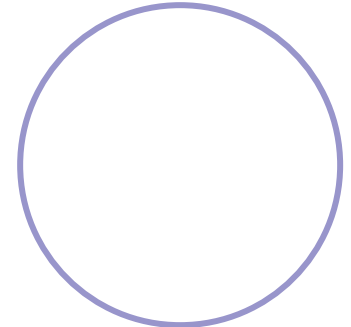
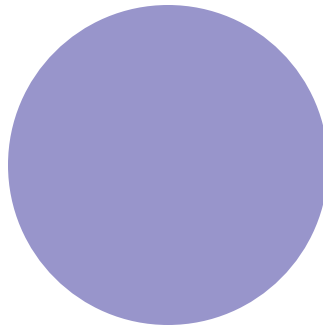
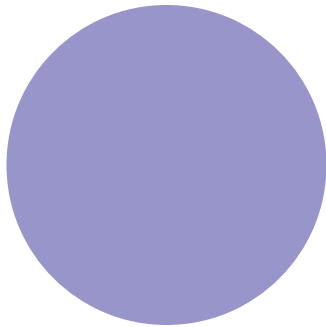




Review of Part 35 Groups and Training Requirements

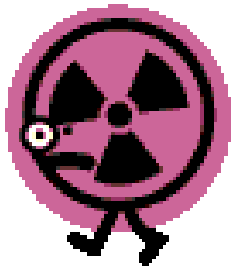




Review of Part 35 Groups and Training Requirements



Group Changes
Part 35 Authorizations



WAIT!

The CA equivalent groups listed in this presentation are rough conversions only.

Review of Part 35 Groups and Training Requirements

- 35.100: Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required.
 - CA Group 1
- 35.200: Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required.
 - Includes generators.
 - CA Groups 2 and 3
- 35.300: Use of unsealed radioactive material for which a written directive is required.
 - CA Groups 2 and 3 using more than 30 μCi of I-131
 - CA Groups 4 and 5



Review of Part 35 Groups and Training Requirements

- 35.400: Use of sources for manual brachytherapy.
 - CA Group 6
- 35.500: Use of sealed sources for diagnosis.
 - CA Group 7
- 35.600: Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.
 - CA Groups 6 and 8, excluding Leksell Gamma Knife Perfexion



Review of Part 35 Groups and Training Requirements

- 35.1000: Other medical uses of radioactive material or radiation from radioactive material.
 - CA Groups 6 and 8.



Review of Part 35 Groups and Training Requirements

Training Requirements



Review of Part 35 Groups and Training Requirements

- 35.190: Training for uptake, dilution, and excretion studies
- 35.290: Training for imaging and localization studies



Review of Part 35 Groups and Training Requirements

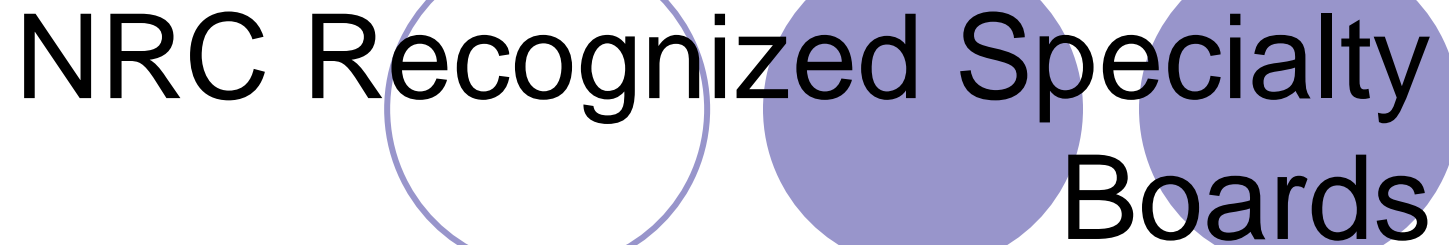
- 35.390: Training for use of unsealed radioactive material for which a written directive is required
- 35.392: Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
* Imaging and localization studies using more than 30 μCi of I-131 must meet these requirements in addition to 35.290.
- 35.394: Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)
- 35.396: Training for the parenteral administration of unsealed radioactive materials requiring a written directive



Review of Part 35 Groups and Training Requirements

- 35.490: Training for use of manual brachytherapy sources
- 35.491: Training for ophthalmic use of strontium-90
- 35.590: Training for use of sealed sources for diagnosis
- 35.690: Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
- 35.1000: Evaluated as applicable for each use.





NRC Recognized Specialty Boards

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

Evaluated and Certified by NRC!

