

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: North Hawaii Community
Hospital

License No.: 53-29099-01

Docket No.: 030-34081

Mail Control No.: 471504

Type of Action: Notify

Date of Requested Action: 09-10-07

Reviewer
Assigned:

ARM reviewer(s): Torres

Response	Deficiencies Noted During Acceptance Review
	<ul style="list-style-type: none">[] Open ended possession limits. Limit possession. Submit inventory.[] Submit copies of most recent leak test results.[] Add - delete IC license condition. Add IC paragraph in cover letter.[] Split license from cover letter. Add SUNSI marking to license.[] Ask the licensee if they have any type-amount of EPAct Material.

Reviewer's Initials: _____

Date: _____

- ☐ Yes ☐ No Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.
- ☐ Yes ☐ No Decommissioning notification should be completed within 30 days.
- ☐ Yes ☐ No Termination request < 90 days from date of expiration
- ☐ Yes ☐ No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
- ☐ Yes ☐ No TAR needed to complete action.

Branch Chief's and/or Sr. HP's Initials: _____

Date: _____

SUNSI Screening according to RIS 2005-31

☐ Yes ☒ No Non-Publicly Available, Sensitive if any item below is checked

General guidance:

- _____ RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
- _____ Exact location of RAM (whether = or > than Category 3 or not)
- _____ Design of structure and/or equipment (site specific)
- _____ Information on nearby facilities
- _____ Detailed design drawings and/or performance information
- _____ Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

- _____ RAM quantities and inventory
- _____ Manufacturer's name and model number of sealed sources & devices
- _____ Site drawings with exact location of RAM, description of facility
- _____ RAM security program information (locks, alarms, etc.)
- _____ Emergency Plan specifics (routes to/from RAM, response to security events)
- _____ Vulnerability/security assessment/accident-safety analysis/risk assess
- _____ Mailing lists related to security response

Branch Chief's and/or Sr. HP's Initials: HTC

Date: 9-21-07

Pre-Licensing Screening

Applicant Information:

Control No. 471504

Name: North Hawaii Community Hospital	Type of Request: Notify Program Code(s): 02120	
Location: HI	License No.: 53-29099-01	Docket No.: 030-34081

STEP 1–Radioactive Materials and Quantities Requested:

Instructions for Step 1: Complete Step 1 for all applications. If all your responses in Step 1 are "No" then do not complete Step 2 (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay.	Yes or No
A. The request is from a new applicant.	N
B. NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit.	N
C. The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been "highlighted" by the reviewer	N

Table of Risk Significant Quantities

(Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

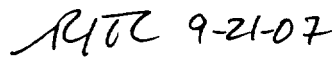
Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)	Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226 ²	0.4	11
Co-60	0.3	8.1	Se-75	2	54
Cs-137	1	27	Sr-90 (Y-90)	10	270
Gd-153	10	270	Tm-170	200	5,400
Ir-192	0.8	22	Yb-169	3	81

¹ The primary values are TBq. The curie (Ci) values are for informational purposes only.

² The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. NOTE—If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).	Yes, No, or Not Applicable (NA)
Total Activity—multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide	—
Unity Rule—multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g., [(total activity for radionuclide A) ÷ (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) ÷ (risk significant quantity for radionuclide B)] ≥ 1.0.	—

Signature and Date for Step 1:

 9-21-07
 License Reviewer and Date



NORTH HAWAII COMMUNITY HOSPITAL

67-1125 MAMALAHOA HIGHWAY ✚ P.O. BOX 2799 ✚ KAMUELA, HAWAII 96743 ✚ 808.885.4444 ✚ FAX 808.881.4624

RECEIVED

SEP 17 2007

DNMS

September 10, 2007

U.S. Nuclear Regulatory Commission, Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

Re: Notification
NRC License No. 53-29099-01
Docket No. 030-34081

Dear License Reviewer:

We have approved Guy Syvertsen, D.O., as an authorized user for byproduct material listed in 10 CFR 35.100 and 35.200, and for any sodium iodide I-131 use permitted by 10 CFR 35.300. Dr. Syvertsen is currently authorized for these uses under Ohio Department of Health License No. 02120180039 issued to Marymount Hospital. A copy of this license is attached.

Please contact our Radiation Safety Consultant, Ronald Frick, at 808-373-7009 if you require additional information.

Sincerely,

Wayne S. Higaki
Assistant Vice President

WH/lma

Enclosures

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIAL

Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as 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 applications of Chapter 3748 of the Ohio Revised Code and all applicable rules promulgated thereunder. This license is subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.

