

VOID SHEET

TO: License Fee Management Branch

FROM: RIII - _____

SUBJECT: VOIDED APPLICATION

Control Number: 301824

Applicant: NORTH OHIO HEART CENTER, INC.

License Number: 34-25913-01

Docket Number: 030-30557

Date Voided: 15 NOVEMBER 1996

Reason for Void: NEED ADDITIONAL TIME TO
RESPOND.

W.P. Reinhold
Signature

15 Nov. 1996
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

270080

9611270280 961115
PDR ADOCK 03030557
C PDR

ML
30
SD
0/1

NOV 19 1996

John W. Schaeffer, M.D.
President
North Ohio Heart Center, Inc.
3600 Kolbe Road
Lorain, OH 44053

SUBJECT: VOID OF AMENDMENT REQUEST DATED SEPTEMBER 5, 1996

Dear Dr. Schaeffer:

This refers to your request for an amendment dated September 5, 1996, and your request for additional time to respond in letter dated November 7, 1996.

As discussed with Bill Walbom on November 15, 1996, we will void your request at this time with the understanding that you can resubmit your request without prejudice to resubmission.

If you resubmit the same request within one year of the date of this letter, we will reactivate our review. Information submitted in response to this letter should refer to VOIDED CONTROL NUMBER 301824, to avoid an additional fee.

Please call me at 630-829-9839 if you have any questions.

Sincerely,

William P. Reichhold
Nuclear Materials Licensing Branch

DOCUMENT NAME: M:\

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>TRK</i>								
NAME	REICHOLD:sjd								
DATE	11/19/96								

OFFICIAL RECORD COPY

301824

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02201
Status Code: 0
Fee Category: 7C
Exp. Date: 20030831
Fee Comments:
Decom Fin Assur Req'd: N

57

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: NORTH OHIO HEART CENTER, INC.
Received Date: 960913
Docket No: 3030557
Control No.: 301824
License No.: 34-25913-01
Action Type: Amendment

2. FEE ATTACHED

Amount: 440
Check No.: 13093

3. COMMENTS

Signed
Date

D. Hersey
9-11-96

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

1. Fee Category and Amount: 7C \$440

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

Amendment ☒
Renewal ☐
License ☐

3. OTHER

Signed
Date

SC
9/24/96

1996 SEP 20 AM 11:56

SEP 30 1996

Log	SEP 7 711
Remitter	
Check No.	13093
Amount	\$440
Fee Category	7C
Type of Fee	Amnd
Date Check Rec'd	9/20/96
Date Completed	9/24/96
By	SC

APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MH88 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

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

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

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

IF YOU ARE LOCATED IN:

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

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

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

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
811 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8084

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

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

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

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

- ☐ A. NEW LICENSE
☒ B. AMENDMENT TO LICENSE NUMBER 34-25913-01
☐ C. RENEWAL OF LICENSE NUMBER

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

North Ohio Heart Center, Inc.
3600 Kolbe Road
Lorain, Ohio 44053

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED Amend to add:

New Horizons Medical Center
Suite 4
2819 S. Hayes Avenue
Sandusky, Ohio 44870

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Frank T. Bloer, Consultant
Assoc. in Medical Physics, LLC

TELEPHONE NUMBER

(216) 581-4350

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

5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE Refer to attached Item #7.1	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT. Refer to attached Item #9	10. RADIATION SAFETY PROGRAM.
11. WASTE MANAGEMENT.	12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 7C AMOUNT ENCLOSED \$ 440.00
13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 (62 STAT. 749) MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.	

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

SIGNATURE

DATE

FOR NRC USE ONLY

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

RECEIVED

SEP 13 1996

REGION III

INDIVIDUALS RESPONSIBLE FOR RADIATION
SAFETY PROGRAMS - THEIR TRAINING & EXPERIENCE

Item #7.1

AUTHORIZED USERS FOR MEDICAL USE

AUTHORIZED USER

AUTHORIZATION

David Grech, M.D.

35.100 and 35.200 limited to cardiovascular
clinical procedure

For above physician, refer to the attached documents for evidence of training and experience.