Specialty Boards Recognized By NRC

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

- 35.190 (Group 1)

- ABNM with “United States” from October 20, 2005 forward
- Any recognized boards for 35.290 and 35.390



Specialty Boards Recognized By NRC

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

- 35.290 (Groups 2 and 3)
 - CBNC with “for Physicians Residing in the United States” from October 29, 2000 until 2006
 - CBNC with “for Physicians Trained in the United States” from 2006 forward
 - ABNM with “United States” from October 20, 2005 forward
 - AOBDR in *Diagnostic Radiology* from July 1, 2000 forward
 - AOBNM in *Nuclear Medicine* from May 18, 2006 forward
 - ABR in *Diagnostic Radiology* with “AU Eligible” from June 2006 forward
 - Any recognized board for 35.390



Specialty Boards Recognized By NRC

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

- 35.390 (Groups 4 and 5)
 - ABNM with “United States” from October 20, 2005 forward
 - ABR in *Radiation Oncology* with “AU Eligible” from June 2007 forward
 - AOBRE in *Radiation Oncology* from May 1, 2007 forward
 - These also satisfy 35.392 and 35.394
- 35.392 (Group 4; ≤ 33 mCi I-131 Only or Diagnostic I-131 > 30 μ Ci)
- 35.394 (Group 5; > 33 mCi I-131 Only)



Specialty Boards Recognized By NRC

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

- 35.390 (Groups 4 and 5)
- 35.392 (Group 4; ≤ 33 mCi I-131 Only or Diagnostic I-131 > 30 μ Ci)
 - Any of the three from 35.390: ABNM with “United States” from October 20, 2005 forward, ABR in *Radiation Oncology* with “AU Eligible” from June 2007 forward, AOB in *Radiation Oncology* from May 1, 2007 forward
 - AOB in *Diagnostic Radiology* from July 1, 2000 forward
 - ABR in *Diagnostic Radiology* with “AU Eligible” from June 2006 forward
 - ABR in *Diagnostic Radiology* with “AU Eligible” from June 2011 forward (same as 35.394)
- 35.394 (Group 5; > 33 mCi I-131 Only)



Specialty Boards Recognized By NRC

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

- 35.390 (Groups 4 and 5)
- 35.392 (Group 4; ≤ 33 mCi I-131 Only or Diagnostic I-131 > 30 μ Ci)
- 35.394 (Group 5; > 33 mCi I-131 Only)
 - Any of the three from 35.390: ABNM with “United States” from October 20, 2005 forward, ABR in *Radiation Oncology* with “AU Eligible” from June 2007 forward, AOB in *Radiation Oncology* from May 1, 2007 forward
 - ABR in *Diagnostic Radiology* with “AU Eligible” from June 2011 forward



Specialty Boards Recognized By NRC

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

- 35.490 (Group 6)
 - ABR in *Radiation Oncology* with “AU Eligible” from June 2007 forward
 - AOBRE in *Radiation Oncology* from May 1, 2007 forward
- 35.590 (Group 7)
 - None specified
- 35.690 (Group 6)
 - ABR in *Radiation Oncology* with “AU Eligible” from June 2007 forward
 - AOBRE in *Radiation Oncology* from May 1, 2007 forward



Supervisors, Preceptors, and Written Attestations

- All work experience must be supervised by a qualified AU. This means the supervising AU meets the qualifications described in the appropriate sections of Part 35.
- Part 35 requires written attestation in many of the pathways. Preceptor must meet the qualifications described in Part 35.
- Can have multiple supervisors and/or preceptors.
- No longer need to be board certified.

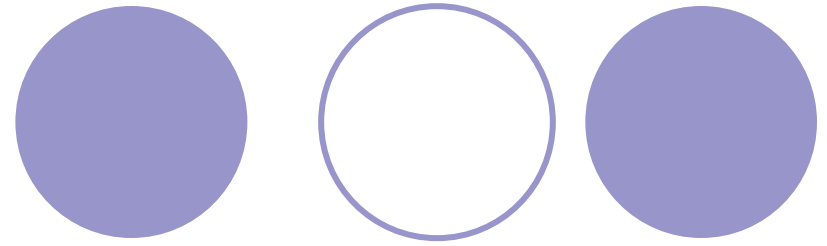


Training Requirements

35.190 (Group 1)



35.190 (Group 1)



1.

Recognized board certification

Written Attestation

2.

AU under 35.290, 35.390

3.

**60 hours of training and experience,
including minimum of 8
hours of classroom and
laboratory training (see 35.190
for detailed T&E requirements)**

Written Attestation



Training Requirements

35.290 (Groups 2 and 3)



35.290 (Groups 2 and 3)

1.

Recognized board certification

 —

Written Attestation
2.

AU under 35.390

 —

Work experience
eluting generator systems
3.

700 hours of training and experience,
including a minimum of 80 hours of
classroom and laboratory training (see
35.290 for detailed T&E requirements)

 —

Written Attestation



Training Requirements

35.390 (Groups 4 and 5)

35.392*, 35.394, 35.396

*Includes imaging and localization studies
using greater than 30 μCi of I-131



35.390 (Groups 4 and 5)

1.

Recognized board certification

Written Attestation

Three cases of:

Oral administration of greater than 33 mCi of I-131 (three of these satisfies the ≤ 33 mCi requirement)

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

AND/OR

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



35.390 (Groups 4 and 5)

2.

