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Chief, Rules and Directives Branch
Office of Administration
U.S. Nuclear Regulatory Commission
Mail Stop T6 D59
Washington, DC 20555

RE: Guidance for Inspections of Medical Licensees.
Federal Register Vol. 67, No. 96. May 17, 2002. Page 35162.

Gentlemen:

These comments concerning applicability of the Hazardous Materials Regulations to loading, unloading, and storage are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include manufacturers and shippers of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instrumentation used in medial applications.

Background

Back on January 8, 1999, the NRC held a public meeting to discuss the development of guidance for streamlined inspection and enforcement of medical use regulations. CORAR participated and later provided written comments because NRC had stated its intent to use the guidance developed for medical use regulation on a pilot basis and would then move on to application of this approach to materials licensees. At the time, CORAR was encouraged by the initiative because NRC proposed the use of Performance Indicators (PI)s as the basis of performance-based rather than prescription-based inspections. NRC proposed at the time to inspect performance against PI's and would not go into detailed compliance review of a licensee if performance against the PI were satisfactory.

During the meeting and in written comments that followed, CORAR made the following general comments concerning the initiative:

Template = ADM-013

E-RIDS = ADM-03
Add = R. Bracus (RWB)

1. CORAR applauds the NRC initiative to streamline licensing, inspection and enforcement and the proposed performance-based, risk-informed approach.

2. The burden on NRC and licensees should be minimized by empowering the regulated community to achieve compliance through self-assessment, quality assurance and corrective action programs.

3. CORAR requested the opportunity to provide NRC with input on any subsequent guidance using industry standards.

4. The scope of the inspection and enforcement pilot should include nuclear pharmacies.

5. NRC should use PI's as a means of determining the effectiveness of licensee compliance programs and should use PI's with the Form 591 at inspection closeout.

6. PI's should reflect the type of licensee and the relative technical complexity.

Specific comments on PI's for medical use were as follows:

1. Every effort should be made to allow licensees to resolve minor deficiencies with respect to PI's at the time of the inspection where a commitment is made in an action plan. Credit should be given to correction of self-identified deficiencies.

2. The determination of the knowledge and competency of management and staff would be better accomplished through interviews rather than looking through training records.

3. Licensees who are operating well below limits for doses to the public should be allowed the flexibility of determining when and how NRC is notified of incidents and should not be penalized for providing "heads-up" information not required by the regulations.

4. Methods used to demonstrate a licensee's control and accountability of material should depend upon the type and quantity of material possessed and not prescriptive for all uses.

5. No PI should be required for written directives for diagnostic radiopharmaceutical use, as this is a relatively low risk activity.

6. There should be no PI for identification of willful violations as the identification of this in the course of inspection warrants escalated enforcement regardless of whether there is an established PI for this.

While CORAR is encouraged that NRC the draft guidance has generally assumed a performance-based, risk-informed form in its approach to inspection, we believe that the content of the drafts do not reflect all of our earlier comments. In addition to the above recommendations made at the beginning initiative that we still urge NRC to consider, we provide the following comments concerning the draft inspection procedures.

General Comments on the Draft Inspection Documents:

General comments on the draft documents, including those in response to the NRC's request for comments on how inspection procedures could be made both performance-based and risk-informed, are as follows:

1. CORAR is encouraged that the draft guidance is performance-based in that inspectors are directed to look at outcomes of performance. There is much less focus on prescriptive compliance criteria. However, CORAR, as indicated in comments to follow, is concerned about the departure from the use of Performance Indicators (PI's). Although the focus of inspections appears to be on performance outcome, the application of PI's and threshold for each would reduce the likelihood of subjective interpretation of licensee performance on a case-by-case basis by inspectors. The application of PI's would also help to achieve performance-based, risk-informed inspection. CORAR would appreciate and take advantage of the opportunity to provide guidance on establishing PI's for medical use as well as for materials licensees.

2. Objective 01.01 of each of the inspection manuals states that the intent is to determine if licensed activities are being conducted in a manner that will protect the health and safety of workers, the general public *and patients*. This is inconsistent with statements 1 – 3 of the Medical Policy Statement, especially with regard to use of diagnostic radiopharmaceuticals. The word "patient" should be removed from the objective statement. CORAR does, however, agree with the statement in the guidance that "the inspector should exercise discretion when interviewing licensee staff in the presence of patients."

3. The guidance documents include several pages of Inspection Requirements that include areas to be reviewed and the Inspection Guidance section then follows that includes a description of what should be covered by the inspector in each of these areas to determine whether or not the licensee meets expectations. It appears that much of this information is duplicated. The inspection manuals would be improved and streamlined if the areas of interest were only listed once with the guidance included with the inspection requirements and repetition of information or guidance avoided.

4. Also, to avoid subjective determination by inspectors and to further streamline the inspection process, each area covered in the inspection manual should have a PI, following the approach proposed by NRC's Medical Use Inspection and Enforcement Pilot. The guidance repeatedly uses phrases such as "inspector concludes performance is adequate" and "licensed activities are appropriate" yet it is unclear against which benchmark or standard the licensee performance is being assessed.

