals in unrestricted areas do not exceed the public dose limits in 10 CFR 20.130[illegible]

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ML 10

4. Items 10.11/10.14/10.15 G of the application states, in part, that surveys in the adjacent patient room may be omitted if the maximum exposure rate on the treatment side of the wall separating the two rooms, at one foot from the wall, does not exceed 4 mR per hour. Your proposed procedure cannot ensure that the exposure rate in contiguous unrestricted areas do not exceed 2 mR in any one hour. Please confirm that the measurement for the worst case scenario shall be taken in contiguous unrestricted areas and that the exposure rate does not exceed 2 mR in any one hour at any location or modify your proposed procedure.

5. Please confirm that if any conditions change to a given scenario, such as the maximum activity administered, room arrangement, or shielding in the construction, that the surveys will be reperformed to determine the resulting exposure rate.

The NRC staff believes that your proposed procedures for determining solubility of radioactive waste to be released into the sanitary sewer are convoluted and very difficult to understand. As such, the users of radioactive material under your license may not clearly understand the criteria and may perform unauthorized disposals of radioactive material. Please consider using the guidelines found in Information Notice 94-07 (enclosed) to determine the solubility of radioactive waste to be released to the sanitary sewer. Also, the NRC staff believes that the first criteria for disposing of nonbiological radioactive material to the sanitary sewer is sufficient. If the NRC staff's understanding is incorrect, you should clarify the use of the additional criteria if you wish to pursue authorization for the additional criteria. Below are the NRC staff's comments concerning your criteria for determining the solubility of radioactive material to be released to the sanitary sewer.

6. Item 11.1.C. of the application describes your criteria for the disposal of radioactive material to the sanitary sewer in accordance with 10 CFR 20.2003.

   a. Criterion 1 states that if the radioactive material is chemical class D as listed in 10 CFR 20, Appendix B, it may be disposed to the sanitary sewer. Class D, in 10 CFR 20, Appendix B, refers to the retention of radioactive material in the pulmonary region of the lung and applies to a range of clearance half-times. The classification is used in Table 1, Columns 2 and 3 of Appendix B and is not relevant to Table 3. Please confirm that this criteria has been deleted.

   b. Criterion 4 states that if the radioactive material has an activity of less than one mCi and a half-life of less than 6.1 hours, it may be disposed of to the sanitary sewer. Please note that the half-life of the radioactive material does not have a bearing on the requirements of 10 CFR 20.2003(a)(2) and (3). Licensed or other radioactive material may be

released to the sanitary sewer provided the quantity released in one month divided by the average monthly volume of water released into the sewer does not exceed the concentration listed in Table 3 of Appendix B to 10 CFR 20, and the sum of the fractions does not exceed unity. Also, 10 CFR 20.2003(a)(4) requires that no more than 5 curies of tritium, 1 curie of carbon-14, and 1 curie of all other radionuclides be released to the sewer in a year. Confirm that the requirements of 10 CFR 20.2003 shall be followed and confirm that this criteria is deleted.

c. Criterion 5 states that radioactive material that is disposed of incidental to use under 10 CFR 35.100, 200, or 300 may be released to the sanitary sewer. Confirm that this criterion is deleted because it cannot be approved. Radioactive waste generated by the activities incidental to 10 CFR 35.100, 200, and 300 includes radioactive waste that does not meet the requirements for disposal in the sanitary sewer (i.e., gloves, paper towels, syringes, etc.).

d. Criterion 6 states that radioactive waste containing tritium, carbon-14, sulfur-35, and chromium-51 in concentrations less than 0.05 microcuries (uCi) per gram may be released to the sanitary sewer. Confirm that the request is for liquid scintillation radioactive wastes covered under 10 CFR 20.2005. Also, note that only tritium and carbon-14 liquid scintillation radioactive wastes are covered by 10 CFR 20.2005.

e. Criterion 7 states that radioactive wastes may be disposed to the sanitary sewer if the material appears to be completely dissolved in water at room temperature with no visual indication of particulates. You should not use visual inspection of the material as a criteria for determining the solubility of the radioactive material because casual inspection may not reveal particulate matter and the insoluble material may not be radioactive in nature. Please confirm that this criterion is deleted.

7. Additional criteria for nonbiological material are described on page 70 of Item 11.1.C. of your application. The NRC staff's comments are as follows:

a. Criterion 2 states that the radioactive waste may be released to the sanitary sewer if it is not listed as Class Y in 10 CFR 20. Class Y refers to the retention of radioactive material in the pulmonary region of the lung and applies to a range of clearance half-times. The classification is used in Table 1, Columns 2 and 3 of Appendix B and is not relevant to Table 3 of Appendix B. Confirm that this criterion is deleted.

b. Criterion 3 states that radioactive waste may be released to the sanitary sewer if it is not listed as insoluble in the CRC Handbook of Chemistry and Physics (CRC). This criterion may not be approved because the CRC does not list every isotope and, therefore, an isotope not listed may actually be insoluble. Please modify or delete this criterion.

c. Criterion 4 states that radioactive waste may be released to the sanitary sewer if the formal solubility is well established in the scientific literature. The NRC staff believes that the scientific literature is not an adequate means of determining the solubility of the radioactive material in and of itself. Please confirm that you shall determine the solubility of radioactive material using the Information Notice 94-07 as a guideline and confirm that this criterion is deleted.

d. Criterion 5 states that radioactive waste may be released to the sanitary sewer if it is diluted to a molar concentration which is less than the square of the formal solubility in mole/liter and its isotopic concentration is less than that listed in 10 CFR Part 20, Appendix B, Table 2, Column 2. Dilution is not related to solubility and may not be used as a criterion. Also, Appendix B, Table 2, Column 2 of 10 CFR Part 20 applies to effluents and is not applicable to the release of radioactive material to the sanitary sewer. Please delete this criterion.

e. Criterion 6 uses the same method as discussed in Item 6.e. of this letter and cannot be approved. Please delete this criterion.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 122207. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5075.

If we do not receive a reply from you within 30 calender days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

ORIGINAL SIGNED BY:
STEVEN R. COURTEMANCHE

Steven R. Courtemanche
Division of Nuclear Materials Safety

License No. 08-00216-22
Docket No. 030-09049
Control No. 122207

Enclosures:
1. 10 CFR Parts 19, 20, 21, 30, and 35
2. Regulatory Guide 10.8
3. Information Notice 94-07

DOCUMENT NAME: R:\WPS\DLTR\L0800216.22
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	SCourtemanche/src							
DATE	04/04/97		04/ /97		04/ /97		04/ /97	

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MS 20
K-4

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

December 9, 1996

MEMORANDUM TO: Mohamed M. Shanbaky, Chief
Nuclear Materials Branch 1, RI

FROM: Larry W. Camper, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: TECHNICAL ASSISTANCE REQUEST DATED DECEMBER 20, 1995, GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER, LICENSE NO. 08-00216-22

I am writing in response to your technical assistance request (TAR) dated December 20, 1995 (Attachment 1), in which George Washington University Medical Center (GWUMC) requested an exemption from 10 CFR 35.315(a)(4) and 415(a)(4) and proposed procedures for disposal of radioactive waste into the sanitary sewer. Each request is addressed separately below.

Exemption from 10 CFR 35.315(a)(4) and 415(a)(4)

GWUMC requested an alternate method for performing surveys in contiguous areas required by 10 CFR 35.315(a)(4) and 415(a)(4). GWUMC submitted numerous criteria for which surveys in adjacent patient rooms would not have to be performed, as well as film badge/TLD data for adjacent areas, taken during previous patient treatments. The staff has reviewed the information and has the following comments:

1) GWUMC did not submit a justification as to why the exemption from 10 CFR 35.315(a)(4) and 415(a)(4) is needed. It is necessary for GWUMC to explain why the exemption is needed before an exemption can be granted.

2) GWUMC indicated that surveys in adjacent patient rooms may be omitted when the administered activity does not exceed 200 mCi plus or minus 10 per cent for dosage calibration. A per cent difference in the dosage calibration cannot be used as a factor in the maximum dose used for determining if contiguous area surveys need to be performed. If the dose received exceeds 200 mCi, surveys in adjacent patient rooms must be re-performed.

3) GWUMC indicated that nursing personnel and visitors in adjacent patient rooms will not receive a dose exceeding 5 mR per day and visitors in patient rooms will not receive a dose exceeding 10 mR per day. The licensee should verify that doses to individuals in unrestricted areas will not exceed the public dose limits in 10 CFR 20.1301, "Dose Limits for Individual Members of the Public."

CONTACT: Torre Taylor, NMSS
(301) 415-7900

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4) GWUMC indicated that the surveys in the adjacent patient room may be omitted if the maximum exposure rate on the treatment side of the wall separating the two rooms, at one foot from the wall, does not exceed 4 mR per hour. The licensee should take the measurement in the adjacent patient room for the worst case scenario, and the exposure rate should not exceed 2 mR in any one hour at any location.

5) GWUMC should verify that if any conditions change to the given scenario, such as maximum activity administered, room arrangement, or shielding in the construction, that the surveys in the adjacent patient room will be re-performed to determine the resulting exposure rate.

The exemption from 10 CFR 35.315(a)(4) and 415(a)(4) cannot be granted at this time since extensive information is needed from the licensee. Please provide the licensee's response to these issues as a TAR to NMSS for review and approval of the exemption.

Alternate Method for Disposal into the Sanitary Sewerage

GWUMC submitted procedures for disposal into the sanitary sewerage for compliance with 10 CFR 20.2003. These procedures are discussed below in detail. The licensee's procedures are very convoluted and difficult to understand. The licensee should first determine if the material is soluble, using Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20" (Attachment 2), as a guideline. If the material is soluble, then other criteria may be applied. However, the licensee should simplify the criteria to ensure that all users of radioactive material will clearly understand the requirements for disposal into the sanitary sewerage to help avoid unauthorized disposal of radioactive material.

The licensee listed several criteria for any isotope not used in biological material which could be met to qualify for disposal into the sanitary sewerage. As the staff understands the request, the following are the licensee's proposed criteria:

1. It is chemical class D as listed in 10 CFR Part 20, Appendix B, OR
2. Is classified as soluble according to the CRC Handbook of Chemistry and Physics, OR
3. Its formal solubility is greater than 0.003 mole/L, OR
4. It is less than 1 mCi of a radionuclide with a half-life less than 6.1 hours, OR
5. It is disposed incidental to use under 10 CFR 35.100, 35.200, and 35.300, OR
6. It is only hydrogen-3 (H-3), carbon-14 (C-14), sulfur-35 (S-35), or chromium-51 (Cr-51) in concentrations less than 0.05 microcurie per gram of solution;

7. AND

The material appears to be completely dissolved in water at room temperature with no visible indication of particulates;

8. AND

The material disposed excludes all byproduct material excluded from Item 5, Line D, of this application (e.g. strontium-90, iodine-129, and isotopes with atomic number grater than 83).

