

RHB Supplemental Document to NUREG-1556 Volume 9 Revision 2

This document serves as a supplement to the guidance document NUREG-1556 Volume 9 Revision 2, Consolidated Guidance About Materials Licenses (Program-Specific Guidance About Medical Use Licenses). The State of California has entered into an agreement with the Nuclear Regulatory Commission granting authority to the Department of Public Health-Radiologic Health Branch to license radioactive material. As part of this agreement and to be in compliance with the Federal regulations, certain parts of the Code of Federal Regulations (CFR) have been adopted or incorporated by reference. For parts of the CFR not adopted or incorporated by reference, equivalent or similar regulations have been developed.

This document serves as a bridge between the Federal and the State regulations, Title 17, California Code of Regulations (17 CCR). Outlined below are the sections of NUREG-1556 Volume 9 Revision 2 with the variations or differences to the Federal regulations, requirements and guidance information for the issuance of a California Radioactive Material License (RML), specifically for medical human use. Any additional guidance documents or forms can be obtained by either visiting the [CDPH-RHB website at www.cdph.ca.gov/rhb](http://www.cdph.ca.gov/rhb) or by contacting RHB via telephone or email. Contact information available on website above.

Any item below is applicable for all sections in which that item appears, and is not limited to the section in which that item appears below. The section numbers of NUREG-1556 Volume 9 Revision 2 below serve as a marker for which the changes, substitutions, or omissions first appear.

NUREG-1556 Vol 9 Rev 2 Section 1 OVERVIEW

- 1.1 (1) 10 CFR Part 35, with exceptions, has been incorporated by reference per **17 CCR 30195**.

Replace Nuclear Regulatory Commission (NRC) with **California Department of Public Health (CDPH or Department), Radiologic Health Branch (RHB)**.

Replace NRC Form 313 “Application for Materials License” with **CDPH Medical Use Application form**.

Replace NRC Form 313A (RSO) “Radiation Safety Officer Medical Use Training and Experience and Preceptor Attestation [10 CFR 35.50]” with **RH 313A (RSO) form**.

Replace NRC Form 313A (AMP) “Authorized Medical Physicist Training and Experience and Preceptor Attestation [10 CFR 35.51]” with **RH 313A (AMP) form**.

Replace NRC Form 313A (ANP) “Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]” with **RH 313A (ANP) form**.

Replace all NRC 313A series forms for Authorized Users with **RH 313A (AU) form**.

- 1.1 (3) Disregard reference to 10 CFR 30.32(j) for noncommercial PET production. It is not applicable to this type of application.

Replace 10 CFR 30.33 with **17 CCR 30194**.

Replace 10 CFR Part 19 “Notices, instructions and reports to workers” with **17 CCR 30255**.

10 CFR Part 20, with exceptions, has been incorporated by reference per **17 CCR 30253**.

Disregard reference to 10 CFR Part 21 “Reporting of defects and noncompliance”. It is not applicable to this type of application.

Disregard reference to NUREG 1556 Volumes 12, 13 and 18 for guidance for licenses for manufacturing and distribution. It is not applicable to this type of application.

Disregard reference to NUREG 1556 Volume 21 for guidance for licenses for accelerator production. It is not applicable to this type of application.

Disregard reference to 10 CFR 70 for pacemakers. It is not applicable to this type of application.

Disregard the statement, “Guidance and model procedures provided in this NUREG that are not required to be submitted are for illustrative purposes to guide licensees in developing their programs. Use of the word ‘should’ implies ‘may’ and is not intended to mean ‘must’ or ‘shall’; the procedures provided in this guidance are intended to serve only as examples.”

- 1.2 Replace 10 CFR 31.11 for in vitro use of radioactive materials with **17 CCR 30503 and 30192.5**.

Disregard reference to 10 CFR Part 30 and NUREG 1556 Volume 21 for PET production. It is not applicable to this type of application.

Disregard reference to 10 CFR Part 32 and NUREG 1556 Volume 12 for commercial PET production. It is not applicable to this type of application.

Disregard reference to NUREG Volumes 12 and 13 for commercial PET distribution. It is not applicable to this type of application.

Replace 10 CFR 30.9 with **17 CCR 30105**.

1.2.1 Replace 10 CFR Part 30.33(a)(2) for applicant facilities with **17 CCR 30194(a)(2)**.

1.2.2 Replace 10 CFR Part 33 for in vitro, animal and medical procedures, and 10 CFR 33.13 through 33.17 for broad scopes licenses with **17 CCR 30195**.

1.3 1.3.3 For transfer of control and bankruptcy, refer to **17 CCR 30194(c)** and **30257**, respectively.

