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Patricia K. Holahan
Chief, Rulemaking and Guidance Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: Request for Comment on Draft Consolidated Guidance (NUREG 1556 Vol. 9) About Medical Use Licenses (STP-02-029)

Dear Ms. Holahan:

The Illinois Department of Nuclear Safety (Department) hereby submits its comments on the revised Draft NUREG-1556 entitled "Program Specific Guidance About Medical Use Licenses." The subject letter requests comments on the guidance developed in accompaniment to the recently published 10 CFR 35 as well as four other specific questions. The Department's comments to those four questions follow. Specific comments concerning the guidance appear later in this letter.

1. For first time applicants preparing an application, the level of information provided in the NUREG is limited. We believe the Commission is missing an opportunity to provide its "clients" with information that could be useful when preparing and implementing a radiation safety program. Although existing licensees would most likely find cause to critique the guidance extensively on details of implementation, the Commission should be reminded that this guidance is used primarily by first time applicants and secondarily as a reference for existing licensees. The individual appendices should be tailored towards meeting regulatory and safety needs, and the applicant encouraged to adopt these or develop alternate procedures that meet their specific needs.

2. The bulk of the model procedures that are indeed procedural are helpful as written (i.e., App I., J., N., O., P., Q., T., as well as portions of R. and U.). Those procedures that are conceptual in nature are of limited value (i.e., K., L., M., and S.) and are more useful to existing licensees rather than applicants due to the

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nature of the information. These sections need to be more prescriptive for new applicants who may not be familiar with assessing doses to the public, conducting internal audits, etc. Also, each appendix should be referenced under each individual topic number to which it could potentially apply for easier cross-referencing, much like the regulatory references which are included in the body of the guidance.

3. We encourage the Commission to develop guidance specific for diagnostic nuclear medicine licensees. These types of licensees, in general, have limited expertise in developing radiation safety programs that can be readily implemented and maintain compliance with existing regulations. There would appear to be a great need for guidance in this area, particularly as it would apply to small clinics using radioactive material where expertise from a radiation oncology department would not be available. Some of these licensees are unaware of the basic license requirements such as maintaining an RSO/Authorized user on site. We have had several cases where these individuals have left the facility indefinitely while nuclear medicine procedures continue without their oversight. The document would not necessarily need to be long, given the revisions to the regulations, nor would it need to outline a plethora of procedures for submittal and review. However, the guidance should provide a general outline of the necessary elements that would need to be addressed in a radiation safety program and some procedures which could be used to meet that goal. Some of the referenced procedural appendices above would be appropriate. However, even some of those such as instrument calibration and leak testing of sources would probably not be necessary as those tasks are usually deferred to a service licensee.

4. With regards to referencing other guidance or consensus standards we suggest that you include a detailed reference, if not a summary of the NRC guidance related to inspection and enforcement of the various aspects of a radiation safety program in a medical environment. Although not an industry standard, that guidance is somewhat consensus-based and more importantly a major part of the Commission's overall redesign of the regulation of medical use of radioactive material. Compliance issues should be discussed for the benefit of the applicant in at least some degree so they know what to expect when developing their procedures and before committing to them in the application.

The following are comments requested by the NRC concerning portions of the guidance that would benefit from additional changes.

5. Section 3, page 3-1, bullet item 5, should include designation of financial resources as part of management's responsibilities. Frequently, radiation safety programs fail because they are not being afforded appropriate financial resources.

6. In Section 8.2, the applicant is to be a legal entity but may be an individual under specific circumstances. The guidance should clarify how this status is to be demonstrated or how the Commission will verify the legal status of an applicant.

7. In Sections 8.5, 8.7, and 8.8, we recommend reference to inclusion of blood irradiators and a reference to NUREG 1556, Volume 5, for additional information, as many medical licensees process blood for their use. We also question the need for providing the information specified in table 8.3 for licensees who need limited authorization for therapeutic uses of radioactive material. It should be considered adequate to list the nuclide(s), maximum individual unit activity and total maximum possession (potentially "As Needed"). Nothing is gained in terms of achieving a performance-based objective by restricting the request to a specific compound or specific treatment. It should be adequate to reference any drug approved by the FDA used within the practice of medicine by an authorized user.

