ILLINOIS EMERGENCY MANAGEMENT AGENCY
DIVISION OF NUCLEAR SAFETY

2022 CHANGES TO PART 330 AND 335
FREQUENTLY ASKED QUESTIONS

- **Do licensees have to continue to identify physicians as authorized users (AU) on the license if they are only performing interpretations of tests and studies?**

  Effective December 2021, the requirement in 32 Ill. Adm. Code 335.1060 that an AU must render an interpretation of a diagnostic image or results of a therapeutic procedure was repealed. IEMA recognizes that the AU may or may not be the physician who interprets such studies. Additionally, IEMA regulations do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of radioactive material to individuals.

  For more information on this topic please see Item 5A. of Instructions Set 52.2, Rev. 4.

- **Were preceptor attestations eliminated for all board-certified individuals?**

  Attestations were eliminated for almost all individuals certified by boards recognized by NRC on its website or as specified in 32 Ill. Adm. Code 335. Board certifications must have the appropriate annotations as specified on the NRC website and meet the recentness of training requirements in 32 Ill. Adm. Code 335.9180.

  For more information on this topic please see Item 5A. of Instructions Set 52.2, Rev. 4.

- **Who will continue to need a preceptor attestation?**

  Individuals applying under the alternate training and experience pathway and all physicians applying to be authorized users requesting approval for parenteral administration of unsealed byproduct material requiring a written directive will continue to need a preceptor attestation, as there is currently no approved board certification.

  Individuals applying for uses under 32 Ill. Adm. Code 335.2140, Emerging Technologies, should consult Agency guidance or contact a license reviewer for further guidance.

  For more information on this topic please see Item 5A. of Instructions Set 52.2, Rev. 4.

- **Can a medical use licensee have more than one Radiation Safety Officer (RSO)?**

  No, there can be only one RSO who is responsible for the Radiation Protection Program (RPP), but there may be more than one Associate Radiation Safety Officer (ARSO), or more than one temporary RSO in accordance with 32 Ill. Adm. Code 335.1040.

  For more information on this topic please see Item 6 of Instructions Set 52.2, Rev. 4.

- **Why would a licensee want to have an Associate Radiation Safety Officer (ARSO)?**

  The licensee may want to request a license amendment to identify one or more individuals to assist the Radiation Safety Officer (RSO). The approved ARSO(s) would be listed on the license. The ARSO(s) would be assigned duties and tasks in the oversight of the radiation safety operations of designated sections of the licensed program, while reporting to the named RSO. The ARSO is not equivalent to the temporary RSO described in 32 Ill. Adm. Code 1040(c).

  The regulations continue to allow a licensee to name only one RSO on a license, who would be responsible for the day-to-day oversight of the RPP. Similarly, licensees with multiple program components or operating locations could appoint one or more qualified ARSOs to perform duties and tasks in the oversight of designated program components or locations of use.

  For more information on this topic please see Item 6B of Instructions Set 52.2, Rev. 4.

- **What happened to the regulatory provision for delegation of RSO duties?**

  The provision for delegation of RSO duties was removed from the regulations, and it has been replaced with the ARSO provisions discussed above. This regulatory change implementing the ARSO position formalizes the Agency's past policy where individuals were delegated duties where there was a demonstrated lack of training and experience of the named RSO in a specific modality. Going forward all individuals fulfilling this role should be named on the license.

  The Agency requires that the ARSO be listed on the license to avoid confusion between individuals working in a radiation program and those that meet uniform training and experience criteria and are formally delegated duties and tasks for oversight of parts of the radiation safety program. The regulator's review of the potential ARSO's training and experience ensures all individuals meet the same standards. This allows the individual who is named as an ARSO to be recognized by the Agency, an Agreement States and the NRC as an RSO or ARSO for the same medical uses on another license without resubmitting their training and experience documents.

  For more information on this topic please see Item 6B of Instructions Set 52.2, Rev. 4.

- **Will a licensee need to notify the Agency when the Associate Radiation Safety Officer (ARSO) discontinues performance of duties?**

  Yes, a licensee is required to notify the Agency no later than 30 days after the ARSO discontinues performance of duties under the license.

