September 20, 2002

Ms. Cindy Cardwell, Chairperson
Conference of Radiation Control
Program Directors, Inc.
Bureau of Radiation Control
Texas Department of Health
1100 West 49th Street
Austin, TX 78756-3189

Dear Ms. Cardwell:

We have reviewed a draft copy of Part G to the Suggested State Regulations for the Control of Radiation (SSRCR), "Use of Radionuclides in the Healing Arts" provided to Lloyd Bolling as an advisor to the SR-6 Committee on May 20, 2002. The regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Parts 20, 32 and 35. We discussed our review with David Walter, State of Alabama, during the period April through June 2002.

We conducted the review to assist the Conference of Radiation Control Program Directors, Inc., in development of a compatible Part G. As a result of our review, we have identified a number of areas, both in the rule and in the rationale, where we believe changes are needed to meet current compatibility criteria. (See enclosed Response to Rationale and Compatibility Chart.) Under the Office of State and Tribal Programs Procedure SA-200, a finding that a regulation meets the compatibility and health and safety categories of the equivalent NRC regulation will be made based on a review of the final SSRCR regulation.

We ask that you address our comments in development of a final Part G Rule. When adopted as final, we also ask that a copy of the final rule be provided to us for review.

We are also enclosing two compatibility resolution documents. These documents clarify compatibility issues between specific SSRCR requirements and the comparable NRC requirements. We are using a process of developing compatibility resolution documents for cases where compatibility determinations were made in the past, but no documentation to support differences is available. Please provide these documents to the appropriate SSRCR committees.

If you have any questions regarding the comments, the compatibility categories or any of the NRC regulations used in the review, please contact me at (301) 415-2325 or Lloyd Bolling of my staff at (301) 415-2327 or via email at LAB@nrc.gov.

Sincerely,

/RA By Dennis M. Sollenberger Acting for/
Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated

cc: Ronald G. Fraass, Executive Director

Cindy Cardwell September 20, 2002

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ISSUES ON SSR DRAFT PART G RATIONALE

Issue 1. Page 2, first paragraph the Rationale states:

> "Because of the major changes made to 10 CFR Part 35, the equivalent Part G of the Suggested State Regulations for the Control of Radiation (SSR) was revised in its entirety. If adopted as written, Part G will be compatible with NRC Part 35."

NRC Staff Analysis: The staff identified a number of compatibility related issues during staff's review of the proposed Part G. These issues will have to be resolved before the NRC staff can recommend Agency concurrence.

Issue 2. Page 2, Sec. A.1., the Rationale states:

> "There are NRC rule sections on which the committee disagrees based on health and safety implications. The committee offers discussions of, and recommendations about, these rule sections below.
>
> Rules G.56 and G.57 correspond to NRC §35.392 and §35.394.
>
> These rules describe the training and experience requirements for authorized users of oral sodium I-131. The NRC has reclassified all training and experience rules from a compatibility category D to a compatibility category B. Category B classifications are for 'activities that have direct and significant transboundary implications.' The committee failed to see any transboundary implications, and requested clarification from the NRC in electronic correspondence dated April 10, 2000. The NRC did not respond to that request, or further verbal requests.
>
> More importantly, these rules do not appear to meet the NRC criteria of 'risk-informed, performance-based' regulations. An authorized user of diagnostic radiopharmaceuticals for imaging and localization studies is required to receive at least 700 hours of didactic training and supervised clinical experience. The committee believes that the use of oral sodium I-131 carries a much higher radiation safety risk to the patient, ancillary personnel and the public than any diagnostic use. Indeed, we feel it carries a higher risk than the use of other common therapy radiopharmaceuticals. It is apparent the NRC also recognizes these radiation safety risks, as evidenced by the requirements of a written directive prior to any dose of I-131 above 30 microcuries being administered to a patient. In addition, Nuclear Material Event Database (NMED) regarding misadministrations that meet NRC abnormal occurrence criteria reinforce this view. The previous Part 35 rules required the prospective authorized user to obtain 80 hours of didactic radiation safety training, as well as supervised clinical experience (3 cases for treatment of thyroid carcinoma and 10 cases for treatment of hyperthyroidism or cardiac dysfunction). The new rule is the same except it drops the number of cases of supervised clinical experience for treatment of hyperthyroidism or cardiac dysfunction from 10 to 3. The committee believes that the high degree of risk and previous misadministrations and abnormal occurrence data warrants a higher level of radiation safety training for

the prospective authorized user. The committee feels that the new 700 hours and 3 supervised cases specified in G.55 for all other types of unsealed radiotherapy uses (P-32, Sr-89, Sm-153, etc.) should also be required for oral sodium I-131 users. Based on the health and safety issues detailed above, the committee cannot recommend adoption of G.56 and G.57. However, in order to maintain compatibility with the NRC, you must adopt both G.56 and G.57.

