TITLE 252. DEPARTMENT OF ENVIRONMENTAL QUALITY
CHAPTER 410. RADIATION MANAGEMENT

SUBCHAPTER 1. GENERAL PROVISIONS

252:410-1-7. Incorporation of federal regulations by reference

(a) **10 CFR.** References in this Chapter to Title 10 of the Code of Federal Regulations (10 CFR) mean the ~~January 1, 2016~~January 1, 2019 publication of 10 CFR.

(b) **40 CFR.** References in this Chapter to Title 40 of the Code of Federal Regulations (40 CFR) mean the July 1, 1998 publication of 40 CFR and 64 Fed. Reg. 5574 (February 3, 1999).

(c) **Citations incorporated.** When a provision of the Code of Federal Regulations is incorporated by reference, all citations contained therein are also incorporated by reference.

SUBCHAPTER 10. RADIOACTIVE MATERIALS PROGRAM

PART 1. GENERAL PROVISIONS

252:410-10-1. Radioactive Materials Program

(a) **Scope.**

(1) The rules in this Subchapter establish license requirements for the following categories of radioactive materials: byproduct material, source material and special nuclear material.

(2) License requirements incorporated by reference from 10 CFR are applicable requirements for all categories of radioactive materials within the scope of this Subchapter.

(b) **Exclusions.** Responsibility for the following regulatory requirements remains with the NRC:

(1) **In 10 CFR 20.** Exemptions to labeling requirements, § 20.1905(g); Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits at nuclear power plants, § 20.2203(c); Reports of individual monitoring, § 20.2206(a)(1), (a)(3), (a)(4) and (a)(5);

(2) **In 10 CFR 30.** Activities requiring license, § 30.3(b); Definitions, 30.4 "Commencement of construction" paragraph (2), "Construction" paragraph (9)(ii), and "Quantities of concern"; Application for specific licenses, § 30.32(k); Terms and conditions of licenses, § 30.34 (d), (e)(1), (e)(3) and (1); Transfer of byproduct material, § 30.41 (b)(6); Tritium reports, § 30.55;

(3) **In 10 CFR 32.** Purpose and scope, § 32.1(c)(1); Subpart A, Exempt concentrations and items, §§ 32.11, 32.12, 32.14, 32.15, 32.16, 32.18 through 32.23, and 32.25 through 32.29; Subpart D, Specifically licensed items, § 32.210;

(4) **In 10 CFR 35.** License required, § 35.11(c)(1); License amendments, § 35.13(a)(1);

(5) **In 10 CFR 36.** Definitions, 36.2 "Commencement of construction" paragraph 2 and "Construction" paragraph 9(ii);

(6) **In 10 CFR 37.** General security program requirements, 37.43(d)(9);

(7) **In 10 CFR 40.** General Provisions, §§ 40.2a and 40.3; Definitions, 40.4 "Commencement of construction" paragraph (2) and "Construction" paragraph (9)(ii); Exemptions, §§ 40.11, 40.12 and 40.13 (a), (b), (c)(1) through (~~5~~4),(c)(5)(iv), (c)(7) through (~~9~~8), 40.14; General Licenses, §§ 40.20 through 40.24; 40.26 through 40.28; License Applications, §§ 40.31 (f) through (l), §§ 40.32 (d) through (g), §§ 40.33 through 40.35, § 40.37, and § 40.38; Licenses, §§ 40.41 (d), (e)(1) and (3), (f) and (g), § 40.42 and § 40.46; Transfer of Source Material, § 40.51 (b)(6); Records, Reports, and Inspections, § 40.60

(c)(3), §§ 40.64 through 40.67; Appendix A;

(8) **In 10 CFR 61.** Other information, § 61.16; Standards for issuance of a license, § 61.23 (i) and (j) regarding physical security information and criticality safety procedures for special nuclear material possessed prior to disposal;

(9) **In 10 CFR 70.** Regulation of special nuclear material for spent fuel, high level radioactive waste and uranium enrichment facilities, §§ 70.1(c),(d) and (e); Definitions, 70.4 "Commencement of construction" paragraph (2) and "Construction" paragraph (9)(ii); Department of Defense, § 70.13; Foreign military aircraft, § 70.14; General license to possess special nuclear material for transport, § 70.20a; General license for carriers of transient shipments of formula quantities of strategic special nuclear material of moderate strategic significance, special nuclear material of low strategic significance, and irradiated reactor fuel regulated under 10 CFR 73, § 70.20b; Subpart D - License Applications, § 70.21(a)(1), (c), (f), (g) and (h); § 70.22 (b), (c) and (f) through (n), § 70.23 (a)(6) through (12) and (b), § 70.23a, and § 70.24; Subpart E - Licenses, § 70.31 (c), (d), and (e), § 70.32 (a)(1), (a)(4) through (7), (b)(1), (b)(3), (b)(4), (c) through (k), and § 70.37; § 70.40; Subpart F - Acquisition, Use and Transfer of Special Nuclear Material, Creditor's Rights, §70.42(b)(6), and § 70.44; Subpart G - Special Nuclear Material Control, Records, Reports and Inspections, § 70.51(c),(d) and (e), § 70.52 through § 70.54, § 70.55(c), § 70.56, and §70.59; Subpart H - Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material, § 70.60 through 70.76; Subpart I - Modification and Revocation of Licenses, § 70.81 and § 70.82; Subpart J - Enforcement, §§ 70.91, 70.92 and Appendix A to Part 70;