5. The Medical Policy Statement states that "the NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety." There is no reference to these standards or any suggestion in the guidance that these be used. These standards should be used in the establishment of PI's and PI's should be applied to each of the focus areas in the inspection manuals.

6. The guidance also repeatedly uses the term "performance expectation" yet in context it is suggested this is to be defined subjectively by the inspector which inevitably will result in inconsistency despite the use of a guidance manual for all inspectors. At a minimum, the licensee should be given the opportunity in the absence of PI's to establish the adequacy of activities such as the performance of surveys, the selection of instrumentation, the effectiveness of training provided, and the effectiveness of the radiation protection program.

7. The guidance repeatedly directs the inspector to discuss significant safety concerns with NRC regional management. The guidance does not state and it should state that inspectors should discuss apparent deficiencies with licensees to afford the opportunity to resolve misunderstanding or provide mitigating information and/or corrective action prior to contacting the regional office.

8. The guidance documents state that "the inspector should keep the licensee apprised of inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee management." CORAR strongly agrees with this guidance and suggests that the ongoing communication not be limited to licensee management and should include those who have involvement, such as the RSO and radiation protection staff, in any issues identified in the course of the inspection to provide the opportunity for clarifying explanation.

9. The determination of whether "changes in ownership or staffing have occurred" and "whether the licensee has submitted appropriate notification to NRC" are not within the scope of performance-based regulation or inspection. If the licensee has already and otherwise demonstrated adequate management oversight and effective radiation protection and control, any discussion of this issue is irrelevant and should be removed from this guidance.

10. The Post-Inspection Actions focus area of the Inspection Requirements refers to Performance Evaluation Factors (PEFs). A reference is also made to IP 87101, a copy of which is not readily available. What are these PEFs and how if at all do they relate to IP's? A review of the PEF's as they apply to medical use regulation needs to be made possible by making them available to stakeholders.

11. The Walk-Through Orientation Tour, as generally described in the Inspection Requirements, should be more than just an opportunity to make general observations. It should also be used as an opportunity to make preliminary PI determinations and eliminate up front any areas of performance where licensee status is found to be satisfactory.

12. The guidance advises inspectors to review licensee ALARA goals and determine if they are sufficiently challenging yet realistic. Without a PI or clearer guidance based on a standard, this determination is vulnerable to subjective inconsistency. The application of standards in a PI for this focus area is critical and necessary.

13. The guidance directs under Radiation Program Administration, audits to be examined with particular attention to the deficiencies identified by the auditors. This is not within the scope

of performance-based regulation and inspection. If a review of the other focus areas, preferably using PI's, results in the conclusion that the radiation protection program effectively achieves radiation safety, then there is no need to do a detailed review of audit results. If there is a specific license requirement for audits to be conducted, the inspector can review a summary report or observe other documentation that shows the audit was completed rather than view the actual details of the audit.

14. In the guidance under Financial Assurance and Decommissioning, CORAR agrees with the approach taken where it states "if during the confirmatory survey, the inspector identifies levels above release limits, the inspector should inform appropriate licensee representatives as soon as possible to review the matter." This is preferable to the approach suggested elsewhere in the guidance to first contact Regional Management.

15. In the guidance under Generic Communication of Information, it states "the inspector should verify the licensee is receiving applicable...documents" and "also verify that the licensee has taken appropriate action in response to these." This does not reflect performance-based regulation and inspection. This matter should only be an issue if review of other areas of focus indicate that the licensee performance suffers from failure to receive and act on these communications.

16. In the guidance under Special License Conditions, it states the "inspector should verify the licensee understands the additional requirements." This is beyond the scope of performance-based regulation and inspection. If the licensee does not understand and, therefore, does not meet these additional license requirements, it will be revealed during the review of other areas of focus.

17. With regard to the guidance on Exit Meetings, NRC should use PI's as a means of determining the effectiveness of licensee compliance programs and should use PI's with the Form 591 at inspection closeout.

18. With regard to the guidance on Post-Inspection Actions, every effort should be made to allow licensees to resolve minor deficiencies with respect to PI's at the time of the inspection where a commitment is made in an action plan. Credit should be given to correction of self-identified deficiencies. The practice of aggregating minor deficiencies, especially if corrected at the time of the inspection, must be eliminated.

19. In the guidance on Walk-Through Orientation Tour, it states "certain inspection items...are better performed by the inspector unannounced; therefore, these types of items should not be discussed during the entrance briefing." This guidance would benefit from the inclusion of specific examples of "these types of items." It is unclear as to what the intent is of the NRC to initially hold back discussion on an item of concern and specific examples are needed to provide meaningful guidance and to allow stakeholders the opportunity to understand this in order to comment.

20. The checklists at the end of each inspection manual should consist of a checklist of Performance Indicators with threshold of adequacy for each.

