

VOID SHEET

TO: License Fee Management Branch

FROM: RIII - CHARLES F. GILL

SUBJECT: VOIDED APPLICATION

Control Number: 301803

Applicant: St. Luke's Medical Center

License Number: 34-00398-10

Docket Number: 030-17512

Date Voided: November 8, 1996

Reason for Void: On 11/8/96 at 1100, Jeff Tenney - VP called to void the amendment request. He said they were undergoing a change of ownership which included dropping the request. Since the review was completed and a deficiency letter issued, a fee refund appears inappropriate.

Charles F. Gill
Signature

11/8/96
Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

- ☐ Refund Authorized and processed
☐ No Refund Due
☒ Fee Exempt or Fee Not Required

Comments: _____

Log completed ☒

Processed by: SAC 11/22/96

270122

011 ML
30
SD

(FOR LFMS USE)
INFORMATION FROM LTS

S8

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

Program Code: 02300
Status Code: 0
Fee Category: 7A 2B
Exp. Date: 20040430
Fee Comments: CODE 23
Decom Fin Assur Req: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: ST. LUKES'S MEDICAL CENTER
Received Date: 960903
Docket No: 3017512
Control No.: 301803
License No.: 34-00398-10
Action Type: Amendment

2. FEE ATTACHED

Amount: ~~-----~~
Check No.: ~~-----~~

* ADDL INFO
399797-58

3. COMMENTS

Signed D. Hersey
Date 9-6-96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / ✓)

1. Fee Category and Amount: (7A) 2B

FEE NOT REQUIRED

2. Correct Fee Paid. Application may be processed for:

Amendment -----
Renewal -----
License -----

3. OTHER -----

Signed SC
Date 9/16/96

SEP 19 1996

RECEIVED BY LFDCB	
Date	<u>Sept. 13, 1996</u>
Log	<u>SEP 4 III</u>
By	<u>SC</u>
Date Completed	<u>9/16/96</u>

026 SEP 13 AM 10:57



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

August 23, 1996

96-26

MEMORANDUM TO: John R. Madera, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety, RIII

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

SUBJECT: TECHNICAL ASSISTANCE REQUEST DATED APRIL 3, 1996,
(CONTROL NUMBER 399797) REGARDING ST. LUKE'S MEDICAL
CENTER

I am responding to your technical assistance request (TAR) (Attached) dated April 3, 1996, transmitting the request by St. Luke's Medical Center regarding the use of its teletherapy unit to perform operational checks (not calibrations) of beam monitoring equipment for various manufacturers. The licensee states that, "the monies paid by the manufacturer is reimbursement not fee for service."

Specifically, the TAR requested two specific actions. These actions and the staff's response are as follows.

- A. "Evaluate the licensee's request and determine whether we can allow them to perform operational checks of beam monitoring equipment for manufacturers. If approved, please specify what, if any, additional information is required and recommend licensing language if a special license condition is proposed. If the request is not approved, please explain why it is not permitted. This would facilitate the licensees' understanding. Also, please determine if St. Luke's Medical Center will be required to obtain a separate materials service license to perform the operational checks."

Response:

Based on discussions with the Office of General Counsel and the Office of the Controller, it was determined that a service license would not be required since the licensee is providing the service to non-licensees. However, irradiation of equipment for other organizations is not directly related to St. Luke's use of the teletherapy unit for human use; therefore, it will require that a separate fee be assessed under fee Category 3F (exposed source irradiators, less than 10,000 curies). Consequently, an application fee of \$1,500 is required. This means that an additional program code for a panoramic irradiator will be added to

Contact: James A. Smith, NMSS
(301) 415-7904

Continuation of 399797
FEE NOT REQUIRED

RECEIVED
SEP 03 1996
REGION III

301803

the current license; therefore, a separate license need not be issued. In addition, once the authorization is granted, the annual fees for fee Category 3F will also apply. The License Fee and Accounts Receivable Branch, Division of Accounting and Finance, Office of the Controller, will notify the licensee of the fee requirements.

