RADIOACTIVE MATERIALS AUTHORIZED USER
TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

INSTRUCTIONS: Before completing this form, review the specific training requirements of Title 10 of the Code of Federal Regulations (10 CFR), Part 35 (January 1, 2013 Edition) as adopted in Title 17 of the California Code of Regulations, Section 30195. All training and experience applicable to this application must have been obtained within 7 years of the date of this application, per 10 CFR §35.59. Mail completed and signed form, in duplicate, to: California Department of Public Health, Radiologic Health Branch, MS 7610, Licensing Section, P.O. Box 997414, Sacramento, CA 95899-7414. For more information, go to **the Radiologic Health Branch website at http://www.cdph.ca.gov/rhb** or phone (916) 327-5106.

PART I: Amendment Request to Add AU

Please add: _____

to Radioactive Materials License Number: _____ for the authorizations indicated below.

Name and title of Senior Management/Radiation Safety Officer (RSO): _____

Signature of senior management/RSO: _____

Date: _____

Specify all use authorizations requested:

10 CFR 35 Subpart D - Unsealed Radioactive Material—Written Directive Not Required
For diagnostic studies:

- ☐ 35.100 Use for uptake, dilution and excretion studies for which a written directive is not required.
- ☐ 35.200 Use for imaging and localization studies for which a written directive is not required.
- ☐ 35.200 Use for imaging and localization studies for which a written directive is not required- cardiac studies only

10 CFR 35 Subpart E - Unsealed Radioactive Material—Written Directive Required
For unsealed therapy:

- ☐ 35.300 Use for which a written directive is required.

  OR for subsection(s) under 35.300:

  - ☐ Oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (less than or equal to 33 millicuries) only.
  - ☐ Oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (greater than 33 millicuries) only.
  - ☐ Parenteral administration of any beta emitter, any photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required only.
  - ☐ Parenteral administration of any other radionuclide, for which a written directive is required only.

10 CFR 35 Subpart F- Manual Brachytherapy
For manual brachytherapy using sealed sources, seeds and implants:

☐ 35.400 Use of sources for manual brachytherapy.

For specific radionuclides and uses under 35.400:

☐ Ophthalmic use of Strontium-90 for eye applicator.

10 CFR 35 Subpart G - Sealed Sources for Diagnosis

☐ 35.500 Use of sealed sources for diagnosis.

10 CFR 35 Subpart H - Photon Emitting Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units, excluding Perfexion™ GSR
For HDR, teletherapy and GSR:

Use of sealed sources in a:

☐ 35.600 Remote afterloader unit (i.e., HDR)

☐ 35.600 Teletherapy Unit

☐ 35.600 Gamma stereotactic radiosurgery unit (GSR)

10 CFR 35 Subpart K - Other Uses (35.1000)
Do not use this form for 35.1000, including Beta-Cath™ IVB, Gliasite®, radioactive seed localization (RSL), Perfexion™ GSR, Epi-Rad90™, seedSelectron®, and microspheres. Refer to the applicable Nuclear Regulatory Commission (NRC) Guidance for the specific training requirements for each modality permitted by 10 CFR 35.1000. Submit the required training and experience documentation separately. For additional information or copies of the appropriate NRC guidance, please contact Radiologic Health Branch (RHB).

PART II: Training and Experience

This part is to be completed for the training and experience of the PROPOSED USER: :

1. For all uses, have you been listed on a California Radioactive Material License (RML) within the last 7 years for all authorization(s) requested in Part I?

☐ Yes:

Provide the RML Number*: _____

If authorized under a broad scope RML, provide a letter from the RSO for that RML stating your authorizations under that RML. No further information is required on this form.

☐ No: If you have been listed on a California Radioactive Material License within the last 7 years for authorizations other than those requested in Part I, provide the RML Number*: _____ then proceed to Number 2 below. If authorized under a broad scope RML, provide a letter from the RSO for that RML stating your authorizations.

*Provide RSO authorization letters for any broad scope RML/license/permit, as applicable, and complete signed copies of any non-California license/permit referenced.

2. For all uses, have you been listed on a Master Materials License, NRC or Agreement State License/ Permit within the last 7 years for authorization(s) equivalent to those requested in Part I?

☐ Yes: provide a complete copy of the license or permit. If authorized under a broad scope license/permit, provide a letter from the RSO for that license/permit stating your authorizations in addition to a complete copy of that license/ permit. No further information is required on this form.