8. We are very concerned with Section 8.9 regarding training of responsible individuals. A summary of the revised regulations regarding the significant change in emphasis on training, availability of the list (future or otherwise) of recognized boards at the NRC's web site, need for preceptor statements and use of form 313 should appear here at a minimum. In addition, the Commission will need to revise the guidance and potentially Form 313 to reflect 10 CFR 35.14 regarding the submission of permits used by master materials licensees or broadscope licensees. We did appreciate the information found in Appendix G with regards to what would constitute acceptable continuing education and experience. We also would like to see the second paragraph on page 8-21 highlighted, bolded, or otherwise have attention brought to it. The Department is constantly in receipt of Curricula Vitae that provide no information relative to the safe use of requested radioactive material from individuals who wish to be authorized on a license.

9. Sections 8.11, 8.12, and 8.13 should include clarification as to what comprises acceptable recentness of training.

10. Section 8.16 indicates that a diagram of patient rooms where therapeutic quantities of radioactive material are used must be submitted. This would appear to be largely unnecessary. Licensees must demonstrate compliance with restricted and

unrestricted exposures by calculation or monitoring. Records of such should be reviewed during inspections. Submission of diagrams does little to ensure such requirements would be met. This would be one area that would be better served as a performance-based item requiring less oversight.

11. In regards to Section 8.17, it seems capricious to require service licensees to submit either a statement that confirms procedures contained in Appendix J of NUREG 1556 Vol. 18 will be followed or the actual procedures to be used for instrument calibration, while allowing medical licensees who wish to perform their own calibrations to simply state that they will develop and implement an acceptable calibration procedure.

12. In Section 8.18, it is not clear from the regulations nor the text of the discussion if the Commission intentionally did not address the issue of frequency of calibration of instruments used to measure the activity of unsealed materials in order to allow flexibility or if an oversight was involved. The regulation itself defers to instrument manufacturers or national standards. The guidance should provide clarification of this issue if the implication is to follow the recommended frequencies as part of the procedures. Elsewhere in the regulations, frequencies for calibrations and checks of other equipment are specified.

13. The guidance in Section 8.19, page 8-46, regarding PDR remote afterloaders suggests that the primary care provider check to ensure the device has not moved, was kinked, etc., but does not provide guidance as to what frequency should be used. If this is found in an industry or consensus standard, it should be inserted here. If the frequency is simply left to the physician's discretion, then the statement in the guidance should be deleted.

14. Regulations address therapy related computer systems (10 CFR 35.457 and 657). However, the guidance only gives passing mention of this topic for Subpart H applications (pg. 8-82) and none for Subpart F. Issues of acceptance testing should be addressed by the guidance as well as specific reference to some of the nationally recognized protocols the Commission used in its discussion. The regulatory caveat of "acceptance testing must include, as applicable, verification of..." should be expounded to provide guidance as to what conditions would determine applicability. This would appear to deserve its own section within Item 9 if not included in 8.20 as "other equipment".

15. In Section 8.22, Item 10, page 8-50, last paragraph, NRC does not require submittal of an audit program of its radiation protection program, which is required to be performed annually by the licensee. The Department believes that since procedures in all other sections will be performance based, you should seriously consider requiring submittal of the audit program to help ensure that a meaningful audit of the radiation safety program will be performed annually and that appropriate corrective measures will be taken in a timely manner.

16. Section 8.23 indicates that the applicant must provide a description of facilities and equipment used for monitoring exposures as well as a statement that written procedures for monitoring exposures will be implemented and maintained. However, the stated criteria indicate that applicants must either monitor exposures or demonstrate that exposures are not likely to exceed ten percent. The information provided in this section concerns the need for monitoring and gives no mention of the alternate of maintaining evidence used to show that monitoring is not required for review during inspection. The Department suggests that information be added to this section regarding how an applicant can demonstrate that exposures are not likely to exceed ten percent of the limit. Does the applicant need to submit documentation of this demonstration to NRC or just maintain it for inspection? The Department is also curious to learn how the Commission anticipates enforcing the monitoring requirement if it is determined during inspection that dosimetry is not exchanged at the "preferred" frequency for the various monitoring devices. What portion of 10 CFR 20 will be cited?

17. Item 8.25 asks applicants to submit a description of how facility design and procedures for operation will minimize contamination. However the guidance includes only an appendix for a model survey program. What information regarding facility design is expected? Should all areas where radioactive materials are used be equipped with negative airflow when compared to surrounding rooms? Should benches and floor be made of non-porous surfaces? If submission of this type of information is necessary, then guidance in that aspect should be provided. Similarly, what procedures for operation to minimize contamination are necessary to be submitted?