1.3.4 Replace 10 CFR 30.34(h) for bankruptcy with **17 CCR 30257**.

NUREG-1556 Vol 9 Rev 2 Section 3 MANAGEMENT RESPONSIBILITY

Replace 10 CFR 35.12 with **17 CCR 30194**.

Replace 10 CFR 61 for Requirements for Land Disposal of Radioactive Waste with **17 CCR Division 1, Chapter 5, Subchapter 4, Group 7**.

NUREG-1556 Vol 9 Rev 2 Section 5 HOW TO FILE

5.1 Replace 10 CFR 35.12 with **17 CCR 30194**.

5.2 Information regarding issued licenses can be requested pursuant to the California Public Records Act.

NUREG-1556 Vol 9 Rev 2 Section 7 LICENSE FEES

Replace 10 CFR 170.31 regarding License Fees with **17 CCR 30230**.

Replace 10 CFR 170.11 for exemptions with **17 CCR 30104**.

Replace 10 CFR 171.11 and 171.16 for licensing fees and schedule with **17 CCR 30230** and **30231**, respectively.

Any questions regarding License Fees can be directed either to the licensing or support staff. Contact information is available on the RHB website.

NUREG-1556 Vol 9 Rev 2 Section 8 CONTENTS OF AN APPLICATION

8 Preface California may require additional information and/or documentation to that stated in NUREG-1556 Volume 9 Revision 2. Refer to the specific items or sections of this document for the required information and/or documentation.

8.2 Additionally, provide the following:

- (1) Articles of Incorporation or Articles of Organization of ownership entity, and
- (2) Organizational Chart from most senior member of management or administration (President, CEO) to the Radiation Safety Officer (RSO).

Before ownership or control of a license is transferred, submit an amendment request with a Change of Ownership request signed by both the transferor and transferee. A sample Change of Ownership letter can be found on the CDPH-RHB website or can be obtained by contacting RHB.

8.4 Additionally, provide an email address with contact information. If different, provide contact information for the license application, license maintenance, and billing.

8.5 Quantify the total possession limited in standard (Curies) or S.I. units (Becquerels). "As needed" is not an acceptable response.

Note that 10 CFR 35.65 was not adopted by California as part of **17 CCR 30195**. Transmission sources associated with any imaging systems must be specifically listed on the RML. Provide the isotope, manufacturer name and model number, serial number, quantity, total activity, and individual source activity.

8.8 For regulations on Financial Assurance and Emergency Plan requirements refer to **17 CCR 30195.1** and **30195.2**, respectively.

8.11 Replace "... the RSO should be on site periodically ..." with "**The Radiation Safety Officer shall be physically present on site at each use location no less than once per month.**"

Replace "Appendix I" with "**Duties and Responsibilities of the Radiation Safety Officer and Delegation of Authority form**". A sample Duties and Responsibilities of the Radiation Safety Officer and Delegation of Authority form can be found on the CDPH-RHB website or can be obtained by contacting RHB.

8.12 In addition to NUREG-1556 Volume 9 Revision 2, authorized users of radioactive materials will also need to fulfill the requirements of general supervision per **17 CCR 30502**.

8.15 In addition to NUREG-1556 Volume 9 Revision 2, provide the following for each use location listed:

- (1) description of area security/access restriction to restricted areas,
- (2) confirmation that all use and storage location will be posted per 10 CFR 20.1902,
- (3) an overall facility diagram indicating all use and storage locations/restricted areas, and, as applicable, generator use/storage areas, radioactive seed use/storage locations and waste storage locations, and
- (4) labelled diagrams for all hot labs and description of remote handling equipment.

Additionally, for high dose rate (HDR) remote afterloaders and gamma stereotactic radiosurgery (GSR), more detailed information is required. Refer to the specific items or sections of this document for the required information and/or documentation, in addition to the CDPH-RHB Guides for each modality. These guidance documents can be found on the CDPH-RHB website or can be obtained by contacting RHB.

8.17 Additionally, provide sample calculations and quantify the minimum detectable activity (MDA) for all wipe test instrumentation, i.e. "MDA for all wipe test instrumentation is less than or equal to 200 dpm for iodine-131 and less than or equal to 2000 dpm for all other isotopes."

8.24 Additionally, provide the following:

- (1) Confirm that all elution, preparation and injection areas will be surveyed, at least, daily, and all other areas where radioactive materials are used or stored will be surveyed, at least, weekly;
- (2) Copies of all survey maps and forms and confirm that the following information will be included on all survey forms:
 - (a) diagram of area surveyed identifying restricted and unrestricted areas,
 - (b) list of items and equipment surveyed,
 - (c) locations where wipes were taken,

- (d) exposure rate and contamination levels recorded in appropriate units, mR/hr and dpm/100 cm², respectively,
- (e) action or trigger levels indicated,
- (f) manufacturer name and model number of all instrumentation used to perform area survey and wipe test,
- (g) background values and location obtained,
- (h) name and signature or initials of surveyor, and date of survey, and
- (i) RSO review and signature.

