

MATERIALS LICENSE

Amendment No. 09

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.

301844

Licensee

In accordance with letter dated
September 13, 19963. License Number 34-18728-01 is amended in
its entirety to read as follows:

4. Expiration Date October 31, 2000

5. Docket or
Reference No. 030-140956. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This LicenseA. Any byproduct
material identified
in 10 CFR 35.100A. Any
radiopharmaceutical
identified in 10 CFR
35.100

A. As needed

B. Any byproduct
material identified
in 10 CFR 35.200B. Any
radiopharmaceutical
identified in 10 CFR
35.200

B. As needed

C. Any byproduct
material identified
in 10 CFR 35.300C. Any
radiopharmaceutical
identified in 10 CFR
35.300C. As needed (Not to
exceed one curie of
iodine-131)D. Any byproduct
material identified
in 10 CFR 31.11

D. Prepackaged Kits

D. As needed

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

C. Medical use described in 10 CFR 35.300.

D. In vitro studies.

CONDITIONS

10. Location(s) of Use: 110 North Poplar Street, Oxford, Ohio.

11. Radiation Safety Officer: Mary C. Moebius, M.D.

270121

9611290049 961105
PDR ADOCK 03014095
C PDR

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

34-18728-01

Docket or Reference Number

030-14095

Amendment No. 09

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized UsersMaterial and Use

- | | |
|---------------------------------|--|
| A. Joseph H. Brandabur, M.D. | 10 CFR 35.100, 35.200, 35.300 and 31.11. |
| B. Mary C. Moebius, M.D. | 10 CFR 35.100, 35.200, 35.300 and 31.11. |
| C. Mary Margaret Knoedler, M.D. | 10 CFR 35.100 and 35.200. |

13. 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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. 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 received May 17, 1990;
- B. Letters dated July 12, 1990 (with attachments), May 3, 1994 and September 13, 1996;
- C. Letter received August 15, 1990 (with attachments);
- D. The licensee shall collect spent noble gas in a shielded container and will establish and implement the model procedure for checking trap effluent that was published in Appendix 0.3 to Regulatory Guide 10.8, Revision 2;
- E. The licensee shall collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that will be checked regularly according to the manufacturer's instructions; and
- F. The licensee shall not directly vent spent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date November 5, 1996

By

Colleen C. Casey
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: 02120
Status Code: 0
Fee Category: 7C
Exp. Date: 20001031
Fee Comments:
Decom Fin Assur Req'd: N

56
13

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: MCCULLOUGH HYDE MEMORIAL HOSPITAL
Received Date: 960918
Docket No: 3014095
Control No.: 301844
License No.: 34-18728-01
Action Type: Amendment

2. FEE ATTACHED

Amount: 440
Check No.: 006293

3. COMMENTS

Signed
Date

D. Hersey
9-19-96

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 23 PM 11:21

SEP 30 1996

Log	<i>Sep 9 III</i>
Remitter	
Check No.	<i>1205</i>
Amount	<i>\$440</i>
Fee Category	<i>7C</i>
Type of Fee	<i>AmD</i>
Date Check Rec'd	<i>9/23/96</i>
Date Completed	<i>9/24/96</i>
By:	<i>SC</i>



The McCullough-Hyde Memorial Hospital, Inc.
OXFORD, OHIO 45056

September 13, 1996

To: United States Nuclear Regulatory Commission
Region III
801 Warrenton Road
Lisle, Illinois 60532-4351

RE: License #34-18728-01

Our facility has just recently required some work on the HVAC (heating/ventilation/air condition) system located near the Intensive Care Unit and the treadmill area.

Due to this complication, the Intensive Care Unit and the Stress Testing area (location submitted in Amendment Dated May 3, 1994) have been temporarily relocated to the third floor.

The time period to correct the current HVAC problem is not expected to exceed two months from this date.

We are submitting to you the close-out survey and wipe test for the area previously used for Stress Testing. This data has been reviewed for possible contamination by our Consulting Health Physicists.

Also included is a map of the area that will be utilized until we are able to return to our regular location. This area will be used primarily for cardiac treadmill and pharmacologic procedures involving the use of Technetium 99m and Thallium 201.