700 hours of training and experience,
including a minimum of 200 hours of
classroom and laboratory training (see
35.390 for detailed T&E requirements)

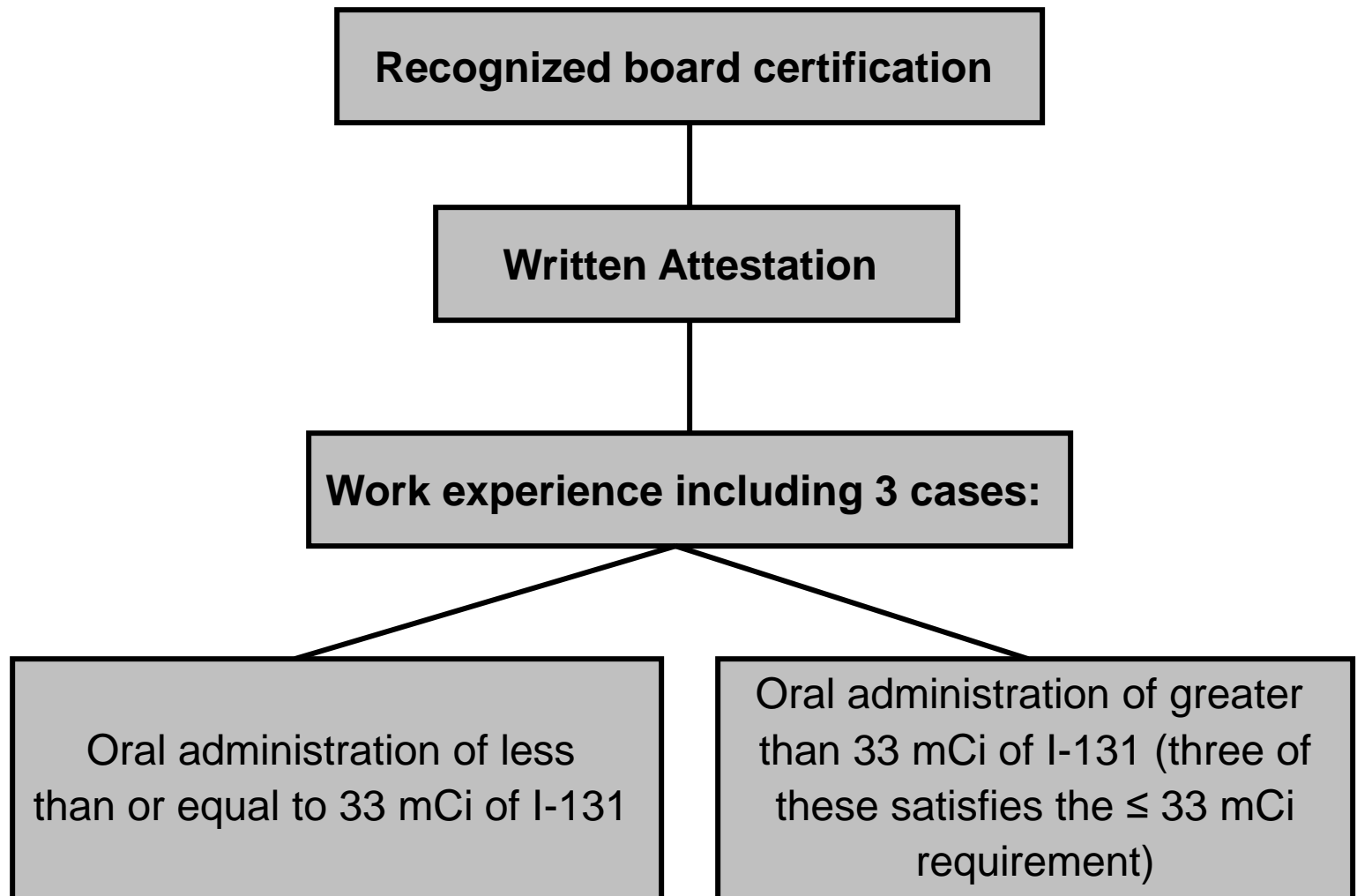
Work experience including 3 cases

Written Attestation



35.392 (Group 4; ≤ 33 mCi I-131 only or Groups 2 and 3; diagnostic I-131 > 30 μ Ci)

1.



35.392 (Group 4; ≤ 33 mCi I-131 only or Groups 2 and 3; diagnostic I-131 > 30 μ Ci)

2.

AU under 35.390 or 35.394

3.

80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive

Work experience including 3 cases:

Written Attestation

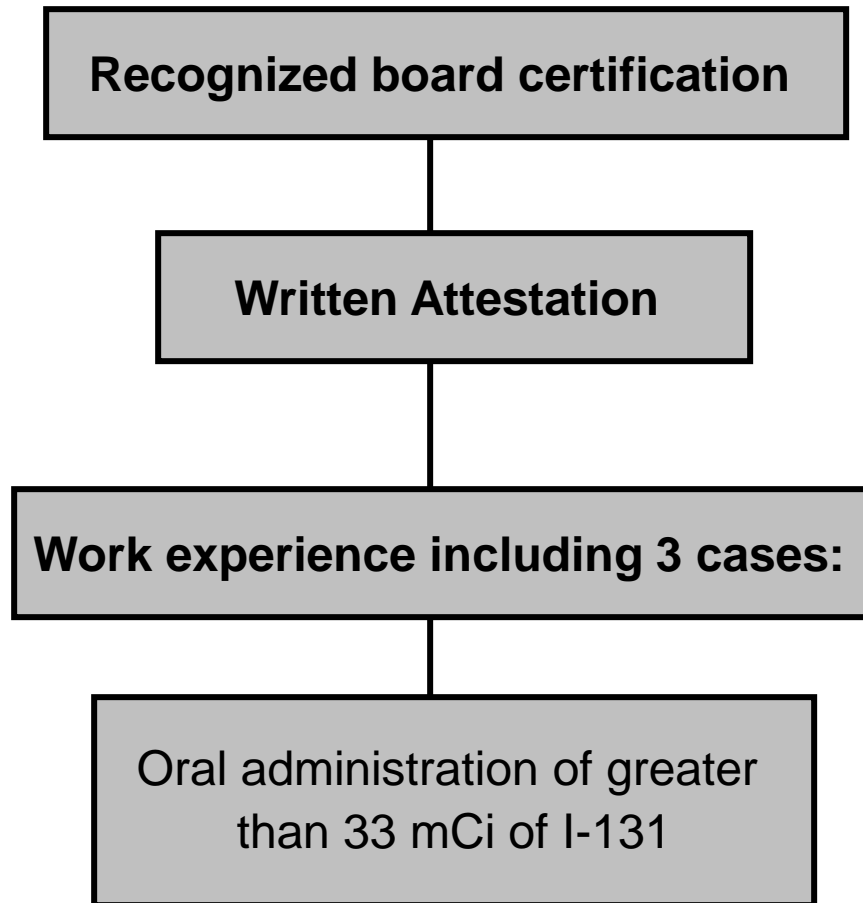
Oral administration of less than or equal to 33 mCi of I-131

Oral administration of greater than 33 mCi of I-131 (three of these satisfies the ≤ 33 mCi requirement)



35.394 (Group 5; > 33 mCi I-131 only)

1.



35.394 (Group 5; > 33 mCi I-131 only)

2.

AU under 35.390

3.

80 hours of classroom and laboratory training,
applicable to the medical use of sodium
iodide I-131 for procedures requiring
a written directive

Work experience including 3 cases:

Written Attestation

Oral administration of greater
than 33 mCi of I-131



35.396 (Groups 4 and 5; other than I-131)

1.

Recognized board certification for 35.490 or 35.690

80 hours of classroom and laboratory training,
applicable to parenteral administrations, for
which a written directive is required, of any beta
emitter, or any photon-emitting radionuclide with
a photon energy less than 150 keV, and/or
parenteral administration of any other radionuclide
for which a written directive is required

Work experience including 3 cases:

Written Attestation



35.396 (Groups 4 and 5; other than I-131)

2.

AU under 35.390

3.

**AU under 35.490
or 35.690**

80 hours of classroom and laboratory training,
applicable to parenteral administrations, for which a
written directive is required, of any beta emitter, or
any photon-emitting radionuclide with a photon
energy less than 150 keV, and/or
parenteral administration of any other radionuclide
for which a written directive is required

Work experience including 3 cases:

Written Attestation



Training Requirements

35.490 (Group 6)

35.491



35.490 (Group 6, manual brachytherapy)

1.

Recognized board certification

Written Attestation

2.

Structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources including 200 hours of classroom and laboratory training and 500 hours of work experience

3 years of supervised clinical experience in radiation oncology

Written Attestation



35.491 (Sr-90 Eye Applicator)

1.

AU under 35.490

2.

24 hours of classroom and laboratory training applicable to the medical use of Sr-90 for ophthalmic radiotherapy

supervised clinical training in ophthalmic radiotherapy

Written Attestation



Training Requirements

35.590 (Group 7)



35.590 (Group 7; sealed sources for diagnosis)

1.

Any NRC recognized board certification

Device Training

2.

8 hours of classroom and laboratory training
in basic radionuclide handling techniques
specifically applicable to the use of the
device

NO PRECEPTOR ATTESTATION!

*Physicians, dentists, and podiatrists

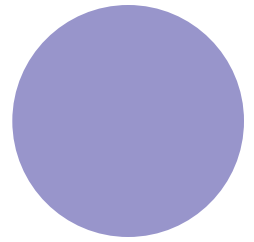
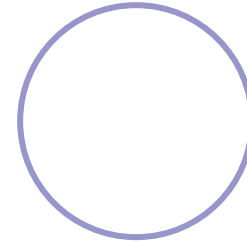
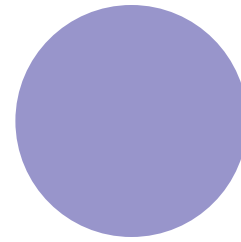