Prior to granting the request, the licensee should be made aware that use of the medical teletherapy unit for purposes other than medical use and the necessary calibrations are not covered under 10 CFR Part 35, but rather are covered under 10 CFR Part 36. Part 36 has many new regulatory requirements that licensees performing solely medical use irradiations under 10 CFR Part 35 are not required to meet. Use of the teletherapy unit as an irradiator under 10 CFR Part 36 may require the licensee to have interlock systems, intrusion alert systems, and fire protection systems that currently are not required for operation of the unit under 10 CFR Part 35. The NRC has granted exemptions from the requirements of 10 CFR Part 36 for other licensees using teletherapy units for uses other than medical use under 10 CFR Part 35. However, the licensee will either have to install these systems or request, with sufficient justification, and receive exemptions from the requirements for these systems before being authorized to perform the operational checks. The NRC has previously granted multiple exemptions from the requirements of 10 CFR Part 36 for teletherapy units used for non-medical use, based upon concerns that alterations to the units may cause added risks of malfunction in the treatment of patients; therefore, the licensee may wish to pursue exemptions before installing the additional safety devices. The licensee may wish to consider the added costs of the additional program code and the installation of these systems prior to entering into an agreement with the various manufacturers.

In granting this request the region should use the following license condition:

"The licensee is authorized to use its teletherapy units at the Solon, Ohio, facility to irradiate beam monitoring equipment for various manufacturers."

- B. "Determine whether the licensee's use of the Solon teletherapy unit meets the definition of principle [sic] activities regarding the implementation requirements in 10 CFR 30.36(d)(4). Then using this determination, evaluate the licensee's request and determine whether we can allow them to keep the Solon, Ohio teletherapy unit in patient-ready, operational status, rather than requiring them to decommission the site pursuant to 30.36(d)(4). If approved, please specify what, if any, additional information is required and recommend licensing language if a special license condition is proposed. If the request is not approved, please explain why it is not permitted. This would facilitate the licensee's understanding."

Response:

The staff agrees with the licensee's interpretation that "principal uses" of the Solon, Ohio, teletherapy unit may include being a back-up teletherapy treatment unit for the Cleveland, Ohio, teletherapy treatment unit; therefore, the implementation requirements of 10 CFR 30.36(d)(4) do not apply, provided the licensee has maintained the unit in an operational status. That is, continuing the monthly spot checks and the annual calibrations required by the licensee under 10 CFR Part 35, are considered part of the authorized use of the unit. Therefore, the region should not require that the licensee decommission the site.

Additionally, the implementation requirements of 10 CFR 30.36(d)(4), are only applicable to facilities in which "[n]o principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements." Since a sealed source within a teletherapy treatment unit should not be viewed as residual radioactivity (typically this means residual contamination), it does not appear that the requirements of 10 CFR 30.36(d)(4) would apply to this licensee, even if the unit had not been maintained in an operational status. However, the requirements of 10 CFR 30.36(d)(3) do not contain a reference to residual radioactivity; therefore, these requirements would apply, but for the fact that "principal uses" may include the monthly spot checks and the annual calibrations, as stated above.

Attachment: RIII TAR dtd 4/3/96



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

96-26

April 4, 1996

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: April 3, 1996

Mail or E-Mail to: Donald A. Cool, Director, Division of Industrial
and Medical Nuclear Safety

From: John Madera (JRM4), Region III, Chief, Nuclear Materials Licensing
Branch *John K. Madera*

Licensee: St. Luke's Medical Center License No. 34-00398-10

☐ Control No. 399797

☐ Letters dated: October 12, 1995 and January 9, 1996

☐ Suggested change in licensing procedure: N/A

☐ Problem/Issue: A. Licensee requested authorization to use the teletherapy unit to perform operational checks (not calibrations) of beam monitoring equipment for various manufacturers. The licensee stated that the following monies which would be paid by the manufacturer are reimbursement, not service fees:

1. Manufacturer will reimburse licensee 100% of annual calibration/monthly spot checks expenses during periods of time that no patients are being treated at the Solon facility and 0% of the annual calibration/monthly spot checks expenses when patient treatment resumes at the facility.
2. Manufacturer will reimburse licensee a percentage of lease that is commensurate with space used and occupancy time.
3. Manufacturer will be responsible for long distance phone calls made by their employees.
4. Manufacturer will not be billed for license fees.

