

MATERIALS LICENSE

Amendment No. 32

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

301392

<p>Licensee</p> <p>1. University Hospital of Cleveland</p> <p>2. 11100 Euclid Avenue Cleveland, OH 44106</p>	<p>In accordance with letter dated May 6, 1996</p> <p>3. License Number 34-05469-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration Date July 31, 2001</p> <hr/> <p>5. Docket or Reference No. 030-02745</p>
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6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material with atomic numbers 3 through 83	A. Any	A. 50 millicuries each nuclide, total possession not to exceed 4 curies
B. Hydrogen-3	B. Any	B. 50 millicuries
C. Molybdenum-99	C. Any	C. 6000 millicuries
D. Technetium-99m	D. Any	D. 6000 millicuries
E. Iodine-131	E. Any	E. 1000 millicuries
F. Iodine-125	F. Any	F. 500 millicuries
G. Phosphorus-32	G. Any	G. 500 millicuries
H. Palladium-103	H. Sealed sources	H. 500 millicuries
I. Xenon-133	I. Any	I. 500 millicuries
J. Cesium-137	J. Sealed sources	J. 4000 millicuries
K. Iridium-192	K. Sealed sources	K. 1000 millicuries
L. Gold-198	L. Sealed sources	L. 1000 millicuries
M. Strontium-90	M. Sealed source	M. 150 millicuries

280021

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ML
230
50

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6. Byproduct, source,
and/or special nuclear
material

N. Cesium-137

O. Cesium-137

P. Americium-241

7. Chemical and/or
physical form

N. Sealed source
(J.L. Shepherd Model
No. 28-6B)

O. Sealed sources (AECL
type ISO-100082Cs)

P. Sealed sources (ICN
Model 400)

8. Maximum amount that
licensee may possess
at any one time
under this license

N. 3000 millicuries

O. 2 sources
720 curies each

P. 5 millicuries

9. Authorized Use

A. through L. Medical diagnosis, therapy and research in humans, Research and development as defined in Section 30.4 of 10 CFR Part 30, including instrument calibration (in house only), and animal studies.

M. Ophthalmic eye applicator for treatment of superficial eye conditions.

N. To be used for licensee's Instrument calibration only.

O. To be used in an AECL Gammacell 1000 Model B irradiator for irradiation of medical specimens and research materials, except explosive or flammable materials.

P. To be used for licensee's Instrument calibration only.

CONDITIONS

10. Location of use: 11100 Euclid, Cleveland, Ohio.

11. Radiation Safety Officer: M. Pejavar Sridhar Rao.

12. A. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.2.

B. Physicians designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee. The licensee shall maintain records of physicians designated as users.

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- C. Licensed material for other than human use shall be used by, or under the supervision of individuals designated by the Radiation Safety Committee A. R. Antunez, M.D., Chairperson. The licensee shall maintain records of individual designated as users.
13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material, and shall further restrict the possession of unsealed licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
14. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration, referred to in 10 CFR 32.210.
- B. Notwithstanding Paragraph A of this condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a test has been made, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Sealed sources need not be leak tested if:
- (I) they contain only hydrogen 3; or
 - (ii) they contain only krypton 85; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries alpha emitting materials; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

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- E. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
- F. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.
15. Pursuant to 10 CFR 40, "Domestic licensing of Source Material", the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material.
16. Notwithstanding the requirements of 10 CFR 35.315(a)(4), the licensee may measure the dose rates in contiguous restricted and unrestricted areas in accordance with the procedures described in letters dated May 6, 1996, and June 19, 1996.
17. The licensee shall possess and use byproduct material for human research use in accordance with the prescriptive and performance criteria in all sections of 10 CFR Part 35 except sections 35.49(a) and (b), 35.100, 35.200, 35.300, 35.400 and 35.500.
18. Notwithstanding the requirements of 10 CFR 35.49(a) and (b), 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400 and 10 CFR 35.500, the licensee may use for medical use any byproduct material or reagent kit. The licensee shall possess and use byproduct material for medical use in accordance with the prescriptive and performance criteria in the other sections of 10 CFR 35. This does not relieve the licensee from complying with applicable Food and Drug Administration (FDA) and other Federal and State requirements.
19. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.

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20. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
 - A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
 - B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
21. The licensee shall not perform iodinations with Iodine 131 or Iodine 125 using quantities in excess of 10 millicuries of Iodine 131 or Iodine 125 without specific written authorization from the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch.
22. Experimental animals administered licensed materials or their products shall not be used for human consumption.
23. The licensee shall maintain records of information important to safe and effective decommissioning at 11100 Euclid Avenue, Cleveland, Ohio per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.
24. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material".
25. This license does not authorize distribution to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR Part 35.
26. "Notwithstanding the requirements of 10 CFR 35.400(d) and (g) the licensee may use iridium-192 as seeds encased in nylon ribbon for topical, interstitial, and intracavitary treatment of cancer. The licensee may deviate from the manufacturer's radiation safety and handling instructions to the extent that the instructions are not applicable to the type of use proposed by the licensee."
27. Notwithstanding the requirements of 10 CFR 35.415(a)(4), the licensee may measure the dose rates in contiguous restricted and unrestricted areas in accordance with procedures described in letters dated October 6, 1994 and May 10, 1995.

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

- A. Application dated February 20, 1990;
- B. Letters dated June 4, 1991 (except item xi Iodine-131 is limited to use of 10 millicuries for iodination procedures) September 9, 1991, October 6, 1994, May 10, 1995, February 2, 1996 and May 6, 1996, and June 19, 1996; and
- C. Letter received October 25, 1991.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date Oct 15, 1996

By

John R. Matson
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02110
STATUS CODE: 0
FEE CATEGORY: 7B 3E
EXP. DATE: 20010731
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: UNIVERSITY HOSPITAL OF CLEVELAND
RECEIVED DATE: 960604
DOCKET NO: 3002745
CONTROL NO.: 301392
LICENSE NO.: 34-05469-01
ACTION TYPE: AMENDMENT

R9

2. FEE ATTACHED
AMOUNT: *
CHECK NO.: *
* ADDL INFO
301301 - R9

3. COMMENTS

SIGNED
DATE

D. Hersey
6-5-96

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

1. FEE CATEGORY AND AMOUNT: (7B) 3E
2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT
RENEWAL
LICENSE

3. OTHER

SIGNED
DATE

SC 6/13/96

RECEIVED
JUN 20 1996
REGION III

Log	Jun 5 III
Remitter	
Check No.	
Amount	
Fee Category	7B 3E
Type of Fee	AND
Date Check Rec'd	6/13/96
Date Completed	
By	SC

University Hospitals of Cleveland

May 6, 1996

US Nuclear Regulatory Commission, Region III
Material Licensing Section
801 Warrenville Road
Lisle, IL 60532-4351.

A. - 02745
030-02745

Attn: Mr. John Madera
Chief, Material Licensing Section

Re: Amendment to License Number 34-05469-01

Dear Mr. Madera,

This letter is to request that our license No. 34-05469-01 be amended to reflect four changes.

The changes are:

1. Increase in our possession limit of Molybdenum-99 and Technetium-99m from 4000 millicuries to 6000 millicuries each. We find that our patient workload in nuclear medicine has increased to a point where we need generators with a higher capacity than at present. The need is urgent, therefore, we will deeply appreciate your expediting this amendment.

2. Change in our mailing address form

2074 Abington Road
Cleveland, OH 44106,

to the new

11100 Euclid Avenue
Cleveland, OH 44106.

There has been no change in our location, nor in the sites where licensed materials are stored or used. This is a change only in the mailing address, which was altered after a new entrance to our hospital complex from an adjacent perpendicular street was designated as the main entrance.

3. Addition of two new members to our Radiation Safety Committee, namely Dr. R.P. Friedland and Dr. M. Rodriguez. Their qualifications are enclosed as Attachment A.

There will be no change in the Chair of the committee.

4. Exemption from the regulation in 10 CFR 35.315(a)(4) for the circumstances described in Attachment B.

RECEIVED

MAY 09 1996

REGION III

ADD'L info - 30/301
FEE NOT REQUIRED

30/301

Mr. John Madera
May 6, 1996
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Briefly, thyroid ablation therapy with radioiodine is always conducted in one of two rooms. The regulation requires that we measure the radiation level in all contiguous areas, including the floor below, each time such therapy is carried out. Since measurement of radiation levels on the floor below is attended by alarm or resentment among its occupants, and since the nature of the building construction is such that the radiation levels there fulfill the requirements of 10 CFR 20 with an ample safety margin (5" of solid concrete), we are requesting that we be exempted from performing those measurements.

Attachment B and an accompanying report, "Evaluation of Floor in Lakeside Room 6525 as Radiation Barrier," together contain the arguments in support of this request.

If you have any questions, please direct them at our radiation safety officer, P. S. Rao, at (216) 844-1295.

A check for \$560.00 is enclosed as payment of the license amendment fee, specified in 10 CFR 170.31, category 7B.

