



Oregon

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January 20, 2010

Martin J. Virgilio, Deputy Executive Director
For Materials, Waste, Research, State, Tribal and
Compliance Program
Office of the Executive Director for Operations
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555



Re: NRC letter dated December 5, 2009 on Management Review Board IMPEP Report

Mr. Virgilio:

The Oregon Radiation Protection Services Section has reviewed the final Oregon Agreement State MRB IMPEP report and offers the following comments related to this review.

The Oregon Radiation Protection Services (RPS) Section Radioactive Materials Licensing (RML) program appreciates the IMPEP team review of our program and constructive recommendations for program improvement. Although RPS management does not wholly agree with all of the outcomes of the final report, we do agree with the overall spirit and purpose of the IMPEP review program.

The Oregon IMPEP review has resulted in our staff addressing each of the areas of concern while also maintaining the review areas which were deemed Satisfactory during the review.

Technical Quality of Inspections – Satisfactory but Needs Improvement:

Issue A: Improve labeling, handling and protection of documents related to Increased Control of IC licensee sensitive or security related information.

Proposed action to resolve this issue: The RPS Licensing/Administrative Manager has developed and staffed a new draft protocol outlining specific requirements for marking, handling and protecting SUNSI information based upon RIS 2005-31 guidance. The final version has been approved and will be fully implemented during the first quarter of CY2010.

Issue B: Upgrading RML Inspection procedures (written protocols)

Proposed action to resolve this issue: The RPS Protocol Committee has assigned RML staff members to develop updated inspection protocols and report forms to be compatible with the NRC IP 87xxx series guidance and will integrate elements of a California model provided from the August IMPEP team to help ensure completion of thorough inspections and consistency in enforcement actions. To date, two draft inspection protocols/reports are near completion.

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Template: EDO-001

E-RIDS: EDO-01

IMPEP Team Recommendation: Develop and utilize a documented formal qualification program for inspection and licensing staff.

Proposed action to respond to this recommendation: The RPS Protocol Committee and Management Team will evaluate the guidance provided in MC1246 and develop an appropriate method of documenting individual training and qualification of staff members.

Technical Quality of Licensing – Satisfactory but Needs Improvement:

Issue A: Review of complex licenses re: NUREG 1556 series and 10CFR35.1000 guidance.

Proposed action to resolve issue: RML staff have developed new draft administrative rules to be compatible with 10 CFR 35.1000 rule, including OAR 333-116-0465 for emerging technologies. Licensing staff have also conducted a review of all related new gamma knife licenses; Authorized Nuclear Pharmacist (ANP) authorizations; and authorizations for medical therapy involving microsphere Yttrium-90 therapy for compatibility with NRC guidance. We have also improved the peer review process for licensing to verify accuracy of Program Code assignments for licenses and related MC2800 Inspection Frequencies.

Issue B: Regulatory oversight of requirement for independent controls on portable gauges.

Proposed action to resolve issue: Oregon Administrative Rules (OAR) currently uses identical language as NRC for this requirement. Furthermore, Oregon requires that the internal device lock be properly secured to prevent unauthorized use of the portable gauge. In order to reaffirm that all Licensing and Inspection staff possess a clear understanding of this requirement, Oregon RPS management has reviewed these requirements with RML staff. In addition, newly developed inspection protocol/report forms will address this element and will include documentation in our formal licensing and inspector qualification training program.

Technical Quality of Incidents and Allegations – Satisfactory but Needs Improvement:

Issue A: Inspector documentation of review of incidents during inspections (e.g. Y-90 microsphere therapy) where on-site investigation is warranted.

Proposed action to resolve issue: RPS will utilize an on-site team approach to investigate root cause and corrective actions required to mitigate future unresolved events at licensee facilities. [e.g., related multiple events at OHSU as noted by the IMPEP review team] Comprehensive evaluations of licensee medical events and internal procedures, including a review of recent inspection histories, will be completed to prevent recurrence of incidents and promote more effective licensee inspections. In addition, RML staff members are drafting a revised protocol to ensure thorough and timely investigation and reporting in the future. [see *Technical Quality of Inspections #1-Issue B above*]

Issue B: Reporting of required information to NMED and NRC HOO

Proposed action to resolve issue: Since the IMPEP review, RPS offered to host a NRC regional training for NMED and SA-300/IC training in Portland, Oregon. May 11-12, 2010 has been confirmed for the course dates. Robert Sant (INL), Randy Erickson (NRC Region IV) and Dr. Janine Katanik are slated to provide this training which will enhance the timeliness of our response and documentation efforts by RPS emergency response staff.