(10) **In 10 CFR 71.** Subpart A - General Provisions, § 71.10; Subpart B - Exemptions, § 71.14(b); Subpart C - General licenses, § 71.19; Subpart D - Application for Package Approval, §§ 71.31 through 71.39; Subpart E - Package Approval Standards, §§ 71.41 through 71.45 and §§ 71.51 through 71.65; Subpart F - Package, Special Form, and LSA-III Tests, §§ 71.70 through 71.77; Subpart G - Operating Controls and Procedures, § 71.85(a), (b) and (c) and § 71.91(b); Subpart H - Quality Assurance, § 71.101(c)(2), (d), and (e) and §§ 71.107 through 71.125;

(11) **In 10 CFR 150.** Persons in offshore waters not exempt, § 150.7; Persons in agreement states exempt, § 150.10; Commission regulatory authority for physical protection in agreement states, § 150.14; Persons not exempt, § 150.15(a)(9); Continued Commission authority pertaining to byproduct material, § 150.15a(b)(6); Persons in agreement states not exempt, Continued Commission authority pertaining to byproduct material in agreement states, § 150.17; Compliance with requirements of US/IAEA safeguards agreement for source material under state agreement license; Submission to Commission of reports for tritium in agreement states, § 150.19; Transportation by aircraft of special nuclear material by agreement state licensee, § 150.21; Violations, § 150.30; Requirements for Agreement State regulation of byproduct material, § 150.31; Funds for reclamation or maintenance of byproduct material, §150.32; and Criminal penalties, § 150.33.

(c) **Effective date.** The requirements of this Subchapter became effective September 29, 2000, the date upon which jurisdiction over all unrevoked and unexpired NRC licenses and plan approvals was transferred to DEQ.

PART 32. BYPRODUCT MATERIAL: SPECIFIC LICENSES FOR MANUFACTURING AND TRANSFERRING CERTAIN ITEMS

252:410-10-32. 10 CFR 32 incorporations by reference

The following provisions are hereby incorporated by reference from 10 CFR 32, Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material:

(1) **General provisions.**

(A) 32.1(a), (b) and (c)(2) - Purpose and scope, excluding issuance of certificates of registration

(B) 32.2 - Definitions

(C) 32.3 - Maintenance of records

(2) **Subpart A - Exempt concentrations and items.**

(A) 32.13 - Same: Prohibition of introduction

(B) 32.24 - Same: Table of organ doses

(3) **Subpart B - Generally licensed items.**

(A) Byproduct material contained in devices for use under 31.5:

(i) 32.51 - Requirements for license to manufacture or initially transfer

(ii) 32.51a - Conditions of licenses

(iii) 32.52 - Material transfer reports and records

(B) Luminous safety devices for use in aircraft:

(i) 32.53 - Requirements for license to manufacture, assemble, repair or initially transfer

(ii) 32.54 - Labeling of devices

(iii) 32.55 - Quality assurance; prohibition of transfer

(iv) 32.56 - Material transfer reports

(C) Calibration or reference sources containing americium 241:

(i) 32.57 - Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer

(ii) 32.58 - Same: Labeling of devices

(iii) 32.59 - Same: Leak testing of each source

(D) Ice detection devices containing strontium-90:

(i) 32.61 - Requirements for license to manufacture or initially transfer

(ii) 32.62 - Quality assurance; prohibition of transfer

(E) 32.71 - Manufacture and distribution of byproduct material for certain *in vitro* clinical or laboratory testing under general license

(4) **Subpart C – Specifically licensed items.**

(~~F~~A) 32.72 - Manufacture, preparation or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35

(~~G~~B) 32.74 - Manufacture and distribution of sources or devices containing byproduct material for medical use

~~(4) Subpart D – Specifically licensed items.~~ (C) 32.201 - Serialization of nationally tracked sources

PART 35. MEDICAL USE OF BYPRODUCT MATERIAL

252:410-10-35. 10 CFR 35 incorporations by reference

(a) **Incorporations by reference.** The following provisions are hereby incorporated by reference from 10 CFR 35, Medical Use of Byproduct Material:

(1) **Subpart A; General Information.**

(A) 35.1 - Purpose and scope
(B) 35.2 - Definitions
(C) 35.5 - Maintenance of records
(D) 35.6 - Provisions for the protection of human research subjects
(E) 35.7 - FDA, other Federal and State requirements
(F) 35.10 - Implementation
(G) 35.11(a), (b) and (c)(2) - License required
(H) 35.12 - Application for license, amendment or renewal
(I) 35.13(a)(2), and (b) through (g) - License amendments
(J) 35.14 - Notifications
(K) 35.15 - Exemptions regarding Type A specific licenses of broad scope
(L) 35.18 - License issuance
(M) 35.19 - Specific exemptions

(2) **Subpart B; General Administrative Requirements.**

(A) 35.24 - Authority and responsibilities for the radiation protection program
(B) 35.26 - Radiation protection program changes
(C) 35.27 - Supervision
(D) 35.40 - Written directives
(E) 35.41 - Procedures for administrations requiring a written directive
(F) 35.49 - Suppliers for sealed sources or devices for medical use
(G) 35.50 - Training for Radiation Safety Officer and Associate Radiation Safety Officer
(H) 35.51 - Training for an authorized medical physicist
(I) 35.55 - Training for an authorized nuclear pharmacist
(J) 35.57 - Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist
(K) 35.59 - Recentness of Training

(3) **Subpart C; General Technical Requirements.**

(A) 35.60 - Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material
(B) 35.61 - Calibration of survey instruments
(C) 35.63 - Determination of dosages of unsealed byproduct material for medical use
(D) 35.65 - Authorization for calibration, transmission, and reference sources
(E) 35.67 - Requirements for possession of sealed sources and brachytherapy sources
(F) 35.69 - Labeling of vials and syringes
(G) 35.70 - Surveys of ambient radiation exposure rate
(H) 35.75 - Release of individuals containing unsealed byproduct material or implants containing byproduct material
(I) 35.80 - Provision of mobile medical service
(J) 35.92 - Decay-in-storage

(4) **Subpart D; Unsealed Byproduct Material–Written Directive Not Required.**

(A) 35.100 - Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required
(B) 35.190 - Training for uptake, dilution, and excretion studies
(C) 35.200 - Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required
(D) 35.204 - Permissible molybdenum-99, strontium-82, and strontium-85 concentrations
(E) 35.290 - Training for imaging and localization studies

(5) **Subpart E; Unsealed Byproduct Material – Written Directive Required**.
(A) 35.300 - Use of unsealed byproduct material for which a written directive is required
(B) 35.310 - Safety instruction
(C) 35.315 - Safety precautions
(D) 35.390 - Training for use of unsealed byproduct material for which a written directive is required
(E) 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)
(F) 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)
(G) 35.396 - Training for the parenteral administration of unsealed byproduct material requiring a written directive

(6) **Subpart F; Manual Brachytherapy**.
(A) 35.400 - Use of sources for manual brachytherapy
(B) 35.404 - Surveys after source implant and removal
(C) 35.406 - Brachytherapy sources accountability
(D) 35.410 - Safety instruction
(E) 35.415 - Safety precautions
(F) 35.432 - Calibration measurements of brachytherapy sources
(G) 35.433 - ~~Decay of s~~Strontium-90 sources for ophthalmic treatments
(H) 35.457 - Therapy related computer systems
(I) 35.490 - Training for use of manual brachytherapy sources
(J) 35.491 - Training for ophthalmic use of strontium-90

(7) **Subpart G; Sealed Sources for diagnosis**.
(A) 35.500 - Use of sealed sources and medical devices for diagnosis
(B) 35.590 - Training for use of sealed sources and medical devices for diagnosis

(8) **Subpart H; Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units**.
(A) 35.600 - Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit
(B) 35.604 - Surveys of patients and human research subjects treated with a remote afterloader unit
(C) 35.605 - Installation, maintenance, adjustment, and repair
(D) 35.610 - Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
(E) 35.615 - Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
(F) 35.630 - Dosimetry equipment
(G) 35.632 - full calibration measurements on teletherapy units

(H) 35.633 - Full calibration measurements on remote afterloader units
(I) 35.635 - Full calibration measurements on gamma sterotactic radiosurgery units
(J) 35.642 - Periodic spot-checks for teletherapy units
(K) 35.643 - Periodic spot-checks for remote afterloader units
(L) 35.645 - Periodic spot-checks for gamma stereotactic radiosurgery units
(M) 35.647 - Additional technical requirements for mobile remote afterloader units
(N) 35.652 - Radiation surveys
(O) 35.655 - ~~Five year~~ Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units
(P) 35.657 - Therapy-related computer systems
(Q) 35.690 - Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