Comments Specific to Inspection Procedure 87119. Medical Broad-Scope Programs

In addition to the comments above concerning the guidance documents in general:

1. Shielding is not included as a focus area in this document and should be.

2. The sentence in Section 02.08 that reads "that the licensee's performance has implemented" should be reworded to "that the licensee has implemented."

3. The guidance in its discussion of Written Directives should state that this focus area dose not apply to diagnostic radiopharmaceuticals.

Comments Specific to Inspection Procedure 87118. Brachytherapy Programs

In addition to the comments above concerning the guidance documents in general:

1. In the guidance under Waste Storage and Disposal, it states that "generally, sealed sources used for brachytherapy, including seeds and ribbons are returned to the manufacturer." This is not true, especially with seeds of half-lives of sixty days or less and seeds that are permanently implanted. These are not usually returned to the manufacturer.

2. The section of guidance titled "Authorized Users" should be renamed "Authorized Individuals" as the scope of this focus area includes individuals other than just users.

Comments Specific to Inspection Procedure 87115. Nuclear Medicine Programs that Involve Diagnostic and Therapeutic Applications

In addition to the comments above concerning the guidance documents in general:

1. The guidance in 03.05 for shielding really only discusses leak tests for sealed sources. There is no guidance at all in this section regarding shielding. Section 03.05 should be renamed Leak Tests. A separate area of guidance for shielding should be included and be based on a PI that includes quantitative thresholds for adequacy.

2. The guidance under Written Directives should be revised to indicate that this does not apply to diagnostic radiopharmaceutical applications.

3. In the guidance under Effluents, it is stated that "the inspector should verify that effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity...." This is an example of where this inspection procedure would greatly benefit from the use of a PI that is derived from an industry standard to avoid a subjective, inconsistent determination from an individual inspector. At the very least, the licensee should be given the opportunity to explain its monitoring program based on industry standard or best practice. The guidance that "the inspector should verify that all

significant release pathways are monitored..." would also benefit greatly from the application of a PI.

4. The section of guidance titled "Authorized Users" should be renamed "Authorized Individuals" as the scope of this focus area includes individuals other than just users

5. In the guidance concerning Financial Assurance and Decommissioning as well as Decommissioning Timeliness, NRC should take into account the fact that most medical use programs involving diagnostic and therapeutic applications are dealing with short-lived materials and/or sealed sources of radioactive material. In many of these situations, licensees will not be required to have technically sophisticated decommissioning plans if any plan at all and decommissioning timeliness issues would not be complex. These sections should be revised and scaled down to apply to most diagnostic and therapeutic environments with the more elaborate discussion provided in the draft reserved for other applications such as broad-scope medical programs.

Comments Specific to Inspection Procedure 8710X. Nuclear Medicine Programs that Involve Diagnostic Applications

In addition to the comments above concerning the guidance documents in general:

1. The guidance in this document is very similar to that in 87115 and should at least be combined as a single document if all of the inspection procedures are not combined. If combined, a statement would be necessary in the guidance for Written Directives, Medical Events and Patient Release that these areas do not apply to diagnostic applications.

2. The guidance in 03.05 for shielding really only discusses leak tests for sealed sources. There is no guidance at all in this section regarding shielding. Section 03.05 should be renamed Leak Tests. A separate area of guidance for shielding should be included and be based on a PI that includes quantitative thresholds for adequacy.

3. In the guidance under Effluents, it is stated that "the inspector should verify that effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity...." This is an example of where this inspection procedure would greatly benefit from the use of a PI that is derived from an industry standard to avoid a subjective, inconsistent determination from an individual inspector. At the very least, the licensee should be given the opportunity to explain its monitoring program based on industry standard or best practice. The guidance that "the inspector should verify that all significant release pathways are monitored..." would also benefit greatly from the application of a PI.

4. In the guidance under General Training, it states that licensee radiation safety training should provide for authorized nuclear pharmacist instruction in the preparation of radioactive drugs. Nuclear pharmacists are trained professionals in the practice of preparing radioactive drugs. Who, therefore, would be required to train authorized nuclear pharmacists?

5. The section of guidance titled "Authorized Users" should be renamed "Authorized Individuals" as the scope of this focus area includes individuals other than just users

6. In the guidance concerning Financial Assurance and Decommissioning as well as Decommissioning Timeliness, NRC should take into account the fact that most medical use programs involving diagnostic applications are dealing with short-lived materials and/or sealed sources of radioactive material. In many of these situations, licensees will not be required to have technically sophisticated decommissioning plans if any plan at all and decommissioning timeliness issues would not be complex. These sections should be revised and scaled down to apply to most diagnostic and therapeutic environments with the more elaborate discussion provided in the draft reserved for other applications such as broad-scope medical programs.

CORAR appreciates the intent of this proposed rule and the opportunity to express these comments. Please contact us if there should be any questions or if any additional information concerning these comments is needed.

Sincerely,

Mark A. Doruff, CHP
Council on Radionuclides and Radiopharmaceuticals