



Rick Scott  
Governor

H. Frank Farmer, Jr., M.D., Ph.D.  
State Surgeon General

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May 13, 2011

James L. Lynch  
State Agreements Officer  
U.S. NRC Region III  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

Dear Mr. Lynch:

We are in receipt of the Integrated Materials Performance Evaluation Program (IMPEP) draft report as the result of the March 20 to April 1, 2011 IMPEP review. Thank you for the opportunity to review the team's draft report prior to being submitted to the Management Review Board. The draft report is well written and accurately conveys your review and findings. Below are a few comments that we feel would clarify and better define a few areas in the report.

**Section 3.3 - Technical Quality of Inspections – First paragraph - Add underlined text**

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 22 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by 18 Bureau inspectors and covered inspections of various license types, including: medical broad scope, medical institutions, medical private practice, portable gauges, industrial radiography, veterinary use, panoramic and self-shielded irradiators, gamma knife, nuclear pharmacy, mobile nuclear medicine, and Increased Security Controls for Large Quantities of Radioactive Materials (Increased Controls). Appendix C lists the inspection casework files reviewed, with case-specific comments, as well as the results of the inspector accompaniments.

**Section 4.1.1 - Legislation – Delete second paragraph and replace with underlined text**

Florida's rulemaking process was changed in 2010. Criteria were established that determines whether a proposed rule has to be submitted for legislative approval. In January 2011, Executive Order 11-01 halted all rules in process, requiring all rules to receive review and approval from the Governor's Office under the newly established Office of Fiscal Accountability and Regulatory Reform (OFARR). OFARR will now review and approve all rulemaking efforts. The Governor's Office has also requested that each agency submit an annual regulatory plan that identifies each rule it expects to promulgate in the next 12 months to be submitted to OFARR no later than July 1, 2011. With OFARR review, it is anticipated that it may take up to 12 months to complete a rule to the point where legislative ratification may or may not be required. While not all rules require legislative ratification, those that do will not become effective until ratified by the Florida Legislature.

**Section 4.1.2 - Program Elements Required for Compatibility – Second paragraph - Insert underlined text**

The Bureau's rulemaking process is governed by the Administrative Procedure Act in Title X, Chapter 120, of the Florida Statutes. The administrative process for regulation adoption is

provided in Chapter 1S-1 of the Florida Administrative Code. With the changes described above now in effect, the State's administrative rulemaking process takes approximately 12 months from drafting to finalizing a rule. OFARR reviews and approves all rulemaking efforts. After the Bureau drafts a proposed regulation, they must publish a notice in the Florida Administrative Weekly (FAW) offering to hold public workshops about the proposed regulations. After the workshops (if held), the Bureau publishes a notice in the FAW of proposed rulemaking and offers the opportunity for a public hearing on the proposed rules. Concurrently, the Bureau must prepare and send an initial rule review file to the Joint Administrative Procedures Committee, which is a legislative committee that oversees rulemaking by all State agencies. If there are no objections or changes needed, the Bureau prepares the final regulation and files it with the Florida Secretary of State. The final rule must be filed within 90 days of the notice of the proposed rule. While not all rules require legislative ratification, those that do will not become effective until ratified by the Florida Legislature.

**Section 4.2.2 – Technical Quality of the Product Evaluation Program – Third paragraph – Insert underlined text**

The Bureau submitted a Technical Assistance Request (TAR) to the NRC for this SS&D on June 28, 2010. The TAR requested NRC's assistance in interpretation of the regulations regarding the definition of a generally licensed device and distribution of these devices to general licensees. NRC's response was dated February 10, 2011. Due to Florida's statutory time limitations on issuance of registrations and licenses, the Bureau was required to issue the registry prior to receiving NRC's response, and was thus not able to consider the TAR response prior to issuance of the SS&D.

**Appendix E - File No. 1**

Typo in licensee name. - Should be "Shands Hospital" not "Shandis Hospital".

**Appendix F - File No. 6**

Delete comment c) - The label is too small to fit on the device and an appropriate label containing all the required information is included in the device manual.

Thank you for the opportunity to provide these comments regarding the draft report. If you have any questions, please contact me at 850-245-4266.

Sincerely,



*For* William A. Passetti, Chief  
Bureau of Radiation Control