NRC Staff Analysis: By definition, to be included in Compatibility Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The assignment of category B to training and experience requirements was made to ensure that these requirements for the medical use of byproduct material are consistent between NRC and Agreement States. Comments on our risk-informed, performance-based regulatory approach and Sodium Iodide-131 training and experience requirements were addressed in a May 2, 2002 letter to Mr. Kirksey E. Whatley, Director of the Office of Radiation Control in the Alabama Department of Public Health (see Attachment).

Issue 3. Page 2, Sec. A.2., Rules G.40b. and G.97b. correspond to NRC §35.75(b) and §35.2075(b). The Rationale states:

"Rule §35.75 has always been controversial. Several questions have arisen since the NRC adopted it. For instance, why is it appropriate to allow a member of the general public to receive a 500 mrem exposure from a released patient, when they cannot receive any more than 100 mrem exposure from any other licensed or registered activity? How do you handle individuals, such as home health nurses, nurses aides and nursing home staff, who, in one year, come into contact with numerous patients who have been released in accordance with §35.75? They might easily exceed 500 mrem TEDE during that year. What does an Agency do with recovered waste that is the result of a released patient?"

NRC Staff Analysis: We believe that the patient release criteria provide licensees with needed flexibility in program management. A dose limit of 5 mSv (0.5 rem) to individuals knowingly exposed while voluntarily helping in the care, support, and comfort of patients provides adequate protection to these individuals. In addition, licensees are required to provide instructions to the released individual, or the individual's parent or guardian, on actions recommended to maintain doses to other individuals as low as reasonably achievable (ALARA) if the total effective dose equivalent to any other individual is likely to exceed 1mSv (0.1 rem). Licensees should consider this latter provision regarding instructions on maintaining exposures ALARA in situations where the individual has been released under §35.75 but remains hospitalized for other reasons. In this case, the maximally exposed individual may be a member of the licensee's staff. The dose limit of 5 mSv (0.5 rem) to individuals comforting patients is consistent with the recommendations of the NCRP and the International Commission on Radiological Protection (ICRP). Finally, we recognize that the values presented in NUREG-1556, Volume 9, for release of patients are based on some conservative values. The licensee may use case-specific information in place of the values used in the guidance document. We believe that case-specific information should include consideration of possible exposures to nurses, nurses aides and nursing home staff from patients released under §35.75.

With regard to waste generated by these patients, the NRC staff does not recommend that such waste be recovered. This waste should be handled in accordance with instructions from

the authorized user (physician) or in accordance with advice provided by the radiation control agency.

Issue 4. Page 4, Sec. A.3., Rules G.91 and G.117 correspond to NRC §35.2047 (Record of a dose to an embryo/fetus or nursing child) and §35.3047 (Reports and notification of a dose to an embryo/fetus or nursing child). The Rationale states:

> "These rules describe the record and reporting requirements for a licensee should an embryo/fetus or nursing infant receive a dose equivalent greater than 50 millisievert (5 rem). The NRC included this rule to help alleviate the number of reports that a licensee must submit as the result of an embryo/fetus or nursing infant exceeding the dose limits of Part 20 (5 millisievert or 500 mrem) when the mother receives a diagnostic dosage. The NRC rule text does not specifically allow the embryo/fetus or nursing infant to receive 5 rem TEDE. However, by allowing an exception to the reporting requirements of Part 20, the NRC appears to be giving tacit approval of such exposures.
>
> The NRC has assigned a compatibility category C to §35.3047, and a compatibility category D to §35.2047, therefore, Agreement States can be more restrictive than the NRC. The committee recommends that these rules not be included in revised medical regulations. By not including them, the current, more restrictive, Part D exposure limits and reporting requirements would continue in effect. Doses exceeding 500 mrem to a nursing child should not occur if the patient is properly questioned and instructed. And Part D rules do not prohibit a physician from knowingly exceeding the 500 mrem limit to the embryo/fetus if they decide the risk is justified. The physician should use their professional medical judgment in performing these studies."

NRC Staff Analysis: We do not agree that this reporting requirement provides tacit approval for exposures in excess of the 10 CFR Part 20 limits. It should be noted that the recording requirement in §35.2047 was deleted from the revised final rule. The information required by §35.3047 is needed so that NRC can comply with Section 208 of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 5848, 42 U.S.C.), as amended, to submit an annual report to Congress of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, e.g., abnormal occurrences. (The "Reports Elimination Act," Pub. L. 104-66, changed the Abnormal Occurrence (AO) report to a yearly publication.)