B. The licensee has two teletherapy units authorized by the license at locations in Cleveland, Ohio and Solon, Ohio. The Cleveland facility is well utilized; however, for economical reasons (e.g., competition from several linear accelerator facilities in the area) the Solon facility has not treated a teletherapy patient since December 27, 1993. Thus, the licensee was requested to respond to the implementation requirements of 10 CFR 30.36(d)(4).

April 4, 1996

In telephone conversations, the licensee has stated that 30.36(d)(4) is not applicable to their circumstances because they have conducted principal activities under the license at the Solon teletherapy facility within the last 24 months, even though the last teletherapy patient was treated at that facility in December 1993. The licensee defines the principal activity for this facility as the backup teletherapy treatment unit for the main Cleveland teletherapy unit. They believe that maintaining the Solon facility in patient-ready, operational status by continuing the annual calibration and monthly spot checks means these activities, authorized by their licensee, are essential to achieving the purposes for which the license was issued and amended. This viewpoint was supported by Region III inspectors during an on-site inspection of the Solon facility in December 1994. The lead inspector recalls giving this regulatory interpretation to the licensee.

The licensee stated that they did not wish to terminate the license at the Solon facility and decommission the site. They have recently requested that the number of authorized users be increased from three to five oncologists. The licensee expects that the resultant increased patient treatments will make the use of the Solon, Ohio teletherapy facility economical. They believe that decommissioning the Solon facility would be detrimental to public health and safety and would not be in the best public interest.

□ Action Required: Region III requests that Action A be expedited pursuant to the licensee's request and because considerable time has passed since we received the request on October 20, 1995. After discussion with NMSS staff, on November 27, 1995, Region III notified the licensee that the request would need to be resubmitted to more clearly state the request. The revised submittal was received on January 17, 1996. Since receiving this second submittal, Region III has been in contact with your staff and are sending this TAR to resolve the related issues based on a request from James A. Smith of your staff.

A. Evaluate the licensee's request and determine whether we can allow them to perform operational checks of beam monitoring equipment for manufacturers. If approved, please specify what, if any, additional information is required and recommend licensing language if a special license condition is proposed. If the request is not approved, please explain why it is not permitted. This would facilitate the licensee's understanding. Also, please determine if St. Luke's Medical Center will be required to obtain a separate materials service license to perform the operational checks.

B. Determine whether the licensee's use of the Solon teletherapy unit meets the definition of principal activities regarding the implementation requirements of 10 CFR 30.36(d)(4). Then, using this determination, evaluate the licensee's request and determine whether we can allow them to keep the Solon, Ohio teletherapy unit in patient-ready, operational status, rather than



SAINT LUKE'S

MEDICAL CENTER

Radiation Therapy

11311 Shaker Boulevard • Cleveland, Ohio 44104 • Phone (216) 368-7077

January 9, 1996

A
030-17512

Mr. Charles Gill
U.S. Nuclear Regulatory Commission
Material Licensing
Region III
801 Warrensville Road
Lisle, Illinois 60532-4351

ADDL INFO
58

Control No: 399310
Re: License #34-00398-10

Dear Mr. Gill:

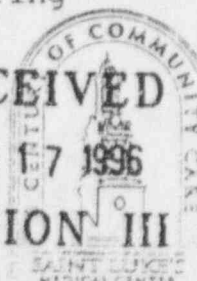
- A. In response to your letter of December 22, 1995, the following is provided as further documentation that the monies paid by the manufacturer is reimbursement not fee for service:
1. Manufacturer will reimburse licensee 100% of annual calibration/monthly spot checks expenses during period of time that no patients are being treated at the Solon facility and 0% of the annual calibration/monthly spot checks expenses when patient treatment resumes at the facility.
 2. Manufacturer will reimburse licensee percentage of lease that is appropriate with space used.
 3. Manufacturer will not be billed for license amendment.
 4. Manufacturer will be responsible for long distance phone calls made by their employees.

It is felt that the above reimbursement explanations show that monies collected by the licensee are reimbursements and not fee for service. We respectfully request that our license be amended to allow operational checks of beam monitoring equipment for various manufacturers.