The entrance to this area will be posted with a sign stating: "Caution-Radioactive Material" during the use of the radiopharmaceutical. At the end of the day, the area will be surveyed with and Action/Trigger Level of 0.2mR/hr. If the survey is below the Action Level, the sign will be removed from the entrance. A wipe test of the area will be performed on a weekly basis during this transition period.

A close-out survey and wipe test will be performed of this area before equipment is returned to the regular location on the second floor.

A check in the amount of \$440.00 has been included as our Amendment fee.

Please do not hesitate to call with any questions; 1-513-524-5361.

Thank you for your consideration,

Mary C. Moebius, M.D.

Mary C. Moebius M.D., R.S.O.

McCullough-Hyde Memorial Hospital
110 North Poplar Street
Oxford, Ohio

9/13/96

DATE

RECEIVED

SEP 18 1996

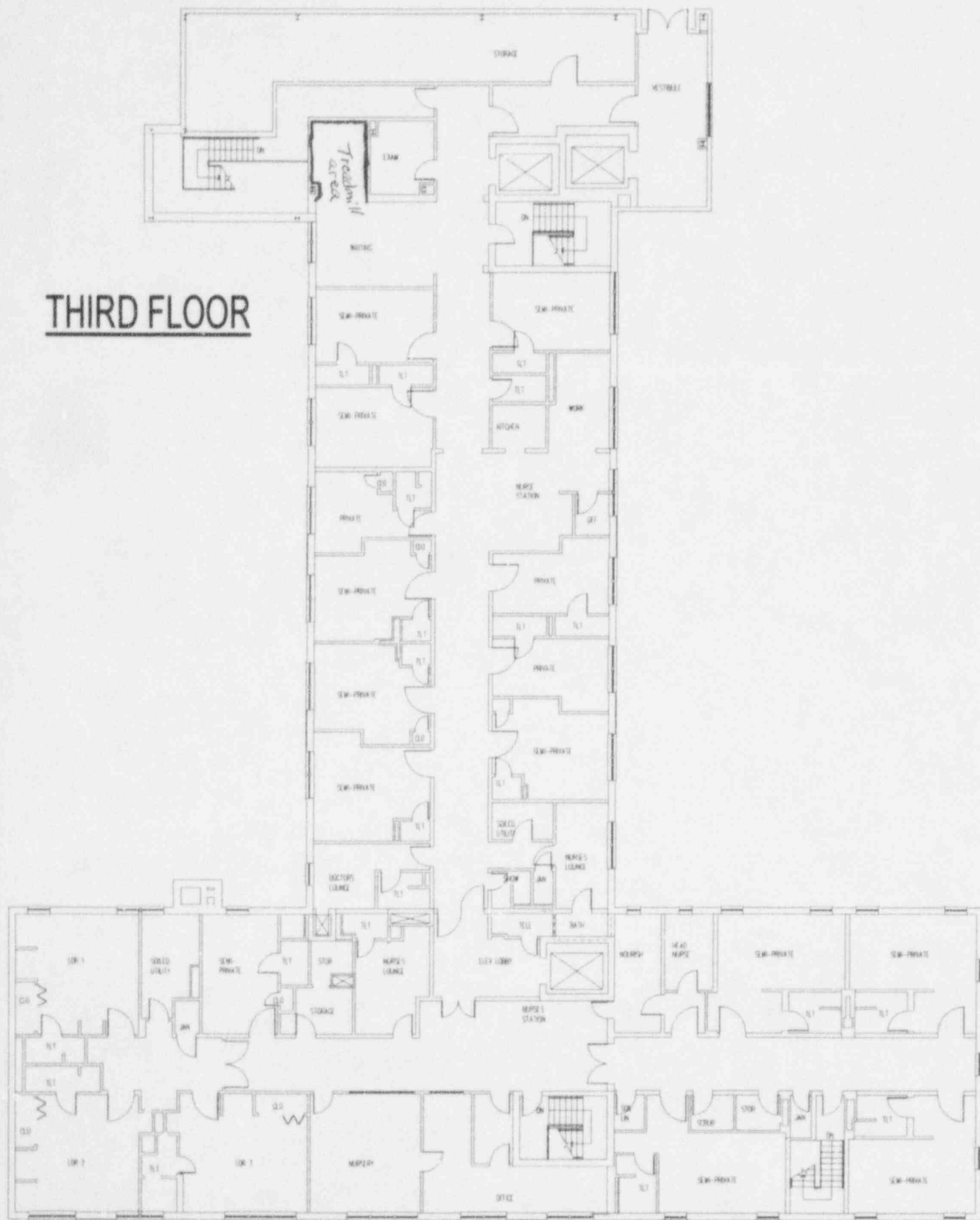
REGION III

SEP 18 1996

301844

Pm: 9-16-96

THIRD FLOOR



ATOMLAB 900 MEDICAL SPECTROMETER
ATOMIC PRODUCTS CORPORATION
SHIRLEY, NEW YORK USA 11967

McCullough-Hyde Hospital
110 North Poplar Street
Oxford, Ohio 45056
(513) 523-2111

ATOMLAB 900 MEDICAL SPECTROMETER S/N 573009
WIPE TEST REPORT

Time: 08:57

Date: Sep 13, 1996

STANDARD:

Nuclide: Other

Date: Sep 13, 1996

Detector: Well

Time: 08:47

Standard Count Time: 120 sec

Standard: 25984 cpm

Activity: 0.100 uCi

LAB BACKGROUND:

Lab. Count Time: 60 sec

Lab. Background: 265 cpm

WIPE RESULTS:

Wipe Count Time: 60 sec

Bkg Reading 0.02 mR/hr

Wipe #	Location	Wipe Counts	Contamination
3.02 mR/hr	Patient Room floor	255 cpm	0 dpm 0.00 uCi
3.02 " 2	Hallway floor	234 cpm	0 dpm 0.00 uCi
3.02 " 3	Treadmill Room floor	250 cpm	0 dpm 0.00 uCi
3.02 " 4	Treadmill Surface	225 cpm	0 dpm 0.00 uCi
3.02 " 5	Table Surface	255 cpm	0 dpm 0.00 uCi

Technologist: *Gij*

