



April 9, 2020

Attn: ACMUI COVID-19 Subcommittee
U.S. Nuclear Regulatory Commission
Two White Flint North
11545 Rockville Pike
Rockville, MD 20852-2738

Re: NRC regulatory relief options for medical licensees during the COVID-19 pandemic

The American College of Radiology (ACR)—a professional association representing nearly 40,000 diagnostic radiologists, interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists—appreciates the outreach from the U.S. Nuclear Regulatory Commission (NRC) and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) to compile regulatory relief ideas for medical use licensees during the COVID-19 pandemic. The following ACR input describes two overarching problems and corresponding alleviations for ACMUI and NRC staff to consider. We recognize there may be additional considerations identified by the ACMUI COVID-19 Subcommittee that could be of assistance to licensees.

Problem 1: Vendors, contractors, regulators/inspectors, and other third parties should only visit medical licensees when necessary for the safety of all involved until further notice. Many hospitals and other institutions have implemented policies that would indirectly prevent technical or administrative tasks required by NRC regulations. For example, a significant number of licensees comply with NRC’s periodic calibration and testing requirements by having “nuclear medicine audits” performed by contracted professionals—these audits may be infeasible or unadvisable during the pandemic. To reduce regulatory burden, and more importantly avoid the added risk of virus exposure that may arise from visits to NRC-licensed medical facilities, ACR recommends the following alleviations be universally applied (i.e., not implemented on a case-by-case basis):

1. NRC and Agreement State agencies should delay all non-essential site inspections of medical licensees until further notice.
2. NRC should implement a clear and temporary policy of enforcement discretion (i.e., will not enforce) with respect to the following deadline-oriented regulatory requirements:
 - a. The six-month leakage testing requirement for sealed sources in 10 CFR 35.67(b)(2);
 - b. The annual calibration requirements for survey instruments in 10 CFR 35.61(a); and,
 - c. The timelines for dosimetry equipment calibration and record-keeping requirements described in 10 CFR 35.630.
3. NRC should issue a State and Tribal Communications (STC) letter with the dual purpose of:
 - a. Notifying Agreement State agencies of these temporary changes; and,
 - b. Recommending implementation of equivalent enforcement policies within Agreement States.

Problem 2: ACR members and radiology practice managers are reporting severely reduced patient volumes. Centers for Disease Control and Prevention (CDC) guidelines recommend delaying all elective ambulatory provider visits, rescheduling elective and non-urgent admissions, and delaying inpatient and outpatient elective surgical and procedural cases. Most NRC-regulated medical uses are generally included in this categorization. Some radiology practices are reporting losses as high as 70 percent, and there are reports of facilities terminating or furloughing employees. To provide some financial relief to licensees and improve job opportunities for unemployed authorized professionals, the ACR recommends the following alleviations be universally applied (i.e., not implemented on a case-by-case basis):

1. We recognize NRC's budget authority recovery requirements; however, NRC should waive or reduce all fees for medical licensees for FY 2020, or minimally delay payment deadlines for FY 2020 until CY 2021.
2. Due to employment terminations and the resultant increase in transitions of authorized professionals from one licensee to another, NRC should prioritize and expedite the review of medical use license amendments.

The above issues and recommendations are non-exhaustive, and we welcome the opportunity to consider and provide feedback on any additional ideas from ACMUI or NRC staff. Please contact Michael Peters, ACR Director of Legislative and Regulatory Affairs, at (202) 223-1670 or mpeters@acr.org with questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'G. McGinty', written in a cursive style.

Geraldine B. McGinty, MD, MBA, FACR
Chair, Board of Chancellors
American College of Radiology