8.29 In addition to the contents of Appendix W of NUREG-1556 Volume 9 Revision 2, for Model Procedures for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return, refer to and address the items in the “**Guidance for the Decay-In-Storage (DIS) Method of Waste Disposal**”. This guidance can be found on the CDPH-RHB website or can be obtained by contacting RHB.

8.30 For licensing fees and scheduling, refer to **17 CCR 30230** and **30231**, respectively.

8.37 The contents of Appendix V of NUREG-1556 Volume 9 Revision 2, for Guidance for Mobile Medical Services, may be followed, but with the following exceptions: (1) the licensee base site shall NOT be a mobile van or coach, and must be a fixed physical location, and (2) therapy procedures shall NOT be performed on mobile vans or coaches.

NUREG-1556 Vol 9 Rev 2 Section 9 AMENDMENTS AND RENEWALS TO A LICENSE

For amendments to and renewals of radioactive material licenses, refer to **17 CCR 30194.2** and **30194(e)**, respectively.

NUREG-1556 Vol 9 Rev 2 Section 10 APPLICATIONS FOR EXEMPTIONS

For exemptions to the regulations, refer to **17 CCR 30104**.

NUREG-1556 Vol 9 Rev 2 Section 11 TERMINATION OF ACTIVITIES

For termination of licenses, refer to **17 CCR 30205**. For termination of licensed activities and vacating installations, refer to **17 CCR 30256**.

NUREG-1556 Vol 9 Rev 2 Appendices

Appendix C Table C.1 Applicability Table:

This information does not supersede this **RHB Supplemental Document to NUREG-1556 Volume 9 Revision 2**.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use:

Quantify the total possession limits in standard (Curies) or S.I. units (Becquerels). "As needed" is not an acceptable response.

Table C.3 Items 7 through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal:

If a referenced California RML is a broad scope license, include a letter of authorization from the RSO of that license for proposed user(s), as they may not be specifically listed on the RML. If a referenced license or permit is not a California RML, include a complete signed copy of that license or permit.

Include a complete list of all radiation detection instrumentation, including manufacturer, model, instrument type (meter, probe, etc.), and location of use.

Appendix D If a referenced California RML is a broad scope license, include a letter of authorization from the RSO of that license for proposed authorized users, proposed authorized medical physicists, and proposed authorized nuclear pharmacist, as they may not be specifically listed on the RML. If a referenced license or permit is not a California RML, include a complete signed copy of that license or permit.

Appendix E In addition to the information in the sample application and checklist, additional information is required based on this RHB Supplemental Document to NUREG-1556 Volume 9 Revision 2. This sample provided is for illustration purposes only and does not constitute a complete license application.

Appendix F Disregard references to NUREG-1556 Volume 20, 10 CFR Part 30 and Part 32. They are not applicable to this type of application. Additionally, 10 CFR 35.26 and 35.15 are not incorporated by reference. Replace 10 CFR 33.13 with **17 CCR 30195**.

- Appendix H Replace NRC Form 314 “Certificate of Disposition of Materials” with **CDPH Form 5314 “Certificate of Disposition of Materials”**. This form can be found on the CDPH-RHB website or can be obtained by contacting RHB.
- Appendix I Replace “Appendix I” with **“Duties and Responsibilities of the Radiation Safety Officer and Delegation of Authority form”**. This form can be found on the CDPH-RHB website or can be obtained by contacting RHB.
- Appendix W In addition to the contents of Appendix W of NUREG-1556 Volume 9 Revision 2, for Model Procedures for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return, refer to and address the items in the **“Guidance for the Decay-In-Storage (DIS) Method of Waste Disposal”**. This guidance can be found on the CDPH-RHB website or can be obtained by contacting RHB.
- Appendix V The contents of Appendix V of NUREG-1556 Volume 9 Revision 2, for Guidance for Mobile Medical Services, may be followed, but with the following exceptions: (1) the licensee base site shall NOT be a mobile van or coach, and must be a fixed physical location, and (2) therapy procedures shall NOT be performed on mobile vans or coaches.

In addition to the model procedures of Appendices I-W, additional information may be required. Refer to the applicable sections and items of the license application above.

Disregard Appendix AA as it is not applicable to this type of application. Refer to **17 CCR 30195**.

Any additional guidance documents or forms can be obtained by either visiting the [CDPH-RHB website at www.cdph.ca.gov/rhb](http://www.cdph.ca.gov/rhb) or by contacting RHB via telephone or email. Contact information available on website above.