Comments:

NO CONTAMINATION ABOVE TRIGGER LEVELS. ROOM MAY BE RELEASED FOR UNRESTRICTED USE

Ken Lova, 1330956

KEN LOVA, HEALTH PHYSICIST

NOV 06 1996

Mary C. Moebius, M.D.
Radiation Safety Officer
McCullough-Hyde Hospital
110 North Poplar Street
Oxford, OH 45056

Dear Dr. Moebius:

Enclosed is Amendment No. 09 to your NRC Material License No. 34-18728-01 in accordance with your request.

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 at (630) 829-9887 so that we can provide appropriate corrections and answers.

- A. In preparing this amendment, we took the opportunity to update and reformat your license as discussed below. These changes were essentially administrative modifications only that should have no effect on your licensed program.

Subitems A.1., A.2., A.3., A.4. and A.5. of this letter were discussed in a telephone conversation between Colleen Casey and Dr. Mary Moebius on October 11, 1996.

1. Please note that, at this time, we changed the expiration date in item no. 4 of your license to reflect the one-time extension of your license, in accordance with 10 CFR 30.36(a)(2), copy enclosed. You should have received additional correspondence from us concerning this regulation and its effects on your license.
2. We deleted Condition No. 13., as it appeared on Amendment No. 08, which authorized the possession, use, transfer and import of up to 999 kilograms of depleted uranium (DU) contained as shielding material for generators.

We were advised that you may have been subject to additional annual fees if you retained the DU authorization on your license, although it is highly unlikely that your licensed program would need this authorization. In light of these considerations, Dr. Moebius directed us to remove the DU authorization from your license during the telecon on October 11, 1996.