RECEIVED

JAN 17 1996

REGION III

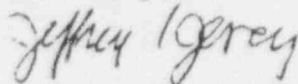


Mr. Charles Gill
U.S. Nuclear Regulatory Commission
January 9, 1996 - Page 2

- B. Dr. Dong Youn Kim has received refresher training in the safety aspects and emergency procedures for the teletherapy unit by Phillip J. Catanzaro, M.D., Ph.D., authorized user and Radiation Safety Officer on reference license. Furthermore, Dr. Catanzaro directly supervised Dr. Kim in performing various teletherapy procedures (see enclosure 1).
- C. It is further requested that Betty Barrow-Obi, M.D., be listed as an authorized user on reference license. Dr. Obi has been under the direct supervision of Kenneth C. Lane, M.D., and has completed her residency in radiation therapy at the University of Texas, M. D. Anderson Cancer Center in Houston, Texas (see attachments 2 and 3).

Any questions regarding this request should be addressed to Thomas K. Stefanakos, M.S.N.E., either in writing or by telephone (216) 447-1045.

Sincerely,



Jeffrey S. Jeney
Vice President,
Ancillary Services

JSJ/j
Enclosure



SAINT LUKE'S
MEDICAL CENTER

11311 Shaker Boulevard, Cleveland, Ohio 44104 • Phone (216) 368-7000

October 12, 1995

Mr. Charles Gill
U.S. Nuclear Regulatory Commission
Material Licensing
Region III
801 Warrensville Road
Lisle, Illinois 60532-4351

Re: License #34-00398-10

Dear Mr. Gill:

As a follow-up to your phone conversation with Mr. Thomas K. Stefanakos, it is requested that the above-referenced license be amended as follows:

I. Authorized users to be added:

A. Hae-Kyung Hong, M.D.

1. Qualifications:

- a. ABR Board Certified in Radiation Oncology.
- b. Previously listed as an authorized user on NRC License #34-04474-02, St. Joseph Hospital and Health Center, 205 West 20th Street, Lorain, Ohio 44052.

B. Don Kim, M.D.

1. Qualifications:

- a. ABR Board Certified in Radiation Oncology.
- b. Listed as an authorized user on PNR License #34-01856-01, Saint Vincent Charity Hospital, 2351 East 22nd Street, Cleveland, Ohio 44115.

RECEIVED

OCT 20 1995



Mr. Charles Gill
U. S. Nuclear Regulatory Commission
October 12, 1995 -2-

- II. Referenced license be amended to authorize the use of the teletherapy unit to perform operational checks on beam monitoring equipment for various manufacturers.

The checks will be conducted under the supervision of the physicist listed on referenced license.

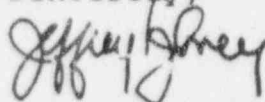
The teletherapy unit will only be operated by same physicist. All safety precautions applicable to patient care will also be applicable to these checks.

The checks are not for calibration purposes. A fee will not be charged for the checks, therefore, a service license is not requested. However, charges will be assessed for incidental expenses, i.e. NRC license fee, physics annual calibration/monthly spot check fees, long distance phone calls, etc. Further, checks will be conducted in such a manner so as not to interfere with patient treatments.

Any questions regarding this request should be addressed to Mr. Stefanakos either in writing or by telephone (216) 447-1045. A check in the amount of \$450.00 to cover the cost of this amendment is enclosed.

Your earliest response to this request is appreciated.

Sincerely,



Jeffrey S. Jeney
Vice President,
Ancillary Services

JSJ/5
Enclosure

96-26

April 4, 1996

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: April 3, 1996

Mail or E-Mail to: Donald A. Cool, Director, Division of Industrial
and Medical Nuclear Safety

From: John Madera (JRM4), Region III, Chief, Nuclear Materials Licensing
Branch

Licensee: St. Luke's Medical Center License No. 34-00398-10

☐ Control No. 399797

☐ Letters dated: October 12, 1995 and January 9, 1996

☐ Suggested change in licensing procedure: N/A

☐ Problem/Issue: A. Licensee requested authorization to use the teletherapy unit to perform operational checks (not calibrations) of beam monitoring equipment for various manufacturers. The licensee stated that the following monies which would be paid by the manufacturer are reimbursement, not service fees:

1. Manufacturer will reimburse licensee 100% of annual calibration/monthly spot checks expenses during periods of time that no patients are being treated at the Solon facility and 0% of the annual calibration/monthly spot checks expenses when patient treatment resumes at the facility.
2. Manufacturer will reimburse licensee a percentage of lease that is commensurate with space used and occupancy time.
3. Manufacturer will be responsible for long distance phone calls made by their employees.
4. Manufacturer will not be billed for license fees.

