

Ohio Department of Health
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

OAC 3701:1 58 51 – Manual Brachytherapy
 OAC 3701:1 58 52 – Ophthalmic Use of Strontium 90
 OAC 3701:1 58 71 Remote Afterloader, Teletherapy and Gamma stereotactic radiosurgery

Name of Proposed Authorized User _____

Requested Authorization(s): (check all that apply)

- | | |
|---|--|
| <input type="checkbox"/> OAC 3701:1-58-43 Manual brachytherapy Sources <input type="checkbox"/> OAC 3701:1-58-55 Gamma stereotactic radiosurgery unit(s) | <input type="checkbox"/> OAC 3701:1-58-55 Remote afterloader unit(s) - HDR <input type="checkbox"/> OAC 3701:1-58-55 Teletherapy <input type="checkbox"/> OAC 3701:1-58-72 Gamma Knife Perfexion <input type="checkbox"/> OAC 3701:1-58-72 Yttrium-90 (Y-90) Microspheres |
|---|--|

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

*In accordance with OAC 3701:1-58-22, the training and experience, including board certification, must have been obtained within seven years preceding the date of the 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**
 - a. Provide a copy of the board certification. (A list of approved board certifications is located at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>)
 - b. For OAC 3701:1-58-55, go to Table 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.
 - c. Skip to and complete Part II Preceptor Attestation

- 2. **Current OAC 3701:1-58-55 Authorized User Seeking Additional Authorization for 3701:1-58-55 Use(s) checked above**
 - a. Go to the table in section 3.e. to document training for new device.
 - b. Skip to and complete Part II Preceptor Attestation

- 3. **Training and Experience for Proposed Authorized User**
 - a. Classroom and Laboratory Training
 - OAC 3701:1-58-51 Manual Brachytherapy
 - OAC 3701:1-58-71 HDR, Gamma stereotactic Radiosurgery, Teletherapy

| Description of Training | Location of Training | Clock Hours | Dates of Training* |
|--|--------------------------------|-------------|--------------------|
| Radiation physics and instrumentation | | | |
| Radiation protection | | | |
| Mathematics pertaining to the use and measurement of radioactivity | | | |
| Radiation biology | | | |
| | Total hours of training | | |

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PART I – TRAINING AND EXPERIENCE (continued)

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

- b. Supervised Work and Clinical Experience for OAC 3701:1-58-51 – Manual Brachytherapy (if more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section)

| Supervised Work Experience | | Total Hours of Experience: | |
|---|--|-----------------------------------|--|
| Description of Experience must include: | Location of Experience & License Number of Facility | Dates of Experience | |
| Ordering , receiving, and unpacking radioactive materials safely and performing the related radiation surveys | | | |
| Checking survey meters for proper operation | | | |
| Preparing, implanting, and safely removing brachytherapy sources | | | |
| Maintaining running inventories of material on hand | | | |
| Using administrative controls to prevent a medical event involving the use of radioactive material | | | |
| Using emergency procedures to control radioactive materials | | | |

| Clinical experience in radiation oncology as part of an approved formal training program | Location of Experience & License Number of Facility | Dates of Experience* |
|---|---|-----------------------------|
| Residency Review Committee for Radiation Oncology of the ACGME | | |
| Royal College of Physicians and Surgeons of Canada | | |
| Committee on Postdoctoral Training of the American Osteopathic Association | | |
| Supervising Individual | License number listing supervising individual as an Authorized User | |

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PART I – TRAINING AND EXPERIENCE (continued)

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

d. Supervised Work and Clinical Experience for OAC 3701:1-58-71

- Remote Afterloader Teletherapy Unit(s) Gamma stereotactic radiosurgery unit(s)
 Gamma Knife Perfexion

| Supervised Work Experience | Total Hours of Experience | |
|--|--|-----------------------------|
| Description of Experience Must Include: | Location of Experience / License Number of Facility | Dates of Experience* |
| Reviewing full calibration measurements and periodic spot-checks | | |
| Preparing treatment plans and calculating treatment doses and times | | |
| Using administrative controls to prevent a medical event involving the use of radioactive material | | |
| Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console | | |
| Checking and using survey meters | | |
| Selecting the proper dose and how it is to be administered | | |

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PART I – TRAINING AND EXPERIENCE (continued)

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

d. Supervised Work and Clinical Experience for OAC 3701:1-58-71 (Continued)

| Clinical experience in radiation oncology as part of an approved formal training program | Location of Experience / License Number of Facility | Dates of Experience* |
|--|---|----------------------|
| Approved by: Residency Review | | |
| Residency Review Committee for Radiation Oncology of the ACGME Royal College of Physicians and Surgeons of Canada Committee on Postdoctoral Training of the American Osteopathic Association | | |
| Supervising Individual | License Number listing Supervising Individual as an Authorized User | |

e. For OAC 3701:1-58-55 use, describe the 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 | | | |
| Safety procedures for the device use | | | |
| Clinical use of the device | | | |
| Supervising Individual <i>If training was provided by supervising individual (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)</i> | License number listing the supervising individual as Authorized User | | |
| Authorized for the following types of use: <input type="checkbox"/> OAC 3701:1-58-55 remote afterloader <input type="checkbox"/> OAC 3701:1-58-55 teletherapy <input type="checkbox"/> OAC 3701:1-58-55 gamma stereotactic surgery unit <input type="checkbox"/> OAC 3701:1-58-72 Gamma Knife Perfexion | | | |

f. Provide completed Part II Preceptor Attestation.

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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, and verifies the 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.”