Training Requirements

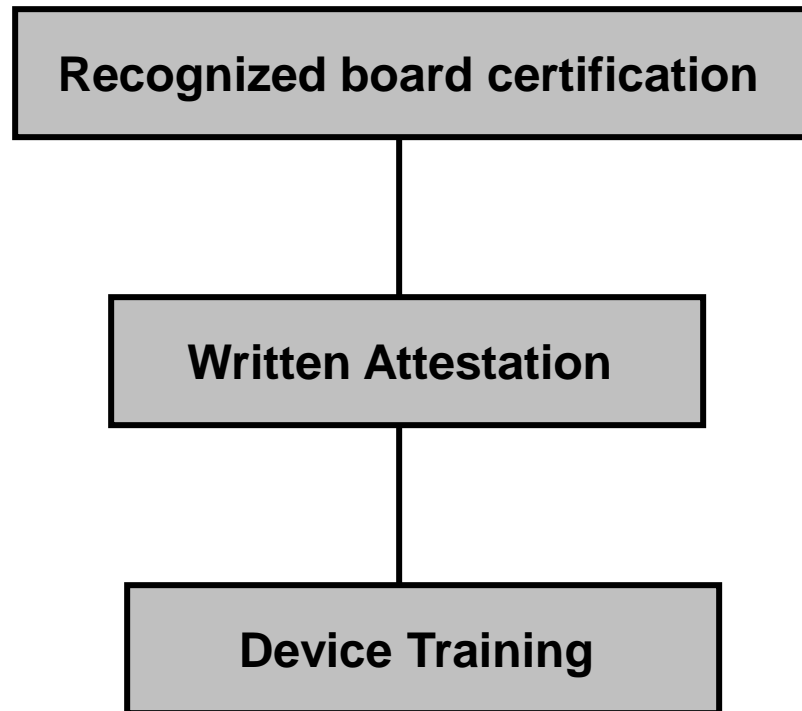
35.690 (Group 6)



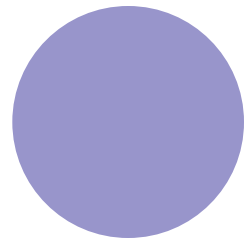
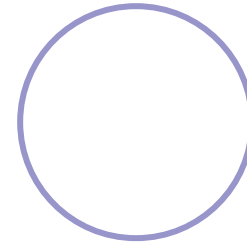
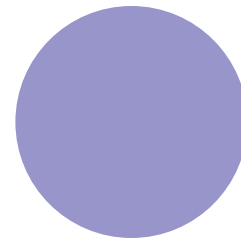
35.690 (Group 6)



1.



35.690 (Group 6)



2.

Structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit including 200 hours of classroom and laboratory training and 500 hours of work experience

3 years of supervised clinical experience in radiation oncology

Device Training

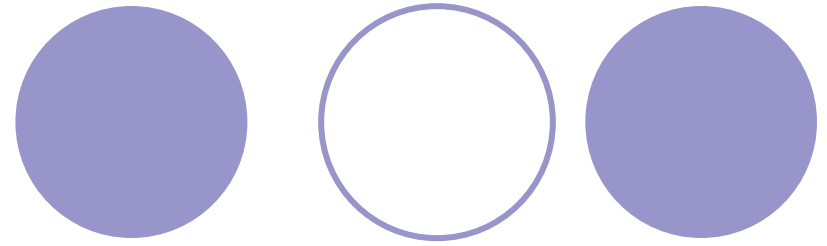
Written Attestation



T&E Forms

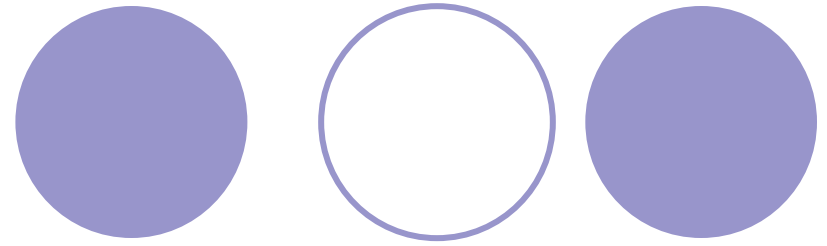


Authorized Users



- All T&E must be obtained in the last seven years.
- There are FOUR forms to document NEW AU Training and Experience.
 - RHB 313A(AUD)
 - RHB 313A(AUT)
 - RHB 313A(AUS)
 - RHB 313A(AU)
- If the user has been board certified or listed on a license over seven years ago, the user must have had related continuing education and experience since the required T&E was completed.
- There is ONE form to document REFRESHER AU Training and Experience.
 - RHB 313A(CE)

RHB 313A



- **AUD** for 100, 200, and 500.
 - Groups 1, 2, and 3.
- **AUT** for 300.
 - I-131 > 30 μ Ci for imaging and localization studies
 - Groups 4 and 5
- **AUS** for 400 and 600
 - Groups 6 and 8
- **AU** for 100, 200, 300, and 500.
 - Groups 1, 2, 3, 4 and 5.
- **CE** for **refresher training** for any authorization.

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- Designed for 35.100, 35.200, 35.300 and 35.500

For 2008 10 CFR 35, visit http://www.access.gpo.gov/nara/cfr/waisidx_08/10cfr35_08.html.

RHB FORM 313A (AU) (7-2010)		CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
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 (<i>check all that apply</i>)		
<input type="checkbox"/> 35.100 Uptake, dilution, and excretion studies		
<input type="checkbox"/> 35.200 Imaging and localization studies		
<input type="checkbox"/> 35.300 Use of unsealed byproduct material for which a written directive is required		
OR (<i>select one of the subset of clinical uses for 35.300</i>)		
<input type="checkbox"/> 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)		
<input type="checkbox"/> 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)		
<input type="checkbox"/> 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		
<input type="checkbox"/> 35.300 Parenteral administration of any other radionuclide for which a written directive is required		
<input type="checkbox"/> 35.500 Sealed sources for diagnosis (specify device _____)		

RHB 313A(AU)

For 2008 10 CFR 35, visit http://www.access.gpo.gov/nara/cfr/waisidx_08/10cfr35_08.html.