B. The licensee has two teletherapy units authorized by the license at locations in Cleveland, Ohio and Solon, Ohio. The Cleveland facility is well utilized; however, for economical reasons (e.g., competition from several linear accelerator facilities in the area) the Solon facility has not treated a teletherapy patient since December 27, 1993. Thus, the licensee was requested to respond to the implementation requirements of 10 CFR 30.36(d)(4).

April 4, 1996

In telephone conversations, the licensee has stated that 30.36(d)(4) is not applicable to their circumstances because they have conducted principal activities under the license at the Solon teletherapy facility within the last 24 months, even though the last teletherapy patient was treated at that facility in December 1993. The licensee defines the principal activity for this facility as the backup teletherapy treatment unit for the main Cleveland teletherapy unit. They believe that maintaining the Solon facility in patient-ready, operational status by continuing the annual calibration and monthly spot checks means these activities, authorized by their licensee, are essential to achieving the purposes for which the license was issued and amended. This viewpoint was supported by Region III inspectors during an on-site inspection of the Solon facility in December 1994. The lead inspector recalls giving this regulatory interpretation to the licensee.

The licensee stated that they did not wish to terminate the license at the Solon facility and decommission the site. They have recently requested that the number of authorized users be increased from three to five oncologists. The licensee expects that the resultant increased patient treatments will make the use of the Solon, Ohio teletherapy facility economical. They believe that decommissioning the Solon facility would be detrimental to public health and safety and would not be in the best public interest.

□ Action Required: Region III requests that Action A be expedited pursuant to the licensee's request and because considerable time has passed since we received the request on October 20, 1995. After discussion with NMSS staff, on November 27, 1995, Region III notified the licensee that the request would need to be resubmitted to more clearly state the request. The revised submittal was received on January 17, 1996. Since receiving this second submittal, Region III has been in contact with your staff and are sending this TAR to resolve the related issues based on a request from James A. Smith of your staff.

A. Evaluate the licensee's request and determine whether we can allow them to perform operational checks of beam monitoring equipment for manufacturers. If approved, please specify what, if any, additional information is required and recommend licensing language if a special license condition is proposed. If the request is not approved, please explain why it is not permitted. This would facilitate the licensee's understanding. Also, please determine if St. Luke's Medical Center will be required to obtain a separate materials service license to perform the operational checks.

B. Determine whether the licensee's use of the Solon teletherapy unit meets the definition of principal activities regarding the implementation requirements of 10 CFR 30.36(d)(4). Then, using this determination, evaluate the licensee's request and determine whether we can allow them to keep the Solon, Ohio teletherapy unit in patient-ready, operational status, rather than

April 4, 1996

requiring them to decommission the site pursuant to 30.36(d)(4). If approved, please specify what, if any, additional information is required and recommend licensing language if a special license condition is proposed. If the request is not approved, please explain why it is not permitted. This would facilitate the licensee's understanding.

☐ Recommended Action: ☒ Approve or ☐ Reject

A. Approval would be appropriate if NMSS deems that this request meets the acceptance criteria established by the NMSS response to Region III TAR No. 95-07. Thus, it appears that the request should be granted if the licensee's reimbursement scheme is not viewed by NMSS as a commercial endeavor, and as such, St. Luke's would not be required to obtain a separate materials service license. Please note that, similar to TAR No. 95-07 circumstances, St. Luke's claims that performing these operational checks would not be a means of producing revenues, rather a partial reimbursement of costs incurred.

B. Approval appears appropriate because the licensee has initiated action that is expected to result in patient treatments resuming at the Solon, Ohio teletherapy facility. Region III agrees with the licensee that denying patients needed treatments would be detrimental to public health and safety and would not be in the best public interest.

