Georgia Department of Natural Resources
4244 International Parkway, Suite 114, Atlanta, Georgia 30354
Lonice C. Barrett, Commissioner
Environmental Protection Division
Harold F. Reheis, Director
(404) 362-2675

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Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Rulemakings and
Adjudications Staff.

(445)

Gentlemen:

The following comments are written in response to Federal Register Notice, August 13, 1998 (Volume 63, Number 156), Proposed Rules for 10 CFR Part 35, Pages 43515-43580.

COMPATIBILITY

An explicit statement of how NRC staff justified the key compatibility and "health and safety" designations is needed. It is not provided in the Federal Register notice and staff indicates such will be available in a "few weeks" (but after the comment period closes). This justifies an extension of the comment period to allow states and others to review the actual basis for the compatibility designation. We request that the comment period, for compatibility designation only, be extended to 30 days following the release and distribution of such justification of the compatibility designations.

SPECIFIC ISSUES IDENTIFIED FOR PUBLIC COMMENT

1. Section 35.2--Should the term ``medium dose-rate remote afterloader'' be defined since it is not used in the rule? (Requirements for medium dose-rate remote afterloaders have been grouped with high dose-rate remote afterloaders in this rulemaking.)- The terms high dose and low dose afterloaders are defined. A high dose-rate afterloader delivers a dose rate in excess of 2 gray (200 rads) per hour and a low dose-rate remote afterloader delivers a dose rate of less than 2 gray (200 rads) per hour, both at the point or surface where the dose is prescribed. By these two definitions, it would imply that a medium dose-rate afterloader would deliver a dose at 2 gray since the other two types of afterloaders deliver doses on either side of this exposure rate. If the term medium dose-rate afterloader is used, then it should be defined or not used at all. The term as used in this section does not add clarity to the rule.

2. Section 35.6--Should this section be revised to require that licensees develop, implement, and maintain procedures for evaluating when a medical procedure would be considered to be a research procedure? - It is not clear how such a requirement is protecting public health and safety. No matter what type of radiation is delivered to a patient, radiation safety for the patient, the worker and the public, must be maintained. ALARA must be maintained. All of the proposed paperwork required above will not add (in a positive manner) to these

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requirements.

3. Removal of Section 35.22 Radiation Safety Committee deleted in its entirety. - For the small, diagnostic use type facilities, the elimination of the Radiation Safety Committee should not adversely impact radiation safety. The effect of removing the Radiation Safety Committee from a medical institution will vary with the size and complexity of the institution and with the political climate within the facility. What is important is that the Radiation Safety Officer still has a direct line of reporting to management on radiation safety issues. At larger institutions with multiple disciplines (diagnostic nuclear medicine, teletherapy, remote afterloaders, nuclear cardiology...), using radioactive materials throughout the facility, a Radiation Safety Committee may be needed to coordinate all of the reporting activities and to ensure that basic radiation safety is being consistently achieved in each area of the facility.

Currently, the Radiation Safety Committee with its required management representative in attendance provides access by the Radiation Safety Officer (RSO) which he/she may be hesitant to attempt via other channels. Safety issues may also be brought up in meetings which may not be conveyed to the RSO personally. The RSO should be present at Committee meetings either as a member or as a technical advisor to the Committee.

Overall, the rule is too prescriptive as it applies to the RSO reporting to management. As written, the rule implies that management has given the RSO the "responsibility" of maintaining a radiation safety program but is not allowing the RSO any "authority" in managing the program. Radiography licensees do not have such restrictive and prescriptive procedures on implementing a radiation safety program. Why does medical? If these parts of a radiation protection program are so important for management oversight, then why aren't they included in a more generic fashion in Sec. 20.1101? No other radiation protection program is impacted with as much management oversight in rulemaking as medical. The management/RSO relationship/reporting requirement is not applicable to a radiation safety program for private practice with only one physician on staff who is the owner/president and the RSO.

4. Section 35.75 Release of Individuals Containing Radiopharmaceuticals or Implants.- The hazards posed to the family and general public by a person containing radiopharmaceuticals depends totally upon the inclination and the ability of the patient to abide by prescribed restrictions for a specific period of time. It is extremely difficult to predict human behavior and impossible to control it outside the confines of the hospital. Some patients would go to a hotel or motel to prevent possible exposure of family members which would then introduce unknown casual exposure to another segment of the public.

Undoubtedly many patients covered under this rule could be safely released from confinement. However many institutions must release I-131 therapy patients to nursing homes or even homeless shelters. It is extremely difficult to explain to a HMO, insurance company, or possibly to a government Medicaid or Medicare case worker the difference between an I-125 eye plaque involving a sealed source and a patient who has just ingested 200 mCi of I-131 – why one may not require hospitalization while the other one would. This rule would interfere with an RSO's ability to protect public health and safety.