RHB FORM 313A (AU) (7-2010)		CALIFORNIA DEPARTMENT OF PUBLIC HEALTH	
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 <i>(check all that apply)</i>			
<input type="checkbox"/> 35.100 Uptake, dilution, and excretion studies			
<input type="checkbox"/> 35.200 Imaging and localization studies			
<input type="checkbox"/> 35.300 Use of unsealed byproduct material for which a written directive is required			
OR <i>(select one of the subset of clinical uses for 35.300)</i>			
<input type="checkbox"/> 35.300 Oral administration of sodium iodide I 131 requiring a written directive in quantities less than or equal to 1.22			

- This is the link to the 2008 10 CFR 35.
- Medical Guide will be referenced here in the future.

RHB 313A(AU)

Name of Proposed Authorized User	State or Territory Where Licensed
Requested Authorizations (check all that apply)	
<input type="checkbox"/> 35.100 Uptake, dilution, and excretion studies	
<input type="checkbox"/> 35.200 Imaging and localization studies	
<input type="checkbox"/> 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)	
<input type="checkbox"/> 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)	
<input type="checkbox"/> 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	
<input type="checkbox"/> 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	
<input type="checkbox"/> 35.300 Parenteral administration of any other radionuclide for which a written directive is required	
<input type="checkbox"/> 35.500 Sealed sources for diagnosis (specify device_____)	



- Medical License
- Check the box with the appropriate authorization

RHB 313A(AU)

- The form will walk you through the different pathways. Choose the appropriate pathway and complete the required sections.

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 in appropriate specialty.
- 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.
- 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.
- 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.

RHB 313A(AU)

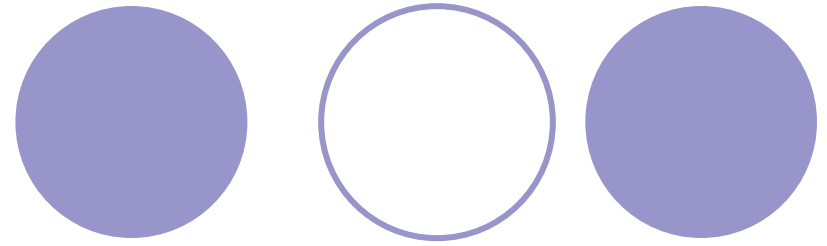
☐ 2. Current Authorized User Seeking Additional Authorization

- 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
- 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.

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- 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.

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☐ 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:			

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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		<input type="checkbox"/> Yes <input type="checkbox"/> No	

drugs to patients or human research subjects (not required for 35.390, 35.392, 35.394, and 35.396)		<input type="checkbox"/> 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)		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Supervising Individual		License/Permit Number listing supervising individual as an authorized user (if not listed on a California Radioactive	

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● Supervising Individual Information

labeled radioactive drugs (required for 35.290)			
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 (<i>check all that apply</i>)**.			
<input type="checkbox"/> 35.190	With experience administering dosages of: <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive <input type="checkbox"/> Parenteral administration of any other radionuclide requiring a written directive		
<input type="checkbox"/> 35.290			
<input type="checkbox"/> 35.390			
<input type="checkbox"/> 35.390 + generator experience in 35.290(c)(1)(ii)(G)			
<input type="checkbox"/> 35.392			
<input type="checkbox"/> 35.394			
<input type="checkbox"/> 35.396			
**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)**.			
<input type="checkbox"/> 35.390 <input type="checkbox"/> 35.392 <input type="checkbox"/> 35.394 <input type="checkbox"/> 35.396	With experience administering dosages of: <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive <input type="checkbox"/> 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.			

● Clinical Cases

● Supervising Individual Information

RHB 313A(AU)

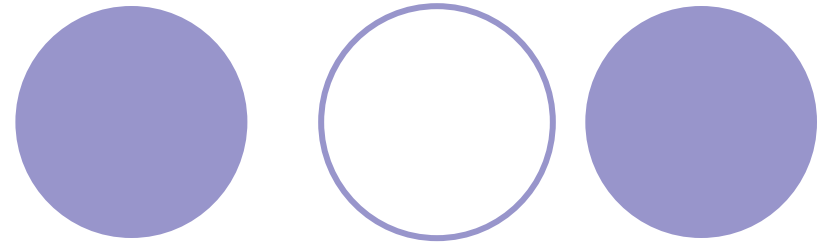
d. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

e. For 35.500 uses only, stop here. For All other uses, complete Part II Preceptor Attestation.

- End of Part II!

RHB 313A(AU)



- Preceptor Attestation must be completed for 35.100, 35.200, and 35.300 (required for 35.400 and 35.600 on form 313A(AUS)).
- Preceptor must still meet the qualifications described in Part 35 for each authorization!

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."

RHB 313A(AU)

First Section

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

Board Certification

☐ I attest that _____ has

Name of Proposed Authorized User

requirements 10 CFR 35.190(a)(1) and has achieved a
authorized user for the medical uses authorized under

OR

Training and Experience

☐ I attest that _____ has

Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom a
and has achieved a level of competency sufficient to functi
authorized under 10 CFR 35.100.

