Advisory Committee on the Medical Uses of Isotopes

Public Teleconference Meeting
April 30, 2020

Meeting Handout

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

Draft Report

April 27, 2020

Subcommittee Members:
Dr. Vasken Dilsizian
Mr. Richard Green
Dr. Hossein Jadvar (Chair)
Ms. Melissa Martin
Ms. Megan Shober
Dr. Harvey Wolkov

Subcommittee Consultants - Non-Voting:
Mr. Gary Bloom (Patients' Rights Advocate)
Mr. Zoubir Ouhib (Therapy Medical Physicist)

NRC Staff Resource:
Ms. Lisa Dimmick

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.

Respectfully Submitted on April 27, 2020,
ACMUI COVID-19 Subcommittee
Advisory Committee on the Medical Uses of Isotopes

Supporting Documentation

ACR®
AMERICAN COLLEGE OF RADIOLOGY
QUALITY IS OUR IMAGE

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,

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

COVID-19 Information for Medical Physicists

AAPM recognizes the uncertainty surrounding the COVID-19 pandemic and the disruption that this has brought to almost every aspect of our lives, and will continue to advocate for the best interest of our members, our profession, and our communities.

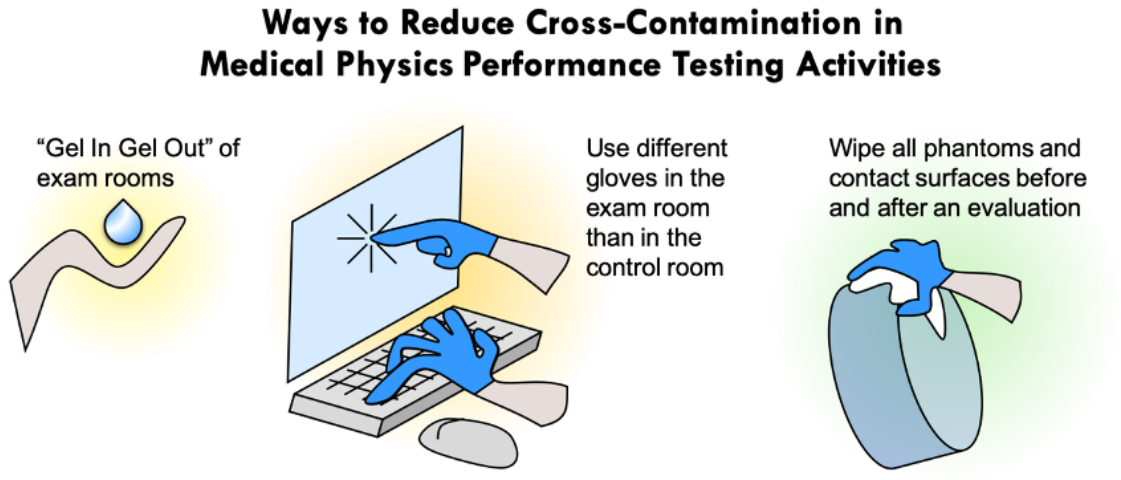
Relevant professional information will be shared as we become aware of it. If you become aware of an item that is not on this list, please share that information by **sending an email**. Members are reminded to visit the provided links and organizational websites to find the most up-to-date information available.

IMPORTANT INFORMATION FOR OUR AAPM MEMBERS

- **Clinical practice resources**
  - March 24, 2020: **Letter from Brent Parker, Chair of AAPM Professional Council** 🔒
  - March 24, 2020: **Setting up a temporary display device for diagnostic interpretation** 🔒
    If you make use of this content, please acknowledge the Clinical Imaging Physics Group at Duke University, who is sharing its procedure to facilitate proper calibration of monitors that will be used for diagnostic interpretation. Users are responsible to confirm that the procedure and settings are appropriate for their practice.

