

Methodology to Indicate Changes to:

DPH-20-017

**Compatibility maintenance with Nuclear Regulatory Commission (NRC)
regulations and personnel dosimeter use in certain non-human uses of X-ray
equipment.**

The proposed changes for comment that are the subject of this notice (15-day public comment period) are indicated as follows:

- Deletions from the proposed text presented during this 15-day public comment period are indicated by double strike-through (~~strike-through~~)
- Additions to the proposed text presented during this 15-day public comment period are indicated by double underline (underline).

Regulation text not subject to this 15-day public comment period are presented for the reader's convenience and are indicated as follows:

- Deleted text as initially proposed is indicated by single strike-through (~~strike-through~~).
- Additions to the regulation text as initially proposed is indicated by single underline (underline).

**TITLE 17, California Code of Regulations
Division 1, Chapter 5, Subchapter 4.0.
Group 2. Licensing of Radioactive Materials
Article 4. Licenses**

Amend Section 30195 to read as follows:

§ 30195. Special Requirements for Issuance of Specific Licenses.

In addition to the requirements set forth in Section 30194, specific licenses for certain specialized uses will be issued only if the following conditions are met:

(a) For human use of radioactive material limited to medical purposes, the applicant submits documentation demonstrating that they are capable of complying with the regulations governing the medical use of radioactive material in title 10, Code of Federal Regulations, Part 35 (10 CFR 35) (January 1, ~~2013~~2021), which is hereby incorporated by reference with the exceptions listed at subsections (a)(1) through (a)(15) below, and upon issuance of a license maintains compliance with said regulations:

- (1) *No change to text.*
- (2) through (3) *No change to initial proposal.*
- (4) *No change to text.*
- (5) through (8) *No change to initial proposal.*
- (9) *No change to text.*
- (10) through (12) *No change to text.*
- (13) *No change to initial proposal.*

(14) ~~The date January 1, 2011 is substituted for the date October 24, 2002 found in 10 CFR 35, section 35.57(a)(1) and (b)(1). Subdivisions (a)(2) and (b)(2) of 10 CFR 35, section 35.57 are replaced by the following:~~

~~(A) "An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist, and physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license or~~

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~~an NRC or Agreement State license or a permit issued by a Department, NRC or Agreement State broad scope licensee or NRC master material license permit or by an NRC master material license permittee of broad scope before January 1, 2011 who perform only those medical uses for which they were authorized, need not comply with the training requirements of 10 CFR 35, sections 35.50, 35.51, or 35.55, and subparts D through H of 10 CFR 35, respectively. The date [effective date of these regulations to be entered by Office of Administrative Law] is substituted for the date January 14, 2019 found in 10 CFR 35, section 35.57(a)(1) and (b)(1), and for the date October 24, 2005 found in section 35.57(a)(2), (a)(3), and (b)(2). The following 10 CFR 35 provisions shall read or are revised as indicated:~~

(A) Section 35.50(c)(3) shall read “Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Commission master material licensee. The individual must also meet the requirements in paragraph (d) of this section.”

(B) Section 35.55(a)(1) shall read “Have graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) (previously named the American Council on Pharmaceutical Education) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination.”

(C) Section 35.57 is revised or shall read as indicated:

1. The date [effective date of these regulations to be entered by Office of Administrative Law] is substituted for the date January 14, 2019 found in subdivisions (a)(1) and (b)(1), and for the date October 24, 2005 found in subdivisions (a)(2) and (a)(3).

2. Subdivision (b)(2) shall read “Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material on a license issued by the Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State broad scope

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licensee, or a permit issued in accordance with a Commission master material broad scope license on or before [effective date of these regulations to be entered by Office of Administrative Law], need not comply with the training requirements of subparts D through H of this part for those materials and uses that these individuals performed on or before [effective date of these regulations to be entered by Office of Administrative Law], as follows.”

(15) *No change to text.*

(b) through (d) *No change to text.*

Note: Authority cited: Sections 114975, 115000 and 131200, Health and Safety Code.
Reference: Sections 114965, 114970, 115060, 115165, 115235, 131050, 131051 and 131052, Health and Safety Code.

Group 2. Licensing of Radioactive Materials
Article 6. Physical Protection of Radioactive Material

Amend Section 30220 to read as follows:

§ 30220. Special Requirements for Issuance of Specific Licenses - Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.