(9) **Subpart I.**

(10) **Subpart K; Other Medical Uses of Byproduct Material or Radiation From Byproduct Material**. 35.1000 - Other medical uses of byproduct material or radiation from byproduct material

(11) **Subpart L; Records.**

(A) 35.2024 - Records of authority and responsibilities for radiation protection programs
(B) 35.2026 - Records of radiation protection program changes
(C) 35.2040 - Records of written directives
(D) 35.2041 - Records for procedures for administration requiring a written directive
(E) 35.2060 - Records of calibrations of instruments used to measure the activity of unsealed byproduct materials
(F) 35.2061 - Records of radiation survey instrument calibrations
(G) 35.2063 - Records of dosages of unsealed byproduct material for medical use
(H) 35.2067 - Records of leaks tests and inventory of sealed sources and brachytherapy sources
(I) 35.2070 - Records of survey for ambient radiation exposure rate
(J) 35.2075 - Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material
(K) 35.2080 - Records of mobile medical services
(L) 35.2092 - Records of decay-in-storage
(M) 35.2204 - Records of molybdenum-99, strontium-82, and strontium 85 concentrations.
(N) 35.2310 - Records of safety instruction
(O) 35.2404 - Records of surveys after source implant and removal
(P) 35.2406 - Records of brachytherapy source accountability
(Q) 35.2432 - Records of calibration measurements of brachytherapy sources
(R) 35.2433 - Records of decay of strontium-90 sources for ophthalmic treatments
(S) 35.2605 - Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
(T) 35.2610 - Records of safety procedures
(U) 35.2630 - Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
(V) 35.2632 - Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations
(W) 35.2642 - Records of periodic spot-checks for teletherapy units

(X) 35.2643 - Records of periodic spot-checks for remote afterloader units
(Y) 35.2645 - Records of periodic spot checks for gamma sterotactic radiosurgery units
(Z) 35.2647 - Records of additional technical requirements for mobile remote afterloader units
(AA) 35.2652 - Records of surveys of therapeutic treatment units
(BB) 35.2655 - Records of ~~5 year~~ full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units

(12) **Subpart M; Reports.**
(A) 35.3045 - Report and notification of a medical event
(B) 35.3047 - Report and notification of a dose to an embryo/fetus or a nursing child
(C) 35.3067 - Report of a leaking source
(D) 35.3204 – Report and notification for an eulate exceeding permissible molybdenum-99, strontium-82 and strontium-85 concentrations

(b) **Exceptions.** The provisions for communication with NRC of 10 CFR § 30.6 referenced in §§ 35.12 and 35.14 are not incorporated by reference. All correspondence regarding license requirements, and any notifications or reports required by this Part, shall be directed to DEQ.

PART 40. DOMESTIC LICENSING OF SOURCE MATERIAL

252:410-10-40. 10 CFR 40 incorporations by reference

The following provisions are hereby incorporated by reference from 10 CFR 40, Domestic Licensing of Source Material.

(1) **General Provisions.**
(A) 40.1 - Purpose
(B) 40.2 - Scope
(C) 40.4 - Definitions
(D) 40.7 - Employee Protection
(E) 40.9 - Completeness and accuracy of information
(F) 40.10 - Deliberate misconduct

(2) **Exemptions.** 40.13(c)(6), (c)(9) and (10) - Unimportant quantities of source material

(3) **General Licenses.** 40.25 - General license for use of certain industrial products or devices.

(4) **License Applications.**
(A) 40.31 (a) through (e) - Application for specific licenses
(B) 40.32 (a) through (c) - General requirements for issuance of licenses.
(C) 40.36 – Financial assurance and recordkeeping for decommissioning

(5) **Licenses.**
(A) 40.41 (a) through (c) and (e) - Terms and conditions of licenses
(B) 40.43 - Renewal of licenses
(C) 40.44 - Amendment of licenses at request of licensee
(D) 40.45 - Commission action on applications to renew or amend

(6) **Transfer of Source Material.**
(A) 40.51 (a), (b)(1) through (5), (b)(7), (c) and (d) - Transfer of source or byproduct material
(B) 40.54 - Requirements for license to initially transfer source material for use under the "small quantities of source material" general license
(C) 40.55 - Conditions of licenses to initially transfer source material for use under the

"small quantities of source material" general license. Quality control, labeling, safety instructions, and records and reports

(7) **Records, Reports and Inspections.**

(A) 40.60 (a), (b), (c)(1) and (2) - Reporting requirements

(B) 40.61 (a) through (f) - Records

(C) 40.62 - Inspections

(D) 40.63 - Tests

(8) **Modification and Revocation of Licenses.** 40.71 - Modification and revocation of licenses