LICENSEE 1. Marymount Hospital 2. 12300 McCracken Blvd. Garfield Heights, Ohio 44125-2975	LICENSE NUMBER 3. 02120180039 EXPIRATION DATE 4. July 1, 2008 BUREAU DOCKET NUMBER 5. DC33-12-97
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6. RADIOACTIVE MATERIAL**7. CHEMICAL AND/OR PHYSICAL FORM****8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE**

- A. Any radioactive material permitted by rule 3701:1-58-32 of the Ohio Administrative Code.
- B. Any radioactive material permitted by rule 3701:1-58-34 of the Ohio Administrative Code.
- C. Any radioactive material permitted by rule 3701:1-58-37 of the Ohio Administrative Code.
- D. Any radioactive material permitted by rule 3701:1-58-53 of the Ohio Administrative Code.
- E. Any radioactive material permitted by rule 3701:1-46-11 of the Ohio Administrative Code.
- F. Iodine - 125 permitted by rule 3701:1-58-43 of the Ohio Administrative Code.
- G. Palladium-103 permitted by rule 3701:1-58-43 of the Ohio Administrative Code.
- H. Cobalt-57

- A. Any radiopharmaceutical form
- B. Any radiopharmaceutical form
- C. Any radiopharmaceutical form
- D. Sealed sources
- E. Prepackaged kits
- F. Sealed sources
- G. Sealed sources
- H. Sealed sources

- A. As needed, not to exceed 3.7 GBq (100 mCi) of Cobalt-57
- B. As needed
- C. As needed, not to exceed 37 GBq (1 Curie) of Iodine-131
- D. 74 GBq (2.0 Curie)
- E. As needed
- F. 74 GBq (2.0 Curie)
- G. 74 GBq (2.0 Curie)
- H. As needed, no single source to exceed 555 MBq (15 mCi)

OHIO DEPARTMENT OF HEALTH
LICENSE FOR RADIOACTIVE MATERIALS
 SUPPLEMENTARY SHEET

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License Number: 02120180039

Bureau Docket Number: DC33-12-97

Amendment No. 18

9. Authorized Use

- A. Any uptake, dilution, and excretion study permitted by rule 3701:1-58-32 of the Ohio Administrative Code.
- B. Any imaging and localization study permitted by rule 3701:1-58-34 of the Ohio Administrative Code.
- C. Any medical use permitted by rule 3701:1-58-37 of the Ohio Administrative Code.
- D. Any sealed source for diagnostic medical use permitted by rule 3701:1-58-53 of the Ohio Administrative Code.
- E. In Vitro studies permitted by rule 3701:1-46-11 of the Ohio Administrative Code.
- F. and G. Brachytherapy sources for therapeutic medical use permitted by rule 3701:1-58-43 of the Ohio Administrative Code.
- H. Check, calibration, and reference sources.

CONDITIONS

10. Licensed material may only be used at the licensee's facilities located at:

Marymount Hospital
12300 McCracken Blvd
Garfield Heights, Ohio 44125-2975

11. The Radiation Safety Officer for this license is:

Guy Syvertsen, D.O.

The Alternate Radiation Safety Officer for this license is:

James E. Masten, M.D.

12. Licensed material is only authorized for use by, or under the supervision of:

1. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and / or authorized medical physicist in accordance with rule 3701:1-58-08 and 3701:1-58-09 of the Ohio Administrative Code.

2. The following individuals are authorized users for the material and medical uses indicated:

Authorized Users	Material and Uses
A. Indu Tara Agarwal, M.D.	A. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 of the Ohio Administrative Code.
B. Gregory Baran, M.D.	B. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 and Iodine-131 as permitted by rule 3701:1-58-37 of the Ohio Administrative Code.
C. Phillip J. Catanzaro, M.D.	C. Iodine-125 and Palladium-103 as permitted by rule 3701:1-58-43 of the Ohio Administrative Code.
D. Jay Ciezki, M.D.	D. Uses permitted by rule 3701:1-58-37 and Iodine-125 and Palladium-103 as permitted by rule 3701:1-58-43 of the Ohio Administrative Code.
E. David Frankel M.D.	E. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 of the Ohio Administrative Code.
F. Gwynne G. Holtz, M.D.	F. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 (Iodine-131 in quantities less than or equal to 33 millicuries) of the Ohio Administrative Code.
G. Cheryl Anthony Hubbard, M.D.	G. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 of the Ohio Administrative Code.
H. Lisa Beth Hughes, M.D.	H. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code.