When patients receive oral therapy doses of I-131, nausea and vomiting are very common side effects. This side effect is disclosed to the patient. Nausea and vomiting has occurred

following a diagnostic dose of I-131. In one instance a sidewalk along a major metropolitan thoroughfare near the hospital was contaminated. A relative returned to the Nuclear Medicine Department, and a decontamination team headed by the RSO successfully decontaminated the sidewalk. Activity from a therapy dose would be much more difficult to remove. This could occur far from the hospital in the case of an out-of-town patient returning home. If the radiation factor became an issue, who would be responsible for decontamination? For reimbursement for decontamination? This rule would interfere with the RSO's ability to control radioactive contamination.

Also to consider: This rule would result in an increase of radiation alarms at landfills caused by household trash of released patients. The landfill regulations do not allow the burial of radioactive material, so NRC or State Offices would be notified. Radioactive material contained in patient excreta is no longer considered regulated, so where does financial liability reside? With the State or NRC? With the administering facility or the patient?

5. Section 35.92 – On deletion of holding material held-for-decay for 10 half lives.- Although the proposed wording is more clear and is less burdensome to the licensee, it does not adequately address the concern of beta-emitters (such as S-35, P-32, or I-125), which are difficult to detect. By requiring the calculation of 10 half lives, we have provided a reliable timetable for scheduling hard-to-detect material for disposal which acts as a deterent for ensuring that facilities do not "jump the gun" when disposing of beta emitters.

Pertaining to Sec. 35.92(a)(2), which states that prior to disposal all radiation labels will be obliterated or removed: This requirement is not in keeping with guidance published in IN 97-03, "Defacing Labels to Comply with 10 CFR.1904(b)". Removing or obliterating labels on medical-use materials is flirting with a ***biohazard***. This rule is not in keeping with current technology or OSHA standards. The rule needs to be rewritten to allow for other acceptable methods of disposing of used syringes and vials without defacing the labels as described in the information notice.

6. Section 35.315 - For each patient who cannot be released in accordance with 35.75, a licensee shall provide a private room with a private sanitary facility.- This rule should be retained as is. Again, the issue arises of demonstrating the need for a private room for one patient while possibly not for another patient as HMOs, insurance companies, and Medicaid/Medicare representatives seek to assign their patient to less expensive facilities.

Experience dictates that bathrooms of I-131 therapy patients must be properly prepared to prevent contamination by even the very conscientious patient. Contamination from an unrestricted bathroom floor could be tracked throughout the hospital. Other users could become contaminated from faucet handles, doorknobs, etc., and some of the contamination could become internalized.

7. Section 35.415 - Safety Precautions - Not to house a patient or research subject receiving brachytherapy in the same room as an individual who is not receiving radiation therapy.- The popular opinions currently held by members of the general public concerning radiation makes it socially and legally questionable to house a non-radioactive patient in a room which has radiation posting on the door. Nursing staff would be understandably disturbed about receiving additional radiation exposure, if that were a factor, while caring for the non-radioactive roommate. Visitors and family members might be expected to experience some apprehension entering a posted room even if it was explained that external radiation exposure

was not a factor.

This rule should be retained since subjecting a member of the public to close proximity to a radiation source is not the patient's choice and is not in keeping with ALARA. The argument has been presented that public education is the answer and not rulemaking. However, health physicists have been trying to educate the public for years but with little success.

8. Section 35.605--Should the maintenance restrictions in paragraph (a) of the proposed rule apply to low dose-rate remote afterloaders? - We do not allow users of nonmedical devices to perform these types of services unless procedures are submitted that show they have had appropriate training in performing these services on the specific devices.

9. Section 35.615--Should the requirements in this section which require the expeditious removal of a decoupled or jammed source be waived for licensees that are using remote afterloaders with beta-emitting sources? - No. That is not in keeping with ALARA. Also, Section 35.615(f) outlines further requirements for the following:

(1) For low dose-rate remote afterloader devices, require...

(2) For high dose-rate remote afterloader devices, require...

(3) For pulsed dose-rate remote afterloader devices, require...

These seem to be generic requirements for all afterloaders. Each of the above sections is worded exactly alike, except for the type of afterloader. There does not seem to be a real need to write the same requirement for each type of afterloader. Why not combine the three into one requirement addressing **all** afterloaders as the title of this section does?

10. Section 35.644--Should the restrictions for electrical interlocks and audiovisual systems apply to low dose-rate remote afterloaders? - It depends on the exposure rates in the room when the source is exposed.

11. Section 35.981--What is the impact of deleting this section? - This section may be deleted, but it is replaced by Sec. 35.55, Training for an authorized nuclear pharmacist, which has many of the same requirements. Therefore there would be no impact.