Sincerely,



Robert J. Dubicki
Senior Vice-President and General Manager, Hospital Services

Enclosures: Check No. 674016 for \$560.00, made out to US Nuclear Regulatory Commission.
Attachment A: Qualifications of Dr. R.P. Friedland and Dr. M. Rodriguez.
Attachment B: Request for exemption from 10 CFR 35.315(a)(4).
Report: "Evaluation of Floor in Lakeside Room 6525 as Radiation Barrier."
Architectural Drawing No. 109, last revised February 15, 1929, entitled "Sixth Floor Framing and Details."
Architectural Drawing No. 103, last revised January 31, 1929, entitled "Basement Framing and Details."

APPENDIX A

Qualifications of new members of Radiation Safety Committee

Following this page are curriculum vitae and brief summaries of training and experience in radiation-related topics for Dr. R.P. Friedland and Dr. M. Rodriguez.

Complete this form for Radiation Safety Committee records. Not required on subsequent applications unless update is desired. Please type or print legibly.

Training & Experience of Robert Friedland, MD Date 4/18/96

- A. Training (The four types are: a) Radiation Protection, b) Radiation Measurements-Instrumentation, c) Radionuclide Calculations, d) Biological Effects of Radiation. Please fill in all four lines):

Training Types	Where	Duration	On Job	Formal Course
a	Univ Calif Berkeley, LBL	1 day	X	X
b	Univ Calif Berkeley, LBL	6 yr	X	
c	Nat Inst Health	5 yr	X	X
d				

- B. Certification, if any (Specialty board, category, month and year):

Neurology, 1979

- C. Experience:

Nuclide	Max. mCi	Where	Duration	Type of Use*		
				R	D	T
Tc-99m		UHC	5 yr	R	D	
F-18		LBL, NIH, UHC	13 yr	R	D	
O-15		NIH, UHC	5 yr	R	D	
Rb-82		LBL	5 yr	R		
C-11		NIH, UHC	3 yr	R		

* Type of Use -- R for research, D for diagnosis, T for therapy

January, 1996

CURRICULUM VITAE
ROBERT P. FRIEDLAND, MD

DATE AND PLACE OF BIRTH:

December 4, 1948
 New York, N.Y.

HOME ADDRESS:

[REDACTED]
 [REDACTED]
 [REDACTED]

MARITAL STATUS:

Separated, two children

PRESENT POSITION AND OFFICE ADDRESS:

Chief, Laboratory of Neurogeriatrics
 Department of Neurology
 Associate Professor of Neurology,
 Psychiatry and Radiology
 Case Western Reserve School of Medicine
 10900 Euclid Avenue
 Cleveland, Ohio 44106-4938
 Phone: (216) 368-1912
 Fax: (216) 368-1989
 E-mail rpf2@po.cwru.edu

SOCIAL SECURITY NUMBER:

051-40-2361

EDUCATION: City College of New York, New York	1965-69
Degree: B.S., Biology	
University of Kentucky College of Medicine	1969-71
Lexington, Kentucky	
Summer Fellowship in Neurology, Department of Neurology	1970
Boston University School of Medicine	
Boston, Massachusetts	
Mount Sinai School of Medicine	1971-73
City University of New York	
New York, New York	
M.D.	June 1973

POSTGRADUATE TRAINING:

Straight Medicine Internship	1973-74
Beth Israel Hospital	
New York, New York	
Neurology Residency and Chief Residency	1974-77
Mount Sinai School of Medicine	
New York, New York	
Weatherhead School of Management, CWRU	
Member, Professional Fellow Program (15 credits)	1992-1993
Banking & Finance 420: Health Finance & Economics (3 credits)	1993
Health Systems Management 456: Issues in Health Management (3 credits)	1994

Robert P. Friedland
Curriculum Vitae

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PROFESSIONAL CERTIFICATION:

Diplomate, National Board of Medical Examiners	1974
Certified, American Board of Psychiatry and Neurology	1979
California, Physician and Surgeon (GO 39005)	1980-Present
Maryland, Physician and Surgeon (D33237)	1986-91
District of Columbia, Medicine and Surgery (17144)	1988-91
Ohio, Doctor of Medicine (35-05-9810)	1990-Present

PROFESSIONAL ACTIVITIES:

Research Fellow, National Institutes of Health (Senile Dementia: Biological and Behavioral Aspects) Albert Einstein College of Medicine New York, New York	1977-78
Associate, Department of Neurology Albert Einstein College of Medicine New York, New York Clinical Study of Aging, Dementia and Cerebral Blood Flow (133 Xe Inhalation)	1977-78
Assistant Attending Neurologist Lincoln Hospital Bronx, New York	1977-78
Clinical Fellow Jacobi Hospital, Department of Neurology Bronx, New York	1977-78
Assistant Professor of Neurology, in Residence University of California, Davis	1978-85
Associate Professor of Neurology, in Residence University of California, Davis	1985
Staff Neurologist Veterans Administration Medical Center Martinez, California	1978-85
Assistant Chief, Neurology Service Veterans Administration Medical Center Martinez, California	1978-84
Attending Neurologist, Highland General Hospital Oakland, California	1979-85

Robert P. Friedland
Curriculum Vitae

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Guest Scientist, Donner Laboratory University of California, Berkeley	1979-85
Chief Neurologist Research Medicine Group Donner Laboratory University of California, Berkeley	1982-85
Director and Founder, Northern California Alzheimer's Disease Center, University of California Davis, Herrick Hospital and Health Center, Berkeley, California	1985
Chief, Brain Aging and Dementia Section Laboratory of Neurosciences National Institute on Aging, NIH	1986-1990
Deputy Clinical Director National Institute on Aging	1986-1990
Clinical Professor Department of Neurology Georgetown University School of Medicine	1988-1990
Director, Alzheimer's Disease and Memory Disorders Clinic Georgetown University Hospital	1988-1990
Clinical Director Acting Director Associate Director NIA Alzheimer's Disease Research Center Alzheimer Center, University Hospitals of Cleveland	1990-1993 1993 1994
Associate Professor Departments of Neurology, Psychiatry and Radiology Case Western Reserve University School of Medicine	1990-Present
Chief, Laboratory of Neurogeriatrics Department of Neurology Case Western Reserve University	1994-Present

Complete this form for Radiation Safety Committee records. Not required on subsequent applications unless update is desired. Please type or print legibly.

Training & Experience of Michael Rodriguez, MD Date 4/30/96

- A. Training (The four types are: a) Radiation Protection, b) Radiation Measurements-Instrumentation, c) Radionuclide Calculations, d) Biological Effects of Radiation. Please fill in all four lines):

Training Types	Where	Duration	On Job	Formal Course
a				
b				
c				
d	University of Miami	3 yr	X	X

- B. Certification, if any (Specialty board, category, month and year):

Gynecologic Oncology, Board Eligible, 7/95

- C. Experience:

Nuclide	Max. mCi	Where	Duration	Type of Use*		
				R	D	T

* Type of Use -- R for research, D for diagnosis, T for therapy

CURRICULUM VITAE

NAME: Michael Rodriguez

ADDRESS: [REDACTED]

DATE AND

PLACE OF BIRTH: 7/31/62 Chicago, IL.

MARITAL STATUS: Married, wife Lisa

EDUCATION:

High School: Loyola Academy, 1976-1980

College: Loyola University of Chicago, 1980-1984

Medical School: University of Illinois at Chicago, 1984-1988

Residency: Indiana University Medical Center, Department
of Obstetrics & Gynecology, 1988-1992

Fellowship: University of Miami, Jackson Memorial
Hospital, Division of Gynecologic Oncology,
1992 - 1995.

CURRENT POSITION:

Assistant Professor
Division of Gynecologic Oncology
Department of Obstetrics and Gynecology
University MacDonalld Womens Hospital
Case Western Reserve University
11100 Euclid Ave, Cleveland OH, 44122
8/1/95 to present

Clinical Assistant Professor
Division of Gynecologic Oncology
Department of Obstetrics and Gynecology
University of Miami/Sylvester Comprehensive
Cancer Center (5/95 to present)
Miami, Fl. 33136

LANGUAGE: English, Spanish

APPENDIX B

Request for exemption from 10 CFR 35.315(a)(4)

Regulation 10 CFR 35.315(a)(4) states, "For each patient or human subject receiving radiopharmaceutical therapy and hospitalized for compliance with §35.75 of this chapter, a licensee shall ... promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation survey instrument to demonstrate compliance with the requirements of Part 20 of this chapter ..."

We request that we be exempted from conducting a survey on the fifth floor of Lakeside Building when radioiodine therapy is under way in Room 6524 or 6525 on the sixth floor.

If the therapy takes place in any other room, then all contiguous areas, including adjacent floors, will be surveyed.

In our institution, thyroid ablation therapy with greater than 30 millicuries of iodine-131 nearly always takes place in Room 6524 or Room 6525 on the sixth floor of Lakeside Building. Both rooms are on the end of a long corridor. All contiguous areas on the same floor are unrestricted areas. The space above is a rooftop and unoccupiable. The area below on the fifth floor is a patient area and is also unrestricted.