ENSURING THE SAFETY OF PATIENTS AND COWORKERS

- Follow all recommendations of your employer or the facility in which you are working
- Follow all recommendations of your state health department and the CDC
- Reschedule performance testing of clinical equipment, if possible (see section on ***Ensuring Testing Requirements Are Met***)
- If you are testing equipment in a clinical environment (e.g., exam or treatment room),
- Wash your hands according to CDC recommendations prior to entering the clinical environment
- Sanitize the surfaces of your testing equipment, using procedures approved by the phantom or device manufacturer, before bringing your equipment into contact with items in the clinical environment; this avoids introducing any infectious agents into the clinical environment
- Determine the facility's procedure for sanitizing objects that you will come into contact with, including keyboards and equipment control panels
  - gloves may be available for your use or you may wish to bring your own
  - do not use personal protection equipment in the facility without permission, including gloves, masks, or protective garments, as many facilities are limiting use to only essential patient care activities
  - use caution in sanitizing computer screens; some sanitizing agents may damage screen surfaces
- Sanitize surfaces that you will touch prior to beginning your work
- Use hand sanitizer before entering and upon exiting the patient exam or treatment room
- If you are using gloves and are not limited in the number that you can use, you may wish to put on new gloves before entering and upon exiting the patient exam or treatment room
- After testing is complete
  - properly discard all disposable materials with which you have come into contact
  - place all linens that you have come into contact with into the dirty linen container
  - sanitize the surfaces of your testing equipment again; this avoids transporting any infectious agents from the clinical environment to another location
  - sanitize surfaces that you have touched just prior to exiting the room



ENSURING TESTING REQUIREMENTS ARE MET

At present, many healthcare facilities have greatly limited access to their facilities. We are hearing from members that some have been denied access to equipment needing performance testing, such as to meet regulatory or accreditation requirements, including after equipment has been serviced.

In response, AAPM has communicated with a number of organizations requesting extensions to the frequency requirements for such testing. We will update this site as we learn of such extensions being put in place. If you are aware of an extension that is not on this list, such as in your state, please **email that information** so that we can update this list.

Requests to defer testing required by state regulations should be directed to the appropriate state agency, who may require facility-specific requests for a variance to be submitted. We will include information about any state-wide extensions, variances, or exceptions if we are provided a link to an official statement from the state.

- **American College of Radiology (ACR)**
  - March 11, 2020: Annual medical physicist equipment survey testing requirements extended to 16 months
    In response to increasing limitations and restrictions of physicist access to imaging facilities due to the COVID-19 outbreak, the ACR will extend the annual medical physicist equipment survey accreditation requirement to a 16-month window from date of last equipment evaluation. Facilities needing a longer extension and those who are unable to obtain physics testing or acceptance testing on new units are asked to contact the ACR for further guidance.
  - For up-to-date guidance, please visit the program-specific links
    - **Breast MRI**
    - **Breast Ultrasound**
    - **CT**
    - **Mammography**
    - **MRI**
    - **Nuclear Medicine and PET**
    - **Radiation Oncology Practice**
    - **Stereotactic Breast Biopsy**
    - **Ultrasound**

- **U.S. Food and Drug Administration (FDA)**
  - March 18, 2020: MQSA Inspection Information Related to COVID-19
    The Division of Mammography Quality Standards (DMQS) has received numerous inquiries regarding COVID-19 and its increasing impact on mammography facilities. The FDA has temporarily postponed domestic inspections including ones performed under contract with its state regulatory partners. The **FDA press release can be found here**. As such, DMQS is providing appropriate regulatory flexibility and posting the following information regarding common scenarios that may arise due to the evolving COVID-19 situation in the United States. **More information can be found here**.

- **Intersocietal Accreditation Commission (IAC)**
  - March 24, 2020: The IAC will grant extensions for up to 18 months for the completion of the annual physicist survey requirement to accommodate urgent facility priorities and to allow the AAPM community flexibility in the management of the influx of requests that will come as the pandemic resides. **More information can be found here**.
  - March 23, 2020: **IAC Letter to AAPM President**

- **The Joint Commission (TJC)**
  - March 16, 2020: **Regular survey visits to hospitals suspended**
  - At this time required testing intervals have not been changed. The Joint Commission does not have the authority to change CMS Conditions of Participation on which the Joint Commission standards are based. In the daily meeting between CMS and the AOs, this was discussed and CMS indicated that organizations that wish to extend testing intervals should **file for an 1135 waiver**.

ENSURING EDUCATIONAL REQUIREMENTS ARE MET

- **The American Board of Radiology**
  - March 5, 2020: **Medical Physics oral exam scheduled for April 26-29 postponed**

- **Online Learning Opportunities**
  - **AAPM Virtual Spring Clinical Meeting**
    - **SAMS credits available!**

- AAPM Virtual Library
- AAPM Online Learning Center

[External] Regulatory Relief

Cindy Tomlinson <cindy.tomlinson@astro.org>

Wed 4/8/2020 6:15 AM

To: Jadvar, Hossein <jadvar@med.usc.edu>
Cc: Harvey Wolkov <hbwolkov@comcast.net>

Dr. Jadvar –

Below please find ASTRO's thoughts on NRC regulatory relief in the medical space.

