U.S. Nuclear Regulatory Commission
Advisory Committee on the Medical Uses of Isotopes

ACMUI COVID-19 Subcommittee

Proposal for NRC Regulatory Relief Options during COVID-19 Pandemic

Final Report

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Subcommittee Charge

The COVID-19 Subcommittee was formed on March 30, 2020, by Dr. Darlene Mettler, Chair of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). The charge of the Subcommittee is to propose potential options for regulatory relief for licensees of the Nuclear Regulatory Commission (NRC) because of and during the COVID-19 pandemic.

Introduction

The emergence of the COVID-19 outbreak has prompted many changes in everyone's personal and professional life. Mitigation through physical distancing and focus of hospitals and clinics on caring for patients with suspected or known COVID-19 has led to a new environment in which individuals and organizations operate.

The Subcommittee received information from a number of stakeholders, including the American College of Radiology (ACR), the American Society of Radiation Oncology (ASTRO), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the American College of Nuclear Medicine (ACNM), American Board of Nuclear Medicine (ABNM), Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR), and reviewed ancillary information that have been released by various governmental entities including the Food and Drug Administration (FDA) and the Center for Medicare and Medicaid Services (CMS). The following proposed regulatory

relief options are a brief review of the result of an amalgamation of this information in consultation with NRC staff.

NRC Medical Licensees COVID-19 Pandemic Regulatory Relief Options

General Comments

It is clear that in view of the major changes in the operations of the hospitals and medical clinics prompted by the COVID-19 outbreak and the general decree for physical distancing (including shelter-in-place and work from home to the extent feasible), telehealth, and postponement of many non-urgent and elective diagnostic and therapeutic procedures, licensees may be unable to meet specific regulatory requirements in a timely manner. However, the licensees may consider alternative pathways in actively managing and meeting the requirements safely to the extent feasible and in keeping with the local guidelines and conditions. If delays are anticipated for regulatory relevant activities, licensees should contact the NRC or regional regulatory office (via phone, email, or letter) in expressing their need for temporary exemption request. NRC has provided a "Temporary Exemption Template for Medical Use Licensees during the COVID-19 Pandemic" on April 10, 2020 (ML20098D638). Questions can be referred to MedicalQuestions.Resource@nrc.gov.

Specific Comments

1) Training and Education
   Currently due to COVID-19 pandemic, there has been a major decline in elective and procedural cases. In compliance with local regulations, if and when an AU cannot be physically present, then the AU can participate remotely via secure virtual platform for radiotherapeutic administration (e.g. I-131, Lu-177 DOTATATE) if the procedure is clinically indicated and cannot be postponed. Moreover, the American Board of Nuclear Medicine (ABNM) has notified the Nuclear Medicine Program Directors in their letter dated March 25, 2020, announcing a one-time modification of case experience requirements in 2020 for all COVID-19 related reasons. In situations when hands-on training (hot lab) is not feasible, then virtual observational training may be considered. Similarly, when work experience cannot be met in person, then virtual training may be considered.

2) Regulatory Reporting
   If delays are anticipated for regulatory relevant reporting, licensees should contact the NRC or regional regulatory office (via phone, email, or letter) to express their need for a temporary exemption request. Delay in non-urgent reporting requirements is reasonable (proposed 90 days). Reporting deadline in 10 CFR 20.2206 (Reports of Individual Monitoring) and NRC Form 5 (Occupational Dose Record for a Monitoring Period) can be considered to be changed from April 30, 2020, to July 31, 2020 (analogous to postponed IRS Tax Filing Day). Licensees should refer to the COVID-19 Regulatory Activities for Nuclear Materials web page for the most up-to-date NRC recommendations (https://www.nrc.gov/about-nrc/covid-19/materials/med-indust-academic.html).

3) Medical Event Reporting
   Only if specifically requested by the licensee, it is reasonable to allow variance on written reporting requirements for an initial report and ameliorating plans of the incident to the NRC or regulatory agency within 15 days and the full incident report in 30 days (vs.15 days). If further delays are anticipated, licensees should contact the NRC or regional regulatory office (via phone, email, or letter) in expressing their need for temporary exemption request.

4) Radiation Safety Activities
   Delay (proposed 90 days) in regular radiation safety activities by the Radiation Safety Officers may be reasonable. However, licensees should consider alternate methods of meeting requirements prior to requesting an exemption. For example, if a Radiation Safety Officer (RSO) typically travels to a clinic to perform calibration or inventory activities, licensees should evaluate whether technologists on-site can perform the required task. This proposal does not apply to urgent situations such as major radioactive spills. All local regulations should be followed for the safety of the RSO and others involved. AU's may participate remotely via secure virtual platform to supervise, review and approve treatment plans, and sign the written directive, etc. Any annual refresher training required for the radiation safety program should be postponed (up to 90 days) during the public health emergency.

5) Physical Presence
   The ACMUI recommends no change to the physical presence requirement for HDR or Gamma Knife Stereotactic Radiosurgery. These are high risk procedures that require the physical presence of the AMP and AU as outlined in Part 35 and appropriate guidance documents.

6) Inspections
   Any inspections that require inspectors and licensees to be physically present and/or in the same room should be postponed up to 90 days.

7) Regulatory Fees
   Due to significant decline in radiology practice volume, and other economic ramifications of COVID-19 pandemic, ACMUI supports delaying payment of all relevant fees for FY 2020 for a specified period (proposed 90 days). Moreover, review of medical use licensees' amendment requests related to COVID-19 can be considered for expedited review.

The ACMUI unanimously approved this report and its recommendations, as presented, during a public teleconference meeting on April 30, 2020.

Respectfully Submitted,
ACMUI COVID-19 Subcommittee
Advisory Committee on the Medical Uses of Isotopes