Each proposed criterion is discussed separately below.

Criterion 1 references use of chemical class D as listed in 10 CFR Part 20, Appendix B. Class D refers to the retention of radioactive material in the pulmonary region of the lung, and applies to a range of clearance half-times. The classification is used in Table 1, columns 2 and 3, of Appendix B, and is not relevant to Table 3, of Appendix B. This criterion should be deleted.

Criteria 2 and 3 are acceptable and may be approved.

Criterion 4 references use of a half-life, which is irrelevant to disposal into the sanitary sewerage. Section 20.2003(a)(2) and (3) of 10 CFR Part 20 allows the release of licensed or other radioactive material released into the sanitary sewerage provided the quantity released in 1 month divided by the average monthly volume of water released into the sewer does not exceed the concentration listed in Table 3 of Appendix B to 10 CFR Part 20. If more than one radionuclide is released, the licensee must determine the fraction of the limit in Table 3 of Appendix B to 10 CFR Part 20, and ensure the sum of the fractions for each radionuclide does not exceed unity. Additionally, 10 CFR 20.2003(4) requires that the release of licensed and other radioactive material not exceed 1 curie of H-3, 1 curie of C-14, and 1 curie of all other radioactive materials combined. Therefore, criterion 4 may be used only if the licensee can ensure these limits will be met, regardless of the half-life of the radionuclide(s) disposed. It may be less resource intensive to hold radioactive material with a half-life of less than 6.1 hours for decay prior to disposal into the sanitary sewerage.

Criterion 5 may not be approved. All disposal of waste generated incident to the use of radioactive material under 10 CFR 35.100, 200, and 300, such as gloves, paper towels, etc., must meet the disposal requirements of 10 CFR Parts 20 and 35, if applicable, with the exception of excreta from individuals undergoing medical diagnosis or therapy. GWUMC stated elsewhere in its application that excreta from individuals undergoing medical treatment was exempt.

Criterion 6 requests disposal of S-35 and Cr-51, in addition to H-3 and C-14, in concentrations less than 0.05 microcurie per gram of solution. It is assumed that this request applies to liquid scintillation wastes, which is authorized in 10 CFR 20.2005. Additionally, S-35 and Cr-51 are not authorized in the provisions of 10 CFR 20.2005, and would be subject to additional review

if the licensee pursues this request. Therefore, only H-3 and C-14 may be disposed under this criterion.

The procedures also included an additional criterion, criterion 7, that materials may be disposed if the material appears to be completely dissolved in water at room temperature with no visible indication of particulates. This condition assumes that any insoluble material will be visible to casual inspection, which is not necessarily the case. Additionally, any visible insoluble material may not be radioactive. The licensee did provide a procedure for adjusting the pH, refrigerating, filtering, and diluting the filtrate; however, this procedure is not adequate to ensure solubility. The licensee should test the waste for solubility in accordance with the methods described in Information Notice 94-07.

Criterion 8 is acceptable and may be approved.

The licensee provided additional criteria for disposal of other nonbiological materials on page 70 of its submittal:

1. Disposed only under the supervision of the Radiation Safety Officer;
2. It is not listed as Class Y in 10 CFR Part 20;
3. It is not listed as insoluble in the CRC Handbook of Chemistry and Physics;
4. If the formal solubility is well established in the scientific literature; AND
5. It is diluted to a molar concentration which is less than the square of the formal solubility in mole/liter, and its isotopic concentration is less than that listed in 10 CFR Part 20, Appendix B, Table 2, Column 2; AND
6. The material appears to be completely dissolved in water at room temperature with no visible indication of particulates;

Each criterion is discussed separately below.

Criterion 1 is acceptable.

Criterion 2 references use of chemical class Y as listed in 10 CFR Part 20, Appendix B. Class Y refers to the retention of radioactive material in the pulmonary region of the lung, and applies to a range of clearance half-times. The classification is used in Table 1, columns 2 and 3, of Appendix B, and is not relevant to Table 3, of Appendix B. This criterion should be deleted.

Criterion 3 is not acceptable and may not be approved. The CRC Handbook of Chemistry and Physics does not list every isotope; therefore, an isotope not listed may actually be insoluble.

Criterion 4 is not acceptable in and of itself. The licensee should determine if the material is soluble, using Information Notice 94-07 as a guideline.

Criterion 5 is not acceptable and may not be approved. Dilution is not related to the solubility and may not be used as a criterion. Additionally, Appendix B, Table 2, Column 2 applies to effluents and is not applicable to release into the sanitary sewerage.

Criterion 7 is not acceptable, as discussed above in the first set of criteria for disposal.

Based on the information submitted with the licensee's request, it is the staff's understanding that all nonbiological material should be encompassed within the first set of criteria, discussed earlier in this response. The majority of the technical criteria discussed above in the second set of criteria is not acceptable. The staff does not fully understand why these additional criteria are needed. The licensee should clarify the use of these additional criteria if our understanding is incorrect, and if the licensee wishes to pursue authorization for these additional disposal criteria.

Attachments:

1. TAR dtd 12/20/95
2. IN 94-07

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: December 2?, 1995

Mail or E-Mail to: Donald A. Cool (DAC), Mail Stop: T8-F5 If E-mail, cc: CLE
Division of Industrial and Medical Nuclear Safety, NMSS

From: Mohamed M. Shanbaky, Region I
Chief, Nuclear Materials Branch 1 MS 12/20/95

Licensee: George Washington University Medical Center License No.: 08-00216-22

☐ Control No.: 122207

☐ Letter dated: August 15, 1995

☐ Suggested change in licensing procedure (enclosed): ____

☐ Problem/Issue: 1.Alternate method of performing surveys(10 'a)(4). The licensee is proposing to perform the survey inside the patient's r t areas.

2. Alternate method to determine solubility (10 CFR 20.2003). The licensee's method is not one of the methods outlined in the solubility Information Notice.

☐ Action Required: Review alternate methods and determine if they meet the requirements of 10 CFR 35.315(a)(4), 35.415(a)(4) and 20.2003.

Recommended Action: 1. The licensee requested a dose rate level of 4.0 millirem per hour on the therapy patient's side of the wall. Recommend that this portion of the TAR be denied. However, if the licensee requests radiological surveys of less than 2 millirem per hour inside the patient room to demonstrate compliance with the dose rate limit in the adjacent area, the request should be approved.

2. Recommend that this method be approved.

Remarks: ____

Headquarter Reviewer: _____
Regional Reviewer: Steven R. Courtemanche
Reviewer Code: K4
Reviewer Phone No.: (610) 337-5075 FAX No.: (610) 337-5269
Request Needed by: February 1, 1996

The George Washington University
175TH ANNIVERSARY 1821-1996
MEDICAL CENTER

RADIATION SAFETY OFFICE

030-09049

License No. 08-00216-22
Docket No. 030-09049
Control No. 111230

August 15, 1995

Francis Costello
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Mr. Costello:

As per our telephone communications on August 4 and 8, and additional telephone conversations with Mr. Courtemanche, please accept the attached revisions to the license application previously submitted on March 28, 1995. These revisions are intended to replace in their entirety, the previously submitted Items 5 & 6 (page 2), Items 7.1 & 7.2 (page 4 only, not entirety), Item 10.7 (page 57), Item 10.12 (pages 58-61), and Items 10.3 & 10.16 (page 68).

I understand that two additional sections of the most recent application will be evaluated at NRC Headquarters, and that the license may be issued now, and may be amended later when these evaluations are complete. I understand that the two sections to be reviewed are:

1. The procedure on page 65, "Radiation Safety Procedures for Brachytherapy Sealed Sources and Radiopharmaceutical Therapy," in section G, which allows alternate assessment criteria for the radiation exposure in the adjacent patient room, in the case of radioiodine therapy only, without directly measuring the radiation level in that room. Of course, we have been measuring and recording the radiation level in the adjacent patient room in each patient case to date, and I understand that we must continue this practice unless and until NRC approves some alternate practice, and must continue to comply with 10 CFR 35.315 and 35.415 in all respects.

2. The procedure on pages 69 and 70, "Radioactive Waste Disposal Methods Used," in section C, which describes how the solubility of nonbiological radioactive material may be determined prior to disposal in a municipal sanitary sewerage system. I understand that, pending evaluation of this procedure, we must continue to dispose nonbiological radioactive material only when it is readily soluble, and must continue to comply with 10 CFR 20.2003 in all respects.

CONTROLLED AS 122207
SEPARATED OUT OF ~~111230~~
8/25/95 ~~AUG 23 1995~~
FAX REC'D

SECTION COPY

2300 EYE STREET, N.W. • ROOM B-42 • WASHINGTON, DC 20037 • (202) 994-2651

I also understand that, upon completion of these evaluations, the University may be required to make timely submission of revised procedures, in substitution for the two sections of the license application evaluated.

If these revisions raise any questions, or if my understanding of the evaluations to be made at NRC Headquarters, and particularly of our regulatory compliance requirements pending completion of these evaluations, is misstated in any way, please advise me directly at: 202-994-3149.

Thank you for your attention to this matter.

Sincerely,

Terry Johnson

Terry Johnson
Radiation Safety Officer

TAJ/gjh (10B1cLicense8/16)

cc: Astra Bain-Dowell.
Acting Director, Office of Research

Katherine A. Kennedy, Ph.D.
Chair of the Radiation Safety Committee

encls.

The George Washington University
175TH ANNIVERSARY 1821-1996
MEDICAL CENTER

RADIATION SAFETY OFFICE

X

License No. 08-00216-22
Docket No. 030-09049
Control No. 111230

March 28, 1995

Steven R. Courtemanche, Health Physicist
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Mr. Courtemanche:

Pursuant to NRC letter of March 8, 1995, and subsequent telephone conversations, the enclosed additional information is formatted as a complete renewal application, for license number 08-00216-22, replacing all previous applications and license commitments in their entirety.

If you have any questions, please call me at 202-994-3149.

Sincerely,

Terry Johnson

Terry Johnson
Radiation Safety Officer

TAJ/gjh (10B1cLicense32895)

cc: Astra Bain-Dowell.
Acting Director, Office of Research, GWU

Katherine A. Kennedy, Ph.D.
Chair of the Radiation Safety Committee

encl.

122207
~~111230~~
~~MAR 29 1995~~

2400 EYE STREET, N.W. • ROOM B-32 • WASHINGTON, DC 20037 • (202) 994-2630

NRC FORM 313 (6-83)
10 CFR 30, 32, 33, 34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-86

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 8 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. 030-09049

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

THIS IS AN APPLICATION FOR (Check appropriate item)

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [XX] C. RENEWAL OF LICENSE NUMBER 08-00216-22; replacing prior submissions in their entirety.