(a) In addition to meeting the requirements set forth in sections 30194, 30194.1, 30195, 30195.1, 30195.2, 30195.3 and 30196, specific licenses shall be issued only if the applicant submits documentation demonstrating that it is capable of complying, and following issuance of the license will continue to comply, with the regulations governing the physical protection of category 1 and category 2 quantities of radioactive material in Title 10, Code of Federal Regulations (10 CFR), Part 37 and Appendix A of 10 CFR Part 37 (January 1, ~~2016~~2021), which are hereby incorporated by reference with the following exceptions.

(1) through (3) *No change to text.*

(4) Except as follows, any reference to the United States Nuclear Regulatory Commission (NRC) or any component thereof shall be deemed to be a reference to the Department:

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(A) through (B) *No change to text.*

(C) Section 37.27 of 10 CFR 37, subject to paragraph (3). Licensees shall comply with all submittals and processes specified in 10 CFR 37.27 by submitting and corresponding directly to the NRC as required by 10 CFR 37.27, except that “mail stop T-07D04M” shall be used in lieu of “mail stop T-8B20” found in § 37.27(c); and

(D) *No change to text.*

(5) *No change to initial proposal.*

(6) through (7) *No change to text.*

(8) The mathematical formula for calculations concerning multiple sources or multiple radionuclides found in the Note to Appendix A of 10 CFR 37 shall read as published on November 30, 2021 in Volume 86, Number 227 of the Federal Register at page 67842, which is hereby incorporated by reference.

Note: Authority cited: Sections 114975, 115000 and 131200, Health and Safety Code.
 Reference: Sections 114965, 114970, 115060, 115165, 115230, 115235, 131050, 131051 and 131052, Health and Safety Code.

Group 3. Standards for Protection Against Radiation

Article 1. General

Amend Section 30253 to read as follows:

§ 30253. Standards for Protection Against Radiation.

(a) The regulations governing standards for protection against radiation in title 10, Code of Federal Regulations, part 20, (10 CFR 20) sections 20.1001 through 20.2402 and Appendices A through G, (January 1, ~~2013~~2021) are hereby incorporated by reference with the following exceptions:

(1) Title 10, Code of Federal Regulations, sections 20.1001, 20.1002, 20.1006, 20.1007, 20.1008, 20.1009, 20.1401, 20.1402, 20.1403, 20.1404, 20.1405, 20.1406,

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20.1905(g), 20.2106(d), 20.2203(c), 20.2206, 20.2207(h), 20.2302, 20.2401, and 20.2402, and Appendix D are not incorporated by reference.

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| (2) through (6) | <i>No change to initial proposal.</i> |
| (7) through (11) | <i>No change to text.</i> |
| (b) | <i>No change to initial proposal.</i> |

Note: Authority cited: Sections 114975, 115000 and 131200, Health and Safety Code.
Reference: Sections 114960, 114965, 114970, 114985, 114990, 115060, 115105, 115110, 115120, 115165, 115230, 115235, 131050, 131051 and 131052, Health and Safety Code.

Group 4. Transportation of Radioactive Material
Article 1. Requirements for Transportation of Radioactive Material

Amend Section 30373 to read as follows:

§ 30373. Transportation Regulations.

(a) Except as authorized in a general license or a specific license, or as exempted in this subchapter, a licensee may not deliver radioactive material to a carrier for transport, or transport radioactive material. Licensees authorized to receive, possess, use or transfer radioactive material shall, if they deliver radioactive material to a carrier for transport, transport radioactive material outside the site of usage as specified in the specific license, or transport radioactive material on public highways, comply with, as appropriate to the mode of transport, title 10, Code of Federal Regulations, part 71 (10 CFR 71) and Appendix A (as of January 1, ~~2016~~2021), which is hereby incorporated by reference with the following exceptions:

(1) 10 CFR 71, sections 71.0 through 71.3, 71.6, 71.7, 71.9 through 71.12, 71.14(b), 71.16, 71.18, 71.19, 71.24, 71.25, 71.31 through 71.45, 71.51 through 71.81, 71.85(a)-(c), 71.91(b), 71.93, 71.95, 71.97(c)(3)(i), 71.99, 71.100, 71.101(c)(2), (d), (e), and (f), 71.103(c) through (f), and 71.107 through 71.131 are not incorporated by reference;

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| (2) through (4) | <i>No change to text.</i> |
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- (5) *No change to initial proposal.*
- (6) through (8) *No change to text.*
- (b) *No change to initial proposal.*
- (c) *No change to text.*

Note: Authority cited: Sections 114765, 114820, 115000 and 131200, Health and Safety Code. Reference: Sections 114740, 114765, 115230, 115235, 131050, 131051 and 131052, Health and Safety Code.