



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

MEMORANDUM

TO: Office of State Budget & Management

FROM: Nadine Pfeiffer, DHSR Rule-making Coordinator *NP*

DATE: June 30, 2023

RE: Federal Certification for Radiation Protection Rule Readoptions, Amendment, Repeals

Rule-making Coordinator's Certificate

As Required by GS 150B-19.1(g)
For Proposed Permanent and Temporary Rules Adopted to
Implement a Federal Law or which upon Receipt of Federal Funds is Conditioned

The attached rule-making package applies to rules 10A NCAC 15 .0301-.0305, .0307-.0310, .0312, .0314, .0315, .0317-.0322, .0324, .0327-.0335, .0337-.0344, .0348, .0351-.0365, .0701 and .0702. These rules are proposed for readoption and repeal for all licensees requiring a specific or a general license for the possession and use of by-product material, source material, or special nuclear material, manufacturing devices containing radioactive material, holding licenses of broad scope, who use radioactive materials for medical use in humans, and who sterilize materials using non-self-contained irradiators.

The readoption and repeal of these rules are necessary to come into compliance with the federal regulations in 10 CFR 30 that governs specific licensing of by-product material, 10 CFR 31 that governs general licensing of radioactive materials, 10 CFR 32 that governs the manufacturing and initial distribution of devices containing radioactive materials, 10 CFR 33 that governs licenses of broad scope, 10 CFR 35 that governs the medical use of radioactive materials in humans, 10 CFR 36 that governs the use of non-self-shielded irradiators used for sterilizing materials for commercial distribution, 10 CFR 40 that governs the licensing of source material, and 10 CFR 70 that governs the licensing of special nuclear material. The specific regulations being readopted are:

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

For readoption, general rules applicable to the specific licensing of byproduct material: 10 CFR 30.1, 30.2, 30.3, 30.4, 30.6, 30.9, 30.10, 30.11, 30.12, 30.13, 30.14, 30.15, 30.18, 30.29, 30.20, 30.21(a), (b), and (d), 30.22, 30.31, 30.32(a) – (d), 30.33, 30.34(a) – (c), (e)(2), (e)(4), and (f) – (k), 30.35, 30.36, 30.37, 30.38, 30.39, 30.41(a), (b)(1) – (b)(5), (b)(7), (c), (d), 30.50, 30.51, 30.52, 30.53, 30.61, 30.62, 30.70, 30.71, 30.72, Appendices A, B, C, D, and E to 10 CFR 30.

For readoption, general domestic licenses for byproduct material: 10 CFR 31.1, 31.2, 31.5, 31.6, 31.7, 31.8, 31.9, 31.10, 31.11, 31.12, and 31.21.

For readoption, specific licenses: manufacture or transfer certain items containing byproduct material: 10 CFR 32.1(a), (b) and (c)(2), 32.2, 32.3, 32.13, 32.24, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.59, 32.61, 32.62, 32.71, 32.72, 32.74, 32.201, 32.210, and 32.211.

For readoption, specific domestic licenses of broad scope for byproduct material: 10 CFR 33.1, 33.11(a), 33.12, 33.13, 33.16, 33.17(a) and (b).

For readoption, medical use of byproduct material in humans: 10 CFR 35.1, 35.2, 35.5, 35.6, 35.7, 35.10, 35.11, 35.12, 35.13, 35.14, 35.15, 35.18, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.49, 35.50, 35.51, 35.55, 35.57, 35.59, 35.60, 35.61, 35.63, 35.65, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.100, 35.190, 35.200, 35.204, 35.290, 35.300, 35.310, 35.315, 35.390, 35.392, 35.394, 35.396, 35.400, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.457, 35.490, 35.491, 35.500, 35.590, 35.600, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.657, 35.690., 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2203, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, 35.3067, and 35.3204.

For readoption, panoramic and underwater irradiators: 10 CFR 36.1, 36.2, 36.11, 36.13, 36.15, 36.17, 36.19, 36.21, 36.23, 36.25, 36.27, 36.29, 36.31, 36.33, 36.35, 36.37, 36.39, 36.41, 36.51, 36.53, 36.55, 36.57, 36.59, 36.61, 36.63, 36.65, 36.67, 36.69, 36.81, and 36.83.

For readoption, domestic licensing of source material: 10 CFR 40.1, 40.2, 40.2a, 40.3, 40.4, 40.5, 40.9, 40.10, 40.11, 40.12(a), 40.13, 40.14, 40.20, 40.21, 40.22, 40.25, 40.26, 40.31(a), (b), (d), and (f) – (i), 40.32, 40.34, 40.35, 40.36, 40.41(a) – (c), (e)(2), (e)(4) and (f), 40.42, 40.43, 40.44, 40.45, 40.46, 40.51(a), (b)(1) – (b)(5), (b)(7), (c) and (d), 40.54, 40.55, 40.60, 40.61, 40.62, 40.63, 40.65, 40.71, and Appendix A to Part 40.

For readoption, domestic licensing of special nuclear material: 10 CFR 70.1(a) and (b), 70.2, 70.3, 70.4, 70.5, 70.9, 70.10, 70.11, 70.12, 70.17, 70.18, 70.19, 70.20, 70.21(a)(2), (a)(3) and (b), 70.22(a), (d) and (e), 70.23(a)(1) – (5), 70.25(a)(2), (b) – (h), 70.31(a) and (b), 70.32(a)(2), (a)(3), (a)(8), (a)(9), (b)(2) and (b)(5), 70.33, 70.34, 70.35, 70.36, 70.38, 70.39, 70.41, 70.42(a), (b)(1) – (b)(5), (b)(7), (c) and (d), 70.50, 70.51, 70.55(a) and (b), 70.56, and 70.81.