



Charlie Crist
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State Surgeon General

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Terrence Reis, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
T8-E24
Washington, D.C. 20555-0001
Only sent via e-mail to (Terrence.Reis@nrc.gov)

Dear Mr. Reis:

Enclosed is a copy of the final revisions to the Florida's Control of Radiation Hazard Regulations, Chapter 64E-5, Florida Administrative Code (FAC). The final regulations are identified by background shading or description in the attached conversion table and correspond to the following equivalent amendments to NRC's regulations.

Rats ID	Title	State Section
NRC Letter 4/9/2008 (ML080990829)	10 CFR 34.3 Definition of Temporary Jobsites under Industrial Radiography Rules	See attached Conversion Table
2002-2	Medical Use of Byproduct Material Parts 20, 32, 35	Multiple- See attached Conversion Table
2005-2	Medical Use of Byproduct Material – Recognition of Specialty Boards	Multiple- See attached Conversion Table
2006-1	Minor Amendments Part 20, 30, 32, 35, 40 & 70. (71 FR 15005)	Multiple- See attached Conversion Table
2007-1	Medical Use of Byproduct Materials – Minor Corrections and Clarifications Parts 32 & 35 (72 FR 45147, 54207)	Multiple- See attached Conversion Table
2009-1	Medical Use of Byproduct Materials – Authorized User Clarification Part 35 (74 FR 33901)	Multiple- See attached Conversion Table

These changes primarily pertain to NRC's medical rule listed in 10 CFR Part 35. Due to resource constraints we understand that NRC does not review "Draft" state regulations. Because Florida's time frame for seeking public comment on proposed rules is 21 days, we did not have time to submit to NRC the published proposed rule prior to them becoming final. This has always been our practice for submitting NRC our rule packages. Therefore please note that these are FINAL rules that went into effect 2/11/2010.

We believe that adoption of these revisions generally satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200.

Due to the large number of rule changes that consist of several RATS it was not practicable to use the RATS table. Instead we used the table listed for a new agreement state for Part 35 and added applicable parts that were identified in certain RATS. This should provide a consistent and easier review against NRC regulations.

There are several issues where we recognize that NRC may comment. Below are a few of these issues. This list is for those where we have identified known compatibility issues and is not intended to be inclusive of changes where we are allowed to be more restrictive. We have provided a more detailed description of these issues in the attached Conversion Table.

1. Training and experience (T&E) of individuals under Part 35. Florida rules adopted a modified version of the NRC Commissioner's recommendations listed SECY 08-0179 (Attached). These recommendations have to do with the "attestation" requirements of RSO, Authorized Medical Physicists, Authorized Nuclear Pharmacists, and Authorized Users. We understand that these recommendations are not currently in NRC rules but anticipate that they will be within the next 3-5 years. We believe that these recommendations are important and have implemented some of them now even though the existing rules are designated as a Compatibility B.
2. NRC requires training and experience requirements under 35.490(b)(1)(ii) and 35.690(b)(1)(ii) (Category B) to be received in a "medical institution" which NRC definition has a Category D designation. Our definition of a medical institution which is used also for facilities with X-ray devices and linear accelerators is more restrictive than NRC's and would have caused our T&E requirements to be more restrictive than NRC's which is allowed under Category B. To address this issue we have expanded the text in the T&E sections to include clinics or private practice facilities which also meet NRC definition of a "medical institution".

3. NRC's medical event reporting criteria specified in 10 CFR 35.3045(b) requires reporting of "any event resulting from intervention of a patient or human research subject in which the administration of radioactive materials or radiation from radioactive materials results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician." This requirement is independent to any dose criteria. Florida rule pertaining to non-written directive procedures described in 64E-5.101(88)(b)2.g. incorrectly requires a dose threshold specified in 64E-5.101(88)(b)2. to also be satisfied. While it is extremely unlikely that a non-written directive procedure that does not exceed the dose threshold would be determined by a physician to meet this criteria as a medical event, the wording is less restrictive than NRC language which is designated as compatibility C. We will correct this rule at the appropriate rulemaking opportunity. The 10 CFR 35.3045(b) requirement is correctly stated in 64E-5.101(88)(a)12. for procedures requiring a written directive.

If you have any questions, please feel free to contact me at (850) 245-4043 or Mike.Stephens@doh.state.fl.us

Sincerely,



Michael N. Stephens
Environmental Health Program Consultant

Enclosures:

10 CFR to 64E-5 Conversion - Compatibility Table
List of Elements (Equivalent to 10 CFR Part 20 Appendix B)
64E-5 Part I
64E-5 Part II
64E-5 Part III
64E-5 Part VI
Federal Policy Statement incorporated by reference in 64E-5.601(5) (Listed in 10 CFR 35.6)
SECY 08-0179 with NRC Commission approval for rule making

cc: Bill Passetti, Chief, Bureau of Radiation Control
Paul Vause, Environmental Administrator, Bureau of Radiation Control
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