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

The George Washington University
Office of Research
2300 I Street, NW, Suite 712
Washington, DC 20037

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED: Licensed material shall be used only at: The George Washington University, 2121 I St., NW, Washington, DC 20052, bounded by Pennsylvania Ave., F St., 19th St., and 25th St., NW, Washington, DC, and 20101 Academic Way, Ashburn, VA 22011

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION: Terry A. Johnson

TELEPHONE NUMBER: 202-994-2630

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5.	RADIOACTIVE MATERIAL. a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6.	PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED
7.	INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.	8.	TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
9.	FACILITIES AND EQUIPMENT. 9.5 = N/A.	10.	RADIATION SAFETY PROGRAM.
11.	WASTE MANAGEMENT.	12.	LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 7B; AMOUNT ENCLOSED $ N/A.

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Allan B. Weingold, M.D., Vice President for Medical Affairs and Executive Dean		5/24/1

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

NRC FORM 313 (6-83)

PRINTED ON RECYCLED PAPER

MAR 20 1995 111230

Items 10.11/10.14/10.15

RADIATION SAFETY PROCEDURES FOR BRACHYTHERAPY SEALED SOURCES AND RADIOPHARMACEUTICAL THERAPY

A. Only high pH solution will be used for liquid oral administration of I-131 as iodide.

B. Only trained Division of Nuclear Medicine personnel will administer radiopharmaceutical to the patient. The staff member who administers any therapeutic dosage of I-131 is routinely bioassayed in 1 to 3 days, as is anyone else ***who was nearby during*** the dosage swallow. If the patient promptly vomits, the entire staff present anywhere in the room (or who clean up), are bioassayed.

C. A radiopharmaceutical therapy patient will not be released until the exposure rate 1 meter from the patient's body is 5 mR per hour or less, or until the remaining total body burden is less than 30 mCi; ***or the release will conform to the requirements of 10 CFR Part 35 effective on the date of the release***. This patient's room and reusable equipment will not be released until monitored, and decontaminated if necessary, according to criteria in 10 CFR 35.315(a)(5 and 7).

D. ***Brachytherapy and radiopharmaceutical therapy*** treatments requiring hospitalization pursuant to 10 CFR 35.75 or 35.404, will be *only* in rooms used privately, with toilets for ambulatory cases.

E. These rooms will be posted and controlled according to 10 CFR 20.1601, 35.315 and 35.415.

F. Pursuant to 10 CFR 20.1301, radiation in unrestricted areas will be limited to 2 millirem per hour, and maintained ALARA throughout the patient treatment. Radiation in controlled areas around the therapy patient room will be limited in exactly the same way. Nobody in these areas will be allowed to receive an external whole-body dose from the patient exceeding 100 millirem.

G. As required by 10 CFR 35.315 or 35.415, dose rates in surrounding areas will be measured and recorded promptly upon the start of therapy, particularly at bedside, 1 meter, yellow visitor's line, hall door opening, and the maximum dose rate point in the adjacent patient room. As required by 10 CFR 20.1302, if the product of the maximum dose rate in the adjacent patient room, and the total treatment time, exceeds ***50 millirem, the dose rates and room arrangements,*** etc., will be evaluated by the RSO / ARSO, who will determine: that the patient in the adjacent room will not receive a dose exceeding ***50 millirem, and that this patient's dose will be kept ALARA; that this patient has not been previously hospitalized during the prior 365 days (or, if so, that the previous stay was not in a room adjacent to any form of radiation therapy); and that the nursing personnel and visitors will not receive a dose exceeding 5 millirem per day while in the adjacent patient room***. Otherwise, one of the patients will be reassigned to a different room.

However, given the shielding value of the hospital wall materials and other factors, in the case of radioiodine therapy *only* (I-131, or I-125 seeds), the survey of the adjacent patient room may be omitted, but ***only when the administered activity does not exceed 200 mCi (± 10% for dosage calibration), and when the patient release (or sealed source explant) is expected on or before the second day following the administration day,*** only in the case of therapy in room 3102E, 3138E, 4102E, or 5138E, ***only when the patient in the adjacent room receives no unusually time-consuming nursing or ancillary services, and has the normal hospital limitation of visiting hours, only after verifying that this patient's stay in the adjacent room did not overlap the previous radioactive therapy, and that this patient's bed is positioned up against the wall farthest from the radiation treatment room, only when the radiation treatment bed is positioned up against the wall farthest from the adjacent patient room, such that the patient's thyroid (in bed) is observed to be less than 42 inches from this wall,*** and *only* if the maximum exposure rate on the treatment side of the wall separating the two rooms ***(at one foot from the wall)*** does not exceed 4 mR per hour; when this provision is used, the maximum exposure rate on the treatment side of the wall must be recorded and identified clearly, in lieu of the maximum exposure rate in the adjacent patient room, and must be remeasured and recorded approximately 24 hours after the start of the therapy (if this latter reading exceeds 1.5 mR per hour, notify the RSO / ARSO immediately).

H. Based on the exposure rate at the ***treatment patient's*** yellow visitors' line, a maximum daily visiting time may be calculated to assure that the visitors' doses cannot exceed ***10*** millirem per day. Any longer visiting times (generally for the spouse or parents of a critically ***or terminally*** ill patient) will be approved in writing by the RSO, and will include provision for visitor dosimetry.

I. The physician performs the safety counseling for all patients, *e.g.*, regarding family protection.

J. The nursing personnel attending the patient ***will have been instructed as required by 10 CFR 35.310 or 35.410, as applicable (see also Item 8, sections C and D). They also will have been instructed in the use of any required personnel dosimetry assigned (see also Item 9.4.G).***

K. The Radiation Safety Office will be contacted in the event of any emergency at 994-2630, or through the page operator at 994-3321 (numbers subject to change at will).

L. Prior to release from the hospital, each brachytherapy patient will be surveyed to verify that no sealed source remains in the body (or that the exposure rate at 1 meter from the patient is no more than 5 mR per hour for permanent implants)***; or the release will conform to the requirements of 10 CFR Part 35 effective on the date of the release***. The survey will also include the bedding, floor, trash, *etc.*

M. Brachytherapy sources are stored in a heavily shielded cabinet in a locked and posted source room, well inside the restricted area of Radiation Oncology. The names of "primaries" (who may remove sources) are posted. This room contains a leaded-glass L-block and tongs for safe source handling. In-hospital transport of sources is done in the original shipping container, or is shielded by ≥ 1 inch of lead (or by a heavy steel container used only for ***Pd-103 or*** I-125).

N. To satisfy the inventory requirements for the use of brachytherapy sources in patient cases, pursuant to 10 CFR 35.406, we will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix M.4 to Regulatory Guide 10.8, Revision 2. If any brachytherapy source cannot be definitely located, the following steps will be taken:

1) The Radiation Safety Officer will be contacted promptly;
2) A careful inventory will verify the identity of the source lost;
3) All personnel involved with the therapy or sources will be contacted to determine how the loss might have occurred;
4) A careful search with sensitive survey meters, will proceed from the source's last known position, along every plausible route of loss;
5) The incident report will include estimates of plausible personnel doses;
6) Telephone notification to the NRC will be made promptly upon determination that the source is no longer in the restricted area, unless the RSO determines it is not required pursuant to 10 CFR 20.2201.

Item 10.14E Supporting Documentation for Exemption Request from 10 CFR 35.315(a)(4)

Attached to Item 9.1 is a drawing of each therapy room showing the location of the bed, which is always arranged *against the opposite wall farthest from the adjacent patient room. These beds may be rotated 90° to accommodate the equipment in the room, but are always directly up against the opposite wall.* The bed in the adjacent patient room is arranged *against the wall farthest from the treatment room.*

The walls between the rooms are 6 inches thick or thicker (ordinary concrete materials were used). This approximates one tenth-value-layer for I-131, which our dosimetry measurements confirm.

NVLAP-certified dosimetry was used to investigate the total dose along the wall just inside the adjacent patient room closest to the radiation therapy patient, for the duration of several typical I-131 therapies (each lasting 2 days). Below is a summary of the dosimetry results (both TLD and film badge) in the rooms adjacent to various approved treatment rooms in the hospital, along with the activity used for each patient:

Start Date	Therapy Room	Adjacent Rooms	Therapy Type	Therapy Activity	Doses	
					Film Badge	TLD
07/15/92	5246 South *	5101 East**	I-131	175 mCi	M	M
08/26/92	5102 East	5104 East	I-131	150 mCi	10 mrem	M
08/31/92	5346 North	5131 East**	I-131	200 mCi	M	M
10/26/92	3102 East	3104 East	I-131	150 mCi	M	10 mrem
11/02/92	5346 North	5131 East**	I-131	175 mCi	M	M
11/04/92	4102 East	4104 East	I-131	200 mCi	M	M

* no longer used for therapy. ** the only room adjacent is around the corner on the East ward.

Our results indicate that doses just inside the adjacent patient rooms are minimal, even though integrated through the entire therapy, or are barely in the range of NVLAP-certified dosimetry detection limits, approximately 10 mrem or less.

The most recent data indicate that the ten I-131 inpatients treated between December 1, 1994, and February 28, 1995, produced maximum initial dose rates in the respective adjacent patient rooms averaging to less than 0.15 mR / hr., from greater than 150 mCi average administered dosage. Since the measurement point in the adjacent room is about 11 feet from the freshly swallowed I-131 bolus in the patient's stomach, and the I-131 exposure factor is approximately 0.22 mR / hr. per mCi at 1 meter, these data indicate the total shielding attenuation is about 95%.

The other important aspect of the safety of this proposal, concerns the measurements on the 1st and 2nd day of therapy, inside the therapy patient's room, along the wall shielding the patient in the adjacent room. When the point of maximum dose rate along this wall, inside the room of the patient given I-131 therapy, receives exposure of 4 mR / hr initially, ***that same point*** will typically not receive an integrated exposure of more than 100 mR during the entire period of hospitalization, even though that period is typically 40 to 50 hours. This is because the rapid initial elimination of the ***I-131 in urine*** by the patient results in an effective mean life of I-131 (effective half-life / ln(2)) which is almost always less than 20 hours, based on our measured exposure data (at 1 meter) spanning the first 2 days (*i.e.*, from administration, to release). The check of the same point 24 hours later, to confirm that the dose rate is ≤ 1.5 mR / hr., is intended to confirm this for each individual patient case.

In the incredible scenario where the patient in the adjacent room is readmitted adjacent to another therapy, the total dose from both therapies will be less than 20 mrem, according to our dosimetry results, ***which is based on the highest exposure rate in the room, which is nowhere near the actual patient bed.*** Extended stay of the patient in the same adjacent room is virtually nonexistent; these adjacent rooms are all assigned exclusively for acute care and for short stays. In any case, our procedures verify that each patient in an adjacent room was not there overlapping the previous therapy.