Page 7-1
Prepared: 8/30/96
License #34-25913-01

Attachment 9.1

Facilities and Equipment Diagram

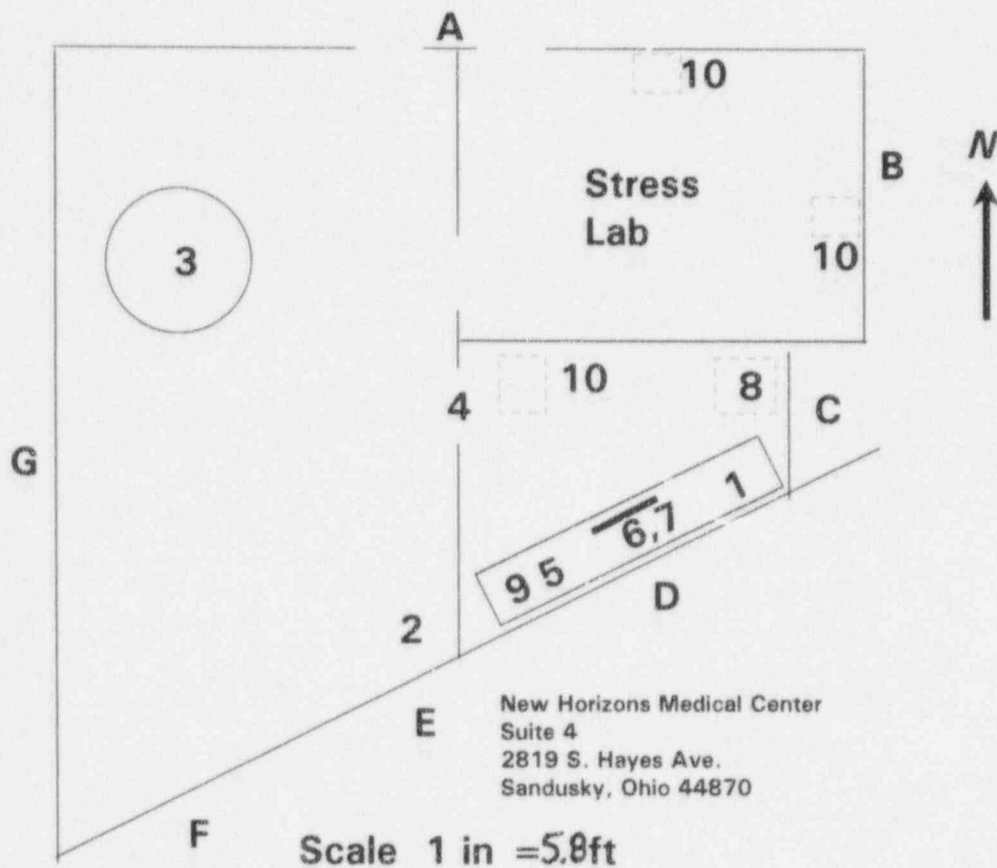
- 1 Survey Equipment
- 2 Uptake/Well
- 3 Camera
- 4 Lockable Door
- 5 Receipt Area
- Generator
- 6 Kit/Dose Preparation
- 7 Isotope Storage
- 8 Waste Storage
- 9 Dose Calibrator
- Fume Hood Cabinet

ADJACENT AREAS

A	Hall
B	Echo
C	Closet
D	Rest Room
E	Exam Room
F	Exterior

Lead Shielding

8	Lead Lined Waste Storage
30"	L x 30" W x 30" H x 1/8" T
6/7	Lead L Shield
11"	L x 11" W x 14" H x 1/2" T
10	Sharps Containers
12"	L x 12" W x 24" H x 1/8" T
	L x W x H x T



Att.9.1
Page 1 of 1
Prepared: 8/30/96
Lic. #34-25913-01



MEMORIAL HOSPITAL
of Rhode Island
DEPARTMENT OF MEDICINE



BROWN UNIVERSITY
School of Medicine

June 24, 1993

To Whom it May Concern:

RE: David Grech, M.D., NRC Certification

This is to certify that Dr. David Grech has successfully completed training in nuclear cardiology to qualify him for licensure by the Nuclear Regulatory Commission in Nuclear Cardiology procedures. Dr. Grech has successfully completed concurrent training in Nuclear Cardiology in the following areas:

- A. Training in basic radioisotope handling techniques. (200 hours)
 - 1. Radiation physics and instrumentation (100 hours)
 - 2. Radiation protection (30 hours)
 - 3. Mathematics pertaining to the use and measurement of radioactivity (20 hours)
 - 4. Radiation biology (20 hours)
 - 5. Radiopharmaceutical chemistry (30 hours)
- B. Experience handling unsealed radioactive materials under the supervision of a qualified instructor (600 hours). This experience has included:
 - 1. Handling of radioactive materials safely including related radiation surveys.
 - 2. Calibration of dose calibrators and diagnostic information.
 - 3. Calculation preparation and calibration of patient doses including radiation safety consideration.
 - 4. Administration of doses to patients.
 - 5. Appropriate internal control procedures.
 - 6. Emergency procedures.

