Methodology to Indicate Changes to DPH-24-001 – Compatibility Maintenance with NRC Regulations

Changes to the regulations are indicated as follows:

- Deleted text is indicated by double strike-through (strike-through).
- Additions to the regulation text are indicated by double underline (underline).

March 28, 2025

Amend section 30196 to read as follows:

§ 30196. Special Requirements for Issuance of Specific Licenses to Manufacture or Transfer Certain Items Containing Radioactive Material.

- (a) The regulations governing manufacturing or initially transferring items containing radioactive material for sale or distribution in Title 10, Code of Federal Regulations (10 CFR), Part 32 (10 CFR 32) (January 1, 2021) are hereby incorporated by reference with the following exceptions:
- (1) Title 10, Code of Federal Regulations, sections 32.1, 32.3, 32.8, 32.11, 32.12, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29, 32.30, 32.31, 32.32, 32.101, 32.102, 32.103, 32.110, 32.301, and 32.303 and NRC Form 653 referenced in section 32.52 are not incorporated by reference.
- (2) Any reference to "byproduct material" in 10 CFR 32 is replaced by the term "radioactive material" as defined in section 30100.
- (3) Except for the definition of "Sealed Source and Device Registry" in 10 CFR 32.2. Any any reference to the United States Nuclear Regulatory Commission (NRC) or any component thereof shall be deemed to be a reference to the Department as defined in section 30100.
- (4) Any reference to the term "Agreement State" shall be deemed to be a reference to the term "Agreement State" as defined in section 30100.
- (5) Any reference to the below identified federal regulation cited within 10 CFR 32 shall be deemed to be a reference to the below identified Department regulation in this subchapter:

Federal regulation cited within 10 CFR 32	Department regulation within this subchapter
§ 30.34(h)	§ 30257
§ 30.33	§ 30194
§ 30.36	§ 30256
§ 30.51	§ 30293
§ 31.2	§ 30190

§ 31.5	§ 30192.1
§ 31.7	§ 30192.2
§ 31.8	§ 30192.3
§ 31.10	§ 30192.4
§ 31.11	§ 30192.5
10 CFR 20 (any section)	§ 30253

- (6) Any reference within 10 CFR 32 to sections found in 10 CFR 35 shall be deemed to be a reference to section 30195(a) except that 10 CFR 35.65(a) (January 1, 2021) cited within 10 CFR 32.74(a)(3) is incorporated by reference in this section for the purpose of issuing a specific license pursuant to this section. Section 35.65(a) of 10 CFR is not incorporated by reference for purposes of issuing a specific license pursuant to section 30195(a).
- (7) Ten 10 CFR 32.72(a)(2)(i) as incorporated by reference in this section is revised to read as follows:
- (A) "Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.17(a)."

NOTE: Authority cited: Sections 114975, 115000, 115091 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 115060, 115091, 115092, 115235, 131050, 131051 and 131052, Health and Safety Code.