Item 11.1 RADIOACTIVE WASTE DISPOSAL METHODS USED

A. Decay-in-storage, in accordance with 10 CFR § 20.2001 or § 35.92.

Any radioactive waste with half-life less than 65 days, generated incidental to authorized medical uses, may be disposed with strict adherence to the requirements of 10 CFR 35.92.

Due to space limitations from long-term lack of access to a LLRW disposal site, we request authorization to use decay-in-storage to dispose of any radioactive material with half-life less than 120 days, provided: that it is labeled clearly on the exterior, and recorded clearly on a decay-in-storage log, to facilitate tracking and identification (by isotope, date, etc.) *as it is placed in storage and removed for disposal; that it is stored in a secured area, and separate from nonradioactive waste and from useful nonradioactive and radioactive material (unless it is stored refrigerated, or segregated by another hazardous property); that it is held for decay a minimum of ten half-lives (based on the longest half-life for the isotopes in a container) before disposal; that it is monitored at the container surface before disposal (with each major discrete source, such as a generator column, separated and monitored individually), with a radiation detection survey meter set on its most sensitive scale, in an area of low background radiation, and with no interposed shielding, to ensure that it has decayed to background radiation level before disposal (otherwise it is returned to storage for more decay); that its radiation labels are removed or obliterated before disposal; that no more than 500 cubic feet per year of this decayed radioactive material is disposed; and that, upon its disposal as nonradioactive waste, the disposal record includes the date of the disposal, the starting date of the waste decay period, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal, and that this record is retained for three (3) years.*

However, radionuclides may also be disposed from storage by another approved method, with strict adherence to the requirements of that method, even after considerable decay has occurred.

B. Release of effluents to unrestricted areas in compliance with 10 CFR 20.1301 and 20.1302, incidental to the authorized use of the radioactive material. However, we presently release no liquid radioactive material effluents into unrestricted areas, *e.g.*, into streams, storm sewers or any body of water, into the ground, or into any sewers other than municipal sanitary sewers. Prior to permitting any such release proposed, we will notify the NRC, Region I, to inquire about licensing and other requirements, and receive reply prior to the release. Any such release made inadvertently will be investigated promptly by the Radiation Safety Officer, who will notify the NRC as required by 10 CFR 20.2202 /.2203.

C. Disposal into sanitary sewerage in compliance with 10 CFR 20.2003. This waste will be readily soluble, at pH 5 to 9, or will be readily dispersible biological material. *Each disposal will be flushed afterward with tap water for several seconds.*

Any isotope not used in biological material will be so disposed <u>only</u> if its chemical form is listed as "Class D" in 10 CFR 20, Appendix B, <u>or</u> as "soluble" in the CRC <u>Handbook of Chemistry and Physics</u> (or a similar reference), <u>or</u> as having "formal solubility" greater than 0.003 mole per liter in the scientific literature; <u>or</u> if the radionuclide is less than 1 mCi of an isotope with half-life less than 6.1 hours, <u>or</u> is disposed incidental to use under 10 CFR 35.100 / .200 / .300, <u>or</u> is only H-3, C-14, S-35 or Cr-51, in concentration less than 0.05 μCi per gram of solution; <u>and only</u> if the material appears to be <u>completely</u> dissolved in water at room temperature, with <u>no</u> visible indication that it bears particulates or flakes, etc. *(if there is <u>any</u> doubt about the dissolution of nonbiological material which clearly meets one of the criteria given above, it may be adjusted to pH 7.0 to 7.3, refrigerated overnight, carefully filtered or decanted, and the filtrate or decantate diluted an additional ten-fold and disposed); <u>and only</u> if the material disposed <u>excludes</u> all byproduct material excluded from Item 5, Line D, of this application* (e.g., *Sr-90, I-129, and isotopes with atomic number > 83).*

Other nonbiological materials may be disposed only under the supervision of the Radiation Safety Officer, only when they are neither listed as "Class Y" in 10 CFR 20, nor listed as "insoluble" in the CRC Handbook of Chemistry and Physics, only when the "formal solubility" is well-established in the scientific literature, and only when they are diluted to a molar concentration which is less than the square of the "formal solubility" in mole / liter (e.g., to less than 9×10^{-6} molar concentration when the "formal solubility" is 3×10^{-3} mole / liter) and to isotopic concentration less than that listed in 10 CFR 20, Appendix B, Table 2, Column 2 (i.e., to isotopic concentration suitable for potable effluent, even though sewage disposal is used; both the molar and isotopic concentrations are determined for the solution before disposal, not including the additional dilution in the sewage); and only when the material appears to be completely dissolved in water at room temperature, with no visible indication that it bears particulates or flakes, etc. (no doubtful dissolution permitted).

The sewage disposal activity limit of 1 curie per year, for all isotopes other than H-3 and C-14, is invariably more restrictive than the monthly sewage concentration limits, in our normal laboratory operations. Since our laboratories operate steadily year-round (such that this activity limit is tantamount to 83 mCi per month), and since the sewage volume of Ross Hall alone is greater than 10 million liters per month, as demonstrated by water bills, the activity limit is more restrictive than the sewage concentration limit, unless the latter is less than 8.3 E-6 μCi / ml (such as the limits for many of the isotopes excluded from Item 5, Line D, or for a few relatively rare or useless isotopes not excluded), even when the entire 83 mCi is assumed to be the most hazardous isotope, which is implausible. Hence, the provisions for limitation of overall activity disposed, in conjunction with the provision that isotopes excluded from Item 5, Line D, are also excluded from sewage disposal (unless supervised by the Radiation Safety Officer, who will review and implement the concentration limits for such isotopes); also provide full assurance of compliance with applicable sewage concentration limits. The provisions for limitation of overall activity disposed include: Authorized Users' "sink limits" (generally 10 mCi of H-3, 2 mCi of C-14, and 2 mCi of all other isotopes combined, per month, per authorized "hot sink"); an Authorized User requirement to log each "hot sink" disposal; and quarterly collection, summary and analysis of "hot sink" disposal logs. These provisions assure that the total quantity of licensed and other radioactive material released into sewage in a year is limited to 5 curies of H-3, 1 curie of C-14, and 1 curie of all other radioactive materials combined.

However, excreta from individuals undergoing any approved medical use of radioactive material are not subject to any limitations or recording, when disposed into a municipal sanitary sewerage.

D. Disposal of scintillation counting media and animal tissues, containing H-3 and C-14, without regard to radioactivity up to 0.05 uCi per gram, averaged over the media or the weight of the entire animal, pursuant to 10 CFR 20.2005. *Contaminated bedding will be disposed separately as radioactive waste.*

E. Return to the manufacturer, supplier, or previous licensee, when licensed to receive back Mo-99/Tc-99m generators, sealed sources, *etc.*; or transfer to a recipient licensed by the NRC or an Agreement State to receive the waste for storage, treatment, disposal and/or retransfer; with each transfer made according to DOT regulations and 10 CFR 20.2001/.2006.

F. Disposal pursuant to 10 CFR 31.11 (not to include "mock I-125" sealed sources).

G. Disposal records will be maintained as required in 10 CFR 20.2108 / 30.51 / 31.11 / 35.92.

H. We presently perform no significant radioactive waste treatment procedures. *i.e.*, compaction, evaporation, incineration, solidification, or liquid scintillation vial crushing.

REGIO[redacted]L TECHNICAL ASSISTANCE REQU[redacted]T FORM

Date: December 20, 1995

Mail or E-Mail to: Donald A. Cool (DAC), Mail Stop: T8-F5 If E-mail, cc: CLE
Division of Industrial and Medical Nuclear Safety, NMSS

From: Mohamed M. Shanbaky, Region I
Chief, Nuclear Materials Branch 1 MMS 12/20/95

Licensee: George Washington University Medical Center License No.: 08-00216-22

□ Control No.: 122207

□ Letter dated: August 15, 1995

□ Suggested change in licensing procedure (enclosed): _____

□ Problem/Issue: 1.Alternate method of performing surveys(10 CFR 35.315(a)(4) and 415(a)(4). The licensee is proposing to perform the survey inside the patient's room instead of the adjacent areas. 2. Alternate method to determine solubility (10 CFR 20.2003). The licensee's method is not one of the methods outlined in the solubility Information Notice.

□ Action Required: Review alternate methods and determine if they meet the requirements of 10 CFR 35.315(a)(4), 35.415(a)(4) and 20.2003.

Recommended Action: 1. The licensee requested a dose rate level of 4.0 millirem per hour on the therapy patient's side of the wall. Recommend that this portion of the TAR be denied. However, if the licensee requests radiological surveys of less than 2 millirem per hour inside the patient room to demonstrate compliance with the dose rate limit in the adjacent area, the request should be approved. 2. Recommend that this method be approved.

Remarks: _____

Headquarter Reviewer: _____
Regional Reviewer: Steven R. Courtemanche
Reviewer Code: K1
Reviewer Phone No.: (610) 337-5075 FAX No.: (610) 337-5269
Request Needed by: February 1, 1996

OFFICIAL RECORD COPY ML 10

Form TAR-10 (G:\TARS\TARFORM)
9/93

The George Washington University
175TH ANNIVERSARY 1821-1996
MEDICAL CENTER

RADIATION SAFETY OFFICE

030-09049

License No. 08-00216-22
Docket No. 030-09049
Control No. 111230

August 15, 1995

Francis Costello
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Mr. Costello:

As per our telephone communications on August 4 and 8, and additional telephone conversations with Mr. Courtemanche, please accept the attached revisions to the license application previously submitted on March 28, 1995. These revisions are intended to replace in their entirety, the previously submitted Items 5 & 6 (page 2), Items 7.1 & 7.2 (page 4 only, not entirety), Item 10.7 (page 57), Item 10.12 (pages 58-61), and Items 10.3 & 10.16 (page 68).

I understand that two additional sections of the most recent application will be evaluated at NRC Headquarters, and that the license may be issued now, and may be amended later when these evaluations are complete. I understand that the two sections to be reviewed are:

1. The procedure on page 65, "Radiation Safety Procedures for Brachytherapy Sealed Sources and Radiopharmaceutical Therapy," in section G, which allows alternate assessment criteria for the radiation exposure in the adjacent patient room, in the case of radioiodine therapy only, without directly measuring the radiation level in that room. Of course, we have been measuring and recording the radiation level in the adjacent patient room in each patient case to date, and I understand that we must continue this practice unless and until NRC approves some alternate practice, and must continue to comply with 10 CFR 35.315 and 35.415 in all respects.