Performing a radiation survey on the fifth floor as per 10 CFR 35.315(a)(4) is unnecessary, because the construction of the treatment rooms constrains the radiation levels below to be in full compliance with the requirements of 10 CFR 20, and there is no likelihood of ever exceeding the limits stated therein. Moreover, conducting a survey there is problematic because of the presence of patients. An intrusion into the room is resented, and an explanation that radiation in the room is being measured tends to foster anxiety and alarm in the patients or their families, the more so if the patients are young children. Hence our request for the exemption.

We support this request with the following three sets of evidence:

1. The floor of both rooms is made of 5" of solid concrete, reinforced by 5/8" steel rods separated by 7" on center.

This information can be verified from copies of the two architectural drawings enclosed with this letter. Drawing No. 109, last revised February 15, 1929, is entitled "Sixth Floor Framing and Details". Room 6525 is the space at the upper left corner of this drawing enclosed within the lines labeled 3½, 4, S½ and S. Room 6524 is the space enclosed within the lines labeled 3½, 4, R and P½. Both areas bear the symbol F.

Drawing No. 103, last revised January 31, 1929, entitled "Basement Framing and Details", contains a slab schedule for all floors. It indicates that the symbol F represents a floor of solid concrete 5" thick, reinforced by 5/8" steel rods separated by 7" on center.

The floor-to-floor distance between the fifth and sixth floors is 12 feet, as is apparent from Drawing No. 103.

2. An evaluation of the floor as radiation barrier was made on April 3, 1996. The transmission of 662 keV gamma radiation from cesium-137 through the floor was measured. After accounting for the difference between the radiation from cesium-137 and from iodine-131, it was shown that radiation levels could not exceed the limits specified in 10 CFR 20.1301.

Specifically, the highest anticipated activity of iodine-131 in a patient in Room 6525 would be expected to cause the instantaneous level in Room 5525 to be far less than 2 mrem/hr stipulated in 10 CFR 1031(a)(2) for an unrestricted area.

Moreover, very conservative assumptions about the number of patients per year, the activity used per patient, and the duration spent by the patients in Room 6525 led to an estimate of the dose to individuals in Room 5525 that was less than 100 mrem per year, which is the limit specified in 10 CFR 1031(a)(1).

The measurements, assumptions and conclusions are presented in detail in the attached report, "Evaluation of Floor in Lakeside Room 6525 as Radiation Barrier".

- 3 Measurements made on three occasions with patients actually in Room 6525 supported the calculations and conclusions made in the above report.

The calculations anticipated that 100 mCi and 150 mCi of iodine-131 in Room 6525 would cause the instantaneous radiation level in Room 5525 to be 0.103 mR/hr and 0.154 mR/hr respectively. As shown below, the measured levels were consistent with or below these values.

The calculations further assumed that every patient would take 48 hours to reach the level of activity at which he or she could be released from confinement in accordance with 10 CFR 35.75. The true durations were half as much or less.

All the measurements therefore provided greater confidence in the conclusions reached in "Evaluation of Floor in Lakeside Room 6525 as Radiation Barrier".

	Date of measurement	Activity of I-131 in Room 6525	Instrument*	Back-ground reading	Reading in Room 5525	Net reading	Time taken by patient to reach 30 mCi
1	April 01, 1996	98.1 mCi	Victoreen 450, SN 1752	0.01 mR/hr	0.02 mR/hr	0.01 mR/hr	21 hours
2	April 24, 1996	99.4 mCi	Victoreen 450P, SN 2299	10 μ R/hr	80 μ R/hr	70 μ R/hr	21 hours
3	May 03, 1996	150 mCi	Victoreen 450P, SN 2299	10 μ R/hr	60 μ R/hr	50 μ R/hr	24 hours

*Both the instruments listed above had been last calibrated on 12/13/95.

EVALUATION OF FLOOR IN LAKESIDE ROOM 6525 AS RADIATION BARRIER

Date: April 03, 1996.

By: PS Rao, RSO, and RA Jucius, ARSO.

Purpose: Evaluate radiation levels in the unrestricted area below Lakeside Room 6525 when the room is occupied by a patient undergoing treatment with iodine-131.

Instrument: Victoreen 190, SN 1404, with pancake GM probe Victoreen 489-1110D, SN 922, last calibrated on 12/13/1995. Correction factor for 662 keV gamma radiation = 1.0.

Materials: Two sealed sources of cesium-137, manufactured by 3M, Model 6505, totalling 138.2 mCi.

Procedure: With the radiocesium still in its lead transport container, the background radiation level in Room 5525 on the fifth floor was measured.

The radiocesium sources were placed on the floor of Room 6525. The radiation level in Room 5525 five feet off the floor and directly below the source was measured.

The sources were then placed on the bed in Room 6525, cranked to its lowest position. Once again the radiation level in Room 5525 five feet off the floor and directly below the source was measured.

The sources were returned to their storage area.

Observations:

	Reading in Room 5525	Corrected net reading
Background	15 μ R/hr	-
Source on floor of Room 6525	780 μ R/hr	765 μ R/hr
Source on bed in Room 6525	420 μ R/hr	405 μ R/hr

Calculations: 1. Difference in gamma ray emission between cesium-137 and iodine-131.

Γ -factor for cesium-137 = 0.33 R/hr per Ci at 1m.

Γ -factor for iodine-131 = 0.22 R/hr per Ci at 1m.

(Source: "Introduction to Health Physics", by Herman Cember (Pergamon, 2nd edition, 1983), Table 6.3, p.149.)

2. Difference in attenuation by concrete floor between cesium-137 and iodine-131.

Half-value thickness in concrete for cesium-137 gamma rays = 4.8 cm.

Half-value thickness in concrete for 500 kVp highly-filtered x-rays = 3.6 cm.

(Source: NCRP Report 49, Table 27, page 88. Publ 1976 by NCRP).

Assume that the 364 keV gamma rays are attenuated similarly to 500 kVp x-rays. Then the 5" concrete floor in Room 5525 is equivalent to

$$(5 \times 2.54) / 4.8 = 2.6 \text{ HVT's for cesium-137 radiation,}$$

and $(5 \times 2.54) / 3.6 = 3.5$ HVT's for iodine-131 radiation.

The difference between the two is $3.5 - 2.6 = 0.9$, which represents a factor of $2^{0.9} = 1.9$. Therefore the floor attenuates the radiation from I-131 by a factor of 1.9 more than the radiation from Cs-137.

3. Calculated radiation levels in Room 5525 when patient with iodine-131 is in Room 6525.

Source	Radiation level in Room 5525 due to source on bed in Room 6525
138.2 mCi of Cs-137	405 μ R/hr
1 mCi of Cs-137	2.93 μ R/hr
1 mCi of I-131	$2.93 \times (0.22/0.33) / 1.9 = 1.03 \mu$ R/hr
100 mCi of I-131	$1.03 \times 100 = 103 \mu$ R/hr
150 mCi of I-131	$1.03 \times 150 = 154 \mu$ R/hr

4. Calculation of effective decay constant, with conservative assumptions.

Typically patients are administered about 100 mCi of I-131. In 24 hours or less, because of rapid excretion of unabsorbed radioiodine, their body burden decreases to 30 mCi, at which point they are no longer required to be confined (10 CFR 35.75) and are discharged from the hospital. Dosages larger than 100 mCi do not appear to extend this time to much above 24 hours. In only one exceptional case, a patient given 157 mCi took 45 hours before the level decreased to 30 mCi.

Assume conservatively that a patient is administered 150 mCi and requires 48 hours to reach the 30 mCi level. The effective decay constant λ can then be calculated from

$$30 = 150 \exp(-\lambda \cdot 48),$$

and is $\lambda = 0.0335 \text{ hr}^{-1}$.

5. Total integrated dose to individual in Room 5525, with conservative assumptions.

If a patient in Room 6525 is administered 150 mCi of I-131, then, from the table above, the dose rate in Room 5525 will be expected to be 0.154 mrem/hr. If a single individual remains in Room 5525 continuously for the entire 48 hours while the activity in the patient decreases from 150 mCi to 30 mCi, then that individual will receive a dose D given approximately by:

$$\begin{aligned}
 D &= \int_0^{48} [0.154 \exp(-0.0335 \cdot t)] dt \\
 &= (0.154) \times (23.9) \\
 &= 3.7 \text{ millirems.}
 \end{aligned}$$

6. Total integrated dose to individual in Room 5525, with realistic assumptions.

Most frequently, a patient is administered 100 mCi, and the activity decreases to 30 mCi in under 24 hours. Using the 24-hour figure, the effective decay constant is given by

$$30 = 100 \exp(-\lambda \cdot 24),$$

and is $\lambda = 0.05 \text{ hr}^{-1}$.

The initial dose rate in Room 5525 has been calculated to be 0.103 mrem/hr. For an individual who remains in Room 5525 continuously for the entire 24 hours while the activity in a patient in Room 6525 decreases from 100 mCi to 30 mCi, the dose received will be

$$\begin{aligned} D &= \int_0^{24} [0.103 \exp(-0.05 \cdot t)] dt \\ &= (0.103) \times (14.0). \\ &= 1.4 \text{ millirems.} \end{aligned}$$

Nevertheless, the conservative figure of 3.7 mrem is used in the discussion below.

