

MATERIALS LICENSE

Amendment No. 11

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.

302630

<p>Licensee</p> <p>1. McCullough-Hyde Hospital</p> <p>2. 110 North Poplar Street Oxford, Ohio 45056</p>	<p>In accordance with letter dated May 2, 1997</p> <p>3. License Number 34-18728-01 is amended in its entirety to read as follows:</p> <p>4. Expiration Date October 31, 2000</p> <p>5. Docket or Reference No 030-14095</p>	
<p>6. Byproduct, Source, and/or Special Nuclear Material</p> <p>A. Any byproduct material identified in 10 CFR 35.100</p> <p>B. Any byproduct material identified in 10 CFR 35.200</p> <p>C. Any byproduct material identified in 10 CFR 35.300</p> <p>D. Any byproduct material identified in 10 CFR 31.11</p>	<p>7. Chemical and/or Physical Form</p> <p>A. Any radiopharmaceutical identified in 10 CFR 35.100</p> <p>B. Any radiopharmaceutical identified in 10 CFR 35.200</p> <p>C. Any radiopharmaceutical identified in 10 CFR 35.300</p> <p>D. Prepackaged Kits</p>	<p>8. Maximum Amount that Licensee May Possess at Any One Time Under This License</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. As needed (Not to exceed one curie of iodine-131)</p> <p>D. As needed</p>

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.

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PDR ADOCK 03014095
C PDR



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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

34-18728-01

Docket or Reference Number

030-14095

Amendment No. 11

CONDITIONS

10. Location(s) of Use: 110 North Poplar Street, Oxford, Ohio.
11. Radiation Safety Officer: Mary C. Moebius, M.D.
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, September 13, 1996, January 22, 1997, and May 2, 1997;
- C. Letter received August 15, 1990 (with attachments);

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUN 13 1997

By


Nuclear Materials Licensing Branch, Region III

COPY

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

Program Code: 02120
Status Code: 0
Fee Category: 7C
Exp. Date: 20001031
Fee Comments:
Decon Fin Assur Req: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: MCCULLOUGH HYDE HOSPITAL
Received Date: 970507
Docket No: 3014095
Control No.: 302630
License No.: 34-18728-01
Action Type: Amendment

2. FEE ATTACHED

Amount: *

Check No.: *

3. COMMENTS

Signed
Date

D. Hersey
5/13/97

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

1. Fee Category and Amount: TC

FEE NOT REQUIRED

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

Amendment
Renewal
License

3. OTHER

Signed
Date

TC
5/14/97

MAY 21 1997

Log	May 7 III
Remitter	
Check No.	
Amount	
Fee Category	TC
Type of Fee	ADD
Date Check Recd	
Date Completed	5/14/97
By:	TC



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

5-2-97

Colleen C. Casey
Nuclear Materials Licensing Branch
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: NRC Material License No. 34-18728-01, Amendment No.10

Dear Ms. Casey,

Please make note of the following:

We confirm that will 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, Rev. 2.

We confirm that we will collect spent noble 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.

We confirm that we will not directly vent spent aerosols and gases to the atmosphere and that no effluent is therefore necessary.

If you have any questions concerning this letter, please contact Mary C. Moebius M.D. at (513) 524-5361.

Thank you,

Richard A. Daniels
President and C.E.O.

RECEIVED

MAY 07 1997

REGION III

302257
FEE NOT REQUIRED

Pm: 5-5-97

302630
MAY 07 1997

DATE: 5-12-97

CORRESPONDENCE CLARIFICATION SHEET

REVIEWER:

~~BJ HOLT~~ Casey

LICENSEE:

McCullough-Hyde

LICENSE NUMBER:

34-18728-01

The following correspondence has been received from the above licensee and it is not clear what action(s) is(are) required: Please review this correspondence and indicate which of the following applies, and please return to Debbie Hersey, as soon as possible.

☒ Additional Information to Control No. 302257 ^{cc'd} _{5/14/97}
Process in as a new action, additional information, and no fee required.

☐ Process as new licensing action. Review has already been started on Control No. _____ and this information cannot be combined with current in-house action.

☐ Can be combined with Control No. _____. Review has not started.

☐ Appears to be information for the license file - file it.

☐ Licensee is adding Nuclear Pharmacists.

☐ Amendment is necessary _____. Amendment is not necessary _____.
(Information for license file)

☐ Licensee is adding authorized users.

☐ A check is included _____. No check is included _____.

Amendment is necessary _____. Amendment is not necessary _____.
(This is a Notification)

☐ Process in as a new licensing action:

- A. Amendment _____
- B. Renewal _____
- C. New License Application _____

☐ Other: _____

Thank You For Your Help!!!

10/16/96

JUN 13 1997

Richard A. Daniels
President and CEO
McCullough-Hyde Hospital
110 North Poplar Street
Oxford, OH 45056

Dear Mr. Daniels:

Enclosed is Amendment No. 11 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.

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 mailing address listed on the license 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.

302630

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 Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC

R. Daniels

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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.: 34-18728-01

Docket No.: 030-14095

Enclosure: Amendment No. 11

DOCUMENT NAME: M:\03014095.CL7

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								
NAME	ERMatson:brt								
DATE	06/11/97								

OFFICIAL RECORD COPY



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

May 14, 1997

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

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 05/02/97)

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. 302630
License No. 34-18728-01