RE: David Grech, M.D.
June 24, 1993
Page 2

C. Supervised clinical training in an institution of nuclear medicine or nuclear cardiology program — (600 hours). This training has included:

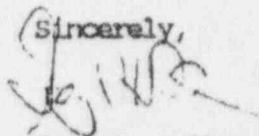
1. Supervised examination of patients.
2. Selection of the proper radiopharmaceutical and dosage.
3. Follow-up of patients when required.
4. Discussion with preceptor of case histories.

In addition to the above outlined training, Dr. Grech also qualifies according to the American College of Cardiology Level 2 in Nuclear Cardiology. In addition to the above described hours completed he has had intensive experience in over 52 patients in which the indications for the nuclear study, the drawing up and calibration of the dosage of radiopharmaceutical, injection of radiopharmaceutical and finally interpretation of the nuclear images was performed.

The didactic portion of Dr. Grech's training was provided by Dr. Douglas R. Shearer from the Department of Diagnostic Imaging, Rhode Island Hospital. Please find enclosed a copy of the certificate.

If I can be of any further assistance please do not hesitate to contact me at 401-729-2791.

Sincerely,



Gary V. Heller, M.D.
Associate Professor of Medicine
Brown University School of Medicine
Director, Nuclear Cardiology
The Memorial Hospital of RI

GVH:mpn

Certificate of Participation

THIS IS TO CERTIFY THAT

David Grech, M.D.

successfully completed the course for physicians entitled

Radioisotope Handling Techniques for Nuclear Medicine Procedures

for a total of two hundred hours of lectures,
demonstrations, and related assignments

SUBJECTS COVERED INCLUDE

Radiation Physics & Instrumentation
Radiation Protection
Mathematics Pertaining to the Use and
Measurement of Radioactivity

Instrumentation for Radionuclide Imaging
Radiation Biology
Radiopharmaceutical Chemistry

as specified in NRC Part 35

Sponsored by
Medical Physics, Department of Diagnostic Imaging
Rhode Island Hospital

Dates:

January 27 - May 20, 1992



Douglas R. Shearer
Douglas R. Shearer, Ph.D., Course Director

NOHC NORTH OHIO HEART CENTER

J.W. Schaeffer, M.D.
F.A.C.C.

K.J. Bescak, M.D.
F.A.C.C.

C.D. O'Shaughnessy, M.D.
F.A.C.C.

M. Vacante, D.O.
F.A.C.C.

N.Z. Farhat, M.D.
F.A.C.C.

D.B. Joyce, M.D.
F.A.C.C.

I.S. Ahmed, M.D.
F.A.C.C.

S.L. Moore, D.O.
F.A.C.C.

W.P. McGuinn, M.D.
F.A.C.C.

L.W. Castle, M.D.
F.A.C.C.

D.R. Grech, M.D.

P.D. Wendschuh, M.D.
F.A.C.C.

A.R. Hulyalkar, M.D.
F.A.C.C.

T.R. Pacheco, M.D.

D.C. Blankenship, M.D.
F.A.C.C.

T.B. Edel, M.D.
F.A.C.C.

☐ Lakeland Medical Center
3600 Kolbe Rd., Suite 127
Lorain, Ohio 44053
(216) 282-3865

☐ Gates Medical Center
125 East Broad St., Suite 305
Elyria, Ohio 44035
(216) 323-4749

☐ Campus Medical Arts Bldg. 2
29101 Health Campus Dr.
Suite 430
Westlake, Ohio 44145
(216) 892-6552

☐ Lakewood Hospital Prof. Bldg.
14601 Detroit Ave., Suite 650
Lakewood, Ohio 44107
(216) 228-9955

☐ New Horizons Medical Center
2819 S. Hayes Ave., Suite 4
Sandusky, Ohio 44870
(419) 625-1004

November 7, 1996

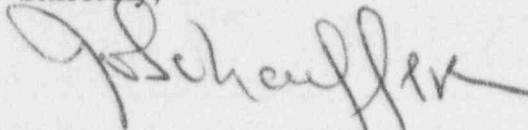
William Reichhold
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Ill 60532-4351

RE: Requested extension for Response to Letter Dated 10/29/96
Control Number: 301824
License Number: 34-25913-01

Dear Mr. Reichhold:

It is respectfully requested that North Ohio Heart Center, Inc. be granted a 30-day extension to the letter from your office dated 10/29/96. This would allow our organization to more completely review the questions posed in your letter and our evaluation of our future plans. If you should have any questions concerning this request, please feel free to contact me.

