Alabama’s Revised Medical Regulations

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NRC started the revision process for Part 35 in 1996. The first revision was adopted in October 2002. It quickly became apparent that there were multiple flaws in the new rule that needed to be addressed. Major revisions to the training & experience sections began in 2003 and were completed in 2005. Our rules revisions began in 2005 and were adopted in June of 2006. These revisions included a complete reorganization of the rules so that they closely followed the layout of the NRC rule. We will discuss some of the changes that have been put in place in the revised rules.
The old rule required every medical institution (an organization where several medical disciplines are practiced) to establish a radiation safety committee, and that it meet at least quarterly. This meant that if you were a licensed private practice facility or clinic that practiced many medical disciplines, you were exempt from establishing a radiation safety committee. The new rule uses the potential radiation safety risks involved in the use of licensed material to determine if a radiation safety committee is required. Under the new rule, if you are a medical institution that uses only one type of radioactive material that requires a written directive, you are no longer required to have a radiation safety committee. However, if your current procedures state that you will have a radiation safety committee, and you wish to abolish the committee, you must revise your procedures, and amend your license to include the new procedures, before you disband the committee.

If you are a licensee that is authorized to possess and use 2 types of radioactive material that require a written directive, then you must establish a radiation safety committee. A written directive is required for any administration that will likely result in a dose of 50 rads to any healthy organ.
This means that if you are a licensee (including a private practice office or clinic) that is authorized to perform diagnostic nuclear medicine that requires a written directive, and is authorized to perform any therapy use, you must establish a RSC.

For example, if you administer both diagnostic studies that require a written directive and also administer I-131 for hyperthyroidism therapy (both covered under Section 52 of .07), you must establish a radiation safety committee. Another example would be if you use an HDR (covered under Section 72 of .07) and administer I-131 for hyperthyroidism. In this case, you also must establish a radiation safety committee.
The new rule also changes the minimum frequency for holding a radiation safety committee meeting from the old quarterly interval to as necessary, but not to exceed 6 months. **However, if your current procedures state that your radiation safety committee will meet at quarterly intervals, you must continue meeting at that frequency until your license is amended to include revised meeting intervals.**

Note that the new rule requires there be a nursing representative on the committee. If you are a licensee that must establish a radiation safety committee, but do not have a nursing staff, you do not need to have a nursing representative on the committee. Also, the new rules do not define what constitutes a quorum. Licensees should define what the quorum requirements are. It is strongly recommended that the quorum be at least the Radiation Safety Officer and a representative of administration. Most licenses are issued to the administration, and therefore the administration is ultimately responsible for all activities occurring under the license.
Duties of the Authorized Physician User

Reference Rule 420-3-26-.07(21)

As has been required in the past, the authorized physician user (AU) is required to:

– Select the patient
– Provide a written prescription for the dosage or dose
– Perform the final interpretation of the results of tests, studies or treatments

Under the old rule, only an authorized user could select the patient to receive radioactive material or radiation therefrom, prescribe the dosage or dose to be administered, and interpret the results of the tests, studies or treatments. The new rule carries this over, but further clarifies the interpretation of the old rule that the authorized user is to provide their intentions in writing. This rule describes what we call the “user concept.” The user concept is predicated on the belief that a physician with adequate radiation safety training (an authorized user) should decide who will receive radioactive material or radiation from radioactive material. This concept also supports the As Low As Reasonably Achievable (ALARA) requirements found in 420-3-26-.03(5)(b).
Written Directives vs Written Prescriptions

Reference Rule 420-3-26-.07(21)(a)2.
- Requires the AU to prescribe the dosage or dose
  - Via a written directive or,
  - Via written reference to the diagnostic clinical procedures manual

Reference Rule 420-3-26-.07(23)(b)
- Specifies what must be included in a written directive

This rule indicates that the authorized user is to make their decisions known in writing. There is a difference between a written directive and a written prescription. As stated earlier, the term written directive is used to indicate that there is a higher radiation safety risk involved because an organ is likely to receive a dose of at least 50 rads as a result of the procedure. A written directive is required to contain specific information as described in Rule .07(23)(b).
Written Directives vs Written Prescriptions

- Reference Rule 420-3-26-07(23)(c)
  Clarifies that if a written directive is not required, the AU must prescribe the dosage or dose in writing

- All requests for use of radioactive material on humans must be in writing from an AU