2. The procedure on pages 69 and 70, "Radioactive Waste Disposal Methods Used," in section C, which describes how the solubility of nonbiological radioactive material may be determined prior to disposal in a municipal sanitary sewerage system. I understand that, pending evaluation of this procedure, we must continue to dispose nonbiological radioactive material only when it is readily soluble, and must continue to comply with 10 CFR 20.2003 in all respects.

CONTROLLED AS 122207

SECTION COPY

SEPARATED OUT OF ~~111230~~

8/25/95 ~~AUG 23 1995~~

FAX REC'D

2300 EYE STREET, N.W. • ROOM B-32 • WASHINGTON, DC 20037 • (202) 994-2634

I also understand that, upon completion of these evaluations, the University may be required to make timely submission of revised procedures, in substitution for the two sections of the license application evaluated.

If these revisions raise any questions, or if my understanding of the evaluations to be made at NRC Headquarters, and particularly of our regulatory compliance requirements pending completion of these evaluations, is misstated in any way, please advise me directly at: 202-994-3149.

Thank you for your attention to this matter.

Sincerely,

Terry Johnson
Radiation Safety Officer

TAJ/gjh (10B1cLicense8/16)

cc: Astra Bain-Dowell,
Acting Director, Office of Research

Katherine A. Kennedy, Ph.D.
Chair of the Radiation Safety Committee

encls.

The George Washington University
175TH ANNIVERSARY 1821-1996
MEDICAL CENTER

RADIATION SAFETY OFFICE

X

License No. 08-00216-22
Docket No. 030-09049
Control No. 111230

March 28, 1995

Steven R. Courtemanche, Health Physicist
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Mr. Courtemanche:

Pursuant to NRC letter of March 8, 1995, and subsequent telephone conversations, the enclosed additional information is formatted as a complete renewal application, for license number 08-00216-22, replacing all previous applications and license commitments in their entirety.

If you have any questions, please call me at 202-994-3149.

Sincerely,

Terry Johnson

Terry Johnson
Radiation Safety Officer

TAJ/gjh (10B1cLicense32895)

cc: Astra Bain-Dowell.
Acting Director, Office of Research, GWU

Katherine A. Kennedy, Ph.D.
Chair of the Radiation Safety Committee

encl.

122207
~~111230~~
~~MAR 29 1995~~

2300 EYE STREET, N.W. • ROOM B-42 • WASHINGTON, DC 20037 • (202) 994-2630

NRC FORM 313 (6-83)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-86

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. 030-09049

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

X

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

THIS IS AN APPLICATION FOR (Check appropriate item)

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [XX] C. RENEWAL OF LICENSE NUMBER 08-00216-22; replacing prior submissions in their entirety.

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

The George Washington University
Office of Research
2300 I Street, NW, Suite 712
Washington, DC 20037

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED: Licensed material shall be used only at: The George Washington University, 2121 I St., NW, Washington, DC 20052, bounded by Pennsylvania Ave., F St., 19th St., and 25th St., NW, Washington, DC, and 20101 Academic Way, Ashburn, VA 22011

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION: Terry A. Johnson

TELEPHONE NUMBER: 202-994-2630

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5.	RADIOACTIVE MATERIAL. a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6.	PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7.	INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.	8.	TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9.	FACILITIES AND EQUIPMENT. 9.5 = N/A.	10.	RADIATION SAFETY PROGRAM.
11.	WASTE MANAGEMENT.	12.	LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 7B; AMOUNT ENCLOSED $ N/A.

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Allan B. Weingold, M.D., Vice President for Medical Affairs and Executive Dean		5/24/1

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

NRC FORM 313 (6-83)

PRINTED ON RECYCLED PAPER

~~MAR 20 1995~~ 11230

A. Only high pH solution will be used for liquid oral administration of I-131 as iodide.

B. Only trained Division of Nuclear Medicine personnel will administer radiopharmaceutical to the patient. The staff member who administers any therapeutic dosage of I-131 is routinely bioassayed in 1 to 3 days, as is anyone else ***who was nearby during*** the dosage swallow. If the patient promptly vomits, the entire staff present anywhere in the room (or who clean up), bioassayed.

C. A radiopharmaceutical therapy patient will not be released until the exposure rate 1 meter from the patient's body is 5 mR per hour or less, or until the remaining total body burden is less than 30 mCi***; or the release will conform to the requirements of 10 CFR Part 35 effective on the date of the release***. This patient's room and reusable equipment will not be released until monitored, and decontaminated if necessary, according to criteria in 10 CFR 35.315(a)(5 and 7).

D. ***Brachytherapy and radiopharmaceutical therapy*** treatments requiring hospitalization pursuant to 10 CFR 35.75 or 35.404, will be *only* in rooms used privately, with toilets for ambulatory cases.

E. These rooms will be posted and controlled according to 10 CFR 20.1601, **35.315 and 35.415.**

F. Pursuant to 10 CFR 20.1301, radiation in unrestricted areas will be limited to 2 millirem per hour, and maintained ALARA throughout the patient treatment. Radiation in controlled areas around the therapy patient room will be limited in exactly the same way. Nobody in these areas will be allowed to receive an external whole-body dose from the patient exceeding 100 millirem.

G. As required by 10 CFR 35.315 or 35.415, dose rates in surrounding areas will be measured and recorded promptly upon the start of therapy, particularly at bedside, 1 meter, yellow visitor's line, hall door opening, and the maximum dose rate point in the adjacent patient room. As required by 10 CFR 20.1302, if the product of the maximum dose rate in the adjacent patient room, and the total treatment time, exceeds ***50 millirem, the dose rates and room arrangements,*** etc., will be evaluated by the RSO / ARSO, who will determine: that the patient in the adjacent room will not receive a dose exceeding ***50 millirem, and that this patient's dose will be kept ALARA; that this patient has not been previously hospitalized during the prior 365 days (or, if so, that the previous stay was not in a room adjacent to any form of radiation therapy); and that the nursing personnel and visitors will not receive a dose exceeding 5 millirem per day while in the adjacent patient room***. Otherwise, one of the patients will be reassigned to a different room.

However, given the shielding value of the hospital wall materials and other factors, in the case of radioiodine therapy *only* (I-131, or I-125 seeds), the survey of the adjacent patient room may be omitted, but ***only when the administered activity does not exceed 200 mCi (± 10% for dosage calibration), and when the patient release (or sealed source explant) is expected on or before the second day following the administration day,*** only in the case of therapy in room 3102E, 3138E, 4102E, or 5138E, ***only when the patient in the adjacent room receives no unusually time-consuming nursing or ancillary services, and has the normal hospital limitation of visiting hours, only after verifying that this patient's stay in the adjacent room did not overlap the previous radioactive therapy, and that this patient's bed is positioned up against the wall farthest from the radiation treatment room, only when the radiation treatment bed is positioned up against the wall farthest from the adjacent patient room, such that the patient's thyroid (in bed) is observed to be less than 42 inches from this wall,*** and *only* if the maximum exposure rate on the treatment side of the wall separating the two rooms ***(at one foot from the wall)*** does not exceed 4 mR per hour; when this provision is used, the maximum exposure rate on the treatment side of the wall must be recorded and identified clearly, in lieu of the maximum exposure rate in the adjacent patient room, and must be remeasured and recorded approximately 24 hours after the start of the therapy (if this latter reading exceeds 1.5 mR per hour, notify the RSO / ARSO immediately).

H. Based on the exposure rate at the ***treatment patient's*** yellow visitors' line, a maximum daily visiting time may be calculated to assure that the visitors' doses cannot exceed ***10*** millirem per day. Any longer visiting times (generally for the spouse or parents of a critically ***or terminally*** ill patient) will be approved in writing by the RSO, and will include provision for visitor dosimetry.

I. The physician performs the safety counseling for all patients, *e.g.*, regarding family protection.

J. The nursing personnel attending the patient ***will have been instructed as required by 10 CFR 35.310 or 35.410, as applicable (see also Item 8, sections C and D). They also will have been instructed in the use of any required personnel dosimetry assigned (see also Item 9.4.G).***

K. The Radiation Safety Office will be contacted in the event of any emergency at 994-2630, or through the page operator at 994-3321 (numbers subject to change at will).

L. Prior to release from the hospital, each brachytherapy patient will be surveyed to verify that no sealed source remains in the body (or that the exposure rate at 1 meter from the patient is no more than 5 mR per hour for permanent implants)***; or the release will conform to the requirements of 10 CFR Part 35 effective on the date of the release***. The survey will also include the bedding, floor, trash, *etc.*

M. Brachytherapy sources are stored in a heavily shielded cabinet in a locked and posted source room, well inside the restricted area of Radiation Oncology. The names of "primaries" (who may remove sources) are posted. This room contains a leaded-glass L-block and tongs for safe source handling. In-hospital transport of sources is done in the original shipping container, or is shielded by ≥ 1 inch of lead (or by a heavy steel container used only for ***Pd-103 or*** I-125).

N. To satisfy the inventory requirements for the use of brachytherapy sources in patient cases, pursuant to 10 CFR 35.406, we will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix M.4 to Regulatory Guide 10.8, Revision 2. If any brachytherapy source cannot be definitely located, the following steps will be taken:

1) The Radiation Safety Officer will be contacted promptly;
2) A careful inventory will verify the identity of the source lost;
3) All personnel involved with the therapy or sources will be contacted to determine how the loss might have occurred;
4) A careful search with sensitive survey meters, will proceed from the source's last known position, along every plausible route of loss;
5) The incident report will include estimates of plausible personnel doses;
6) Telephone notification to the NRC will be made promptly upon determination that the source is no longer in the restricted area, unless the RSO determines it is not required pursuant to 10 CFR 20.2201.

Item 10.14E Supporting Documentation for Exemption Request from 10 CFR 35.315(a)(4)

Attached to Item 9.1 is a drawing of each therapy room showing the location of the bed, which is always arranged *against the opposite wall farthest from the adjacent patient room. These beds may be rotated 90° to accommodate the equipment in the room, but are always directly up against the opposite wall.* The bed in the adjacent patient room is arranged *against the wall farthest from the treatment room.*

The walls between the rooms are 6 inches thick or thicker (ordinary concrete materials were used). This approximates one tenth-value-layer for I-131, which our dosimetry measurements confirm.

NVLAP-certified dosimetry was used to investigate the total dose along the wall just inside the adjacent patient room closest to the radiation therapy patient, for the duration of several typical I-131 therapies (each lasting 2 days). Below is a summary of the dosimetry results (both TLD and film badge) in the rooms adjacent to various approved treatment rooms in the hospital, along with the activity used for each patient:

Start Date	Therapy Room	Adjacent Rooms	Therapy Type	Therapy Activity	Doses	
					Film Badge	TLD
07/15/92	5246 South *	5101 East**	I-131	175 mCi	M	M
08/26/92	5102 East	5104 East	I-131	150 mCi	10 mrem	M
08/31/92	5346 North	5131 East**	I-131	200 mCi	M	M
10/26/92	3102 East	3104 East	I-131	150 mCi	M	10 mrem
11/02/92	5346 North	5131 East**	I-131	175 mCi	M	M
11/04/92	4102 East	4104 East	I-131	200 mCi	M	M

* no longer used for therapy. ** the only room adjacent is around the corner on the East ward.