Sincerely,



John W. Schaeffer, M.D., President
North Ohio Heart Center, Inc.

JWS/ds

RECEIVED
NOV 13 1996
REGION III

NOV 13 1996

CONVERSATION RECORD

|TIME

|DATE

Morning 29 October 1996

☐ VISIT☐ CONFERENCE

TELEPHONE

INCOMING

☒ OUTGOING

NAME OF PERSON(S) CONTACTED

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

Frank Bloe, Consultant North Ohio Heart Center, Inc. (216) 581-4350

John W. Schaeffer President (216) 323-4749

SUBJECT

Additional information for renewal.

SUMMARY

The following additional information is needed to complete your amendment request.

1. Please clarify who controls the keys to the "hot lab" door.
2. Please specify if you own the facility or if you rent an office from a landlord. If you are renting a facility, please provide documentation that the management body of this commercial facility has granted its permission to use and store radioactive materials at the rental office. ALSO, an agreement between you and the management body stating that they will allow you access to the facilities if there is disharmony between you and the management of the facility.
3. Since you have more than one facility of use listed on the license, please clarify the following.

SENIOR MANAGEMENT

- A. Describe the type of administrative structure, organization, and procedures senior management will have to ensure safe operation by users at all facilities.

- B. Submit an organizational chart showing the management structure, reporting paths and flow of authority. Please clearly show the management structure and related authority for implementation and conduct of the radiation safety program at each individual facility.
- C. Please clarify the management oversight and mechanisms used to ensure adequate control over day-to-day licensed activities at each site, including the assignment of duties and allocation of necessary resources.
- D. Please submit a statement of delegation of authority to the Radiation Safety Officer (RSO) ~~and the Radiation Safety Committee (RSC)~~ signed by senior management. This statement should include provisions for the RSO to carry out his authority over each site's program without redirection or hindrance by site management.
- F. Please submit senior management's commitment to give the RSO sufficient time to perform duties, appropriate staff support and provisions for RSO absence.
- F. Please submit senior management's commitment to conduct periodic site tours and meetings with site management, and the RSO.
- G. Describe the mechanisms for informing senior management of unsafe practices and incidents, and senior management's role in responding to such circumstances.
- H. Describe the methods and checks senior management will establish to ensure that the RSO possesses and reviews current regulations.
- I. Describe the chain of authority for ensuring compliance with regulatory requirements.
- J. Describe senior management's review of and involvement with program audits and evaluations.
- K. Describe how site management will assist senior management with the tasks to ensure that the radiation safety program is implemented at that specific site.

DUTIES OF THE RADIATION SAFETY OFFICER

The duties of the RSO need to include the following additional items.

- A. Describe at what frequency the RSO will report to, and meet with, executive and site management.
- B. Describe the RSO's program for regular site visits, monitoring and feedback to site personnel, as well as support staff, to ensure that daily operations at each site including radiation safety activities, approved procedures, safe practices, and compliance with regulations and licensing conditions.
- C. Describe the type of audit program the RSO will conduct at each site. Clarify the audit frequency and the reporting of audit results to each site.
- D. Describe the RSO's mechanisms for responding to unsafe practices and urgent situations that may occur at any site.
- E. Specify that the RSO has the authority to make decisions and terminate unsafe practices and activities jeopardizing the safety of workers, the public, or environment.

ADDITIONAL INFORMATION

Please clarify if your clinics are involved with the following activities.

- A. Do you transport licensed materials between sites?
- B. Do you share safety equipment between sites?

④ *Authorized User - Is Dr. Grech Licensed to practice medicine in OH?*
If you do any of the above, please explain the circumstances and procedures you have to perform the above activities.

Please respond to the above within 15 days and refer to mail control 301824.

Please contact me at 630-829-9839 if you have any questions.

ACTION REQUIRED

Phone call.

NAME OF PERSON DOCUMENTING CONVERSATION
DATE

Bill Reichhold

SIGNATURE

29 October 1996

Bill Reichhold



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

September 16, 1996

Michael Vacante, M.D.
Radiation Safety Officer
North Ohio Heart Center Incorporated
3600 Kolbe Road
Lorain, OH 44053

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Application Dated 09/05/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☐ New License ☒ Amendment ☐ Renewal
☐ Termination ☐ Auth User (Amendment not required)
☐ Other _____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301824
License No. 34-25913-01