Rule 420-3-26-07(23)(c) further clarifies the Agency’s intent that prior to administering any dosage or dose that does not require a written directive, it must be approved, in writing, by an authorized user. There are exceptions, such as emergencies, where an oral directive from an authorized user may be given and documented later (within 48 hours).
Duties of the Authorized Medical Physicist

- Reference Rule 420-3-26-.07(21)
- Only an authorized medical physicist (AMP) named on the license can:
  - Perform full calibration measurements, periodic spot checks, and radiation surveys on:
    - Teletherapy units
    - Remote afterloader units
    - Gamma stereotatic units

The old rules did not specifically discuss requirements for remote afterloaders (HDR’s, MDR’s, LDR’s, and PDR’s), or gamma stereotatic units (aka gamma knife). The new rules include regulatory sections on all of these, and include actions that can only be performed by an authorized medical physicist, or visiting authorized medical physicist who is trained to work with your specific devices. These duties include such things as calibrations, certain spot checks and radiation surveys.
The new rule is similar to the old rule, however it now also includes discussion of supervision by authorized nuclear pharmacists for preparation of radioactive material. It continues to require the authorized user to be immediately available (via telephone within 10 minutes) to the supervised individual, and to be able to be physically present within 1 hour of notification. It also clarifies that the licensee remains responsible for the actions taken by a supervised individual.

Please note that physical presence as specified in the rules, may be required at all times during a treatment.
The NRC defines “physical presence” as meaning that a person is close enough to hear and understand someone speaking at a normal conversation volume. They would probably be no more than 20 feet away from each other, depending on the background noise. The NRC specifically states that electronic communications cannot be used to extend the separation distance for physical presence.
Major changes concerning the physical presence requirements have occurred. Rule 420-3-26-.07(76)(f)1. deals with Low Dose Rate, Medium Dose Rate and Pulsed Dose Rate Remote Afterloaders, and requires an authorized medical physicist and either an authorized user, or a physician, under the supervision of the authorized user, who has been trained in the operation and emergency response for the unit, to be physically present at the initiation of all patient treatments involving the unit. This rule also requires the authorized medical physicist and either an authorized user, or an individual, under the supervision of the authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
Rule 420-3-26-.07(76)(f)2. deals with High Dose Rate Remote Afterloaders, and requires an authorized medical physicist and an authorized user to be physically present at the initiation of all patient treatments involving the unit. This rule also requires an authorized medical physicist and either an authorized user, or a physician, under the supervision of the authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.
This rule requires an authorized medical physicist and an authorized user to be physically present during the entire treatment of all patients with the gamma knife.

A key point for all of these physical presence rules is that the authorized medical physicist is required to be physically present at all times that a patient is being treated. This is a critical problem when it comes to time and duty management for a medical physicist. This point was made to the NRC. They acknowledged that they understood the requirements, and indicated that this was their intention. Because this is considered a radiation safety issue, Agreement States like Alabama are required to have rules that are at least as restrictive as the NRC rules.
Under the old rules, which originated in the 1980’s, an individual had to be board certified or board eligible. Boards whose eligibility requirements had been deemed acceptable were listed, by name, in the rule text. Then, to allow greater flexibility while maintaining adequate radiation safety training, alternative training sections were included that reflected the minimum radiation safety training requirements of the boards. However, once a board was named in the rules, they no longer were held accountable for maintaining radiation safety training at the same standards that had been accepted in the first place. When the new rules were created, the NRC decided to hold the boards more accountable for their radiation safety training requirements. No longer would the boards be named in the rule text. Rather, the boards would have to reapply for acceptance, documenting that their eligibility requirements include at least the minimum radiation safety training specified in the new rule. Then, after acceptance, the board eligibility requirements would be reassessed on a regular basis to assure that they maintain an adequate level of radiation safety. In addition, the new rules require that all candidates (even those who are board certified), must have written attestation that they have satisfactorily completed the training requirements, and have achieved a level of competency sufficient to function independently as an authorized user, authorized medical physicist, radiation safety officer or authorized nuclear pharmacist.
The new rule requires that an authorized medical physicist receive training in hands-on operation of any devices for which they wish authorization, as well as training in the safety procedures, clinical use and the operation of any treatment planning systems. Verification of this training would be through documentation, copies of which would be sent to the Agency in support of the licensees amendment request.
Training for authorized nuclear pharmacists is a new section that, in the past, was
specified in guidance documents. This rule standardizes the training requirements
for nuclear pharmacists nationwide.