OHIO DEPARTMENT OF HEALTH
LICENSE FOR RADIOACTIVE MATERIALS
 SUPPLEMENTARY SHEET

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License Number: 02120180039

Bureau Docket Number: DC33-12-97

Amendment No. 18

Authorized Users

Material and Uses

- | | |
|---------------------------------|---|
| I. Dong Y. Kim | I. Iodine-125 and Palladium-103 as permitted by rule 3701:1-58-43 of the Ohio Administrative Code. |
| J. Ronald J. Lorig, M.D., Ph.D. | J. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 of the Ohio Administrative Code. |
| K. Arull Mahadevan, M.D. | K. Uses permitted by rule 3701:1-58-37 and Iodine-125 and Palladium-103 as permitted by rule 3701:1-58-43 of the Ohio Administrative Code. |
| L. James E. Masten, M.D. | L. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and Iodine-131 as permitted by rule 3701:1-58-37 of the Ohio Administrative Code. |
| M. Susan Lynn O'Malley M.D. | M. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 of the Ohio Administrative Code. |
| N. Howard Potash, M.D. | N. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code. |
| O. Shetal Niranian Shah, M.D. | O. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 of the Ohio Administrative Code. |
| P. Guy Syversten, D.O. | P. Uses permitted by rules 3701:1-58-32, 3701:1-58-34, 3701:1-46-11 and Iodine-131 as permitted by rule 3701:1-58-37 of the Ohio Administrative Code. |

13. All persons performing activities meeting the definition of "Nuclear Medicine Technologist" as specified in R.C. 4773.01 shall be licensed and in good standing with the state of Ohio.
14. All sealed sources that are used or obtained shall have been evaluated and approved under the provisions of rule 3701:1-46-49 of the Ohio Administrative Code or by equivalent NRC or Agreement State regulation.
15. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of sealed source licensed material to quantities below the minimum limit specified in rule 3701:1-40-17(B) of the Ohio Administrative Code for establishing decommissioning financial assurance.
16. In addition to the requirements in rule 3701:1-58-30 of the Ohio Administrative Code any patient administered gamma emitting radiopharmaceuticals or permanent brachytherapy sources shall be provided a patient release card to include:
 - (1) The patient's name.
 - (2) The radionuclide administered and its activity.
 - (3) The facility name which administered the radionuclide.
 - (4) The date of the administration of the radionuclide.
 - (5) The expiration date of the card.

The card is not applicable to those patients who are institutionalized (Hospitals, Nursing Homes, Correctional Institutions, etc.) or whose radiation levels do not exceed 0.1 mR/hr at one meter.

OHIO DEPARTMENT OF HEALTH
LICENSE FOR RADIOACTIVE MATERIALS
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License Number: 02120180039

Bureau Docket Number: DC33-12-97

Amendment No. 18

17. 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 Ohio Department of Health's statutes, rules, and orders shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Renewal application dated March 25, 2003; and
 - B. Amendment 11, license number 02120180039, is amended and renewed in its entirety.
 - C. Letter dated September 20, 2004. (Amendment #12)
 - D. Application for amendment dated April 10, 2005. (Amendment #13)
 - E. Amendment to convert to Chapter 3701:1-58 of the Ohio Administrative Code (Amendment #14)
 - F. Letter dated January 30, 2006 (Amendment #15)
 - G. Director's Order dated April 21, 2006. (Amendment #16)
 - H. Application for amendment dated August 22, 2006. (Amendment #17)
 - I. Application for amendment dated April 17, 2007. (Amendment #18)

For the Ohio Department of Health

DATE:

6/21/07

BY:


Director, Ohio Department of Health

SEP 21 2007

DATE

This is to acknowledge the receipt of your letter/application dated 9-10-07, and to inform you that the initial processing, which includes an administrative review, has been performed.

☒ There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card:

The action you requested is normally processed within days.

☐ A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 471504.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Colleen Murnahan
Licensing Assistant

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: 20110531
: Fee Comments:
: Decom Fin Assur Req'd: N
: ::::::::::::::::::::::::::::::::::::::

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: NORTH HAWAII COMMUNITY HOSPITAL
Received Date: 20070917
Docket No: 3034081
Control No.: 471504
License No.: 53-29099-01
Action Type: Notifications

2. FEE ATTACHED

Amount: _____
Check No.: /

3. COMMENTS

Signed
Date

Colleen Murashan
9-18-07

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

1. Fee Category and Amount: _____

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

Amendment _____
Renewal _____
License _____

3. OTHER _____

Signed
Date



NORTH HAWAII
COMMUNITY HOSPITAL

67-1125 MAHALEPUA HIGHWAY
KAMUELA, HAWAII 96743

CERTIFIED MAIL™



7007 1490 0000 3744 3397



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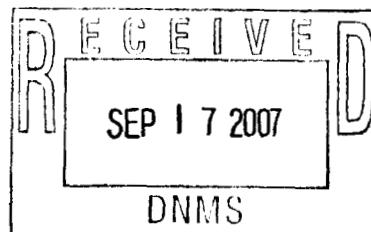
76011

U.S. POSTAGE
PAID
KAMUELA, HI
96743
SEP 12, 07
AMOUNT

\$5.38
00096668-13

**RETURN RECEIPT
REQUESTED**

U.S. Nuclear Regulatory Commission,
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064



7601134005