Our results indicate that doses just inside the adjacent patient rooms are minimal, even though integrated through the entire therapy, or are barely in the range of NVLAP-certified dosimetry detection limits, approximately 10 mrem or less.

The most recent data indicate that the ten I-131 inpatients treated between December 1, 1994, and February 28, 1995, produced maximum initial dose rates in the respective adjacent patient rooms averaging to less than 0.15 mR / hr., from greater than 150 mCi average administered dosage. Since the measurement point in the adjacent room is about 11 feet from the freshly swallowed I-131 bolus in the patient's stomach, and the I-131 exposure factor is approximately 0.22 mR / hr. per mCi at 1 meter, these data indicate the total shielding attenuation is about 95%.

The other important aspect of the safety of this proposal, concerns the measurements on the 1st and 2nd day of therapy, inside the therapy patient's room, along the wall shielding the patient in the adjacent room. When the point of maximum dose rate along this wall, inside the room of the patient given I-131 therapy, receives exposure of 4 mR / hr initially, ***that same point*** will typically not receive an integrated exposure of more than 100 mR during the entire period of hospitalization, even though that period is typically 40 to 50 hours. This is because the rapid initial elimination of the ***I-131 in urine*** by the patient results in an effective mean life of I-131 (effective half-life / 1n(2)) which is almost always less than 20 hours, based on our measured exposure data (at 1 meter) spanning the first 2 days (*i.e.*, from administration, to release). The check of the same point 24 hours later, to confirm that the dose rate is ≤ 1.5 mR / hr., is intended to confirm this for each individual patient case.

In the incredible scenario where the patient in the adjacent room is readmitted adjacent to another therapy, the total dose from both therapies will be less than 20 mrem, according to our dosimetry results, ***which is based on the highest exposure rate in the room, which is nowhere near the actual patient bed.*** Extended stay of the patient in the same adjacent room is virtually nonexistent; these adjacent rooms are all assigned exclusively for acute care and for short stays. In any case, our procedures verify that each patient in an adjacent room was not there overlapping the previous therapy.

Item 11.1 RADIOACTIVE WASTE DISPOSAL METHODS USED

A. Decay-in-storage, in accordance with 10 CFR § 20.2001 or § 35.92.

Any radioactive waste with half-life less than 65 days, generated incidental to authorized medical uses, may be disposed with strict adherence to the requirements of 10 CFR 35.92.

Due to space limitations from long-term lack of access to a LLRW disposal site, we request authorization to use decay-in-storage to dispose of any radioactive material with half-life less than 120 days, provided: that it is labeled clearly on the exterior, and recorded clearly on a decay-in-storage log, to facilitate tracking and identification (by isotope, date, etc.) as it is placed in storage and removed for disposal; that it is stored in a secured area, and separate from nonradioactive waste and from useful nonradioactive and radioactive material (unless it is stored refrigerated, or segregated by another hazardous property); that it is held for decay a minimum of ten half-lives (based on the longest half-life for the isotopes in a container) before disposal; that it is monitored at the container surface before disposal (with each major discrete source, such as a generator column, separated and monitored individually), with a radiation detection survey meter set on its most sensitive scale, in an area of low background radiation, and with no interposed shielding, to ensure that it has decayed to background radiation level before disposal (otherwise it is returned to storage for more decay); that its radiation labels are removed or obliterated before disposal; that no more than 500 cubic feet per year of this decayed radioactive material is disposed; and that, upon its disposal as nonradioactive waste, the disposal record includes the date of the disposal, the starting date of the waste decay period, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal, and that this record is retained for three (3) years.

However, radionuclides may also be disposed from storage by another approved method, with strict adherence to the requirements of that method, even after considerable decay has occurred.

B. Release of effluents to unrestricted areas in compliance with 10 CFR 20.1301 and 20.1302, incidental to the authorized use of the radioactive material. However, we presently release no liquid radioactive material effluents into unrestricted areas, *e.g.*, into streams, storm sewers or any body of water, into the ground, or into any sewers other than municipal sanitary sewers. Prior to permitting any such release proposed, we will notify the NRC, Region I, to inquire about licensing and other requirements, and receive reply prior to the release. Any such release made inadvertently will be investigated promptly by the Radiation Safety Officer, who will notify the NRC as required by 10 CFR 20.2202 /.2203.

C. Disposal into sanitary sewerage in compliance with 10 CFR 20.2003. This waste will be readily soluble, at pH 5 to 9, or will be readily dispersible biological material. *Each disposal will be flushed afterward with tap water for several seconds.*

Any isotope not used in biological material will be so disposed only if its chemical form is listed as "Class D" in 10 CFR 20, Appendix B, or as "soluble" in the CRC Handbook of Chemistry and Physics (or a similar reference), or as having "formal solubility" greater than 0.003 mole per liter in the scientific literature; or if the radionuclide is less than 1 mCi of an isotope with half-life less than 6.1 hours, or is disposed incidental to use under 10 CFR 35.100 / .200 / .300, or is only H-3, C-14, S-35 or Cr-51, in concentration less than 0.05 μCi per gram of solution; and only if the material appears to be completely dissolved in water at room temperature, with no visible indication that it bears particulates or flakes, etc. (if there is any doubt about the dissolution of nonbiological material which clearly meets one of the criteria given above, it may be adjusted to pH 7.0 to 7.3, refrigerated overnight, carefully filtered or decanted, and the filtrate or decantate diluted an additional ten-fold and disposed); and only if the material disposed excludes all byproduct material excluded from Item 5, Line D, of this application (e.g., Sr-90, I-129, and isotopes with atomic number > 83).

Other nonbiological materials may be disposed only under the supervision of the Radiation Safety Officer, only when they are neither listed as "Class Y" in 10 CFR 20, nor listed as "insoluble" in the CRC Handbook of Chemistry and Physics, only when the "formal solubility" is well-established in the scientific literature, and only when they are diluted to a molar concentration which is less than the square of the "formal solubility" in mole / liter (e.g., *to less than 9×10^{-6} molar concentration when the "formal solubility" is 3×10^{-3} mole / liter) and to isotopic concentration less than that listed in 10 CFR 20, Appendix B, Table 2, Column 2* (i.e., *to isotopic concentration suitable for potable effluent, even though sewage disposal is used; both the molar and isotopic concentrations are determined for the solution before disposal, not including the additional dilution in the sewage); and only when the material appears to be completely dissolved in water at room temperature, with no visible indication that it bears particulates or flakes,* etc. *(no doubtful dissolution permitted).*

The sewage disposal activity limit of 1 curie per year, for all isotopes other than H-3 and C-14, is invariably more restrictive than the monthly sewage concentration limits, in our normal laboratory operations. Since our laboratories operate steadily year-round (such that this activity limit is tantamount to 83 mCi per month), and since the sewage volume of Ross Hall alone is greater than 10 million liters per month, as demonstrated by water bills, the activity limit is more restrictive than the sewage concentration limit, unless the latter is less than 8.3 E-6 μCi / ml (such as the limits for many of the isotopes excluded from Item 5, Line D, or for a few relatively rare or useless isotopes not excluded), even when the entire 83 mCi is assumed to be the most hazardous isotope, which is implausible. Hence, the provisions for limitation of overall activity disposed, in conjunction with the provision that isotopes excluded from Item 5, Line D, are also excluded from sewage disposal (unless supervised by the Radiation Safety Officer, who will review and implement the concentration limits for such isotopes); also provide full assurance of compliance with applicable sewage concentration limits. The provisions for limitation of overall activity disposed include: Authorized Users' "sink limits" (generally 10 mCi of H-3, 2 mCi of C-14, and 2 mCi of all other isotopes combined, per month, per authorized "hot sink"); an Authorized User requirement to log each "hot sink" disposal; and quarterly collection, summary and analysis of "hot sink" disposal logs. These provisions assure that the total quantity of licensed and other radioactive material released into sewage in a year is limited to 5 curies of H-3, 1 curie of C-14, and 1 curie of all other radioactive materials combined.

However, excreta from individuals undergoing any approved medical use of radioactive material are not subject to any limitations or recording, when disposed into a municipal sanitary sewerage.

D. Disposal of scintillation counting media and animal tissues, containing H-3 and C-14, without regard to radioactivity up to 0.05 uCi per gram, averaged over the media or the weight of the entire animal, pursuant to 10 CFR 20.2005. *Contaminated bedding will be disposed separately as radioactive waste.*

E. Return to the manufacturer, supplier, or previous licensee, when licensed to receive back Mo-99/Tc-99m generators, sealed sources, *etc.*; or transfer to a recipient licensed by the NRC or an Agreement State to receive the waste for storage, treatment, disposal and/or retransfer; with each transfer made according to DOT regulations and 10 CFR 20.2001/.2006.

F. Disposal pursuant to 10 CFR 31.11 (not to include "mock I-125" sealed sources).

G. Disposal records will be maintained as required in 10 CFR 20.2108 / 30.51 / 31.11 / 35.92.

H. We presently perform no significant radioactive waste treatment procedures, *i.e.*, compaction, evaporation, incineration, solidification, or liquid scintillation vial crushing.

The George Washington University
175TH ANNIVERSARY 1821-1996
MEDICAL CENTER

RADIATION SAFETY OFFICE

030-09049

License No. 08-00216-22
Docket No. 030-09049
Control No. 111230

August 15, 1995

Francis Costello
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Mr. Costello:

As per our telephone communications on August 4 and 8, and additional telephone conversations with Mr. Courtemanche, please accept the attached revisions to the license application previously submitted on March 28, 1995. These revisions are intended to replace in their entirety, the previously submitted Items 5 & 6 (page 2), Items 7.1 & 7.2 (page 4 only, not entirety), Item 10.7 (page 57), Item 10.12 (pages 58-61), and Items 10.3 & 10.16 (page 68).

I understand that two additional sections of the most recent application will be evaluated at NRC Headquarters, and that the license may be issued now, and may be amended later when these evaluations are complete. I understand that the two sections to be reviewed are:

1. The procedure on page 65, "Radiation Safety Procedures for Brachytherapy Sealed Sources and Radiopharmaceutical Therapy," in section G, which allows alternate assessment criteria for the radiation exposure in the adjacent patient room, in the case of radioiodine therapy only, without directly measuring the radiation level in that room. Of course, we have been measuring and recording the radiation level in the adjacent patient room in each patient case to date, and I understand that we must continue this practice unless and until NRC approves some alternate practice, and must continue to comply with 10 CFR 35.315 and 35.415 in all respects.