As with other training and experience sections, this rule allows for board
certification. The accepted certification is Board Certified Nuclear Pharmacist
(BCNP) by the Board of Pharmaceutical Specialties. There is an alternative training
and experience pathway as well. Regardless of the training and experience
pathway taken, the applicant must have written attestation, signed by a preceptor
authorized nuclear pharmacist, that must be submitted by the licensee to allow the
individual to be named on a license.
Here is a list of the rules describing the authorized user training and experience requirements for the different types of medical use of radioactive material. There is a slight difference in how the uses are categorized in the new rule. While in the past the delineation was between diagnostic and therapeutic uses of materials, now the relative risk of the material is also used to help identify the groups. Therefore, training sections 47 and 51 are for uses that are diagnostic, but also do not require a written directive. Training section 56 encompasses the traditional radiopharmaceutical therapies, but also includes such things as dosages of I-131 for a diagnostic whole body scan.
As mentioned earlier, one of the biggest changes that has occurred is that all training options, including certification by an accepted board, require a written attestation signed by an individual who is already listed on a license as an authorized user, authorized medical physicist, radiation safety officer or authorized nuclear pharmacist.

The NRC maintains a web page that is updated as new board certifications are granted acceptance by either the NRC or an Agreement State. The list of currently accepted boards can be found at this web address.
Grandfathering

- Grandfather provisions are in place for AMP’s that have been named on other Agency, Agreement State or NRC licenses.

- The grandfather provisions are limited to the activities that the AMP has previously been authorized to perform.

There have been many questions regarding grandfather provisions for authorized medical physicists. The NRC issued a Regulatory Issues Statement clarifying the current grandfathering provisions. If you are an authorized user, authorized medical physicist or authorized nuclear pharmacist that is named on an Agreement State or NRC license prior to the effective date of the new rule, you can be authorized on a new or amended license to perform the same duties for which you have previously been authorized. For example, if you were authorized on a Florida license as an authorized medical physicist for a HDR, you can be added to an Alabama license to perform the authorized medical physicist duties for a HDR, as long as you have documented hands on experience with the type of HDR and treatment planning system you will be working with in Alabama. However, being on another license as an authorized medical physicist for a HDR does not allow you to come into Alabama and be approved to be an authorized medical physicist for a Sr-90 eye applicator.

This does not present a major problem for authorized users and authorized nuclear pharmacists, because they have always been placed, by name, on specific licenses. The problem is that not all medical physicists are named on a radioactive material license, so they are not eligible for grandfathering. The ABR knew this requirement was coming as early as 2000, and had 5 years to prepare for it. They were reminded of the new requirements many times during that period. The Agreement States were notified in 2000, and again in 2002, that if they were not currently naming medical physicists on their licenses, they needed to do so before they adopt the revised rules to avoid this problem. Agreement States have until October 2008 to adopt the equivalent of the NRC’s training and experience rules. So if they are still using the old rules, they have time to get all their medical physicists on licenses to avoid this problem.
Grandfathering

- If you have not been named on a specific license or permit issued by a broad medical licensee, you must meet current training & experience requirements.

- Even board certification is not currently grandfathered.

Without being named on a specific license or a permit issued by a broad medical licensee like UAB or USA, you must meet current training & experience requirements. This includes medical physicists ABR certified in Therapeutic Radiologic Physics before June 2007. ABR has indicated to the NRC that they will not meet the new training and experience requirements until June 2007, so their certification is not eligible for acceptance as documentation of adequate training and experience until that time.
The old rule was pretty easy to follow, and had specified thresholds (either activity or exposure rate) on which to base releases. However, it did not allow temporary implant patients to be released at all. It was decided that besides allowing for temporary implants, more latitude should be given to licensees in determining whether a patient could be released from their control.

However, some additional radiation safety requirements were added to the new rule. Approval for the release is to be made by an authorized user approved for the type of radioactive material use for which the patient being released has received.

Both oral and written radiation safety instructions are to be given to all released patients or their responsible guardian.

We frequently receive calls from landfills whose radiation alarms have been set off by household waste. If the Agency is able to trace the radioactive material back to the originating licensee, and is unable to rectify the situation in other ways, the licensee is responsible for the proper disposal of the waste. Currently, we have 5 major landfill facilities in Alabama that have radiation alarms. In 2006 we received 22 reports of alarms that were verified as radioactive material in the waste. Virtually all were I-131.