Discussion: 10 CFR 20.1301(a)(2) stipulates that the dose in an unrestricted area may not exceed 2 millirems in an hour. The maximum radiation level in Room 5525 due to 150 mCi on the bed in Room 6525, neglecting any absorption within a patient, is calculated to be 0.154 mrem/hr, far less than the limit.

10 CFR 20.1301(a)(1) stipulates that no member of the public receive more than 100 mrem in a year. This restriction is met as shown by the following discussion. The number of patients housed in Room 6525 for I-131 treatment during a year has fluctuated, the highest being 17 during 1995. Of them, 2 were administered about 150 mCi, and the rest were administered about 100 mCi or less. For the purpose of this discussion, let us assume conservatively that there will be 30 patients in a year, of whom one half (15) are administered 150 mCi and the other half 100 mCi. Let us further assume that they all remain in their room for 48 hours before discharge. Then, again neglecting radiation absorption within the patients, the total dose to an individual who is continuously present in Room 5525 for the entire 48 hours of each of the 30 treatments will be:

$$\begin{aligned} &15 \text{ patients/yr} \times 3.7 \text{ mrem/patient} \\ &+ 15 \text{ patients/yr} \times (100 \text{ mCi} / 150 \text{ mCi}) \times 3.7 \text{ mrem/patient} \\ &= 93 \text{ mrem/yr,} \end{aligned}$$

which is less than 100 mrem/yr, the limit stated in 10 CFR 20.1301(a)(1).

In practice, no patient who is housed in Room 5525 is likely to remain there during all the 30 treatments in Room 6525 during a year and will therefore receive a dose far less than the above figure. If Room 5525 were to be converted into an office, the average duration spent in it by a member of the hospital staff would be 8 hours per day, and therefore his or her dose during a year would about be one-third of the above figure or less.

Conclusion. The floor in Room 6525 provides sufficient radiation shielding that the radiation levels in Room 5525 will comply with the requirements of 10 CFR 20.



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

November 20, 1995

MEMORANDUM TO: Cynthia Pederson, Director
Division of Nuclear Material Safety and Safeguards, RIII

FROM: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS *AKW*

SUBJECT: TECHNICAL ASSISTANCE REQUEST DATED AUGUST 21, 1995,
WILLIAM BEAUMONT HOSPITAL, LICENSE NO. 21-01333-01

Madera
95-44
Tor file

I am writing in reference to a technical assistance request from John Madera dated August 21, 1995, for William Beaumont Hospital (attached). The licensee requested exemptions from 10 CFR 35.315(a)(4) and 35.315(a)(8).

Exemption from 10 CFR 35.315(a)(4)

The licensee requested an exemption from performing a survey in the adjacent patient room after administration of a therapy dosage of iodine-131 (¹³¹I). The licensee's justification for this exemption is that patients and family members occupying the room adjacent to a therapy patient have expressed concern and anxiety after staff performs the measurements. Hospital admissions have increased to the point where it is no longer feasible to vacate the adjacent room during therapy administrations. The licensee will continue to monitor and record the dose rate in the only other adjacent unrestricted area, which is a hallway.

The licensee has provided a description of the surrounding areas, shielding in the wall of the adjacent patient room and information regarding the measurements performed to demonstrate compliance with 10 CFR 20.1301. The measurements were performed after administration of a 159 millicurie dosage of ¹³¹I.

The licensee described four circumstances in which confirmatory surveys would be performed. One of these circumstances requires additional clarification. The licensee shall commit to performing confirmatory surveys whenever the administered dosage exceeds 159 millicuries, which is the dosage on which the original measurements are based, and not when the administered dosage exceeds 200 millicuries of ¹³¹I. In addition, the licensee should be reminded that, should the shielding in the south wall of the "therapy" room be modified, it may be necessary to conduct new surveys to ensure compliance with the requirements in 10 CFR 20.1301.

After the region receives the above licensee commitment and pursuant to 10 CFR 35.19, the region may approve the licensee's request for an exemption from 10 CFR 35.315(a)(4) requiring surveys in the adjacent patient room during therapy treatments. The following license condition should be used:

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

"Notwithstanding the requirements of 10 CFR 35.315(a)(4), the licensee may measure the dose rates in contiguous restricted and unrestricted areas in accordance with procedures described in letter(s) dated _____."

Exemption from 10 CFR 35.315(a)(8)

The licensee requested an exemption from performing bioassays within 3 days of preparation and/or administration of a dosage of ¹³¹I. The licensee requested the exemption as the thyroid burden of the radiopharmacy staff is performed routinely on a weekly basis whenever they handle more than 10 millicuries of radioiodine in a fume hood or more than 1 millicurie outside the fume hood. The weekly bioassay is scheduled so as not to interfere with the patient schedule. The licensee indicated that compliance with this regulation sometimes requires additional bioassays to be performed during the week which may conflict with the patient schedule. Additionally, there have been scheduling conflicts when a dosage is administered on a Friday, and the radiopharmacy staff member may not be in on the following Monday, resulting in the licensee being in violation of this regulation.

Based on the licensee's routine weekly bioassay of radiopharmacy staff who prepare and administer ¹³¹I therapy dosages, and pursuant to 10 CFR 35.19, the region may approve the licensee's request for an exemption from 10 CFR 35.315(a)(8). The following license condition should be used:

"Notwithstanding the requirements of 10 CFR 35.315(a)(8), the licensee may perform bioassays in accordance with procedures detailed in letter(s) dated _____."

Attachment: TAR dtd 8/21/95



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

AUG 22 1995

IMAB
95-44
E: TAF-CPM

REQUEST FOR TECHNICAL ASSISTANCE

DATE: AUGUST 21, 1995

TO: DON COOL, Chief, Medical, Academic, and Commercial
Use Safety Branch, NMSS

FROM: JOHN MADERA *JM*, Chief, Nuclear Materials Safety Branch
Region III

LICENSEE: WILLIAM BEAUMONT HOSPITAL LICENSE NO. 21-01333-01

X Control No. 98873 (enclosed)
Letter dated _____ (enclosed)
Suggested change in licensing procedure (enclosed)
Other (see remarks)

Problem/Issue: LICENSEE IS REQUESTING EXEMPTIONS FROM 10 CFR 35.315(a)(4) AND
35.315(a)(8).

Action Required: PLEASE REVIEW AND PROVIDE YOUR COMMENTS.

Alternatives Considered: _____

Recommended Alternative: _____

Remarks: THE LICENSEE HAS PROVIDED AN ADEQUATE BASIS AND JUSTIFICATION FOR
THEIR REQUEST. WE RECOMMEND ISSUING THE EXEMPTIONS.

Regional Reviewer: PATTY PELKE

Reviewer Code: R6 (PJP2)

Reviewer Phone No. 708-829-9868

ATTACHMENT

Beaumont

William Beaumont Hospital
Royal Oak

A
030-0200
R6

July 11, 1995

United States Nuclear Regulatory Commission
Region III
Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: Additional Information Requested for Review of Amendment to
NRC License 21-01333-01

CONTROL NUMBER: 97859

Dear Patricia J. Pelke,

In response to your letter dated March 6, 1995 (see attachment) the following information is offered to support our request for two exemptions from 10 CFR 35.

1. Exemption from 10 CFR 35.315(a)(4)

a. Clarification of Section

Item 4 of our letter dated November 9, 1994 should have requested exemption from Section 35.315 (a)(4) instead of Section 35.15(4).

b. Therapy Room Locations

The "therapy room" (Room No. 5538) is the end room of one of two wings comprising the nursing unit on the fifth floor (top floor of the hospital). The north and east walls are outside walls. The west wall is adjacent to the hallway and includes the only door to the "therapy room". The south wall is the only wall adjacent to another patient room (Room No. 5536).

Lead-lined dry wall (1/8 inch thickness of lead) was installed in the south wall of the "therapy room" in April 1995. The integrity of the structural shielding was certified visually during installation. ✓

c. Radiation survey of the adjacent patient room

The radiation survey was performed to demonstrate compliance with the requirements of Section 20.1301 (a)(1) "The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem in a year," and Section 20.1301 (a)(2) "The dose in any unrestricted area does not exceed 0.002 rem in any one hour." The provisions for performance of the survey were as follows. The patient was administered a dose of

RECEIVED

JUL 17 1995
REGION III

159 millicurie of liquid sodium iodide I-131 orally on 5/23/95 at 10:50 AM. The attached table (Table 1) lists the measured exposure rates (mR/hr) inside the adjacent patient room and at the doorway to the "therapy room" (unrestricted areas). The maximum reading at the surface of the wall between the therapy and adjacent patient room was recorded. The total integrated dose was calculated for each location. ✓

The room set up is consistent for all inpatient therapies. The semi-private room is converted to a private room by removal of the second patient bed and furniture. The therapy patient bed is positioned against the north outside wall near the window (east outside wall). The patient chair is positioned on the north wall. The patient is instructed not to move the furniture in the room and to stay in bed during the first day after the dose administration except to go to the bathroom. The patients are confined to the room during the treatment.

