Medical Use Licensee Temporary Exemptions

During the Emergency Caused by the COVID-19 Pandemic

Updated: August 18, 2020

This table provides a list of 10 CFR Part 19, 20, 30, and 35 requirements for the which the NRC may consider expedited requests for temporary exemption. Licensees may seek a temporary exemption from these requirements to address the challenges licensees may face during the COVID-19 Public Health Emergency (PHE). This table may be updated as the NRC identifies additional requirements for which the NRC may consider expedited requests for temporary exemption.

Regulation	Description of Regulation
35.60(b)	The requirement in 10 CFR 35.60(b) is that the licensee calibrate the instrumentation required in 10 CFR 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions. *(Note: this exemption should only be applied to instrumentation for which nationally recognized standards or manufacturer's instructions require calibration at time intervals of a month or longer. Exemptions from § 35.60(b) should not be issued for other instrumentation without further review. In addition, this exemption should not be combined with extensions in calibrations intervals recommended by nationally recognized standards due to COVID-19 emergency.)*
35.61(a)	The requirement in 10 CFR 35.61(a) is that the licensee calibrate survey instruments used to show compliance with 10 CFR Parts 20 and 35 annually.
35.67(b)(2)	The requirement in 10 CFR 35.67(b)(2) is that the licensee test sealed sources and brachytherapy sources for leakage at intervals not to exceed 6 months at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.
35.67(g)	The requirement in 10 CFR 35.67(g) is that the licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession.
35.290(a)(1) and 35.290(c)(1)(ii)(G)	The requirement in 10 CFR 35.290(a)(1) is that the licensee require an authorized user for uses authorized under 10 CFR 35.200 to be a physician certified by a medical specialty board whose certification process has been recognized by the NRC or Agreement State that requires candidates to complete training and experience that includes work experience under the supervision of an authorized user, that involves – Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs in accordance with 10 CFR 35.290(c)(1)(ii)(G).
35.290(c)(1)(ii)(G)	The requirement in 10 CFR 35.290(c)(1)(ii)(G) is that the licensee require an authorized user for uses authorized under 10 CFR 35.200 to be a physician that has completed training and experience that includes work experience under the supervision of an authorized user, that involves – Eluting generator systems

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	appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs.
35.310(a)	The portion of 10 CFR 35.310(a) that requires licensees to provide radiation safety instruction at least annually to personnel caring for patients or human research subjects who cannot be released under 10 CFR 35.75.
35.410(a)	The portion of 10 CFR 35.410(a) that requires licensees to provide radiation safety instruction at least annually to personnel caring for patients or human research subjects who cannot be released under 10 CFR 35.75.
35.610(d)(2)	The portion of 10 CFR 35.610(d)(2) that requires licensees to provide operational and safety instructions at least annually to individuals who operate the unit at the facility.
35.630(a)	The requirement in 10 CFR 35.630(a) is that the licensee perform calibration on the dosimetry system in accordance with the conditions in paragraph (a)(1) or paragraph (a)(2).
35.633(a)(3)	The requirement in 10 CFR 35.633(a)(3) is that the licensee perform calibration at intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days.
35.633(a)(4)	The requirement in 10 CFR 35.633(a)(4) is that the licensee perform full calibration at intervals not exceeding 1 year for low dose-rate remote afterloader units.
35.635(a)(3)	The requirement in 10 CFR 35.635(a)(3) is that the licensee perform full calibration at intervals not exceeding 1 year for gamma stereotactic radiosurgery units.
35.655(a)	The requirement in 10 CFR 35.655(a) is that the licensee shall have each **[teletherapy unit/gamma stereotactic unit]** fully inspected and serviced at intervals not to exceed **[5 years for each teletherapy unit/7 years for each gamma stereotactic radiosurgery unit]**.
35.3045(d)	The requirement in 10 CFR 35.3045(d) is that the licensee submit a written report to the appropriate regional office within 15 days after discovery of a medical event.
20.1101(c)	The requirement in 10 CFR 20.1101(c), is that the licensee shall periodically (at least annually) review the radiation protection program content and implementation.
19.13(b)	The requirement in10 CFR 19.13(b), is that each licensee shall provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year if (1) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or (2) The individual requests his or her annual dose report.

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Regulation	Description of Regulation
30.34 (Annual Radiation Safety Training License Condition)	The requirement in License Condition **[number]** is to comply with the commitment in the letter dated XXXX to provide annual radiation safety refresher training as described in NUREG-1556, Volume 9.