



April 29, 2021

Materials Licensing Reviewer
Materials Licensing Branch
US Nuclear Regulatory Commission – Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: Materials License 21-08317-01, Munson Medical Center

Dear Reviewer,

Please add Jessica D. Arden, M.D., Ph.D. as an Authorized User for Materials and Uses 10 CFR 35.400 and 35.600 (limited to Iridium-192 in an HDR remote afterloading brachytherapy unit.

See Dr. Arden's NRC Form 313A AUS.

Thank you for your assistance with these items.

Sincerely,

Handwritten signature of Casey Kadow in cursive.

Casey Kadow
System VP Ancillary Services

Handwritten signature of Dennis J. Aurand in cursive.

Dennis Aurand, MS, DABR[®]
Diagnostic Medical Physicist
Radiation Safety Officer
daurand@mhc.net
phone: 231.392.8612

RECEIVED APR 30 2021

NRC FORM 313A (AUS)
(MM-YYYY)

U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (MM/DD/YYYY)

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.57, 35.490, 35.491, and 35.690]

Name of Proposed Authorized User
Jessica Arden, M.D., Ph.D.State or Territory Where Licensed
Michigan

Requested Authorization(s) (check all that apply)

35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s)

35.400 Ophthalmic use of strontium-90 35.600 Gamma stereotactic radiosurgery unit(s)

35.600 Remote afterloader unit(s)

PART I – TRAINING AND EXPERIENCE
(Select one of the three methods below)

*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

1. Board Certification

- Provide a copy of the board certification.
- For 35.690, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.
- For a board certification issued on or before October 24, 2005, that is listed in 10 CFR 35.57(b)(2)(iii), provide the following:
 - Documentation that the individual performed each use checked above on or before October 24, 2005.
 - Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.
- Stop here.

2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above

- Go to the table in section 3.e. to document training for new device.
- If board certified, provide a copy of the certificate and stop here. If not board certified, provide completed Part II Preceptor Attestation.

3. Training and Experience for Proposed Authorized User

- a. Classroom and Laboratory Training 35.490 35.491 35.690 x

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	80	7/1/2016 - 3/30/2021
Radiation protection	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	20	7/1/2016 - 3/30/2021
Mathematics pertaining to the use and measurement of radioactivity	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	20	7/1/2016 - 3/30/2021
Radiation biology	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	384	7/1/2016 - 3/30/2021

Total Hours of Training:

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(for uses defined under 35.400 and 35.600)
[10 CFR 35.57, 35.490, 35.491, and 35.690] (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work and Clinical Experience for 10 CFR 35.490 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

Supervised Work Experience		Total Hours of Experience:	500
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2016 - 3/30/2021
Checking survey meters for proper operation	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2016 - 3/30/2021
Preparing, implanting, and safely removing brachytherapy sources	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2016 - 3/30/2021
Maintaining running inventories of material on hand	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2016 - 3/30/2021
Using administrative controls to prevent a medical event involving the use of byproduct material	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2016 - 3/30/2021
Using emergency procedures to control byproduct material	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2016 - 3/30/2021

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: <input checked="" type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Council on Postdoctoral Training of the American Osteopathic Association	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	7/1/2016 - 3/30/2021
Supervising Individual M. Saada Jowad	License/Permit Number listing supervising individual as an Authorized User 21-01333-01	

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(for uses defined under 35.400 and 35.600)
[10 CFR 35.57, 35.490, 35.491, and 35.690] (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User	

d. Supervised Work and Clinical Experience for 10 CFR 35.690

- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

Supervised Work Experience		Total Hours of Experience:	500
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2016 - 3/30/2021
Preparing treatment plans and calculating treatment doses and times	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2016 - 3/30/2021
Using administrative controls to prevent a medical event involving the use of byproduct material	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2016 - 3/30/2021
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2016 - 3/30/2021
Checking and using survey meters	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2016 - 3/30/2021
Selecting the proper dose and how it is to be administered	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2016 - 3/30/2021

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(for uses defined under 35.400 and 35.600)
[10 CFR 35.57, 35.490, 35.491, and 35.690] (continued)

3. Training and Experience for Proposed Authorized User (continued)**d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)**

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: <input checked="" type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Council on Postdoctoral Training of the American Osteopathic Association	Beaumont Health 3601 W. 13 Mile Rd. Royal Oak, MI 48073	7/1/2016 - 3/30/2021
Supervising Individual M. Saada Jawad		License/Permit Number listing supervising individual as an Authorized User 21-01333-01

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation	7/1/2016 - 3/30/2021		
Safety procedures for the device use	7/1/2016 - 3/30/2021		
Clinical use of the device	7/1/2016 - 3/30/2021		
Supervising Individual. (If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.) M. Saada Jawad		License/Permit Number listing supervising individual as an Authorized User 21-01333-01	
Authorized for the following types of use: <input checked="" type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

f. Provide completed Part II Preceptor Attestation.

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(for uses defined under 35.400 and 35.600)
[10 CFR 35.57, 35.490, 35.491, and 35.690] (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.490:

I attest that Jessica D. Arden, MD PhD has satisfactorily completed the 200 hours of
Name of Proposed Authorized User

classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

I attest that _____ has satisfactorily completed the 24 hours of
Name of Proposed Authorized User

classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

Second Section

For 35.690:

I attest that Jessica D. Arden, MD PhD has satisfactorily completed 200 hours of classroom
Name of Proposed Authorized User

and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

Third Section

For 35.690: (continued)

I attest that Jessica D. Arden, MD PhD has received training required in 35.690(c) for device
Name of Proposed Authorized User

operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

AND

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[10 CFR 35.57, 35.490, 35.491, and 35.690] (continued)

Fourth Section

I attest that Jessica D. Arden, MD PhD is able to independently fulfill the radiation safety-related duties as an authorized user for:

Name of Proposed Authorized User

Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

Fifth Section

Complete one of the following for attestation and signature:

 Authorized User:

I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s)
 35.400 Ophthalmic use of strontium-90 35.600 Gamma stereotactic radiosurgery unit(s)
 35.600 Remote afterloader unit(s) 35.57 for 35.400 and/or 35.600 uses, as applicable

OR

 Residency Program Director (for 35.490 and/or 35.690 only):

I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements for:

35.400 Manual brachytherapy sources 35.57 for 35.400 uses
 35.600 Teletherapy unit(s) 35.57 for teletherapy unit(s)
 35.600 Remote afterloader unit(s) 35.57 for remote afterloader unit(s)
 35.600 gamma stereotactic radiosurgery unit(s) 35.57 gamma stereotactic radiosurgery unit(s)

I affirm that this faculty member concurs with the attestation I am providing as program director.

I affirm that the residency training program is approved by the:

Residency Review Committee of the Accreditation Council for Graduate Medical Education
 Royal College of Physicians and Surgeons of Canada
 Council on Postdoctoral Training of the American Osteopathic Association

I affirm that the residency training program includes training and experience specified in:

35.490 35.690

Name of Facility:	Beaumont Health		
License/Permit Number:	21-01333-01		
Name of Preceptor or Residency Program Director (Typed or printed)	Telephone Number	Date	
H. Saada Jawad	(248) 551 - 7057	4/22/2021	
Signature			