The maximum total integrated dose equivalent derived from the survey measurements taken in the adjacent room is 13.0 millirem (13% of the legal limit). The maximum instantaneous dose rate measured in the adjacent patient room was 0.5 millirem per hour (25% of the legal limit). Two instruments were utilized to perform the measurements and the exposure rates correlated within 10 percent of each other. The GM meter was Ludlum Model 3 (serial No. 76429) calibrated on 12/8/94. The ionization survey meter was a Bicon RSO-5 (Serial No. A902G) calibrated on 9/16/94.

d. Confirmatory Surveys Performed by the RSO

Confirmatory surveys shall be performed by the RSO or RSO designate under the following circumstances: (a) whenever the adjacent room is vacant at the time of dose administration, (b) whenever the administered dose exceeds 200 millicurie I-131 (which is a 25% increase in the administered dose on which our measurements are based), (c) whenever any modifications to the room set-up occur, (d) whenever there is any modification of the rooms that could effect the structural shielding, and (e) at least once per year in conformance with 10 CFR Part 35.315 (a)(4). *this should be to 0.01*

2. Exemption from 10 CFR 35.315(a)(8)

a. Clarification of Section

Item 5 of our letter dated November 9, 1994 should have requested exemption from Section 35.315 (a)(8) instead of Section 35.15(8).

b. Frequency at which therapeutic doses (in excess of 30 millicurie) are administered at our institution.

William Beaumont Hospital (Royal Oak and Troy) treated 35 inpatients with doses in excess of 30 millicurie I-131, and *changed*

dispensed 134 outpatient therapy doses (less than 30 millicurie of I-131) in 1994. In the Comments that were published along with the Final Rule in the Federal Register on October 16, 1986, the NRC responded as follows to this comment:

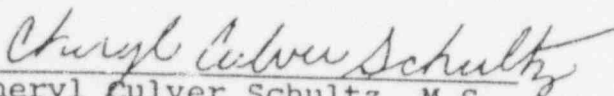
Comment: "We administer several dosages of I-131 each week. A weekly measurement of the technician's thyroid burden should be sufficient."

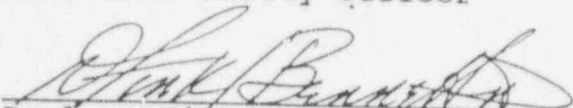
NRC Response: "The regulation assumes administration of a therapeutic dosage is an occasional event. Those licensees who frequently administer I-131 may propose an alternative monitoring program that would be approved as a license condition"

In our letter dated November 9, 1994, we requested weekly measurement of thyroid burden instead of the 72 hour requirement of 10 CFR Part 35.

Thank you for your continued consideration of this amendment request.

Sincerely,


Cheryl Culver Schultz, M.S.
Radiation Safety Officer


Darlene Fink-Bennett, M.D.
Chairperson, Radiation Safety Committee

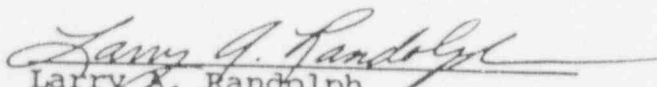

Larry A. Randolph
Associate Hospital Director

TABLE 1: Measured exposure rates and calculated integrated dose equivalent.

			UNRESTRICTED AREAS (mR/hr)			RESTRICTED AREA (mR/hr)	
				Adjacent	Patient	Room	Therapy Room
Date	Time	Elapsed Time (Hr)	Door to Tx Room	Surface of Wall between Rooms	Bed 1 middle of bed	Bed 2 middle of bed	At 1 meter from upright patient
5/23/95	11:00 AM	0	0.35	0.25	0.08	0.05	28
	12:00 PM	1.0	0.35	0.4	0.15	0.07	30
	1:00 PM	2.0	0.35	0.5	0.2	0.05	25
	3:00 PM	4.0	0.35	0.5	0.2	0.05	25
Dose Equivalent	(MILLIREM)		7.7	11.0	4.4	1.5	660
5/24/95	9:00 AM	22.0	0.25	0.25	0.05	0.03	10
	2:00 PM	27.0	0.2	0.2	0.04	0.01	7.0
	4:00 PM	29.0	0.15	0.15	0.02	0.01	*5.0
Dose Equivalent	(MILLIREM)		2.0	2.0	0.4	0.2	74
TOTAL DOSE Equivalent	(MILLIREM)		9.7	13.0	4.8	1.7	734

* PATIENT APPROVED FOR DISCHARGE



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

MAR 06 1995

William Beaumont Hospital
ATTN: Cheryl Culver Schultz
Radiation Safety Officer
3601 West 13 Mile Road
Royal Oak, MI 48073-6769

Dear Ms. Schultz:

Enclosed is Amendment No. 61 to your NRC License No. 21-01333-01 in accordance with your request. Based on our February 22, 1995 telephone conversation, the hospital expansion described in your November 9, 1994 letter includes only facilities contiguous to those currently located at 3601 West 13 Mile Road, Royal Oak; therefore, we did not add any additional places of use to Condition 10. Please review your license carefully to ensure that you understand all the terms and conditions contained therein. In addition, be advised that we have not authorized Items 4. and 5. of your letter, both Part 35 exemption requests, at this time. In order to complete our review of these requests, it will be necessary for you to submit the following additional information:

1. EXEMPTION FROM 10 CFR 35.315(a)(4):

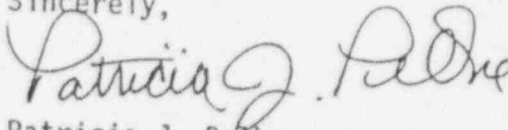
- a. Item 4 of your letter requested an exemption to Section 35.15 (4), however, it appears that you are requesting an exemption from Section 35.315(a)(4), please clarify.
- b. Please specify the location of the "therapy room" and adjacent "patient room" in greater detail, and include their respective room numbers. Also, clarify whether or not the proposed remodeling of the "therapy room" has been completed.
- c. Please provide a radiation survey of the adjacent patient room which demonstrates your compliance with the requirements of Section 20.1301 (a)(1) and (2) of 10 CFR Part 20. Include the provisions you have established to ensure that the isotope, activity used, and room set-up (for the worst case scenario) are not modified in any manner that could result in exposure levels that are higher than those represented in the radiation survey you submit.
- d. Confirmatory surveys should be performed by the RSO periodically to assure that the radiation levels are in compliance with the limits specified in 10 CFR Part 20. Please submit your procedures and frequency for performing confirmatory surveys.

2. EXEMPTION FROM 10 CFR 35.315 (a)(8):

- a. Item 5 of your letter requested an exemption to Section 35.15(8), however it appears that you are requesting an exemption from Section 35.315(a)(8), please clarify:
- b. Please submit information regarding the frequency at which therapeutic doses (greater than 30 millicuries) of iodine-131 are administered at your institution. It would be in your best interest to provide any additional information that would support your request in accordance with the Comments that were published along with the Final Rule in the Federal Register on October 16, 1986 (copy enclosed).

Information submitted in response to this letter should be referenced as additional information to Control Number 97859. If you have any further questions, please contact me at (708) 829-9887.

Sincerely,



Patricia J. Petke
Nuclear Materials Licensing Section

Enclosure: As stated

Beaumont

William Beaumont Hospital

Royal Oak

November 9, 1994

United States Nuclear Regulatory Commission
Region III
Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: Amendment to NRC License 21-01333-01

To whom it may concern:

Enclosed is a check for \$500.00 for amendment of our NRC License no. 21-01333-01.

1. Please correct the spelling of the name of the Radiation Safety Officer on License No. 21-01333-01 to Cheryl Culver Schultz, M.S. Condition 11.B. of our recent amendment (No. 60) has the last name spelled incorrectly as "Shultz".

2. Condition 20 of our NRC license authorizes us to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage prior to disposal. Please increase the physical half-life to 90 days to permit us to use the decay-in-storage method for sulfur-35.

3. A major hospital expansion of the William Beaumont Hospital in Royal Oak shall be completed in 1994. The South Tower Addition will include three new laboratories. A laboratory currently approved for in vitro use of phosphorus-32 and sulfur-35 shall be relocated from the Research Institute on the Royal Oak campus to one of these laboratories in the new South Tower Addition.

The East Tower expansion will include two new clinical laboratories. The Immunology Laboratory, where radioimmunoassay is performed, shall be relocated from the second floor of the North Tower to the lower level of the East Tower. The Special Chemistry Laboratory will also be relocated to the lower level of the East Tower. The new Special Chemistry Laboratory will have a Hewlett Packard (HP 5890 Series II) gas chromatograph which utilizes a 15 millicurie sealed nickel-63 source. These new laboratories are scheduled to open in November 1994.

All of these laboratories have been reviewed and approved by the Radiation Safety Committee for in vitro use of radioactive material. These laboratories meet the criteria listed in our NRC license application for Clinical and Research Laboratories.

4. This amendment request applies to our William Beaumont Hospital, Troy, Michigan facility. Please exempt us from 10 CFR 35.15 (4) which requires us to measure the dose rates in contiguous

unrestricted areas with a radiation survey meter promptly after administration of an inpatient therapeutic dosage of a radiopharmaceutical (as specified in 10 CFR Part 35.75). A patient room is directly adjacent to our designated inpatient therapy room. Dose rate measurements in the adjacent patients room have consistently been in compliance with the requirements of 10 CFR 20.