2. The procedure on pages 69 and 70, "Radioactive Waste Disposal Methods Used," in section C, which describes how the solubility of nonbiological radioactive material may be determined prior to disposal in a municipal sanitary sewerage system. I understand that, pending evaluation of this procedure, we must continue to dispose nonbiological radioactive material only when it is readily soluble, and must continue to comply with 10 CFR 20.2003 in all respects.

CONTROLLED AS 122207
SEPARATED OUT OF 111230
8/25/95 AUG 23 1995
FAX REC'D

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I also understand that, upon completion of these evaluations, the University may be required to make timely submission of revised procedures, in substitution for the two sections of the license application evaluated.

If these revisions raise any questions, or if my understanding of the evaluations to be made at NRC Headquarters, and particularly of our regulatory compliance requirements pending completion of these evaluations, is misstated in any way, please advise me directly at 202-994-3149.

Thank you for your attention to this matter.

Sincerely,

Terry Johnson

Terry Johnson
Radiation Safety Officer

TAJ/gjh (10B1cLicense8/16)

cc: Astra Bain-Dowell,
Acting Director, Office of Research

Katherine A. Kennedy, Ph.D.
Chair of the Radiation Safety Committee

encls.

The George Washington University
175TH ANNIVERSARY 1821-1996
MEDICAL CENTER

RADIATION SAFETY OFFICE

X

License No. 08-00216-22
Docket No. 030-09049
Control No. 111230

March 28, 1995

Steven R. Courtemanche, Health Physicist
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Mr. Courtemanche:

Pursuant to NRC letter of March 8, 1995, and subsequent telephone conversations, the enclosed additional information is formatted as a complete renewal application, for license number 08-00216-22, replacing all previous applications and license commitments in their entirety.

If you have any questions, please call me at 202-994-3149.

Sincerely,

Terry Johnson

Terry Johnson
Radiation Safety Officer

TAJ/gjh (10B1cLicense32895)

cc: Astra Bain-Dowell.
Acting Director, Office of Research, GWU

Ketherine A. Kennedy, Ph.D.
Chair of the Radiation Safety Committee

encl.

122207
~~111230~~
~~MAR 30 1995~~

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NRC FORM 313 (6-83)
10 CFR 30, 32, 33, 34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-86

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. 030-09049

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

X

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [XX] C. RENEWAL OF LICENSE NUMBER 08-00216-22; replacing prior submissions in their entirety.

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

The George Washington University
Office of Research
2300 I Street, NW, Suite 712
Washington, DC 20037

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED: Licensed material shall be used only at: The George Washington University, 2121 I St., NW, Washington, DC 20052, bounded by Pennsylvania Ave., F St., 19th St., and 25th St., NW, Washington, DC, and 20101 Academic Way, Ashburn, VA 22011

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Terry A. Johnson

TELEPHONE NUMBER

202-994-2630

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5.	RADIOACTIVE MATERIAL. a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6.	PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7.	INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.	8.	TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9.	FACILITIES AND EQUIPMENT. 9.5 = N/A.	10.	RADIATION SAFETY PROGRAM.
11.	WASTE MANAGEMENT.	12.	LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 7B; AMOUNT ENCLOSED $ N/A.

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE: Allan B. Weingold, M.D., Vice President for Medical Affairs and Executive Dean

SIGNATURE

DATE 5/24/1

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

NRC FORM 313 (6-83)

PRINTED ON RECYCLED PAPER

~~MAR 20 1995~~ 122207 ~~11230~~

A. Only high pH solution will be used for liquid oral administration of I-131 as iodide.

B. Only trained Division of Nuclear Medicine personnel will administer radiopharmaceutical to the patient. The staff member who administers any therapeutic dosage of I-131 is routinely bioassayed in 1 to 3 days, as is anyone else ***who was nearby during*** the dosage swallow. If the patient promptly vomits, the entire staff present anywhere in the room (or who clean up), are bioassayed.

C. A radiopharmaceutical therapy patient will not be released until the exposure rate 1 meter from the patient's body is 5 mR per hour or less, or until the remaining total body burden is less than 30 mCi***; or the release will conform to the requirements of 10 CFR Part 35 effective on the date of the release***. This patient's room and reusable equipment will not be released until monitored, and decontaminated if necessary, according to criteria in 10 CFR 35.315(a)(5 and 7).

D. ***Brachytherapy and radiopharmaceutical therapy*** treatments requiring hospitalization pursuant to 10 CFR 35.75 or 35.404, will be *only* in rooms used privately, with toilets for ambulatory cases.

E. These rooms will be posted and controlled according to 10 CFR 20.1601, **35.315 and 35.415.**

F. Pursuant to 10 CFR 20.1301, radiation in unrestricted areas will be limited to 2 millirem per hour, and maintained ALARA throughout the patient treatment. Radiation in controlled areas around the therapy patient room will be limited in exactly the same way. Nobody in these areas will be allowed to receive an external whole-body dose from the patient exceeding 100 millirem.

G. As required by 10 CFR 35.315 or 35.415, dose rates in surrounding areas will be measured and recorded promptly upon the start of therapy, particularly at bedside, 1 meter, yellow visitor's line, hall door opening, and the maximum dose rate point in the adjacent patient room. As required by 10 CFR 20.1302, if the product of the maximum dose rate in the adjacent patient room, and the total treatment time, exceeds ***50 millirem, the dose rates and room arrangements,*** etc., will be evaluated by the RSO / ARSO, who will determine: that the patient in the adjacent room will not receive a dose exceeding ***50 millirem, and that this patient's dose will be kept ALARA; that this patient has not been previously hospitalized during the prior 365 days (or, if so, that the previous stay was not in a room adjacent to any form of radiation therapy); and that the nursing personnel and visitors will not receive a dose exceeding 5 millirem per day while in the adjacent patient room***. Otherwise, one of the patients will be reassigned to a different room.

However, given the shielding value of the hospital wall materials and other factors, in the case of radioiodine therapy *only* (I-131, or I-125 seeds), the survey of the adjacent patient room may be omitted, but ***only when the administered activity does not exceed 200 mCi (± 10% for dosage calibration), and when the patient release (or sealed source explant) is expected on or before the second day following the administration day,*** ***only*** in the case of therapy in room 3102E, 3138E, 4102E, or 5138E, ***only when the patient in the adjacent room receives no unusually time-consuming nursing or ancillary services, and has the normal hospital limitation of visiting hours, only after verifying that this patient's stay in the adjacent room did not overlap the previous radioactive therapy, and that this patient's bed is positioned up against the wall farthest from the radiation treatment room, only when the radiation treatment bed is positioned up against the wall farthest from the adjacent patient room, such that the patient's thyroid (in bed) is observed to be less than 42 inches from this wall,*** and *only* if the maximum exposure rate on the treatment side of the wall separating the two rooms ***(at one foot from the wall)*** does not exceed 4 mR per hour; when this provision is used, the maximum exposure rate on the treatment side of the wall must be recorded and identified clearly, in lieu of the maximum exposure rate in the adjacent patient room, and must be remeasured and recorded approximately 24 hours after the start of the therapy (if this latter reading exceeds 1.5 mR per hour, notify the RSO / ARSO immediately).

H. Based on the exposure rate at the ***treatment patient's*** yellow visitors' line, a maximum daily visiting time may be calculated to assure that the visitors' doses cannot exceed ***10*** millirem per day. Any longer visiting times (generally for the spouse or parents of a critically ***or terminally*** ill patient) will be approved in writing by the RSO, and will include provision for visitor dosimetry.

I. The physician performs the safety counseling for all patients, *e.g.*, regarding family protection.

J. The nursing personnel attending the patient ***will have been instructed as required by 10 CFR 35.310 or 35.410, as applicable (see also Item 8, sections C and D). They also will have been instructed in the use of any required personnel dosimetry assigned (see also Item 9.4.G).***

K. The Radiation Safety Office will be contacted in the event of any emergency at 994-2630, or through the page operator at 994-3321 (numbers subject to change at will).

L. Prior to release from the hospital, each brachytherapy patient will be surveyed to verify that no sealed source remains in the body (or that the exposure rate at 1 meter from the patient is no more than 5 mR per hour for permanent implants); ***or the release will conform to the requirements of 10 CFR Part 35 effective on the date of the release***. The survey will also include the bedding, floor, trash, *etc.*

M. Brachytherapy sources are stored in a heavily shielded cabinet in a locked and posted source room, well inside the restricted area of Radiation Oncology. The names of "primaries" (who may remove sources) are posted. This room contains a leaded-glass L-block and tongs for safe source handling. In-hospital transport of sources is done in the original shipping container, or is shielded by ≥ 1 inch of lead (or by a heavy steel container used only for ***Pd-103 or*** I-125).

N. To satisfy the inventory requirements for the use of brachytherapy sources in patient cases, pursuant to 10 CFR 35.406, we will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix M.4 to Regulatory Guide 10.8, Revision 2. If any brachytherapy source cannot be definitely located, the following steps will be taken:

1) The Radiation Safety Officer will be contacted promptly;
2) A careful inventory will verify the identity of the source lost;
3) All personnel involved with the therapy or sources will be contacted to determine how the loss might have occurred;
4) A careful search with sensitive survey meters, will proceed from the source's last known position, along every plausible route of loss;
5) The incident report will include estimates of plausible personnel doses;
6) Telephone notification to the NRC will be made promptly upon determination that the source is no longer in the restricted area, unless the RSO determines it is not required pursuant to 10 CFR 20.2201.

Item 10.14E Supporting Documentation for Exemption Request from 10 CFR 35.315(a)(4)

Attached to Item 9.1 is a drawing of each therapy room showing the location of the bed, which is always arranged ***against the opposite wall farthest from the adjacent patient room. These beds may be rotated 90° to accommodate the equipment in the room, but are always directly up against the opposite wall.*** The bed in the adjacent patient room is arranged ***against the wall farthest from the treatment room.***

The walls between the rooms are 6 inches thick or thicker (ordinary concrete materials were used). This approximates one tenth-value-layer for I-131, which our dosimetry measurements confirm.