18. Section 8.26 indicates the licensee must develop, implement and maintain procedures for various elements including conducting contamination surveys. Yet, those procedures do not need to be submitted. We agree with the comments provided by the Sloan Kettering Medical Center that the Commission should provide in this guidance clarification of the requirements of 10 CFR 20 regarding

application of ALARA, as it is within these procedures that ALARA is best applied. It is a disservice to the applicant/licensee to not summarize those materials in this guidance. For example, under the revised performance-based and risk-informed rule, it is not clear if it would be considered acceptable to eat, drink, smoke, apply cosmetics, or conduct other hand to face actions in areas where radioactive materials were being used. Although the practice may not be ALARA, if no intake or exposure occurs as a result, it would appear there is likely no violation of 10 CFR 20 or 35. In the past, such activities would be prohibited by license condition or through reference to a submitted procedure. If such procedures are no longer submitted, (Item 8.26) how would these basic safety precautions, (i.e., proper use of personal protective equipment, disposal of radioactive materials into labeled containers, appropriate use of personnel monitors, etc.) be enforced? What extent of procedures would the licensee/applicant be expected to have available? This item also suggests that submission of emergency procedures is unnecessary. Yet, in subsequent section (8.38), submission is necessary. The Department contends that there are therapeutic quantities of loose forms of material that are used that pose equivalent risk levels to those from sealed sources. Given this fact, some form of equity should be reached as to when such procedures need to be submitted for review.

19. Under Section 8.36, if a licensee is opting to perform service and maintenance of therapy systems there should be inclusion of the procedures to be followed for such activities along with the submitted level of training and experience of the individual. The submittal may be as simple as confirming service will only be in accordance with the manufacturer's service manual and recommendations, or it may be as involved as specifically developed procedures unique to the device which would have to be reviewed and evaluated on a case-by-case basis.

20. Section 8.40, page 8-78, references 10 CFR 20.1801 for security of radioactive material in storage from unauthorized removal or access. The paragraph then goes on to suggest that rooms where patients are hospitalized must be secured to prevent unauthorized access or removal of radioactive material. Is NRC implying that the treated patient could be subject to theft of implanted/administered material? Also, material in these cases is not considered in storage. The Commission should reconsider the language used to more clearly describe its intent (i.e., control spread of potential contamination perhaps).

21. Within Section 8.41, under operation of the remote afterloader, mention should be made of the degree of involvement necessary by members of the treatment team

and who should comprise that team. This information previously had been part of the NRC's policy and guidance regarding afterloaders. Portions of this guidance as well as the standard conditions have since become codified so a commitment to the make up of the team should not be unduly burdensome or unreasonable.

22. We believe that unless a license authorizes the administration of radioactive material or radiation to a human, a medical license should not be granted to an applicant. Class 3 mobile service providers addressed under Section 8.42 should be referred to other guidance in the development of appropriate license submittals. At a minimum the mobile service applicant should be made plainly aware that the license to be issued will not allow use in or on humans. Also, within this section it is suggested that actions limited to imaging of a previously injected patient may not be considered a licensed activity for the imaging service. This situation should be further described, as it would appear that only under a discrete situation within a very narrow interpretation of regulations would this be true. In fact inclusion of this cited statement would appear to be more confusing to the applicant than warranted and could be deleted. See Item 26. for additional comments regarding mobile services.

23. Section 8.44, Item 11, page 8-90, we believe that the licensee must submit waste disposal procedures with the application including calculations demonstrating that expected concentrations of effluents as a result of waste disposal will be below regulatory limits (i.e., disposal via the sewer, evaporation, etc.). Would the Commission consider on-site incineration worthy of submission and review or would the affirmation that the effluent will be compliant with the regulations be considered acceptable? The NRC's "commitment to develop" statement is unacceptable for waste disposal that could (and does) end up in the public domain. We also would expect to see some kind of statement in this section about responsibilities of the licensee for waste discovered in the public domain. So far the Commission has managed to circumvent this issue for which the states ultimately have had to respond. The Commission's approach of "as long as it's less than 500 mrem" (regarding patient release criteria) while at the same time insisting that other release of material achieve an ALARA limit of 25 mrem or less is rather difficult to reconcile.