Patients and family members occupying the room adjacent to a therapy patient have expressed concern and anxiety after observing us performing the dose rate measurements. Although every effort is made by the nuclear medicine physician and staff to relieve these anxieties, many patients and their relatives continue to feel at a greater risk because of the radiation emanating from the adjacent room.

To prevent this situation from occurring we have made every effort to vacate the adjacent room. Patient admissions have increased to the point where it is no longer feasible to vacate the two hospital beds adjacent to the therapy patient's room.

We plan to remodel the therapy room by installing 1/8 inch of lead dry wall to the wall between the inpatient therapy room and adjacent room. That will guarantee that the maximum instantaneous dose rate from an unattenuated 200 millicurie source will not exceed 0.7 mR/hr on the inside surface of the adjacent patient room. At the normal rate of decay and with the excretion of the radiopharmaceutical this modification will also guarantee that no one in the adjacent room will exceed the limit of 100 millirem dose equivalent to members of the public. We will continue to monitor and record the dose rate in the only other adjacent unrestricted area, the hallway. Dose rate measurements will continue to be performed in the adjacent patient room under the following circumstances: (a) when the room is vacant, and (b) when the administered dose exceeds 200 millicurie.

5. Please exempt us from 10 CFR Part 35.15 (8) that requires the thyroid burden of each individual who helped prepare or administer a dosage of I-131 in excess of 30 millicurie to be measured within three days after administering the dosage. Measurements of the thyroid burden of the radiopharmacy staff are performed routinely on a weekly basis whenever they handle more than 10 millicurie of radioiodine in a fume hood or more than 1 millicurie outside the fume hood. The day and time for performance of the weekly bioassay is scheduled so as not to interfere with our patient schedule. Compliance with this regulation sometimes requires additional bioassays to be performed on the radiopharmacy staff during the week which may conflict with our patient schedule. Similarly, we request that individuals who administer the radioiodine in accordance with 10 CFR 35.75 be permitted to have their thyroid burden measured within one week instead of three days. The reasons for this request are as follows:

(a) When an inpatient therapy dose is scheduled for a Friday, the individual who administers the dose must be available for bioassay on the following Monday. If that individual becomes unavailable for work on the following Monday due to an illness, we are in violation of this regulation.

(b) Increasing the time interval between the dose administration and the bioassay to one week will allow us to schedule a specific time each week that does not interfere with patient procedures.

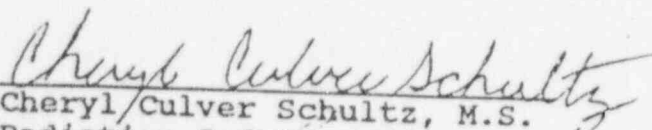
(c) The minimum detectable level for our bioassay of thyroid burden is less than 0.04 microcurie of I-131. The Intake Retention Factor when the time interval after intake equals 7 days is 9.95×10^{-2} (page B-103 of NUREG/CR-4884). The estimate of intake for an uptake of 0.04 microcurie measured 7 days after intake is 0.4 microcurie. This is less than the Evaluation Level of 1 microcurie recommended for I-131 (0.02 times ALI value of $5E+1$ microcurie). The Evaluation Level is defined in Regulatory Guide 8.9 as the level at which an intake should be evaluated beyond the initial bioassay measurement. The calculated committed dose equivalent (CDE) to the thyroid (maximally exposed organ) is 0.04 rem and the committed effective dose equivalent (CEDE) is equal to 0.0012 rem. According to Regulatory Guide 8.7, Subsection 2.2, the CDE must be calculated only if the CEDE exceeds 1 rem. Measurements taken 7 days after the intake comply with the requirements of 10 CFR Part 20.2106, Records of individual monitoring results.

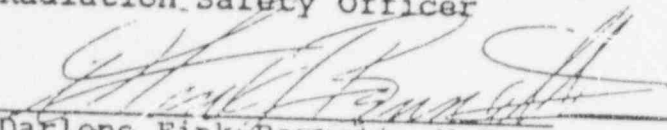
6. Please amend item 6.M. of our NRC license to increase the possession limit for Iridium-192 sealed sources (BYK Mallinckrodt Model CI LBV) from 2 sources not to exceed 10 curies each to 3 sources not to exceed 10 curies each. The third source would be one removed from the Nucletron Corporation Microselectron-HDR remote afterloading brachytherapy unit for the purpose of replacement. Currently, the source removed retains between 3 and 4 Curies Ir-192. It is packaged in its original shipping container and returned to the manufacturer. This amendment would permit us to store one of the Ir-192 sources after removal from the Microselectron-HDR unit for decay for approximately 2 additional half-lives (148 days). The original activity (10 Curies) would have decayed to less than 1 Curie and the source could then be used for research studies authorized in Item 9.N. of our NRC license. This would provide a cost savings for the Radiation Oncology research program. Also, the 1 Curie Iridium-192 source for research Microselectron-HDR requires a special order and is not readily available on a timely basis.

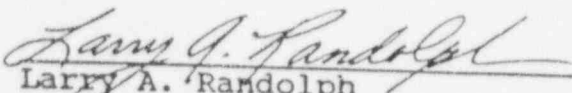
The source would be packaged in its original shipping container by authorized Nucletron personnel. The shipping container would be placed inside the 9th floor North Tower Brachytherapy Storage and Preparation Room for decay in storage until the residual activity was less than 1 Curie. This room is locked at all times with coded

access. Only authorized Nucleotron personnel would open the package and install it inside the research Nucleotron-HDR unit. The source would be included in our quarterly sealed source inventory. Leak testing would be performed after removal from the Microselectron-HDR (prior to storage for decay) and prior to installation into the research Microselectron-HDR. All other conduct related to this source would be in accordance with the conditions of our license and NRC regulations.

Sincerely,


Cheryl Culver Schultz, M.S.
Radiation Safety Officer


Darlene Fink-Bennett, M.D.
Chairperson, Radiation Safety Committee


Larry A. Randolph
Associate Hospital Director

OCT 15 1996

Robert J. Dubicki
Senior Vice-President
and General Manager
University Hospitals
of Cleveland
11100 Euclid Avenue
Cleveland, OH 44106

Dear Mr. Dubicki:

Enclosed is Amendment No. 32 to your NRC Material License No. 34-05469-01 in accordance with your request dated May 6, 1996, for an exemption from the requirements of 10 CFR 35.315. Upon completion of our review, we have granted the exemption. Please refer to License Condition 16. Please note that the old License Condition 16 which exempted you from color labels for gas chromatographs has been deleted. This was done because in accordance with the new 10 CFR 20.1901(b), you are not required to label gas chromatograph detector cells with a color label.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
 - a. When Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
 - b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

301392

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. When you decide to terminate all activities involving materials authorized under the license; or
 - b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.
4. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;
 - b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - d. Change ownership of your organization.
5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C. Since serious consequences to employees and the public can result from failure to comply

R. Dubicki

-3-

with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Evelyn R. Matson
Nuclear Materials Licensing Branch

License No.: 34-05469-01

Docket No.: 030-02745

Enclosure: Amendment No. 32

DOCUMENT NAME: M:\03002745.CL6

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" =
Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII <i>EM</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	EMatson:jaw								
DATE	10/15/96								

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

October 2, 1996

96-48

MEMORANDUM TO: Cynthia D. Pederson, Director
Nuclear of Nuclear Materials Safety, RIII

FROM: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS *[Signature]*

SUBJECT: TECHNICAL ASSISTANCE REQUEST DATED JULY 1, 1996, UNIVERSITY
HOSPITAL OF CLEVELAND, LICENSE NO. 34-05469-01

I am writing in response to your technical assistance request (TAR) dated July 1, 1996 (Attached), in which the University Hospital of Cleveland requested an exemption from 10 CFR 35.315(a)(4). Specifically, the licensee requested an exemption from measuring the dose rates in the patient rooms below, and on the roof area above, the designated radiation therapy treatment rooms. The licensee stated that the exemption is needed as an intrusion into a patient's room is resented by the patient, and that an explanation that radiation in the room is being measured fosters anxiety and alarm in the patients, or their families. The licensee indicated that the construction of the area above the treatment rooms is essentially the same as the floor area below the treatment rooms, and that the dose rates will be the same; therefore, they requested approval to include the roof as an area exempt from the survey requirement. According to the licensee, the roof is not readily accessible, and should workmen need to be in the area for an extensive period of time, the radiation therapy treatment would be canceled, postponed, or relocated.

The licensee submitted information describing the shielding in the construction of the relevant areas, occupancy of the areas above and below the treatment rooms, calculated dose rates, and actual measurements taken during recent radiation therapy treatments.

The staff has reviewed the information submitted by the licensee, and has determined that, pursuant to 10 CFR 35.19, the region may approve the licensee's request for an exemption from 10 CFR 35.315(a)(4). The following license condition should be used:

"Notwithstanding the requirements of 10 CFR 35.315(a)(4), the licensee may measure the dose rates in contiguous restricted and unrestricted areas in accordance with procedures described in letters dated May 6, 1996 and June 19, 1996."