  For more information on this topic please see Item 6B of Instructions Set 52.2, Rev. 4.

- **What about temporary RSOs?**

  Temporary RSOs are still allowed under 32 Ill. Adm. Code 335.1040(c) for situations where the RSO will be absent from the program for up to 60 days per year for vacations, medical leaves, etc. 32 Ill. Adm. Code 335.45(b)(2) has notification requirements when naming a temporary RSO.

  For more information on this topic please see 32 Ill. Admin. Code 335.1040.

- **Can an ARSO provide a preceptor statement for someone applying to be a Radiation Safety Officer?**

  Yes, provided the ARSO has experience with the radiation safety aspects of similar types of use of byproduct material for which the ARSO is providing the attestation.

  The regulatory reference for this topic can be found in 32 Ill. Adm. Code 335.9010.

- **If a licensee is authorized for specific medical uses and wants to expand those medical uses, does the Radiation Safety Officer (RSO) need additional training for the new uses?**

  Yes. The RSO needs to obtain additional training, or document that they received related training and experience within the past 7 year.

  The regulatory reference for this topic can be found in 32 Ill. Adm. Code 335.9010(f).

- **If a licensee previously committed to having a Radiation Safety Committee (RSC) and at least one of the two modalities was 32 Ill. Adm. Code Subpart E, but now Part 335 does not require an RSC for the licensee's facility, does the licensee need to request and receive an amendment to the license before implementing the change**?

  32 Ill. Adm. Code Part 335.1040(f) was modified to remove Subpart E from the pool of subparts that require a licensee to establish a Radiation Safety Committee (RSC). Subpart E includes unsealed radioactive material for imaging and localization studies for which a written directive is not required. It does not include diagnostic tests that require a written directive since these tests fall under Subpart F.

  If a licensee previously made commitments for an RSC because they were authorized for two modalities and one of the modalities was Subpart E, then an amendment is necessary to remove these commitments.

  For more information on this topic please see Item 6C. of Instructions Set 52.2, Rev. 4.

- **Why is an ophthalmic physicist (OP) added to the regulations?**

  Several medical events have occurred over the years that were caused by fundamental errors in calculating doses for strontium-90 eye applicators. The identification of these problems is typically performed by the authorized medical physicist (AMP). However, nationally there are small ophthalmic therapy licensees in rural or isolated areas that had difficulty finding a local AMP. Therefore, the ophthalmic physicist has been added to identify another individual that could perform the medical physics tasks associated with ensuring that ophthalmic therapies are administered in accordance with written directives.

  For more information on this topic please see Item 5C. of Instructions Set 52.2, Rev. 4.

  Do licensees still need to receive an amendment before permitting an authorized user (AU), authorized medical physicist (AMP), or ophthalmic physicist (OP) to work under the license?

  Effective December 2021, licensees may allow individuals meeting the criteria specified in 32 Ill. Adm. Code 335.40 (recentness of training with either applicable board certification or current identification on a license for the requested use) to begin work under a license without first receiving an amendment. However, 32 Ill. Adm. Code 335.45 requires notification with supporting documentation to the Agency within 30 days of allowing an individual to work under the provisions of subsection 335.40(b). If you have previously submitted an amendment request to add an AU, AMP or OP and wish for the request to be

considered as a notification under 32 Ill. Adm. Code 335.45, please notify the Agency at ema.speclic@Illinois.gov. Similar provisions for authorized nuclear pharmacists (ANP) exist in 32 Ill. Adm. Code 330.260(c)(6)(B).

The regulatory references for this topic can be found in 32 Ill. Adm. Code 335.40 and 335.45.

- **Why is IEMA requiring an increased frequency under 32 Ill. Adm. Code 335.4020 Mo-99 breakthrough tests?**

  Medical use licensees have reported that numerous generators had shown no Mo-99 breakthrough in the first eluate but failed the Mo-99 breakthrough tests performed on subsequent eluates. It is important to measure the Mo-99 concentration in each eluate to ensure patients are not administered amounts of Mo-99 in excess of regulatory limits.