Another part of the rule states that if a patient checks them self out of the licensee’s facility without approval of the licensee, the Agency must be notified so that we can contact the patient, review the situation, and discuss it with the patient and their family.

And finally, if a released patient dies and a member of the public could receive an exposure of more than 500 millirem from the deceased patient’s body, the Agency must be notified.
This rule is all new. Current rules in 420-3-26-.03 do not discuss limitations on radiation exposures to the embryo or fetus of non-occupationally exposed workers. Rule 420-3-26-.03(14)(a)1. authorizes a member of the public to receive up to 500 millirem exposure from a patient released in accordance with .07(41). This rule could be interpreted as including nursing children, but it clearly does not address embryos or fetuses. Rule 420-3-26-.03(13) discusses dose equivalent to embryos and fetuses, but it is only for such doses that occur as a result of an occupational radiation exposure to the pregnant woman.

This rule sets the reporting threshold for unintended radiation exposures to embryos, fetuses and nursing children that occurs as a result of a medical administration of radioactive material, or radiation from radioactive material. If an authorized user knows or suspects that a woman is pregnant, and makes the medical decision, using his or her medical and radiation safety knowledge, that the radiation exposure, while greater than 500 mrem, is acceptable, the threshold can be exceeded without notifying the Agency.

However, if an unintended exposure above the threshold occurs, the licensee should notify the Agency by telephone within 24 hours after they become aware of the problem, and should submit a written report within 15 days.
Calibration and Reference Sources

- Reference Rule 420-3-26-.07(35)
- 30 mCi sealed sources
- 15 mCi of any RAM with ½ life <120 days
- Allows any RAM with ½ life >120 days in limited quantities
- Tc99m in any amount

The new rule allows larger sources to be possessed by a medical licensee without them being specifically listed on the license. Sealed source activities are up from 15 mCi to 30 mCi per source. The new rule allows up to 15 mCi of any radioactive material with a ½ life of <120 days (up from a ½ life of <100 days). You are now allowed to possess any radioactive material (sealed or unsealed) with a ½ life greater than 120 days in limited quantities. This type of material was limited to certain isotopes with activities of no more than 200 microcuries in the old rule. The old rule limited you to 50 mCi of Tc99m, while the new rule allows any amount of it necessary.
Quality Control of Diagnostic Equipment

- Reference Rule 420-3-26-.07(31)
- May follow written manufacturer’s recommendations
- May require a license amendment

There is a slight terminology change in this rule. The manufacturer’s recommendations are to be written. They may be in the owner’s manual, or may be in correspondence from the manufacturer or their representative. Quality control tests are best set by the manufacturer. The manufacturer should be confident enough to state these recommendations in writing. Statements by representatives of a manufacturer, that are not in written, signed format are not acceptable.

Note that if your current written quality control procedures are more restrictive than the manufacturer’s written recommendations, you must amend your procedures and license to allow you to use the less restrictive manufacturer’s procedures.
Dose Calibrator Requirements

- Reference Rule 420-3-26-.07(34)
- Licensees must determine and record the activity of every dosage before administration
- Part of the rule is specifically for beta only emitters

This rule continues to require every dosage of radioactive material to be measured to determine the activity within 30 minutes of administration to the patient. However, it now allows for dosage calibration using direct measurements or by combinations of direct measurements, volumetric measurements and mathematical calculations. The use of mathematical and volumetric measurements is designed and included in the rules specifically for use with pure beta emitters such as P-32 and Sr-89.

This rule is not meant to discourage the use of dose calibrators. Instead it is designed to allow maximum flexibility for a licensee to accommodate newer isotopes, while maintaining assurances that dosages administered fall within acceptable limits of the prescribed dosage.
For a number of years, we have had to deal with a confusing misadministration rule. That rule included a definition for misadministrations that had 6 sections. It also encompassed a definition for recordable events that could have been termed “minor misadministrations”, which also had 6 sections. And finally, there was an inclusion in the notification and reporting rule text that required the licensee to notify the referring physician and our Agency under 3 additional conditions.
Misadministration

- Old rule stemmed from a change in definition by the NRC in 1993
- Because it was a definition, it required compatibility
- Substantial change from the old definition
- Our rule text tried to maintain the lower thresholds we had in earlier rule text

This convoluted, multi-threshold system was a result of the NRC’s change in the definition of the term “misadministration” in 1993. At that time, the NRC was receiving more notifications of misadministrations than all the Agreement States combined. This despite the fact that the NRC had about half as many licensees as the Agreement States. They decided to handle this problem by substantially increasing the thresholds for misadministrations. However they maintained a review of somewhat lower threshold events by adding the recordable event. The way they made this change was by placing them in the definitions section of the rule. By making them definitions, they increased the compatibility level so that the Agreement States had to adopt similar thresholds.