CONTACT: Torre Taylor
(301) 415-7900

Attachment: TAR dtd 7/1/96

OCT 07 1996



UNITED STATES
NUCLE. REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

JUL 03 1996

96-45
I MAB

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: July 1, 1996

To: Don Cool, Director, Division of Industrial and Medical Nuclear Safety, NMSS

From: *John A. Madera*
John Madera, Chief, Nuclear Materials Safety and Safeguards Branch, RIII

Licensee: University Hospital of Cleveland

License No. 34-05469-01

☐ Control No.: 301392 (enclosed)

☐ Letters dated: May 6, 1996 and June 19, 1996 (enclosed)

☐ Problem/Issue: Licensee is requesting an exemption from the survey requirements of 10 CFR 35.315(A)(4) during iodine-131 treatments.

☐ Action Required: Please review the information submitted and provide recommendations.

☐ Recommended Action: RIII Recommends approval as submitted.

☐ Remarks: Justification appears adequate and consistent with previous exemptions granted.

Headquarters Reviewer: _____
Regional Reviewer: EVELYN MATSON
Reviewer Code: R9
Reviewer Phone No.: (708) 829-9822 EMAIL: ERM
Request Needed by: 7/31/96

sent blueprint #110
back to region. not
needed.

University Hospitals of Cleveland

June 19, 1996

Ms. Evelyn R. Matson
US Nuclear Regulatory Commission, Region III
Nuclear Materials Licensing Branch
801 Warrenville Road
Lisle, IL 60532-4351

Re: License Number 34-05469-01
Our letter dated May 6, 1996
Additional information regarding exemption from 10 CFR 35.315(a)(4)

Dear Ms. Matson,

Thank you for faxing me the "Conversation Record" of our telephone conversation of June 5, 1996. I am responding to the points raised therein about our request for exemption from some surveys when I-131 therapy is conducted. The points are reproduced below in italics.

1. *"Your letter implies that surveys will continue to be performed after each administration in areas adjacent to rooms 6524 and 6525 on the 6th floor. Please confirm if this understanding is correct."*

Surveys will continue to be performed in areas on the sixth floor adjacent to room 6524 or 6525, whenever it houses a patient hospitalized for compliance with 10 CFR 35.75.

2. *"Because the roof is adjacent to rooms 6524 and 6525 and could possibly be occupied by workmen, currently the regulations require this area to be surveyed after each administration. If you wish to add this location as an area that will not be surveyed, provide a description of the radiation levels encountered during a patient treatment that demonstrates compliance with 20.1301."*

We do wish to include the roof above rooms 6524 and 6525 as an area that will not be surveyed. The instantaneous radiation level there, as well as the cumulative exposures to any individuals in the area, will be same as on the fifth floor under the rooms, which in turn were demonstrated in our letter of May 6, 1996 to be well below the limits stated in 10 CFR 20.1301.

This assertion will be borne out by the following discussion based on the drawings enclosed with this letter.

To understand the drawings it will be helpful to be aware that Lakeside Building is constructed rather like a stepped pyramid. The fifth and sixth floors are smaller than the fourth floor, and the seventh floor is smaller than the sixth. This can be seen from the three drawings entitled "Lakeside / Bishop 5th Floor", "Lakeside / Bishop 6th Floor", and "Lakeside / Bishop 7th Floor". The region of interest is near the top left corner in each of the drawings.

The roof above Rooms 6524 and 6525 is on the same level as the seventh floor of the building. The only access to it is through windows in private offices (Rooms 7504F, 7504G, and 7504H) which abut the roof area and have double-hung windows opening out onto it but no doors. No

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REGION III

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The floor-to-floor distance between the fifth and sixth floors, and between the sixth and seventh floors, are both 12' 6", as can be seen from the drawing entitled "Comparative Building Elevations - All Levels".

The roof immediately above Rooms 6524 and 6525 is made of 5" of solid concrete. This can be verified from Architectural Drawing No. 110, entitled "Seventh Floor Framing". The region of interest is at the top left corner, specifically the areas within the lines labeled 3½, 4, S½ and S, and the lines labeled 3½, 4, R and P½. Both areas bear the symbol F_2 to indicate the floor construction. Architectural Drawing No. 103, entitled "Basement Framing and Details", was submitted with the letter dated May 6, 1996, and contains a slab schedule for all floors. It shows that the symbol F_2 represents solid concrete 5" thick.

In addition, the roof area is augmented by layers of insulation, rubber sheeting and a 2" layer of pebbles, which serve to attenuate the radiation from the rooms below still further.

The floor under Rooms 6524 and 6525 is made of solid concrete 5" thick, reinforced by 5/8" steel rods separated by 7" on center (please refer to letter of May 6, 1996). The solid barriers above and below the rooms are therefore nearly identical.

From the above arguments, it can be seen that the radiation shielding between Room 6524 or 6525 and the roof is practically the same as that between either room and the fifth floor. In addition, the distance between the rooms and the roof above is the same as that between the rooms and the floor below.

The calculation in our letter of May 6, 1996 showed that 150 mCi of iodine-131 in one of the treatment rooms would be expected to produce an instantaneous radiation level of 0.154 mR/h on the fifth floor. Approximately the same level would be expected to be present on the roof too. It would therefore be in compliance with 10 CFR 20.1301(a)(2), which stipulates that the dose in an unrestricted area may not exceed 2 millirems in an hour.

The letter of May 6, 1996 also presents an estimate of the cumulative dose to an individual who is present on the fifth floor below the radioiodine therapy room every time such therapy is performed, and remains there continuously for the entire duration spent by the radioiodine patient in the therapy room. That estimate is 93 millirems for an entire year. Because the radiation shielding towards the roof is equivalent to that towards the fifth floor, the same estimate must hold true for the roof as well. This demonstrates compliance with 10 CFR 20.1301(a)(1), which stipulates that no member of the public receive more than 100 mrem in a year.

In practice, it is highly improbable that anybody will spend any significant length of time on the roof. If an emergency such as a roof leak were to draw workmen to the roof, the radioiodine therapy would likely be cancelled, postponed, or moved to a different location. If the therapy were to proceed in Room 6524 or 6525 and the patient is administered 150 mCi of I-131, the highest possible dose to a workman on the roof, calculated conservatively, will be about 0.154 mrem/h. This dose will decrease as the patient excretes the iodine. Spending 48 hours continuously on the roof, an impossible scenario, will give the workman a dose of 3.7 mrem (see our letter of May 6, 1996), so that his true dose will be some fraction of this number.

3. *"Describe the circumstances under which all areas, the roof and the 5th floor will be surveyed. Surveys must be performed whenever room configurations change, shielding or floor/wall thickness changes due to construction etc, and whenever the patient dose exceeds 150 millicuries."*

Surveys will be performed in areas adjacent to Room 6524 or 6525 on the same floor under all circumstances.

Surveys on the fifth floor under Room 6524 or 6525 will be performed if floor construction is changed in any way so as to reduce the shielding between the sixth and fifth floors, or if the patient dosage exceeds 150 millicuries.

Surveys on the roof above Room 6524 or 6525 will be performed if floor construction is changed in any way so as to reduce the shielding between the seventh and sixth floors, or if the patient dosage exceeds 150 millicuries, and if new construction on the seventh floor has added a doorway to provide ready access to the roof and thereby permit anyone other than maintenance staff to be on the roof.

4. *"Provide a comparison between the calculated expected radiation levels in adjacent areas versus the actual ambient radiation levels measured in the past in these areas."*

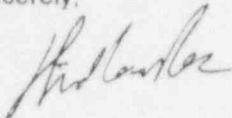
Expected radiation levels were calculated by first recording the levels from cesium-137 sources, and then making conservative corrections in the readings for the different energies of gamma rays from cesium-137 and iodine-131. The following table compares expected and measured levels due to iodine-131 administered to patients in Room 6525. It has been adapted from information presented in our letter dated May 6, 1996.

	Date of measurement	Activity of I-131 in Room 6525 (mCi)	Radiation level in Room 5525		
			Measured ($\mu\text{R/h}$)	Measured ($\mu\text{R/h per mCi}$)	Calculated ($\mu\text{R/h per mCi}$)
1	4/01/96	98.1	10	0.10	1.03
2	4/24/96	99.4	70	0.70	"
3	5/03/96	151.1	50	0.33	"
4	6/07/96	99.0	22	0.22	"

The measurement of 4/01/96 was made with a Victoreen 450 ion chamber survey meter which reads down to 0.01 mR/h. Later measurements were made with a Victoreen 450P survey meter which is equipped with a sealed, pressurized ion chamber and which can read down to 1 $\mu\text{R/h}$. The latter is capable of greater accuracy at low radiation levels close to background, and therefore the readings of 4/24/96 through 6/07/96 should be given greater weight when assessing the above results.