Issue 5. Page 5, Sec. B.2., the Rationale states:

> "Part G requires the licensee to submit required written procedures for review by the Agency (G.8b.ii.). The NRC does not require these written procedures to be submitted for review. They intend to review such procedures only when a problem is found during an inspection that <u>should</u> have been addressed by one of these required procedures. The committee believes that it is better to determine the adequacy of a written procedure <u>before</u> a problem occurs. Waiting until after a problem occurs to review written procedures is reactive, not pro-active, and the committee doesn't believe this is in the best radiation safety interest of patients or occupational workers. What's more, the review and

discussion of a written procedure opens the lines of communication, and allows the building of a rapport between the licensee and the regulating agency. It can also increase the confidence of both parties in the resultant radiation safety program."

NRC Staff Analysis: For high risk therapeutic medical uses, the NRC requires licensees to develop and submit written procedures for the requirements in §§35.615, 35.642, 35.643, and 35.645, which are equivalent to SSR Sections G.74, G.80, G.81, and G.82. For low risk diagnostic medical uses, the risk-informed, performance-based regulatory approach permits licensees to develop and utilize their own procedures without prior NRC review and approval. NRC encourages the Agreement States to adopt this regulatory approach in order to conserve licensee and agency resources by operating more efficiently, while maintaining an adequate level of radiological health and safety. The NRC staff believes that with adequately trained and experienced staff, this regulatory approach will minimize potential radiation safety problems.

Issue 6. Page 7, item 5, the Rationale states:

"The committee has added sections G.18g. and G.87 because we believe it is prudent that the Radiation Safety Committee meet at specified minimum intervals (at least once a year) to review the effectiveness of the radiation safety program, and that records of these meetings be available for review."

NRC Staff Analysis: In the revised Part 35 (§35.24), only those licensees with two or more different types of uses of byproduct material under Subparts E, F and H, or two or more types of therapy units under Subpart H, are required to establish a Radiation Safety Committee. The risk-informed, performance-based regulatory approach permits licensees to establish their own meeting frequency in accordance with the licensee's program needs and activity. This approach also allows licensees the flexibility to use their own judgement regarding the composition of their Radiation Safety Committees. We believe that the training and experience of the authorized users and the specific duties required of the Radiation Safety Officer ensures that the use of radioactive materials at medical facilities is in accordance with Part 35.

Issue 7. Pages. 7-8, item 6, the Rationale states:

"During a public meeting between the NRC and the Organization of Agreement States, there was a discussion about Part 35. During those discussions, many individuals commented that the specific duties of the authorized user should be detailed in the rules. The committee has responded by including rule text that specifies the duties of an authorized user (G.20). The committee also considered alternative text for G.20, but decided that a single option in the actual rule text was less confusing. However, to allow maximum flexibility, the alternative G.20 text is as follows:

G.20 - Duties of Authorized User, Authorized Medical Physicist, and Authorized Nuclear Pharmacist.

a. A licensee shall assure that only authorized users of radioactive material:

i. Select the patients to receive radioactive material or radiation from radioactive material;

ii. Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and

iii. Interpret the results of tests, studies, or treatments.

(NOTE: If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision. Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in the patient's record and a written directive is prepared within 48 hours of the oral directive.)

NRC Staff Analysis: NRC does not have a section comparable to SSR Section G.20, noted above. In accordance with 10 CFR 35.24 entitled "Authority and responsibilities for the radiation protection program" licensee management is required to approve in writing any individual before allowing them to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist. The risk-informed, performance-based regulatory approach recognizes that authorized users have adequate training and experience, and provides them with enough flexibility to conduct licensed activities in a safe manner. The NRC staff believes that the requirements in SSR Section G.20 are overly prescriptive and unnecessary.

Issue 8. Page 8, item 7, the Rationale states:

"The committee has carried over rule text regarding the availability of an authorized user to communicate with a supervised individual (G.21c.). The NRC does not include this text in their rule. The committee believes that communication is key to supervision, and has left this section in the revised rule as optional, bracketed text."

NRC Staff Analysis: SSR Section G.21c., specifies the exact times, in minutes or hours, for communication between the authorized user and the supervised individual. The NRC does not utilize this prescriptive approach. Although acceptable under NRC's adequacy and compatibility policy, this requirement is more prescriptive and does not reflect the risk-informed, performance-based approach used in the revised Part 35. NRC recognizes the training and experience of the various categories of authorized users and holds each of them responsible for adequately supervising and communicating with their supervised staff. The NRC staff believes that this requirement is unnecessary.

Attachment: Letter to Kirksey E. Whatley
dated May 2, 2002 (ML021220739)