Remarks: On March 28, 1996, Charles F. Gill of my staff discussed this matter with James A. Smith of your staff. Mr. Smith was the reviewer for the earlier, similar TAR No. 95-07.

Headquarters Reviewer: _____

Regional Reviewer: Charles F. Gill (CFG)

Reviewer Code: S8

Reviewer Phone No. (708)829-9814 Fax No. (708)515-1259

Request Needed by: 04/30/96 for Action A

05/15/96 for Action B

DOCUMENT NAME: M:\SL399797.TAR

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	<input checked="" type="checkbox"/> E	DNMS/RIII	<input checked="" type="checkbox"/> E				
NAME	CFGill:brt	<input checked="" type="checkbox"/> C	JRMade	<input checked="" type="checkbox"/> E				
DATE	04/03/96		04/03/96					

OFFICIAL RECORD COPY



SAINT LUKE'S
MEDICAL CENTER

Radiation Therapy

11311 Shaker Boulevard, Cleveland, Ohio 44104 • Phone (216) 368-7077

January 9, 1996

A
030-17512

Mr. Charles Gill
U.S. Nuclear Regulatory Commission
Material Licensing
Region III
801 Warrensville Road
Lisle, Illinois 60532-4351

ADDL INFO.
58

Control No: 399310
Re: License #34-00398-10

Dear Mr. Gill:

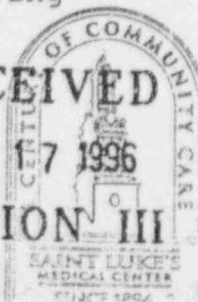
- A. In response to your letter of December 22, 1995, the following is provided as further documentation that the monies paid by the manufacturer is reimbursement not fee for service:
1. Manufacturer will reimburse licensee 100% of annual calibration/monthly spot checks expenses during period of time that no patients are being treated at the Solon facility and 0% of the annual calibration/monthly spot checks expenses when patient treatment resumes at the facility.
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It is felt that the above reimbursement explanations show that monies collected by the licensee are reimbursements and not fee for service. We respectfully request that our license be amended to allow operational checks of beam monitoring equipment for various manufacturers.

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JAN 17 1996

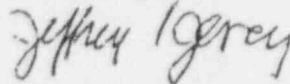
REGION III



- B. Dr. Dong Youn Kim has received refresher training in the safety aspects and emergency procedures for the teletherapy unit by Phillip J. Catanzaro, M.D., Ph.D., authorized user and Radiation Safety Officer on reference license. Furthermore, Dr. Catanzaro directly supervised Dr. Kim in performing various teletherapy procedures (see enclosure 1).
- C. It is further requested that Betty Barrow-Obi, M.D., be listed as an authorized user on reference license. Dr. Obi has been under the direct supervision of Kenneth C. Lane, M.D., and has completed her residency in radiation therapy at the University of Texas, M. D. Anderson Cancer Center in Houston, Texas (see attachments 2 and 3).

Any questions regarding this request should be addressed to Thomas K. Stefanakos, M.S.N.E., either in writing or by telephone (216) 447-1045.

Sincerely,



Jeffrey S. Jeney
Vice President,
Ancillary Services

JSJ/j
Enclosure



SAINT LUKE'S
MEDICAL CENTER

11311 Shaker Boulevard, Cleveland, Ohio 44104 • Phone (216) 368-7000

October 12, 1995

Mr. Charles Gill
U.S. Nuclear Regulatory Commission
Material Licensing
Region III
801 Warrensville Road
Lisle, Illinois 60532-4351

Re: License #34-00398-10

Dear Mr. Gill:

As a follow-up to your phone conversation with Mr. Thomas K. Stefanakos, it is requested that the above-referenced license be amended as follows:

I. Authorized users to be added:

A. Hae-Kyung Hong, M.D.

1. Qualifications:

- a. ABR Board Certified in Radiation Oncology.
- b. Previously listed as an authorized user on NRC License #34-04474-02, St. Joseph Hospital and Health Center, 205 West 20th Street, Lorain, Ohio 44052.