Ms. Evelyn R. Matson
June 19, 1996
Page 4

Sincerely,



P. S. Rao
Radiation Safety Officer

Enclosures: Drawing entitled "Lakeside / Bishop 5th Floor", dated 2/27/80, last revised 12/94.
 Drawing entitled "Lakeside / Bishop 6th Floor", dated 2/26/80, last revised 12/94.
 Drawing entitled "Lakeside / Bishop 7th Floor", dated 11/88.
 Drawing entitled "Comparative Building Elevations - All Levels", dated 9/16/80, revised
 08/85.
 Architectural Drawing No. 110, last revised February 8, 1929, entitled "Seventh Floor
 Framing".



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

JUL 03 1996

96-48

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: July 1, 1996

To: Don Cool, Director, Division of Industrial and Medical Nuclear Safety, NMSS

From: *Kevin A. Madera*
John Madera, Chief, Nuclear Materials Safety and Safeguards Branch, RIII

Licensee: University Hospital of Cleveland

License No. 34-05469-01

☐ Control No.: 301392 (enclosed)

☐ Letters dated: May 6, 1996 and June 19, 1996 (enclosed)

☐ Problem/Issue: Licensee is requesting an exemption from the survey requirements of 10 CFR 35.315(A)(4) during iodine-131 treatments.

☐ Action Required: Please review the information submitted and provide recommendations.

☐ Recommended Action: RIII Recommends approval as submitted.

☐ Remarks: Justification appears adequate and consistent with previous exemptions granted.

Headquarters Reviewer: _____

Regional Reviewer: EVELYN MATSON

Reviewer Code: R9

Reviewer Phone No.: (708) 829-9822 EMAIL: ERM

Request Needed by: 7/31/96

University Hospitals of Cleveland

June 19, 1996

Ms. Evelyn R. Matson
US Nuclear Regulatory Commission, Region III
Nuclear Materials Licensing Branch
801 Warrenville Road
Lisle, IL 60532-4351.

Re: License Number 34-05469-01
Our letter dated May 6, 1996
Additional information regarding exemption from 10 CFR 35.315(a)(4)

Dear Ms. Matson,

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2. *"Because the roof is adjacent to rooms 6524 and 6525 and could possibly be occupied by workmen, currently the regulations require this area to be surveyed after each administration. If you wish to add this location as an area that will not be surveyed, provide a description of the radiation levels encountered during a patient treatment that demonstrates compliance with 20.1301."*

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REGION III

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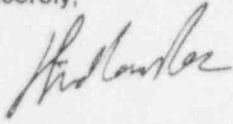
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June 19, 1996
Page 4

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University Hospitals of Cleveland

June 19, 1996

Ms. Evelyn R. Matson
US Nuclear Regulatory Commission, Region III
Nuclear Materials Licensing Branch
801 Warrenville Road
Lisle, IL 60532-4351.

Re: License Number 34-05469-01
Our letter dated May 6, 1996
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From the above arguments, it can be seen that the radiation shielding between Room 6524 or 6525 and the roof is practically the same as that between either room and the fifth floor. In addition, the distance between the rooms and the roof above is the same as that between the rooms and the floor below.

The calculation in our letter of May 6, 1996 showed that 150 mCi of iodine-131 in one of the treatment rooms would be expected to produce an instantaneous radiation level of 0.154 mR/h on the fifth floor. Approximately the same level would be expected to be present on the roof too. It would therefore be in compliance with 10 CFR 20.1301(a)(2), which stipulates that the dose in an unrestricted area may not exceed 2 millirems in an hour.

The letter of May 6, 1996 also presents an estimate of the cumulative dose to an individual who is present on the fifth floor below the radioiodine therapy room every time such therapy is performed, and remains there continuously for the entire duration spent by the radioiodine patient in the therapy room. That estimate is 93 millirems for an entire year. Because the radiation shielding towards the roof is equivalent to that towards the fifth floor, the same estimate must hold true for the roof as well. This demonstrates compliance with 10 CFR 20.1301(a)(1), which stipulates that no member of the public receive more than 100 mrem in a year.

In practice, it is highly improbable that anybody will spend any significant length of time on the roof. If an emergency such as a roof leak were to draw workmen to the roof, the radioiodine therapy would likely be cancelled, postponed, or moved to a different location. If the therapy does proceed in Room 6524 or 6525 and the patient is administered 150 mCi of I-131, the highest dose rate to a workman on the roof, calculated conservatively, will be about 0.154 mrem/h. This figure will decrease as the patient excretes the iodine. Spending 48 hours continuously on the roof, an impossible scenario, will give the workman a dose of 3.7 mrem (see our letter of May 6, 1996), so that his true dose will be some fraction of this number.

3. *"Describe the circumstances under which all areas, the roof and the 5th floor will be surveyed. Surveys must be performed whenever room configurations change, shielding or floor/wall thickness changes due to construction etc, and whenever the patient dose exceeds 150 millicuries."*

Surveys will be performed in areas adjacent to Room 6524 or 6525 on the same floor under all circumstances.

Surveys on the fifth floor under Room 6524 or 6525 will be performed if floor construction is changed in any way so as to reduce the shielding between the sixth and fifth floors, or if the patient dosage exceeds 150 millicuries.

Surveys on the roof above Room 6524 or 6525 will be performed if floor construction is changed in any way so as to reduce the shielding between the seventh and sixth floors, or if the patient dosage exceeds 150 millicuries, and if new construction on the seventh floor has added a doorway to provide ready access to the roof and thereby permit anyone other than maintenance staff to be on the roof.

4. *"Provide a comparison between the calculated expected radiation levels in adjacent areas versus the actual ambient radiation levels measured in the past in these areas."*

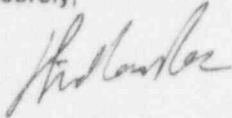
Expected radiation levels were calculated by first recording the levels from cesium-137 sources, and then making conservative corrections in the readings for the different energies of gamma rays from cesium-137 and iodine-131. The following table compares expected and measured levels due to iodine-131 administered to patients in Room 6525. It has been adapted from information presented in our letter dated May 6, 1996.

	Date of measurement	Activity of I-131 in Room 6525 (mCi)	Radiation level in Room 5525		
			Measured ($\mu\text{R/h}$)	Measured ($\mu\text{R/h per mCi}$)	Calculated ($\mu\text{R/h per mCi}$)
1	4/01/96	98.1	10	0.10	1.03
2	4/24/96	99.4	70	0.70	"
3	5/03/96	151.1	50	0.33	"
4	6/07/96	99.0	22	0.22	"

The measurement of 4/01/96 was made with a Victoreen 450 ion chamber survey meter which reads down to 0.01 mR/h. Later measurements were made with a Victoreen 450P survey meter which is equipped with a sealed, pressurized ion chamber and which can read down to 1 $\mu\text{R/h}$. The latter is capable of greater accuracy at low radiation levels close to background, and therefore the readings of 4/24/96 through 6/07/96 should be given greater weight when assessing the above results.

Ms. Evelyn R. Matson
June 19, 1996
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Sincerely,



P. S. Rao
Radiation Safety Officer

Enclosures: Drawing entitled "Lakeside / Bishop 5th Floor", dated 2/27/80, last revised 12/94.

 Drawing entitled "Lakeside / Bishop 6th Floor", dated 2/26/80, last revised 12/94.

 Drawing entitled "Lakeside / Bishop 7th Floor", dated 11/88.

 Drawing entitled "Comparative Building Elevations - All Levels", dated 9/16/80, revised
 08/85.

 Architectural Drawing No. 110, last revised February 8, 1929, entitled "Seventh Floor
 Framing".

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
CONVERSATION RECORD

(X) TELEPHONE (X) OUTGOING () INCOMING () CONVERSATION

TIME: 4:00

DATE: 6/5/96

NAME OF PERSON(S) CONTACTED:

ORGANIZATION:

TELEPHONE NO.:

P.S. Rao
University Hospital of Cleveland
216-844-1295
fax 216-844-3300

SUBJECT:

Amendment request to License No. 34-05469-01
Letter dated May 6, 1996

SUMMARY:

In order to pursue your request for an exemption to 35.315(a)(4), I need the following additional information:

1. Your letter implies that surveys will continue to be performed after each administration in areas adjacent to rooms 6524 and 6525 on the 6th floor. Please confirm if this understanding is correct.
2. Because the roof is adjacent to rooms 6524 and 6525 and could possibly be occupied by workmen, currently the regulations require this area to be surveyed after each administration. If you wish to add this location as an area that will not be surveyed, provide a description of the radiation levels encountered during a patient treatment that demonstrates compliance with 20.1301.
3. Describe the circumstances under which all areas, the roof and the 5th floor will be surveyed. Surveys must be performed whenever room configurations change, shielding or floor/wall thickness changes due to construction etc., and whenever the patient dose exceeds 150 millicuries.
4. Provide a comparison between the calculated expected radiation levels in adjacent areas versus the actual ambient radiation levels measured in the past in these areas.

ACTION REQUIRED:

Please provide the additional information requested within 15 days, provide two copies of your response and refer to Control Number 301392

ACTION TAKEN:

Faxed copy of this conversation record to the RSO.

NAME OF PERSON DOCUMENTING CONVERSATION

Evelyn R. Matson

SIGNATURE



DATE

June 5, 1996