  The regulatory reference for this topic can be found in 32 Ill. Adm. Code 335.4020.

- **Who needs to report breakthrough values in excess of regulatory limits for Mo 99/Tc 99m and Sr-82/Rb-82 generators? Who do they have to report to?**

  Under 32 Ill. Adm. Code 335.4020(d), a licensee that elutes the generator must report the results to the Agency and the distributor of the generator. This could be a commercial nuclear pharmacy or a medical use licensee who elutes their own generators.

  The regulatory reference for this topic can be found in Ill. Adm. Code 335.4020(d).

- **How long do licensees that elute generators have to notify IEMA when an eluate from a generator exceeds the permissible concentration listed in 32 Ill. Adm. Code 4020(a)?**

  Under 32 Ill. Adm. Code 4020(d), licensees eluting generators must make a telephone notification to the Agency and the distributor within 7 calendar days after discovering that an eluate exceeded the permissible concentration listed in 32 Ill. Adm. Code 4020(a). The licensee must also submit a written report to the Agency within 30 days of this discovery.

  The regulatory reference for this topic can be found in 32 Ill. Adm. Code 335.4020(d) and 310.110.

- **What reports are made to IEMA by the licensee who eluted the generator when an eluate exceeds the permissible concentrations listed in 32 Ill. Adm. Code 4020(a)?**

  The licensee eluting the generator must report generator and elution information, whether dosages were administered, and when the distributor was notified. If patient dosages were administered, a dose assessment must be performed, and the methodology of the dose assessment described. If an error occurred in the licensee's breakthrough determination, the report must include action taken by the licensee, probable cause, evaluations and assessments of failure in the licensee's equipment, procedures, or training that contributed to the excessive readings.

  The regulatory reference for this topic can be found in 32 Ill. Adm. Code 335.4020(d) and 310.110.

- **May a licensee use calibration, transmission, or reference sources to aid in performance of patient imaging and localization procedures if the sources otherwise meet the requirements of 32 Ill. Adm. Code 335.2040?**

Yes. Some licensees may not recognize that use of calibration, transmission, or reference sources during imaging procedures meets the definition of medical use if this results in radiation exposure to the patient. 32 Ill. Adm. Code 335.2040 recognizes that medical use of calibration, transmission, and reference sources must be performed in accordance with the requirements in 32 Ill. Adm. Code 335.6010 and a physician authorized for 32 Ill. Adm. Code 335.4010 medical uses by 32 Ill. Adm. Code 335.9040 to use these sources.

The regulatory reference for this topic can be found in 32 Ill. Adm. Code 335.9040.

- **If a licensee uses calibration, transmission, or reference sources in patient imaging and localization procedures when the sources otherwise meet the requirements of 32 Ill. Adm. Code 335.2040, do these sources need to be specifically listed on the license?**

  No. Calibration, transmission, or reference sources that are used for medical use in accordance with the requirements of 32 Ill. Adm. Code 335.6010 and are not bundled to result in an activity greater than that specified in 32 Ill. Adm. Code 335.2040 do not have to be listed on the license.

  The regulatory reference for this topic can be found in 32 Ill. Adm. Code 335.2040.

- **When individuals are required to be "physically present" during various phases of several therapeutic medical uses, does "within audible range and in such proximity that immediate assistance can be given if required" include through use of "walkie-talkies"?**

  No. Use of communication devices, including "walkie-talkies," would enable the identified individuals to be at a distance from the location of therapeutic medical use, and thus not "physically present" (i.e., "within audible range and in such proximity that immediate assistance can be given if required"). However, use of communication devices, including "walkie-talkies," by identified individuals is permitted when the requirement is for the individual to be "immediately available" (i.e., "available on an on-call basis to respond to an emergency").

  The regulatory reference for this topic can be found in 32 Ill. Adm. Code 335.8050.

NOTE: During the transition period Agency Inspectors may use discretion when citing an item of noncompliance in the Radiation Protection Program where there is not a significant health or safety risk.