Suggested State Regulations - Group 6
of the Conference of Radiation Control Program Directors, Inc.
A Partnership Dedicated to Radiation Protection

(2)

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Tom Hill, Chairman
Suggested State Regulations Council
Radioactive Materials Program
Department of Natural Resources
4244 International Parkway, Suite 114
Atlanta, Georgia 30354

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Dear ~~Mr. Hill~~ Tom:

During our meeting of the SR-6 Committee in November, 1996, we discussed some recommendations to be made to the Nuclear Regulatory Commission (NRC) for their review during their upcoming rewrite of Part 35.

Although these recommendations were included in the minutes to this meeting, I would like to send them separately to you for review and routing to the NRC. Attached you will find a copy of these recommendations and a summary statement.

Please feel free to contact me if you have any questions.

Sincerely,

David

David Walter, Chairman

Enclosure

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During our November 18-20, 1996 meeting the SR-6 Committee set out to suggest a template for performing a complete revision to Part 35. In reviewing Part 35 the committee makes the following general comments:

1) Sealed source therapy sections are OK as is with the following additions:

> HDR and gamma knife requirements need to be added. Because of physical safeguards built into the gamma knife, rules do not need to be as comprehensive as the current teletherapy rules. For example, a gamma knife's full inspection interval can be extended to seven years rather than the five years required for other teletherapy devices.

2) Radionuclide therapy is also OK, although the committee voiced concerns about whether the new release criteria will allow too much radioactivity to be released from confinement, thus increasing exposure to the general public.

3) The most contentious area is diagnostic nuclear medicine. The committee believes that the current rules are overly prescriptive for the health and safety concerns involved, and sometimes appear to intrude on the practice of medicine. The recommended approach is to split out or reclassify diagnostic nuclear medicine into groups based on dose driven health and safety concerns.

General requirements for <u>all</u> groups should include the following Part 35 sections:

35.6 research provisions
35.7 other federal/state requirements
35.11 license required
35.12 amendments (although it should allow visiting authorized users and pharmacists as the suggested revision to Part G is written)
35.15 broad scope exemption
35.19 specific exemptions by the Commission
35.21 radiation safety officer
35.22 radiation safety committee **only** for institutions (in addition, specify <u>annual</u> meetings for Group 1 described below, <u>semiannual</u> for Group 2 described below and <u>quarterly</u> for all others)
35.23 statements of authority
35.25 supervision
35.32 QMP (modified with no prescriptive elements)

35.33 notifications, reports, and records of misadministrations (some members believe that this should exclude diagnostic nuclear medicine and should be revised to increase the iodine level from 30 uCi to a level that will result in a TODE for the thyroid of 50 rads)

35.49 suppliers of sealed sources or devices for medical use

35.51 calibration of meters

35.57 authorization for calibration and reference sources (to expand this, consider allowing any sealed source with an exposure not to exceed 5 mR/hr at one foot)

35.59 Requirements for possession of sealed sources and brachytherapy sources

35.60 syringe shields and labeling

35.61 vial shields and labels

35.75 patient release criteria (include provisions for temporary implant patients)

35.90 storage of volatiles and gasses

35.92 decay in storage

35.205 control of aerosols and gasses

The committee then divided the licensed uses under Part 35 into seven groups based on radiation health and safety. These groups are described below:

Group 1) Licenses for diagnostic nuclear medicine only, in which the licensee receives only unit doses of radioactive material (with a maximum unit dose of 50 millicuries), and iodine doses (prepared capsules only) not to exceed 1 millicurie. This group also includes sealed sources for diagnostic studies. These licenses would not be required to have dose calibrators, a QM program or surveys. They would need to follow camera QC and have a calibrated portable survey meter available for possible emergency use. They would need a simplified record of the administration of doses that would include the radionuclide, activity (time decayed), patient name, time and initials of the individual administering the dose.

Group 2) Licenses for non unit dose radioactive material (includes generators and bulk technetium), which includes any unsealed form of iodine, or iodine capsules exceeding 1 millicurie. These licenses should require use of a dose calibrator, a QM program for iodine doses >1 millicurie, a record of measurement from the dose calibrator for non unit doses, a survey meter and full surveys. They would need a simplified dose record as stated for Group 1, and should be required to perform a molybdenum 99 breakthrough test only on the first elution of a generator.

Group 2M) Licenses for mobile diagnostic nuclear medicine with limited iodine 131 (capsules only, <10 millicuries per capsule). Licensee must follow administrative and technical requirements for mobile nuclear medicine, have a QM program for iodine use >1 millicurie, use a dose calibrator, record measurements for non unit doses, maintain a simple administration record of doses and perform surveys. A survey meter should be required, and molybdenum breakthrough tests should be performed on the first elution of a generator.

Group 3) Licenses for unsealed source therapy nuclear medicine, including iodine and strontium(as well as future pure beta emitters. These licenses should require a dose calibrator for gamma emitters and volumetric calibration using calibration from a supplier that participates in a measurement quality assurance program with the NIST. These licensees should also be required to maintain a QM program, have both a contamination meter and a dose rate meter, follow requirements of Part 19 and current rules 35.310 (safety instruction) and 35.315 (safety precautions).

Group 4) Licenses for sealed source therapy implants. Delete the list of specific radioisotopes, but keep the specific approved uses of these sealed sources. These licenses should require a QM program, a dose rate meter, source inventories, survey requirements, following requirements of Part 19, and current rules 35.410 and 35.415 .

Group 5) Licenses for teletherapy (including HDR and gamma knife). These licenses should be required to have a QM program, and a dose rate meter. They should also be required to follow current rules 35.605, 35.606 and 35.632. Revisions to 35.610 and 35.615 should be made to include HDR. The calibrated dosimetry system described in 35.630 need not be as prescriptive as it currently is. Other, additional requirements may be necessary based on the inclusion of HDR and gamma knife.

Group 5M) Licenses for mobile HDR. These licenses should be required to follow administrative and technical requirements for mobile units, possess a dose rate meter, follow maintenance and repair restrictions, and license amendment requirements. The safety instruction and precautions sections should be modified for the HDR use. Other requirements need further consideration.

The committee then discussed some additional training considerations for the above suggested licensing revisions. There should be careful review of all authorized users. What is the role of the authorized user in Groups 1, 2 and 2M? With increased emphasis on dose driven rules, what is the role of the technologist, and how do they relate to the authorized user? Is there a need to specify training and experience criteria for technologists? Also, should the authorized user be required to select the patient, prescribe the dose and interpret the results?

To summarize, although the committee does not support the idea of general licensure for any nuclear medicine program, it does support a total revision of the current Part 35. This revision should lead to risk-based, dose-driven rules that are less prescriptive than the current rules. To that end, the committee recommends the following:

A. Divide medical use licensees into licensing groups based on their potential risk.

B. Modify the QMP to reflect the recommendations of the proposed Part G.

C. Relax the requirements for unit dose diagnostic nuclear medicine to eliminate dose calibrator, survey, camera QC, and records requirements.

D. Modify the patient release criteria to provide for interim release of temporary implant patients.

E. Allow shared rooms for certain radioactive material therapy patients (exposure driven).

F. Include modifications for HDR use.

G. Overall, training and experience criteria for both technologists and authorized users needs to be reevaluated.

H. Define "treatment site" as stated in the definition of misadministration in 35.2. Where is the dose calculated for this purpose? Does this mean the target volume, along the central axis, etc. Is a homogeneity correction required?