12. Subpart L--Should all record-keeping requirements be grouped into one Subpart or should they be incorporated into the section requiring the record? -

(1) The latter makes it easier for the licensee to reference and determine record-keeping requirements and therefore makes it easier for them to maintain compliance.

(2) In addition to the comments solicited in the summarized questions, the body of the draft solicited the following additional comments on the rule:

The Commission is soliciting specific public comment on which record-keeping requirements could be deleted in the final rule and the basis for the deletion. For example, should the record-keeping requirements in Sec. 35.2063 be retained for byproduct material administered pursuant to Secs. 35.100 and 35.200 because of the low risk associated with

this type of use?- No, because of the low risk.

Sec. 35.2067(b) may need to have an additional reference which states that additional brachytherapy records may be required by 35.2406.

Also, Section 35.2024, Records of authority and responsibility for radiation protection programs, and Sec. 35.2026 Records of radiation protection program safety changes, are far too prescriptive and burdensome for record-keeping. It is not applicable to a radiation safety program for a private practice with only one physician on staff who is the owner/president and the RSO. These types of facilities are becoming more numerous, so it does have an impact on our licensees.

Sec. 35.2067 - Pertaining to leak-test records - This seems to be highly prescriptive as to what information is required on a leak-test record. Other leak-test rules in 10 CFR only require that a leak-test record be kept in units of microcuries and kept for inspection by the Commission. What is the performance based criteria for having all of the information listed in the proposed rule on the leak-test record for medical sources, when performance-based (rules) criteria for nonmedical sources do not require this information?

Subpart M--Grouping of Reporting Requirements -It should make it easier for the licensee to reference and determine reporting requirements and therefore makes it easier for them to maintain compliance. The following nine items share the same comment:

(a) Sec. 35.2632(8) Records of teletherapy full calibrations requiring the signature of the authorized medical physicist who performed the full calibration.

(b) Sec. 35.2633(4) Records of remote afterloader full calibrations requiring the signature of the authorized medical physicist who performed the full calibration.

(c) Sec. 35.2635(5) Records of gamma stereotactic radiosurgery unit full calibrations requiring the signature of the authorized medical physicist who performed the full calibration.

(d) Sec. 35.2642(9) Records of periodic spot-checks for teletherapy units requiring the signature of the authorized medical physicist who reviewed the record of the spot-check.

(e) Sec. 35.2643(5) Records of periodic spot-checks for remote afterloaders requiring the signature of the authorized medical physicist who reviewed the record of the spot-check.

(f) Sec. 35.2645(5) Records of periodic spot-checks for gamma stereotactic radiosurgery units requiring the signature of the authorized medical physicist who reviewed the record of the spot-check.

(g) Sec. 35.2647(5) Records of additional technical requirements for mobile remote afterloaders requiring the signature of the individual who performed the check.

(h) Sec. 35.2652(4) Records of surveys of therapeutic treatment units requiring the signature of the individual who performed the test.

(i) Sec. 35.2655(f) Records of 5-year inspection for teletherapy and gamma stereotactic surgery units requiring the signature of the inspector.

The record should only contain the name of the individual. This appears to be a prescriptive and not a performance based requirement. A signature does not necessarily mean the individual has actually read or reviewed the report. By allowing the use of just the name the file can be maintained electronically using current and future technology.

13. Section 35.3047--Should the Abnormal Occurrence Policy Statement criteria for reporting of exposures to an embryo/fetus or nursing child be modified? Is there a better term than "responsible relative or guardian" that could be applied to those situations where the mother is not notified, e.g., in the referring physician's medical judgment telling the mother would be harmful; the mother is a minor; or the mother is not competent to make decisions regarding medical care? What is the impact of the proposed reporting requirement on licensee procedures, activities, or medical practices? Not telling the mother only because she is a minor is not a responsible rule. The other two parts of the rule would cover the notification: i.e. it would be harmful to the mother or the mother is not competent. The medical community and the laws of each state will determine if a mother is allowed information that may affect her child if she is a minor. The rule as written is inappropriate.

NRC COMMENTS SOLICITED BUT NOT IN THE SUMMARIZED SECTION:

Section 35.80 would be retitled, "Provision of Mobile Service", and revised; and Section 35.647, Additional technical requirements for mobile remote afterloaders: NRC specifically requested comments on these issues relative to whether mobile medical licensees operate under reciprocity in other regulatory jurisdictions. We agree with the analysis and comments in the Statements of Consideration. The State of Georgia's "Rules and Regulations for Radioactive Materials" do not allow for medical licensees to operate under reciprocity.

ADDITIONAL COMMENTS

1. Sec. 35.27 Supervision.- 35.27(c) of this rule can be omitted. Rule-making will not stop a misadministration caused by poor management; either by an abusive manager who will not tolerate any questions or by poor management of a "too-knowledgeable person" who will not ask questions.