Part II- First Section

Check one of the following for each requested authorization:

For OAC 3701:1-58-51 - Manual Brachytherapy Sources:

Board Certification

I attest that (name of proposed AU) _____ has satisfactorily completed the requirements in OAC 3701:1-58-51(A)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under OAC 3701:1-58-43.

OR

Training and Experience

I attest that (name of proposed AU) _____ has satisfactorily completed the 200 hours of classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by OAC 3701:1-58-51(B)(1) and (B)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under OAC 3701:1-58-43.

For OAC 3701:1-58-52 - Ophthalmic Use of Strontium-90:

I attest that (name of proposed AU) _____ has satisfactorily completed the 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, and has used strontium-90 for ophthalmic treatment of 5 individuals, as required by OAC 3701:1-58-42(B), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Part II- Second Section

For OAC 3701:1-58-71 remote afterloader, teletherapy gamma stereotactic surgery unit

Board Certification

I attest that (name of proposed AU) _____ has satisfactorily completed the requirements in OAC 3701:1-58-71(A)(1).

OR

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PRECEPTOR ATTESTATION (Continued)

Training and Experience

I attest that (name of proposed AU) _____ has satisfactorily completed the 200 hours of classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by OAC 3701:1-58-71(B)(1) and (B)(2).

AND

Part II- Third Section

For OAC 3701:1-58-71 remote afterloader, teletherapy gamma stereotactic surgery unit :

I attest that (name of proposed AU) _____ has received training required in OAC 3701:1-58-71(C) for device operation, safety procedures, and clinical use for the type(s) of use which authorization is sought, as checked below.

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

AND

Part II- Fourth Section

I attest that (name of proposed AU) _____ has achieved a level of competency sufficient to function independently as an authorized user for:

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

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AND

Part II- Fifth Section

Complete the following for preceptor attestation and signature:

I meet the requirements in 3701:1-58-51, 3701:1-58-52 and 3701:1-58-71, as an authorized user for:

- OAC 3701:1-58-43 Use of sealed sources for manual brachytherapy
- OAC 3701:1-58-43 Ophthalmic use of strontium-90
- OAC 3701:1-58-55 Remote afterloader unit(s)
- OAC 3701:1-58-55 Teletherapy unit(s)
- OAC 3701:1-58-55 Gamma stereotactic radiosurgery unit(s)

| | |
|--------------------------------|---------------------|
| Preceptor Name | Preceptor Signature |
| Telephone number | Date |
| License Number / Facility Name | |

HEA-0125 SUPPLEMENT – FOR 3701:1-58-72 Y-90 Microspheres

Name of Proposed Authorized User: _____

Type of Y-90 Microsphere for which Authorization Sought:

- TheraSphere
- SIR-sphere

Authorized User Requirements for Y-90 Microspheres:

Yes No Authorized for
 3701:1-58-43 "Use of Manual Brachytherapy Sources" or
 3701:1-58-37 "Use of unsealed radioactive material for which a written directive is
 required"

OR

Yes No Meets the Training Requirements of
 3701:1-58-43 "Use of Manual Brachytherapy Sources" or
 3701:1-58-37 "Use of unsealed radioactive material for which a written directive is
 required"

OR

Yes No Is an interventional radiologist who meets the training and experience guidelines as
 follows:

- American Board of Radiology certification in diagnostic radiology and subspecialty certification in interventional radiology; or
- Three years supervised clinical experience in diagnostic radiology and one additional year of supervised clinical experience in interventional radiology.
- Completed 80 hours of classroom and laboratory training (document below)
- Completed supervised work experience (document below)

AND

Yes No Successfully completed training in the operation of the delivery system, safety
 procedures, and clinical use for each type of Y-90 microspheres for which
 authorization is sought by an authorized AU or vendor (document below).

Training Documentation:

| | Location of Training | Dates of Training | Clock Hours |
|--|----------------------|-------------------|-------------|
| Radiation physics and instrumentation | | | |
| Radiation protection | | | |
| Mathematics pertaining to the use and measurement of radioactivity | | | |
| Radiation biology | | | |
| Total Hours of Training | | | |

Supervised Work Experience:

| | Location of Experience | Dates of Experience |
|--|------------------------|---------------------|
| Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys. | | |
| Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters. | | |
| Evaluation of each patient or human research subject for the dose/activity of Y-90 microspheres to be administered to each treatment site. | | |
| Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject. | | |
| Using administrative controls to prevent a medical event involving the use of byproduct material. | | |
| Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures. The procedures should address any special circumstances that may be encountered, such as electrostatic charge of microspheres and proper survey instrument and survey technique for beta emitters. | | |
| Follow up and review of each patient's or human research subject's case history for Y-90 microspheres. | | |

Supervising Individual: _____ Signature: _____

License Number Listing Supervising Individual as an AU: _____

- Supervising Individual Meets the OAC Requirements for 3701:1-58-72 Use of Y-90 Microspheres and attests that the above named individual has achieved a level of competency sufficient to function independently as an authorized user for the use of Y-90 Microspheres.

Device Training:

| | Location of Training | Dates of Training | Clock Hours |
|--|----------------------|-------------------|-------------|
| Operation of the delivery system, safety procedures, and clinical use for each type of Y-90 microspheres for which authorization is sought by an authorized AU or vendor | | | |

Supervising Individual: _____ Signature: _____

License Number Listing Supervising Individual as an AU
or Vendor Name and Representative: _____

- Supervising Individual Meets the OAC Requirements for 3701:1-58-72 Use of Y-90 Microspheres