> Any annual trainings for already credentialed licensees that are required to take place during the national emergency should be either canceled (where appropriate) or postponed.
> Any inspections that require inspectors and licensees to be present and/or in the same room should either be postponed or transitioned to an online virtual platform. Inspectors should be flexible and postpone as much as possible. Licensees are understandably focused on the safety of their patients and staff, and may not have the personnel available to accommodate an inspection during the national emergency.
> Physical presence requirements for HDR and Gamma Knife should not be changed during the national emergency. These are high-risk treatments that require the physical presence requirements as outlined in Part 35 and appropriate guidance documents.
> Training and experience requirements should not be changed during the national emergency. We see no impact of COVID-19 on the ability of physicians to meet current T&E requirements at this time.

Please let me know if you have any questions.

-Cindy

Cindy Tomlinson, MPP
Senior Patient Safety and Regulatory Affairs Manager
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The following are recommendations for regulatory relief during the COVID-19 era from our various committees and industry partners. They are divided into sections with [] noting who authored (person, organization) the recommendations.

Reporting Requirements (including adverse event reporting)

1. A delay in some reporting requirements is reasonable during the period of emergency. Sites could request a waiver for delay or the NRC could grant a blanker waiver for non-agreement states. Such a decision would also help inform agreement states on reasonable courses of action. The annual reporting to the NRC and agreement states of radiation safety programs should be delayed 2-3 months. An extension of the April 30 deadline for 2019 NRC Form 5 reports would also be useful. [David Schuster, SNMMI Committee on Radiopharmaceuticals]
2. Reporting of adverse events remains an important public safety occurrence. It is reasonable to allow variance on the notification requirements (10 CFR 35.3045) of the physician and patient to greater than 24 hours during emergency periods – doubling the time would be reasonable. The 15 day requirement for the submission of a full written report to may not be feasible during surge COVID-19 conditions. Possible ameliorations include lengthening the 15 day requirement to 30-45 day or allowing a brief incident report describing the event with initial plan within the 15 day window and a full report after an appropriate day (30-45 days). [David Schuster, SNMMI Committee on Radiopharmaceuticals]
3. Move the reporting deadline in 10 CFR 20.2206(c) and NRC Form 5 information from April 30, 2020 to July 31, 2020, analogous to the movement of Tax Day. [Michael Guastella, CORAR]
4. One manufacturer uses Mirion as a dosimetry vendor. Mirion is located in California and there are issues with them meeting dosimetry demand and keeping up with dose reporting, including Form 5s and REIRS report. During the COVID-19 Pandemic, we recommend that NRC grant extensions for submitting Form 5s and REIRS reports that are due on April 30th. [Michael Guastella, CORAR & Sue Bunning, MITA]

Practice Licensing Requirements

1. Under 10 CFR 35.13 for license amendments, CORAR nuclear pharmacy members foresee needing to have rapid coverage of nuclear pharmacists across State lines with documentation to show that Authorized Nuclear Pharmacists (ANPs) are licensed and qualified per 10 CFR 35.55. However, this may be without a formal amendment if COVID-19 restrictions last more than 60 days, which is currently allowed by the rule. Many Boards of Pharmacy are issuing guidance that if an ANP holds any valid Board of Pharmacy (BOP) license in the US they will honor reciprocity – please see example attached. We recommend that NRC issue a clarifying statement on ANP reciprocity during the COVID-19 Pandemic. [David Schuster, SNMMI Committee on Radiopharmaceuticals]