☐ No: If you have been listed on a Master Materials License, NRC or Agreement State License/Permit within the last 7 years for any authorizations other than those requested on Page 1, provide a complete copy of the license/permit then proceed to Number 3 below. If authorized under a broad scope license/permit, provide a letter from the RSO for that RML stating your authorizations in addition to a complete copy of that license/permit.

3. For the use(s) requested, have you been certified by any of the following specialty boards within the last 7 years:

SPECIALTY BOARD MUST BE LISTED ON THE NRC RECOGNIZED CERTIFICATION LIST available at the NRC website at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html. Contact RHB at (916) 440-7976 if link does not work.

a) For 35.100 (specialty boards listed under 35.200 and 35.300 are also accepted):

☐ Yes: provide a copy of the certificate and proceed to Part III, Preceptor Attestation.

☐ No: proceed to Number 4.

b) For 35.200 (specialty boards listed under 35.300 are also accepted):

☐ Yes: provide a copy of the certificate and proceed to Part III, Preceptor Attestation.

☐ No: proceed to Number 4.

c) For all use of unsealed material requiring a written directive under 35.300:

☐ Yes: provide a copy of the certificate, skip to and answer Numbers 4(e)(1) to 4(e)(4) only, and then proceed to Part III, Preceptor Attestation.

☐ No: proceed to Number 4.

d) For 35.300 for oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) only:

☐ Yes: provide a copy of the certificate, skip to and answer Number 4(e)(1) only and then proceed to Part III, Preceptor Attestation

☐ No: proceed to Number 4.

e) For 35.300 for oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) only:

☐ Yes: provide a copy of the certificate, skip to and answer Number 4(e)(2) only and then proceed to Part III, Preceptor Attestation.

☐ No: proceed to Number 4.

*Provide RSO authorization letters for any broad scope RML/license/permit, as applicable, and complete signed copies of any non-California license/permit referenced.

f) For 35.300 for parenteral administration of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, or parenteral administration of any other radionuclide for which a written directive is required only:

☐ Yes: provide a copy of the certificate, skip to and answer the following:

1. For beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV: Number 4(e)(3) only and
2. For any other radionuclide: Number 4(e)(4) only and

Proceed to Part III, Preceptor Attestation.

☐ No: proceed to Number 4.

g) For 35.400:

☐ Yes: provide a copy of the certificate and proceed to Part III, Preceptor Attestation. If requesting Sr-90 eye applicator, complete Number 4(i) and Part III, Preceptor Attestation.

☐ No: proceed to Number 4.

h) For 35.500: no certification required. Proceed to Number 4.

i) For 35.600:

☐ Yes: provide a copy of the certificate, provide the following information, and then proceed to Part III, Preceptor Attestation (attach additional pages if necessary):

1. Date(s) of training for device operation, safety procedures and clinical use: _____
2. Training provider/supervising individual: _____
3. Location of training/facility name: _____
4. License/Permit Number on which the supervising individual is listed as an authorized user for the use(s) requested*: _____ State: _____

☐ No: If you have been listed on a California Radioactive Material License within the last 7 years as an AU, AMP or ANP for authorizations other than those requested on Page 1, provide the RML

4. Answer the following for the uses requested:
For 35.100: Answer a., b. and c. below, and then proceed to Part III, Preceptor Attestation.
For 35.200: Answer a., b., c. and d. below, and then proceed to Part III, Preceptor Attestation.
For 35.300: Answer a., b. and e. below, and then proceed to Part III, Preceptor Attestation.
For 35.400: Answer a., f., h. and i. below, and then proceed to Part III, Preceptor Attestation.
For 35.500: Answer a. and j. below. No further information is required.
For 35.600: Answer a., g., h. and j. below, and then proceed to Part III, Preceptor Attestation.

a.) Classroom and laboratory training applicable to the use(s) requested in the following areas:

Subject Area	Total Hours
Radiation physics and instrumentation	
Radiation protection	
Mathematics pertaining to the use and measurement of radioactivity	
Chemistry of radioactive material	
Radiation biology	
Total combined hours of classroom and laboratory training	

*Provide RSO authorization letters for any broad scope RML/license/permit, as applicable, and complete signed copies of any non-California license/permit referenced.

b) Work experience under a preceptor authorized for the uses requested involving the following:

Subject Area	Total Hours
Ordering, receiving and unpacking radioactive materials safely and performing related surveys	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	
Calculating, measuring, and safely preparing patient or human research subject dosages	
Using administrative controls to prevent a medical event involving the use of unsealed radioactive material	
Using procedures to contain spilled radioactive material safely and using proper decontamination procedures	
Total combined hours of work experience	

c.) Did work experience obtained under an Authorized User authorized for the uses requested involve administering dosages of radioactive drugs to patients or human research subjects for which a written directive was not required?