Oregon IMPEP MRB Commentary for the Record

The on-site review team and MRB both emphasized a desire for the IMPEP process to be fair, complete and accurate. RPS management respectfully offers the following related comments to the MRB meeting and this report:

*During the IMPEP MRB meeting, Oregon representatives gave testimony regarding specific findings from the IMPEP review team visit. In addition, Cindy Cardwell (Texas OAS representative on the MRB) made a significant comment relating to an MRB recommendation for RPS to provide an inspector knowledge **testing** process. These comments are not reflected in the Final Report. The below items are included to ensure a complete record.*

A. Technical Quality of Licensing-

- 1. Oregon RPS has a very good peer process to verify accuracy of Program Codes and related MC2800 Inspection Frequencies. Only one licensee out of ~470 was identified by the IMEP review team with a less frequent inspection cycle than MC2800. For multiple license types, Oregon RML program inspects licensees more frequently than required by MC2800 guidance.*
- 2. RPS also has a high rate of accuracy for its licensing program. The review team noted inconsistent application of 10 CFR Part 35.1000 guidance for certain complex and/or infrequently encountered licensing actions. These inconsistencies represent a very low proportion of our overall licensing actions, and deal with emerging technologies. During the MRB meeting, discussion also identified concerns about lack of clarity in the emerging technology NRC regulations.*

B. Technical Quality of Inspections-

The review team/report notes several positive aspects relating to RPS inspector abilities. It was noted that our veteran inspector, tasked with training a new inspector, was found to be unfamiliar with a specific Oregon regulation relating to portable gauge security measures. However, based upon prior RPS Supervisory Accompaniments, the trainer has demonstrated, on multiple occasions, his knowledge and competency on the subject. In fact, he is our RML Lead Worker and the most senior, experienced portable gauge inspector on staff. It is likely that he misunderstood the IMPEP review team member's portable gauge question. All RML inspection staff have also received updated training on this issue.

The review team also noted that our newest RML inspector was not knowledgeable about the same portable gauge rule. Again, in the recent past, he demonstrated his knowledge during RPS training and Supervisory Accompaniments. However, his understanding of this area of rules was incomplete and we acknowledge the valid review team concern that additional training and understanding of the related rules is recommended.

C. Technical Staffing and Training

The Final Report contains a recommendation for RPS to use a documented formal qualification program for RML staff, including oral/written evaluations of their understanding of regulations and guidance documents. During the MRB meeting, Cindy Cardwell (Texas OAS Representative) pointed out that the NRC does not require specific testing methodology for other OAS programs. As a result, the MRB agreed to amend the Final Report language recommending that RPS "verify" staff competency, (versus MRB needing to require all OAS programs to develop new testing systems for staff competency). The final report did not correct this technical comment.

D. Technical Quality of Incident and Allegation Activities

OHSU microsphere events involved one of the new emerging technology issues and represents a small fraction of the incidents evaluated in 2009. RPS management team has addressed this issue through additional training and development of protocols to provide better guidance for investigating potential reportable medical events.

Oregon Radiation Protection Services will also have an opportunity to increase general RML staff knowledge by being the host of the next OAS meeting in Portland, Oregon from August 23-26, 2010. This will provide an opportunity for staff to learn about overall processes and updates on future critical issues related to licensing and enforcement of regulatory issues.

In conclusion, Oregon Radiation Protection Services, both appreciates, and values the IMPEP process as a means to improve and maintain a high quality radioactive materials licensing program. Thank you for the opportunity to provide feedback regarding these important components of our program.

Sincerely,


Terry D. Lindsey, Manager
Radiation Protection Services Section

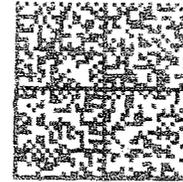
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