301844

3. We deleted Condition No. 14., as it appeared on Amendment No. 08, because the regulations in 10 CFR 30.35(g) contain the same provision. Therefore, this Condition is no longer necessary.
 4. At this time, we limited your authorization for iodine-131, as listed in 10 CFR 35.300 and Item 8.C., in order to preclude your having to file an emergency plan, per 10 CFR 30.32(i) and 30.72, enclosed. Your total possession limit for iodine-131 is one curie and includes waste activity also. Dr. Moebius advised us of the possession limit you wish to have for iodine-131 in the telecon on October 11, 1996.
 5. We noted that your letter dated September 13, 1996, was signed by Mary Moebius, M.D. Please be reminded that all correspondence to us must be signed by a senior management official. In the alternative, a senior management official may designate an authorized signatory to us, in writing, such as the Radiation Safety Officer or a mid-level management representative.
- B. Please note that we are requesting the following clarifications, commitments and additional information at this time in order to complete and/or update your license. Please address the information requested below and submit it to us as additional information to Control No. 301844. We will then continue our review, without an additional fee, limited to this requested information.

Be advised that, if you include a request for anything other than this information, an amendment fee will be required. If necessary to facilitate a more timely review, you may submit your responses to the items below as separate documents, referencing each as additional information to Control No. 301844.

Please provide the following:

1. Please be advised that we cannot authorize you to release your old nuclear medicine space for unrestricted use (even by other members of your staff) until we have received and reviewed a copy of the results of your close-out survey. The survey should consist of exposure rate measurements to show that all sources of radioactive material have been removed, and contamination checks of areas where radioactive materials were used or stored. Average radiation levels associated with surface contamination and removable contamination should not exceed those specified in the enclosed decontamination guide. Please submit the following information with your close-out survey:

- a. A diagram of your old facility with survey and wipe test results keyed to specific locations.
- b. The name of the person performing the survey.
- c. The date the survey was performed.
- d. The instrument(s) used for exposure rate measurements and for analysis of the wipes.
- e. Background readings.
- f. The date that the survey instrument was last calibrated.

When submitting the close-out survey, please reference it as additional information to Control No. 301844. We will amend your license, without an additional fee, to remove the temporary stress test facility from your license at that time.

2. Condition No. 14. on the new amendment no. 09, enclosed, contains three commitments (14.D., 14.E. and 14.F.) that can be incorporated into your license in a more suitable manner. To accomplish this optional incorporation, please respond with positive commitments as follows:

- a. Please confirm that you will collect spent noble gas in a shielded container and that you will establish and implement the model procedure for checking trap effluent that was published in Appendix 0.3 to Regulatory Guide 10.8, Rev. 2, enclosed.
- b. Please confirm that you will collect spent aerosol in a shielded trap and, for reusable traps, you will monitor the trap effluent with an air contamination monitor that will be checked regularly according to the manufacturer's instructions.
- c. Please confirm that you will not directly vent spent aerosols and gases to the atmosphere and that no effluent estimation is therefore necessary.

Upon receipt of your letter containing these commitments, we will list your letter in License Condition no. 14. and we will delete subcondition nos. 14.D., 14.E. and 14.F. If you elect to not make these commitments, your license will remain in its current format.

- C. If your understanding differs from ours in any of these matters, or if you have questions concerning this amendment, please contact Colleen C. Casey at (630) 829-9841.
- D. 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 an authorized user or 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).
 3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.
 4. Request and obtain a license amendment before you:
 - a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
 - b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;
 - c. Change Radiation Safety Officers;
 - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

- e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - f. 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. Since serious consequences to employees and the public can result from failure to comply 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
Colleen C. Casey
Nuclear Materials Licensing Branch

License No.: 34-18728-01

Docket No.: 030-14095

- Enclosures:
- 1. Amendment No. 09
 - 2. 10 CFR Part 30
 - 3. 10 CFR Part 35
 - 4. NRC Form 313
 - 5. Reg. Guide 10.8, Rev. 2.

DOCUMENT NAME: M:\03014095.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>CC</i>						
NAME	CCASEY:jaw						
DATE	10/09/96						

OFFICIAL RECORD COPY



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

September 19, 1996

Mary C. Moebius, M.D.
Radiation Safety Officer
McCullough Hyde Memorial Hospital
110 N. Poplar Street
Oxford, OH 45056

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 09/13/96)

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. 301844
License No. 34-18728-01