Yes or No _____

d.) Did the work experience obtained under an Authorized User authorized for the uses requested involve elution of generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs?

Yes or No _____

e.) (1.) Number of clinical cases of oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) involving personal participation: _____

Supervising individual: _____

Location of experience/facility name and date: _____

License/Permit Number on which the supervising individual is listed as an authorized user for the use requested*: _____ State: _____

(2.) Number of clinical cases of oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) involving personal participation: _____

Supervising individual: _____

Location of experience/facility name and date: _____

License/Permit Number on which the supervising individual is listed as an authorized user for the use requested*: _____ State: _____

*Provide RSO authorization letters for any broad scope RML/license/permit, as applicable, and complete signed copies of any non-California license/permit referenced.

(3.) Number of clinical cases of parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required (attach additional pages if necessary) - specify radionuclides: _____

Supervising individual: _____

Location of experience/facility name and date: _____

License/Permit Number on which the supervising individual is listed as an authorized user for the use requested*: _____ State: _____

(4.) Number of clinical cases of parenteral administration of any other radionuclide, for which a written directive is required (attach additional pages if necessary) - specify radionuclides: _____

Supervising individual: _____

Location of experience/facility name and date: _____

License/Permit Number on which the supervising individual is listed as an authorized user for the use requested*: _____ State: _____

f.) Work experience under an Authorized user authorized for the use(s) requested involving the following:

Subject Area	Total Hours
Ordering, receiving and unpacking radioactive materials safely and performing related radiation surveys	
Checking survey meters for proper operation	
Preparing, implanting, and 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 material	
Total combined hours of work experience	

g.) Work experience under an Authorized User authorized for the use(s) requested involving the following:

Subject Area	Total Hours
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 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	
Total combined hours of work experience	

h.) Did you complete 3 years of supervised clinical experience in radiation oncology, under an Authorized User authorized for the uses requested, as part of a formal training program approved by the Residency Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association?

Yes or No _____

*Provide RSO authorization letters for any broad scope RML/license/permit, as applicable, and complete signed copies of any non-California license/permit referenced.

i.) Have you obtained supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic or private practice that includes the use of Strontium-90 for the ophthalmic treatment of at least 5 individuals, including the following: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; follow-up and review of each individual's case history?

Yes or No _____ If yes, identify device: _____

j.) Have you completed training for device operation, safety procedures and clinical use for the authorization(s) requested provided by the vendor for new users or supervised by an authorized user/authorized medical physicist, as appropriate, who is authorized for the use(s) requested?

Yes or No _____ If yes, identify device: _____

Supervising individual: _____

Location of experience/facility name and date: _____

License/Permit Number on which the supervising individual is listed as an authorized user for the use requested*: _____ State: _____

PART III: Preceptor Attestation

This part is to be completed by the PRECEPTOR AUTHORIZED USER:

I hereby attest that the proposed user has satisfactorily completed the applicable training requirements of Title 10 of the Code of Federal Regulations Part 35 (January 1, 2013 Edition), as adopted under Title 17 of the California Code of Regulations, Section 30195, for the use(s) requested, and has achieved a level of competency sufficient to function independently as an authorized user of each type of use the proposed user is requesting authorized user status.

I hereby attest that I am an authorized user on a California Radioactive Material License, Master Materials License or NRC/ Agreement State License/Permit for the use(s) requested.

Preceptor Authorized User Name (print): _____

Date: _____

Signature: _____

(Preceptor Attestation not valid without original signature)

Telephone Number: _____

License/Permit Number preceptor is listed as RSO for the use(s) requested:

CA Radioactive Material License*: _____

Master Materials License, NRC or Agreement State License/Permit*: _____

Provide a complete copy of that license/permit.

*Provide RSO authorization letters for any broad scope RML/license/permit, as applicable, and complete signed copies of any non-California license/permit referenced.