24. In Section 9, second paragraph, the following conditions should also require an amendment:

- Release of a restricted area.

- Change to a less restrictive operating procedure or equipment modification that potentially affects occupational/non-occupational exposures including survey frequencies or release of effluents.
- Changes in waste disposal practices.
- Change in anything under 35.19.

25. In Section 10, page 10-1, references to the appropriate decommissioning standards should be made. Licensees must submit records of close-out surveys and obtain NRC/State approval prior to release of the entire site or a portion thereof for unrestricted use. This should be made clear in this section.

26. There are several comments regarding Appendix V. Given the various nuances associated with this type of authorization and our previous comments, it would be worth consideration as a separate guidance and certainly part of any developed guidance directed at diagnostic use of radioactive materials. Comments are itemized below.

a. Page V-1 indicates there are "three types" of mobile service, but they list two different "third types" for a total of four types. The second "third type" indicates it is limited to therapy sealed sources.
b. Page V-3 indicates the section referring to the "Client Site" is only for therapy. It is not clear if diagnostic use is prohibited, unregulated, or simply absent from the discussion. It goes on to indicate therapy sites must be listed by address. Diagnostic sites should also be listed if radioactive material is to be delivered to that site, as pharmacies are not authorized to deliver radioactive materials to sites not listed on a license.
c. Page V-3 should mention the surveys that must be performed surrounding the vehicle to ensure exposures do not exceed 2.0 mrem in any one hour and 100 mrem in a year.
d. Page V-4 does not mention that the source holders must be approved as DOT containers or that sources must be placed in approved containers prior to their transport.
e. Page V-4 indicates that each client must perform all the checks of the instruments. More accurately, the client is responsible for those checks. Those mobile service individuals may perform the checks and simply transfer paperwork to their client. Other sections of this guidance indicate equipment checks must be performed each day, not at each site. Consideration needs to be given to services provided to multiple sites in a single day.

f. Page V-6 does not mention decontamination equipment maintained on board the vehicle. This information must be identified in a submittal per regulation.

g. Page V-6 indicates predetermined calculations of exposure rates for an unshielded therapy source should be performed, yet, there is no mention of the same type of evaluation for or any other diagnostic or reference sources. This appears to be inconsistent.

h. Page V-7 does not mention any required hazardous materials training (per DOT) for transporting the sources. This should be added.

27. We disagree with the Commission's conclusions that intravascular brachytherapy systems should continue to be considered as an "emerging technology" in the final regulation and being treated as such in the guidance. At this juncture in time at least three readily available systems have received FDA approval, have been listed in the SSD Registry, and are being widely distributed to specific licensees not of broad scope. Although these systems may not have been specifically addressed in the regulation, at a minimum the Commission should include their latest policy guidance for this technology as an appendix for easy reference and distribution.

28. The Department recommends some additional guidance on security in light of recent events. The medical community is especially sensitive to this currently as they often have large numbers of patients, visitors, interns, volunteers, and students in relative close proximity to radioactive materials. In contrast, industrial facilities can restrict the public to remain outside of their fenceline and are familiar with the backgrounds of most employees. Use of Safeguards Advisory dated October 16, 2001, would be a good place to start with this guidance.

29. The Commission has used a performance-based and risk-informed approach in developing its amended regulations. This will create new challenges for inspectors as they evaluate the adequacy of procedures. Previously, inspectors relied on licensing staff to ensure that the procedures were adequate and tied down in a license prior to inspection. Under the new approach, inadequacies will only be noted during an inspection or if an incident occurs. It is also common for inspectors to read and rely on the information found in licensing guides to form a basis as to what may be considered as adequate. The new guidance will not be as helpful to inspectors in this area. This aspect is even more important given the reliance on 10 CFR 20 to provide the basis for regulation of radiation safety. It is the Department's experience that Radiation Safety Officers and authorized users

are very busy maintaining the operation of their facility, and it would be helpful for them to have model procedures to adapt for their own use. We strongly suggest that the guidance include model procedures, as this would be helpful for both licensee and regulatory staff.

Thank you for the opportunity to comment. Please contact me at (217) 785-9947 if you have any questions.

Sincerely,

Joseph G. Klinger, Chief
Division of Radioactive Materials

JGK:CGV:DMP

cc: James Lynch, NRC Region III