2. Sec. 35.41 Procedures for administrations requiring a written directive.- 35.41(b) is really not necessary. It is too prescriptive. (3) and (4) of (b) can be combined with (a). If a licensee has to develop a plan that provides high confidence that (1) and (2) occur, then it follows that (b) may not be necessary. Aren't we now telling them how to write the plan? Isn't that what we are trying to get away from?

3. Sec. 35.50 Training for Radiation Safety Officer - 35.50(b)(2) states, "Has obtained written certification, signed by a preceptor RSO..." and 35.50(c) states, "Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has RSO responsibilities." Comments are:

(1) 35.50(b)(2) Why not have the licensee's management sign a statement that the person has meet the training criteria? Many times the old RSO leaves and will not sign a preceptor statement for a person. Also, if the RSO is a poor manager and management wants to replace him, but will still allow him privileges at the licensee's facility, the RSO is not about to sign off on someone else taking their place. Too many times egos get in the way of good people being allowed to do the job correctly.

(2) 35.50(c) Why not a person certified by a board approved by the Commission who is either identified on the license or the licensee has notified the Commission as prescribed in Sec. 35.14? This could possibly allow for certified/registeredtechnologists, who many times would be a better choice as an RSO than an authorized user. Registered technologists would certainly meet the second part of paragraph (c).

4. Sec. 35.65 Authorization for calibration and reference sources.- 35.65(c) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed 7.4 MBq (200 <Greek-l>Ci) each **and** not to exceed 1000 times the quantities in appendix B of Part 30 of this chapter whichever is more limiting. - We believe the "and" should be "or".

5. Sec. 35.69 Labeling and shielding of vials and syringes.- 35.69(b) is covered under Section 19.12, "Instruction to Workers". It is also covered by another federal agency under the "Workers Right to Know Act". As worded, the rule is not needed under this section. It does not need to be repeated a third time.

6. Sec. 35.630 Dosimetry equipment. - 35.630(a)(1) should use the abbreviation "NIST" after National Institute of Standards and Technology as was done with Association of Physicists in Medicine (AAPM). The abbreviation "NIST should be used in 35.630(a)(2) in place of National Institute of Standards and Technology to maintain continuity of writing style.

7. Sec. 35.652 Radiation surveys. - 35.652(a) states in part, "...a licensee shall make such surveys as defined in the Sealed Source and Device Registry to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Registry.

Maximum radiation levels and average radiation levels could be made a generic number as with radiography cameras and source changers. Radiographers do not have to comply with readings on the SSD registration sheet. They have to survey to ensure the source is in the proper place and that a generic exposure rate is not exceeded.

The radiation level numbers for each device are tedious to look up. There is no need for such specificity for each type of afterloader. It may make sense to put in the average acceptable reading for each type of afterloader (i.e. high does rate, low dose rate, and pulsed), than for each brand and model number. Generic readings would also be more in keeping with Part 20 and less prescriptive than the proposed rule while at the same time alerting the licensee to a potential problem if a certain radiation level is exceeded.

8. Sec. 35.900 Radiation Safety Officer.--35.900 (6) American Board of Medical Physics in radiation oncology physics; and (7) Royal College of Physicians and Surgeons of Canada in nuclear medicine; - Need to capitalize "radiation oncology physics" and "nuclear medicine" for consistency with existing Part 35 and for internal consistency.

9. Sec. 35.900 Radiation Safety Officer.--Sec. 35.910 Training for uptake, dilution, and excretion studies; and Sec.35.920 Training for imaging and localization studies. - All three of these need to include the American Board of Cardiology for cardiology studies and for RSO of same.

10. The Revision of NRC's Regulatory Program discusses, "(1)Regulatory oversight alternatives for diagnostic procedures that are consistent with the lower overall risk of these procedures;... and (2) Redesigning Part 35 so that regulatory requirements for new treatment modalities can be incorporated in a timely manner." - Significant changes have been made in Nuclear Cardiology in the past 15 years. Changes are currently on-going (e.g., beta restinosis). Based on the low-risk associated Sec. 35.100 and Sec. 35.200 there does not seem to be a performance based reason not to include the new Board for cardiologists.

11. Section 35.2070, Records of surveys for ambient radiation exposure rate, would require the licensee to maintain records of radiation surveys for 3 years. One change has been made from the current record-keeping requirements for radiation surveys. The name of the individual performing the survey rather than the initials of the individual would be required to be recorded.- Why the change to a name instead of initials? I have always been able to identify the individual by their initials during inspections. This does not seem to be a performance based requirement.

Thank you for the opportunity to comment on and to participate in development of the revisions to 10 CFR Part 35.

Sincerely,

Lauren McGaughey
Senior Radiological Health Specialist
Radioactive Materials Program