NVLAP-certified dosimetry was used to investigate the total dose along the wall just inside the adjacent patient room closest to the radiation therapy patient, for the duration of several typical I-131 therapies (each lasting 2 days). Below is a summary of the dosimetry results (both TLD and film badge) in the rooms adjacent to various approved treatment rooms in the hospital, along with the activity used for each patient:

Start Date	Therapy Room	Adjacent Rooms	Therapy Type	Therapy Activity	Doses	
					Film Badge	TLD
07/15/92	5246 South *	5101 East**	I-131	175 mCi	M	M
08/26/92	5102 East	5104 East	I-131	150 mCi	10 mrem	M
08/31/92	5346 North	5131 East**	I-131	200 mCi	M	M
10/26/92	3102 East	3104 East	I-131	150 mCi	M	10 mrem
11/02/92	5346 North	5131 East**	I-131	175 mCi	M	M
11/04/92	4102 East	4104 East	I-131	200 mCi	M	M

* no longer used for therapy. ** the only room adjacent is around the corner on the East ward.

Our results indicate that doses just inside the adjacent patient rooms are minimal, even though integrated through the entire therapy, or are barely in the range of NVLAP-certified dosimetry detection limits, approximately 10 mrem or less.

The most recent data indicate that the ten I-131 inpatients treated between December 1, 1994, and February 28, 1995, produced maximum initial dose rates in the respective adjacent patient rooms averaging to less than 0.15 mR / hr., from greater than 150 mCi average administered dosage. Since the measurement point in the adjacent room is about 11 feet from the freshly swallowed I-131 bolus in the patient's stomach, and the I-131 exposure factor is approximately 0.22 mR / hr. per mCi at 1 meter, these data indicate the total shielding attenuation is about 95%.

The other important aspect of the safety of this proposal, concerns the measurements on the 1st and 2nd day of therapy, inside the therapy patient's room, along the wall shielding the patient in the adjacent room. When the point of maximum dose rate along this wall, inside the room of the patient given I-131 therapy, receives exposure of 4 mR / hr initially, ***that same point*** will typically not receive an integrated exposure of more than 100 mR during the entire period of hospitalization, even though that period is typically 40 to 50 hours. This is because the rapid initial elimination of the ***I-131 in urine*** by the patient results in an effective mean life of I-131 (effective half-life / ln(2)) which is almost always less than 20 hours, based on our measured exposure data (at 1 meter) spanning the first 2 days (*i.e.*, from administration, to release). The check of the same point 24 hours later, to confirm that the dose rate is ≤ 1.5 mR / hr., is intended to confirm this for each individual patient case.

In the incredible scenario where the patient in the adjacent room is readmitted adjacent to another therapy, the total dose from both therapies will be less than 20 mrem, according to our dosimetry results, ***which is based on the highest exposure rate in the room, which is nowhere near the actual patient bed.*** Extended stay of the patient in the same adjacent room is virtually nonexistent; these adjacent rooms are all assigned exclusively for acute care and for short stays. In any case, our procedures verify that each patient in an adjacent room was not there overlapping the previous therapy.

Item 11.1 RADIOACTIVE WASTE DISPOSAL METHODS USED

A. Decay-in-storage, in accordance with 10 CFR § 20.2001 or § 35.92.

Any radioactive waste with half-life less than 65 days, generated incidental to authorized medical uses, may be disposed with strict adherence to the requirements of 10 CFR 35.92.

Due to space limitations from long-term lack of access to a LLRW disposal site, we request authorization to use decay-in-storage to dispose of any radioactive material with half-life less than 120 days, provided: that it is labeled clearly on the exterior, and recorded clearly on a decay-in-storage log, to facilitate tracking and identification (by isotope, date, etc.) ***as it is placed in storage and removed for disposal; that it is stored in a secured area, and separate from nonradioactive waste and from useful nonradioactive and radioactive material (unless it is stored refrigerated, or segregated by another hazardous property); that it is held for decay a minimum of ten half-lives (based on the longest half-life for the isotopes in a container) before disposal; that it is monitored at the container surface before disposal (with each major discrete source, such as a generator column, separated and monitored individually), with a radiation detection survey meter set on its most sensitive scale, in an area of low background radiation, and with no interposed shielding, to ensure that it has decayed to background radiation level before disposal (otherwise it is returned to storage for more decay); that its radiation labels are removed or obliterated before disposal; that no more than 500 cubic feet per year of this decayed radioactive material is disposed; and that, upon its disposal as nonradioactive waste, the disposal record includes the date of the disposal, the starting date of the waste decay period, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal, and that this record is retained for three (3) years.***

However, radionuclides may also be disposed from storage by another approved method, with strict adherence to the requirements of that method, even after considerable decay has occurred.

B. Release of effluents to unrestricted areas in compliance with 10 CFR 20.1301 and 20.1302, incidental to the authorized use of the radioactive material. However, we presently release no liquid radioactive material effluents into unrestricted areas, *e.g.*, into streams, storm sewers or any body of water, into the ground, or into any sewers other than municipal sanitary sewers. Prior to permitting any such release proposed, we will notify the NRC, Region I, to inquire about licensing and other requirements, and receive reply prior to the release. Any such release made inadvertently will be investigated promptly by the Radiation Safety Officer, who will notify the NRC as required by 10 CFR 20.2202 /.2203.

C. Disposal into sanitary sewerage in compliance with 10 CFR 20.2003. This waste will be readily soluble, at pH 5 to 9, or will be readily dispersible biological material. ***Each disposal will be flushed afterward with tap water for several seconds.***

Any isotope not used in biological material will be so disposed only if its chemical form is listed as "Class D" in 10 CFR 20, Appendix B, or as "soluble" in the CRC Handbook of Chemistry and Physics (or a similar reference), ***or as having "formal solubility" greater than 0.003 mole per liter in the scientific literature; or if the radionuclide is less than 1 mCi of an isotope with half-life less than 6.1 hours, or is disposed incidental to use under 10 CFR 35.100 / .200 / .300, or is only H-3, C-14, S-35 or Cr-51, in concentration less than 0.05 μCi per gram of solution; and only if the material appears to be completely dissolved in water at room temperature, with no visible indication that it bears particulates or flakes,*** etc. ***(if there is any doubt about the dissolution of nonbiological material which clearly meets one of the criteria given above, it may be adjusted to pH 7.0 to 7.3, refrigerated overnight, carefully filtered or decanted, and the filtrate or decantate diluted an additional ten-fold and disposed); and only if the material disposed excludes all byproduct material excluded from Item 5, Line D, of this application*** (e.g., ***Sr-90, I-129, and isotopes with atomic number > 83).***

Other nonbiological materials may be disposed only under the supervision of the Radiation Safety Officer, only when they are neither listed as "Class Y" in 10 CFR 20, nor listed as "insoluble" in the CRC Handbook of Chemistry and Physics, only when the "formal solubility" is well-established in the scientific literature, and only when they are diluted to a molar concentration which is less than the square of the "formal solubility" in mole / liter (e.g., to less than 9 x 10^{-6} molar concentration when the "formal solubility" is 3 x 10^{-3} mole / liter) and to isotopic concentration less than that listed in 10 CFR 20, Appendix B, Table 2, Column 2 (i.e., to isotopic concentration suitable for potable effluent, even though sewage disposal is used; both the molar and isotopic concentrations are determined for the solution before disposal, not including the additional dilution in the sewage); and only when the material appears to be completely dissolved in water at room temperature, with no visible indication that it bears particulates or flakes, etc. (no doubtful dissolution permitted).

The sewage disposal activity limit of 1 curie per year, for all isotopes other than H-3 and C-14, is invariably more restrictive than the monthly sewage concentration limits, in our normal laboratory operations. Since our laboratories operate steadily year-round (such that this activity limit is tantamount to 83 mCi per month), and since the sewage volume of Ross Hall alone is greater than 10 million liters per month, as demonstrated by water bills, the activity limit is more restrictive than the sewage concentration limit, unless the latter is less than 8.3 E-6 μCi / ml (such as the limits for many of the isotopes excluded from Item 5, Line D, or for a few relatively rare or useless isotopes not excluded), even when the entire 83 mCi is assumed to be the most hazardous isotope, which is implausible. Hence, the provisions for limitation of overall activity disposed, in conjunction with the provision that isotopes excluded from Item 5, Line D, are also excluded from sewage disposal (unless supervised by the Radiation Safety Officer, who will review and implement the concentration limits for such isotopes); also provide full assurance of compliance with applicable sewage concentration limits. The provisions for limitation of overall activity disposed include: Authorized Users' "sink limits" (generally 10 mCi of H-3, 2 mCi of C-14, and 2 mCi of all other isotopes combined, per month, per authorized "hot sink"); an Authorized User requirement to log each "hot sink" disposal; and quarterly collection, summary and analysis of "hot sink" disposal logs. These provisions assure that the total quantity of licensed and other radioactive material released into sewage in a year is limited to 5 curies of H-3, 1 curie of C-14, and 1 curie of all other radioactive materials combined.

However, excreta from individuals undergoing any approved medical use of radioactive material are not subject to any limitations or recording, when disposed into a municipal sanitary sewerage.

D. Disposal of scintillation counting media and animal tissues, containing H-3 and C-14, without regard to radioactivity up to 0.05 uCi per gram, averaged over the media or the weight of the entire animal, pursuant to 10 CFR 20.2005. *Contaminated bedding will be disposed separately as radioactive waste.*

E. Return to the manufacturer, supplier, or previous licensee, when licensed to receive back Mo-99/Tc-99m generators, sealed sources, *etc.*; or transfer to a recipient licensed by the NRC or an Agreement State to receive the waste for storage, treatment, disposal and/or retransfer; with each transfer made according to DOT regulations and 10 CFR 20.2001/.2006.

F. Disposal pursuant to 10 CFR 31.11 (not to include "mock I-125" sealed sources).

G. Disposal records will be maintained as required in 10 CFR 20.2108 / 30.51 / 31.11 / 35.92.

H. We presently perform no significant radioactive waste treatment procedures, *i.e.*, compaction, evaporation, incineration, solidification, or liquid scintillation vial crushing.

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02110
STATUS CODE: 2
FEE CATEGORY: 7B 2B
EXP. DATE: 19890930
FEE COMMENTS: _____
DECOM FIN ASSUR REQD: Y

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: GEORGE WASHINGTON UNIV. MEDICAL CTR
RECEIVED DATE: 950825
DOCKET NO: 3009049
CONTROL NO.: 122207
LICENSE NO.: 08-00216-22
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: ~~_____~~
CHECK NO.: ~~_____~~

3. COMMENTS
SEPARATED OUT FROM 111230.

SIGNED M A Perkins
DATE 9/25/95

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED ✓)

1. FEE CATEGORY AND AMOUNT: 7B 2B Cont'n of 111230

2. CORRECT FEE PAID. ✓ APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ~~_____~~
RENEWAL ~~_____~~
LICENSE ~~_____~~

3. OTHER _____
_____

SIGNED Brenda Bo
DATE 9/15/95

FEE NOT REQUIRED

RECEIVED BY LFDCB
Date 9/15/95 ± (95)
Log Sept 6
By B Bzo
Date Completed 9/15/95