B. Don Kim, M.D.

1. Qualifications:

- a. ABR Board Certified in Radiation Oncology.
- b. Listed as an authorized user on RNR License #34-01856-01, Saint Vincent Charity Hospital, 2351 East 22nd Street, Cleveland, Ohio 44115.

RECEIVED

OCT 20 1995



Affiliated with Case Western Reserve University

REGION III

399310

Mr. Charles Gill
U. S. Nuclear Regulatory Commission
October 12, 1995

-2-

- II. Referenced license be amended to authorize the use of the teletherapy unit to perform operational checks on beam monitoring equipment for various manufacturers.

The checks will be conducted under the supervision of the physicist listed on referenced license.

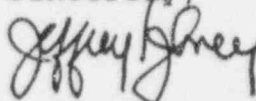
The teletherapy unit will only be operated by same physicist. All safety precautions applicable to patient care will also be applicable to these checks.

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Your earliest response to this request is appreciated.

Sincerely,



Jeffrey S. Jeney
Vice President,
Ancillary Services

JSJ/j
Enclosure

OCT 02 1996

Jeffrey S. Jeney, Vice President
Ancillary Services
St. Luke's Medical Center
11311 Shaker Boulevard
Cleveland, OH 44104

Dear Mr. Jeney:

We have completed the review of your request (letters dated October 12, 1995 and January 9, 1996) that your license be amended to authorize the use of the Solon, Ohio Teletherapy Unit to perform operational checks on beam monitoring equipment for various manufacturers. We determined that a service license would not be required since you would be providing the service to non-licensees. However, irradiation of equipment for other organizations is not directly related to St. Luke's use of the teletherapy unit for human use; therefore, it will require that a separate fee be assessed under fee Category 3F (exposed source irradiators, less than 10,000 curies). Consequently, an application fee of \$1,500 is required. This means that an additional license condition for use of a panoramic irradiator would be added to the current license; therefore, a separate license need not be issued. In addition, once the authorization is granted, the annual fees for fee Category 3F will also apply. The License Fee and Accounts Receivable Branch, Division of Accounting and Finance, Office of the Controller, will notify you of the fee requirements. You may also obtain this information by calling Shirley Crutchfield at (301) 415-6097.

Prior to granting the request, you should be made aware that use of the medical teletherapy unit for purposes other than medical use and the necessary calibrations are not covered under 10 CFR Part 35, but rather are covered under 10 CFR Part 36 (**enclosed**). Part 36 has many new regulatory requirements that licensees performing solely medical use irradiations under 10 CFR Part 35 are not required to meet. Use of the teletherapy unit as an irradiator under 10 CFR Part 36 may require you to have interlock systems, intrusion alert systems, and fire protection systems that currently are not required for operation of the unit under 10 CFR Part 35. The NRC has granted exemptions from the requirements of 10 CFR Part 36 for other licensees using teletherapy units for uses other than medical use under 10 CFR Part 35. However, you will either have to install these systems or request, with sufficient justification, and receive exemptions from the requirements for these systems before being authorized to perform the operational checks. The NRC has previously granted multiple exemptions from the requirements of 10 CFR Part 36 for teletherapy units used for non-medical use, based upon concerns that alterations to the units may cause added risks of malfunction in the treatment of patients; therefore, you may wish to pursue exemptions before installing the additional safety devices. Also, you may wish to consider the added costs of the additional program code and the installation of these systems prior to entering into an agreement with the various manufacturers.

301803

J. Jeney

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Based on the above information please determine whether you wish to withdraw or continue your request to amend your license to authorize the use of the Solon, Ohio Teletherapy Unit to perform operational checks on beam monitoring equipment for various manufactures. If you withdraw your request, the licensing action will be voided. If you continue the request, please provide the information described above regarding adding authorization to your license for use of a panoramic irradiator. Please submit the requested information to us as additional information to Control No. 301803, within 30 days. We then will continue our review, without an additional fee, limited to your beam monitoring equipment operational check request. Be advised, however, that if you request any other changes to your license, an amendment fee will be required.

Sincerely,

Original Signed By
Charles F. Gill
Nuclear Materials Licensing Branch

License No. 34-00398-10
Docket No. 030-17512

Enclosure: 10 CFR Part 36

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