For 35.200: Check one of the following and skip to Third Section

Board Certification

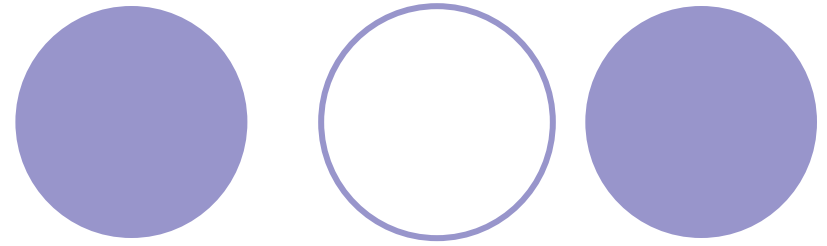
☐ I attest that _____ has

Name of Proposed Authorized User

requirements 10 CFR 35.200(a)(1) and has achieved a

- There are multiple sections!
- Complete for each requested authorization.
- Follow the instructions for each authorization.

RHB 313A(AU)



- 35.300 has subset of authorizations!
- Pick the appropriate one:

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

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

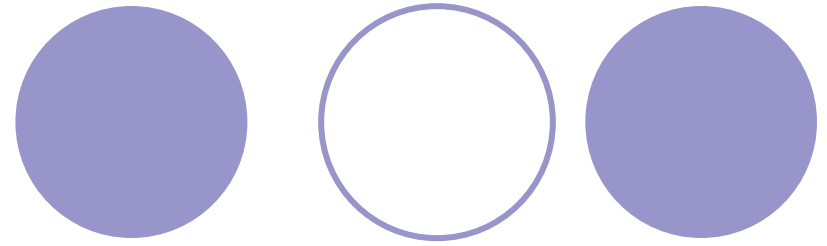
For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

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

- Forms with inconsistencies will not be considered.



RHB 313A(AU)



● Choose the appropriate pathway

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 requirements in 35.390(a)(1).
Name of Proposed Authorized User

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390(b)(1).
Name of Proposed Authorized User

OR

☐ I attest that _____ has satisfactorily completed the training and experience requirements in 35.290(a)(1) *and* additional training as required by 10 CFR 35.390(b)(1).
Name of Proposed Authorized User

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

Complete and continue to Third Section

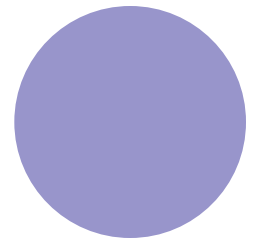
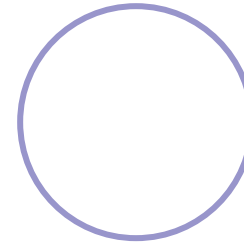
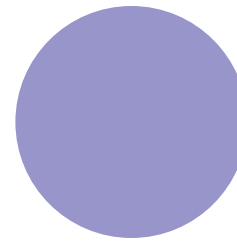
☐ I attest that _____ has satisfactorily completed the required clinical case
Name of Proposed Authorized User

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

- Complete the second section if required.

RHB 313A(AU)



- Preceptor Qualification
- Submit a copy of the RML if it is not a CA license.
- If listed on a broad scope license, provide a copy of the license and a letter from the RSO, verifying the preceptor's authorizations **for the dates training took place.**

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)			

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- Use this form to document recent training and experience for physicians who have not been listed on a Radioactive Materials License in the last seven years or board certified over seven years ago.

RHB FORM 313A (CE)

(7-2010)

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

AUTHORIZED USER REFRESHER TRAINING AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, 35.300, 35.400, 35.500, and 35.600)
[10CFR 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.590, and 35.690]

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

RHB 313A(CE)

- Was the physician board certified? Was he/she listed on a Radioactive Materials License?

PART I – TRAINING AND EXPERIENCE (Complete entire section)	
<p>* Training and Experience, including board certification, must have been obtained within the seven years preceding the date of application or the individual must have obtained related continuing education and experience since the initial required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the types of uses checked above, obtained within the past seven years.</p>	
<p><u>1. Training and experience obtained over seven years ago:</u></p>	
<input type="checkbox"/>	<p>1. <u>Board Certification</u></p> <ul style="list-style-type: none">Specialty Board and Category: _____Month and Year Certified: _____
<p>OR</p>	
<input type="checkbox"/>	<p>2. <u>Past Authorized User</u></p> <ul style="list-style-type: none">California Radioactive Materials Number: _____, or attach a copy of the NRC or Agreement State License.

RHB 313A(CE)

- Use the next section to document RECENT training and experience.

2. Continuing education and experience within the past seven years:

FIELD OF TRAINING A	LOCATION AND DATES OF TRAINING B	Type and Length of Training	
		LECTURE/ LABORATORY COURSES (HOURS) C	SUPERVISED LABORATORY EXPERIENCE (HOURS) D
a. Radiation physics and instrumentation			
b. Radiation protection			
c. Mathematics pertaining to use and measurement of radioactivity			
d. Chemistry of byproduct material for medical use (not required for 35.590)			
e. Radiation biology			

4. Clinical Training and Experience (Use back if more space is needed)

For 35.300 or any subset of clinical uses under 35.300, complete this section. For all others, skip to page 3.