Local Inspections/Audits

1. During time of emergency, delaying regular inspections by the radiation safety officer(s) of the site is reasonable and likely advisable. Reducing the opportunities for exposure is preferable to help ensure radiation safety officers are available to respond to urgent situations such a radiation spills. [David Schuster, SNMMI Committee on Radiopharmaceuticals]
2. Traditionally nuclear pharmacy chains conduct independent corporate audits annually per 10 CFR 20.1101. However with chain nuclear pharmacy corporate auditors grounded, because of COVID-19 travel restrictions, auditors cannot travel. As a result, "remote audits" are conducted where auditors dial into nuclear pharmacy databases, using remote tools to obtain required data, to support the audits. We recommend that NRC issue a clarifying statement on "remote audits." [Michael Guastella, CORAR]
3. From a corporate radiation safety standpoint, we have suspended our in-person performance based compliance auditing of the radiation protection program. We are still conducting remote desktop radiation record audits to the extent possible. This may result in some of our compliance auditing commitments to be overdue. [Elizabeth Gillenwalters, PETNET]
4. From a site radiation safety program perspective, relief on timeframes related to radiation protection program tasks would also be helpful. For example, Landauer is currently limiting staff and our dosimetry processing and results are slower than usual. This could result in employees wearing their dosimetry longer than the listed wear period and impacts the timeframe for ALARA investigations. A site that experiences limited staff due to illness may also need extra time to complete radiation protection tasks and review/approve documentation. [Elizabeth Gillenwalters, PETNET]
5. I haven't heard of delays with recalibration of radiation monitoring equipment, however that is a real possibility as well. [Elizabeth Gillenwalters, PETNET]

Training and Experience

1. The NRC has a regulatory path for education outside of a formal training program should some residency of fellow trainees not complete the requirements prior to completion in June. Per recent NRC communication, a national shortage of authorized users was not identified when NRC staff were evaluating possible changes to the training requirements. [David Schuster, SNMMI Committee on Radiopharmaceuticals]

Clinical Setting

1. Social distancing has made me wonder why we need a physicist in the IR suite every time we do a Y90 microspheres therapy. In my 15 years doing SirSpheres and TheraSpheres, we have never used their services (we have a tech doing all of the surveying). Waiting for the physicist to arrive frequently delays the therapy and unnecessarily increases the duration of the sedation (this potentially could have adverse effects). Could the requirement for a physicist to be present in the IR suite during every Y90 therapy be relaxed to have a physicist in the building or immediately reachable by phone in case there ever is a spill or accident? [Kenneth Bennet, SNMMI Coding and Reimbursement Committee]

Supply Chain

1. Anything they can do to facilitate the supply of radionuclides from overseas given the drop in commercial flights. Mo-99, Sr-82, there must be others. Working with the FDA to improve importation. Military flights? I believe these may still be working in the opposite direction for enriched uranium. [Adrian Nun, SNMMI FDA Task Force]
2. CORAR requests that the NRC and Organization of Agreement States focus on all licensing activities that can immediately improve supply of radioisotopes for diagnosis and therapy, with the highest urgency. [Michael Guastella]
3. Extreme patient triaging leading to a significant reduction of number of Nuc Med studies means less demand for Moly-99/T99m radio-isotopes for which supplies chains are at risk of not being able to sustain themselves (lack of customers) and may shut down/go bankrupt endangering future use/security/availability of medical radio-isotopes. [Holly Thompson, SNMMI Government Relations Committee]
4. Local storage of Radioactive material at supply chain sites? If not being sold/distributed (due to reduction in above) what is the capacity and safety of radioactive material build-up at productions sites? [Holly Thompson, SNMMI Government Relations Committee]

Additional Comments

1. CORAR suggests that NRC put in to place a general framework to help nuclear pharmacies with regulatory requirements, license commitments, and requirements of marketing authorizations when COVID-19-related issues arise. The proposed general framework for when COVID-19-related issues arise is:
   A. Nuclear pharmacy staff do as much as possible to meet regulatory requirements or commitments.
   B. If there is a challenge, nuclear pharmacy staff (e.g. RSO) investigate alternative ways to comply with the requirements or commitments.
   C. If unable to comply with the commitment or requirement, the nuclear pharmacy staff will document why the commitment or requirement can't be met.
   D. Lastly, nuclear pharmacy staff will comply with the requirements or commitments, and document compliance, as soon as local COVID-19 conditions allow. [Michael Guastella]
2. Put in to place a general framework to help us with regulatory requirements, license commitments, and requirements of marketing authorizations when COVID-19-related issues arise. The proposed general framework for when COVID-19-related issues arise is:
   A. Do as much as we can to meet the regulatory requirement or commitment.
   B. If there is a challenge with that, then consider alternative ways to meet the requirement.
   C. If we are unable to meet the commitment or requirement, then document why we can't meet it.
   D. Lastly, meet the requirement as soon as local conditions allow. [Sue Bunning, MITA]