The Agreement States were not seeing the numbers of misadministrations the NRC was seeing, and were not as eager to increase our reporting thresholds. We decided to maintain our lower reporting thresholds, but, to maintain compatibility with the NRC, included them in the actual rule, not in the definitions. By setting the thresholds lower, the licensee should review their procedures before the NRC’s thresholds are reached. This helped minimize the likelihood of escalation of problems to the thresholds the NRC had set. We are required to report misadministrations meeting the NRC’s criteria to the NRC. However, if a licensee is required to report an event to our Agency that does not exceed the NRC’s thresholds, we don’t have to report it to the NRC. This did not seem to present a problem for our licensees. Last year, we had 1 event involving the medical use of radioactive material reported to our Agency. This event did not meet the NRC’s threshold, so we did not have to report it to them. However, corrective actions were taken by the licensee to prevent a recurrence of the event. This kind of response should minimize the likelihood of a problem escalating to the level of the NRC’s reporting thresholds. We prefer this proactive stance when it comes to radiation safety.
The new NRC rule is not in the definitions, and is not assigned as high a compatibility, so we were able to achieve our goal of ALARA and proactive response, while simplifying the rule. Instead of a total of fifteen sections, the new rule consists of only three sections, each describing a threshold.
Misadministration

1. 500 mrem EDE, 5 rem organ, tissue or skin dose and:

   – Total dose delivered is off by 20% or more, or
   – Total dosage delivered off by 20% or more, or falls outside the prescribed dosage range, or
   – A single fractionated dose delivered is off by 50% or more

The first includes a dose that differs from the prescribed dose by more than 500 millirem (5 millisieverts) effective dose equivalent, or 5 rem (0.05 sieverts) to an organ or tissue, or 5 rem (0.05 sieverts) shallow dose equivalent to the skin; and any of the following:

(i) The total dose delivered differs from the prescribed dose by 20 percent or more; or

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

For example, a patient is prescribed to receive a 10 mCi dosage of Choltec, but instead is administered a 12.1 mCi dosage. The total dose to the upper large intestine exceeds 5 rem, and the total dosage delivered is more than 20% greater than the prescribed dosage. This meets the criteria of a misadministration as specified in 420-3-26-.07(120)(a)1., and must be reported to the Agency.
The second section includes a dose that exceeds 500 millirem (5 millisieverts) effective dose equivalent, 5 rem (0.05 sieverts) to an organ or tissue, or 5 rem (0.05 sieverts) shallow dose equivalent to the skin as a result of any of the following:

1. An administration of a wrong radioactive drug; or
2. An administration of a radioactive drug containing radioactive material by the wrong route of administration; or
3. An administration of a dose or dosage to the wrong individual or human research subject; or
4. An administration of a dose or dosage delivered by the wrong mode of treatment; or
5. A leaking sealed source.

For example, an I-125 prostate seed was damaged while implanting it. This seed continues to leak while in the patient. Because of this, the patient’s thyroid receives a dose greater than 5 rem. This meets the criteria of a misadministration as specified in 420-3-26-.07(120)(a)2., and must be reported to the Agency.
The third section involves a dose to the skin or an organ or tissue, **other than the treatment site**, that exceeds 5 rem (0.05 sieverts) and exceeds 50 percent of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

For example, the written directive states that as a result of treatment to a target organ, another organ is expected to receive a dose of 3.4 rem. However, for whatever reason, the actual dose to that organ is calculated to be 5.9 rem. This meets the criteria specified in 420-3-26-.07(120)(a)3., and must be reported to the Agency.

An important point to remember is that if any of these events occur as the result of intervention by the patient, it is not considered a misadministration.
In conclusion, the new rules do incorporate some major changes, and are arranged differently than the old rules. This may cause some confusion at first while everyone gets used to the new layout.

You are encouraged to call us with any questions you may have.

Our web site can be a resource tool. It includes all the latest rules, forms, and new information. I hope you will visit it often. If you have any recommendations or suggestions about how we can make our site better, please let us know.