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			

RHB 313A(CE)

- Don't forget the supervising individual's information if requesting 35.300.

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 <i>(check all that apply)**</i> .	
<input type="checkbox"/> 35.390 <input type="checkbox"/> 35.392 <input type="checkbox"/> 35.394 <input type="checkbox"/> 35.396	With experience administering dosages of: <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive <input type="checkbox"/> 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.	

RHB 313A(CE)

- Use this table to document any other T&E you'd like to include:

KEY TO COLUMN C—Personal participation consists of:

- Supervised examination of patients to determine the suitability for radionuclide diagnosis and/or treatment and recommendation for prescribed dosage.
- Dose calibration and actual administration of dose to the patient including calculation of the radiation dose and related measurements.
- Supervised interpretation of results of diagnostic studies.
- Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and therapy.

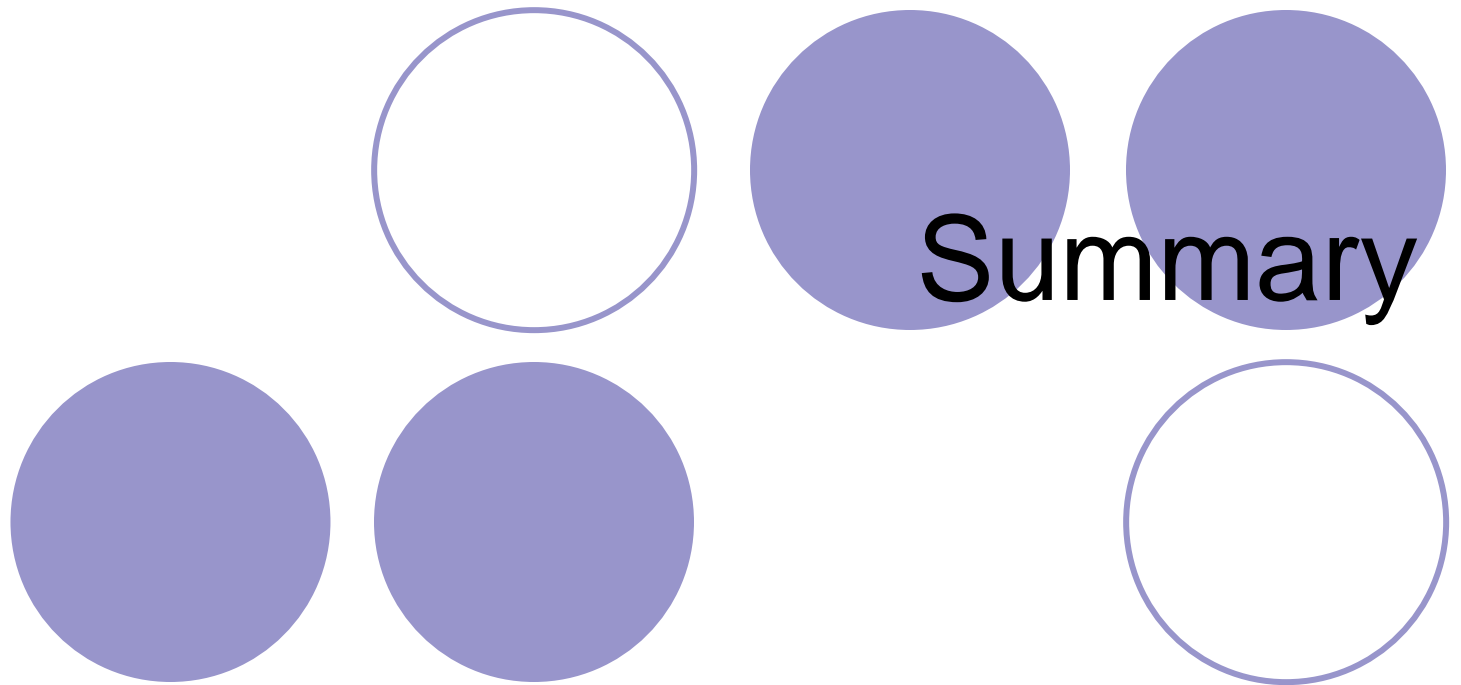
ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets) D

RHB 313A(CE)

- Move on to Part II- Preceptor Attestation...

PART II – PRECEPTOR ATTESTATION			
<p>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.</p> <p>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."</p> <p>First Section</p> <p><input type="checkbox"/> I attest that _____ has satisfactorily completed the training and experience <small>Name of Proposed Authorized User</small></p> <p>documented in this form and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses requested above.</p>			
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)			

- Complete all sections as necessary and you are done!



Summary



- If you qualified for “greater” authorizations, you are also qualified for the “lower” authorizations, i.e. qualified for 35.390 = qualified for 35.190, 35.290, 35.392, 35.394, and 35.396.
- If you have three cases of I-131 of greater than 33 mCi, you do not need ≤ 33 mCi.
- If you are requesting authorization for imaging and localization studies and wish to use > 30 μ Ci of I-131, you must also meet the qualifications for 35.392 and complete the T&E form(s) for 35.200 and 35.300.
- If requesting authorization for device(s), you must obtain device training for each type of device.
- Preceptor attestation is required for every pathway except current AU
- Preceptor attestation is not required for 35.500.