RHB FORM 313A (AU) **CALIFORNIA DEPARTMENT OF PUBLIC HEALTH**
(7-2010)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, 35.300, and 35.500)
[10CFR 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, and 35.590]

Name of Proposed Authorized User	State or Territory Where Licensed

Requested Authorizations *(check all that apply)*

☐ 35.100 Uptake, dilution, and excretion studies

☐ 35.200 Imaging and localization studies

☐ 35.300 Use of unsealed byproduct material for which a written directive is required

OR *(select one of the subset of clinical uses for 35.300)*

☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ 35.300 Parenteral administration of any beta-emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ 35.300 Parenteral administration of any other radionuclide for which a written directive is required

☐ 35.500 Sealed sources for diagnosis (specify device_____)

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. <u>Board Certification</u>**

a. Provide a copy of the board certification in appropriate specialty.
b. If using only 35.500 materials, stop here. If using only 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.
c. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience. Complete Part II Preceptor Attestation.
d. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Complete Part II Preceptor Attestation.

☐ **2. <u>Current Authorized User Seeking Additional Authorization</u>**

a. Authorized User on California Radioactive Materials License Number: _____, under the requirements below or equivalent Agreement State requirements (attach a copy of the NRC or Agreement State license). Check all that apply.

☐ 35.190 ☐ 35.290

☐ 35.390 **or** ☐ 35.392 **and/or** ☐ 35.394

☐ 35.490 **or** ☐ 35.491 only ☐ 35.690

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b. If currently authorized under 35.100 requesting 35.200 authorization, provide documentation on classroom and laboratory training and supervised work experience. The tables in sections 3.a. and 3.b. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.100 and/or 35.200 and requesting 35.300 authorization, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

d. If currently authorized for 35.390 and requesting authorization for 35.290 only, provide documentation on generator experience in table 3.b.

e. If currently authorized for a subset of clinical uses under 35.300, requesting additional subset of clinical uses, provide documentation on additional required supervised clinical case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation. If requesting 35.100, 35.200, and/or 35.300 authorization(s), provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

f. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

g. If currently authorized under any of the above uses and seeking 35.500 authorization, provide documentation on training on use of the requested device(s). Table in section 3.d. may be used to document this experience.

☐ **3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training (completion of this table is required for all authorizations)

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			
Chemistry of byproduct material for medical use (not required for 35.590)			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience (completion of this table is not required for 35.590).
(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 or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		☐ Yes ☐ No	

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Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	
Administering dosages of radioactive drugs to patients or human research subjects (not required for 35.390, 35.392, 35.394, and 35.396)		☐ Yes ☐ No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs (required for 35.290)		☐ Yes ☐ No	

Supervising Individual	License/Permit Number listing supervising individual as an authorized user (if not listed on a California Radioactive Materials License, attach a copy of NRC or Agreement State license)

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***.

☐ 35.190
☐ 35.290
☐ 35.390
☐ 35.390 + generator experience in 35.290(c)(1)(ii)(G)
☐ 35.392
☐ 35.394
☐ 35.396

With experience administering dosages of:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive

☐ Parenteral administration of any other radionuclide requiring a written directive

**Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

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c. Supervised Clinical Case Experience (completion of this table is not required for 35.190, 35.290, and 35.590)
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required (List radionuclides)			

Supervising Individual	License/Permit Number listing supervising individual as an authorized user (if not listed on a California Radioactive Materials License, attach a copy of NRC or Agreement State license)

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***.

☐ 35.390
☐ 35.392
☐ 35.394
☐ 35.396

With experience administering dosages of:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive

☐ Parenteral administration of any other radionuclide requiring a written directive

**Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

e. For 35.500 uses only, stop here. For All other uses, complete 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, 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

For 35.190: Check one of the following and skip to Third Section

Board Certification

☐ I attest that _____ has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements 10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, as required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290: Check one of the following and skip to Third Section

Board Certification

☐ I attest that _____ has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements 10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 10 CFR 35.200.

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 700 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 80 hours of classroom and laboratory training, as required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 10 CFR 35.200.

For 35.390: Check one of the following and continue to Second Section

Board Certification

☐ I attest that _____ has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements in 35.390(a)(1).

OR

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Training and Experience

☐ I attest that _____ has satisfactorily completed the 700 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390(b)(1).

OR

☐ I attest that _____ has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements in 35.290(a)(1) *and* additional training as required by 10 CFR 35.390(b)(1).

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

Check one of the following and continue to Second Section

☐ I attest that _____ has satisfactorily completed the 80 hours of training and
Name of Proposed Authorized User

laboratory training, as required by 10 CFR 35.392 (c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

Check one of the following and continue to Second Section

☐ I attest that _____ has satisfactorily completed the 80 hours of training and
Name of Proposed Authorized User

laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

For 35.396: Check one of the following and continue to Second Section

Board Certification:

☐ I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

OR

Current 35.490 or 35.690 Authorized User:

☐ I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690 or
Name of Proposed Authorized User

equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

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☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

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Second Section (required for 35.390, 35.392, 35.394, and 35.396 only)

Complete and continue to Third Section

☐ I attest that _____ has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)(G) listed below, and has satisfactorily achieved a level of competency to function independently as an authorized user for:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive

☐ Parenteral administration of any other radionuclide requiring a written directive

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Third Section

Complete the following for preceptor attestation and signature:

☐ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.190 ☐ 35.290 ☐ 35.390 ☐ 35.390+ generator experience

☐ 35.392 ☐ 35.394 ☐ 35.396

Complete the following for 35.390, 35.392, 35.394, and 35.396.

☐ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive

☐ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date

License/Permit Number and Facility Name (if not a California Radioactive Materials License, attach a copy of NRC or Agreement State license)