February 2010

Bureau of Radiation Control
RADIOACTIVE MATERIALS SECTION
Information Notice 2010-01

Revision 10 Filing Instructions:
Changes to Chapter 64E-5, Florida Administrative Code (F.A.C.)

Changes to "Control of Radiation Hazard Regulations," Chapter 64E-5, F.A.C., became effective February 11, 2010. **These changes are indicated as Revision 10 or (R10) in the margin and rose highlighting.**

These instructions apply to the complete version (brown cover) of Chapter 64E-5, F.A.C. Be sure that Revisions 1 through 9 changes have been inserted before making these changes. This may be verified by checking page ii of the index. **Visit our website at www.doh.state.fl.us/environment/radiation/ to download R10 pages to replace. An electronic copy of the chapter is also available**

PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
Cover	Cover	Cover
Index	i through xii	i through xvi
Part I General Provisions	Part I Index Part I Pages 1-26 (all)	Part I Index Part I Pages 1-27
Part II Licensing of Radioactive Materials	Part II Index Part II Pages 29/30, 45/46, 47/48, 53/54, 59/60, 65/66	Part II Index Part II Pages 29/30, 45/46, 47/48, 53/54, 59/60, 65/66
Part III Standards for Protection Against Radiation	Part III Index Part III Pages 11/12, 25/26, 41/42, 43/44, 45/46	Part III Index Part III Pages 11/12, 25/26, 41/42, 43/44a, 44b/44c (new), 44d/44e, 45/46
Part VI Use of Radionuclides in the Healing Arts	Part VI Index Part VI Pages 1-48 (all)	Part XV Index Part VI Pages 1-94
Part XIII Radiation Safety Requirements for Possession and Use of Sealed or Unsealed Sources of Radioactive Materials	Part XIII Index Part XIII Pages 1/2, 3/4	Part XIII Index Part XIII Pages 1/2, 3/4, 13/14 (new), 15/16 (new)

PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
Attachment - 7 Radioactive Materials Application License Non-Human Use Form DH-1054 12/09	Radioactive Materials License Application Non-Human Use Form DH-1054 05/1997	Radioactive Materials License Application Non-Human Use Form DH-1054 12/09
		New Radioactive Materials License Application Human Use Form DH-1322 12/09
		New Federal Policy for the Protection of Human Subjects (Federal Policy) as described in 45 CFR Part 46 dated 11/9/2009 (See 64E-5.601)

Below is a brief summary of the substantial changes. Please see rule text for details.

Part I: Definitions to support the terms for the medical use of radiations to include medical events, authorized nuclear pharmacist. Note the definition of misadministration is now called a medical event and several definitions were moved to Part VI.

Part II: New applications forms for both medical use and non-human use of radioactive materials have been developed and only one copy and an original application needs to be submitted to the department. Nuclear pharmacy and sealed source distribution rules were changed to include the equivalent to 10 CFR Part 1000 (Other medical uses or radioactive materials not previously listed), as well as remote afterloaders. Reciprocity time frames reduced from 365 days to 180 days to comply with NRC requirements. Provisions to exceed this time frame are described.

Part III: Member of the public radiation dose limits increased to include higher doses from patients containing radioactive materials, isotopes with half-life 120 days or less may now be disposed of by decay in storage (DIS) methodology provided it is not a sealed source, reporting requirements added should an embryo/fetus receive 5 rem dose equivalent from radiation received from radioactive materials or a nursing child exceeds 5 rem total effective dose equivalent or has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

Part VI MAJOR REWRITE: Training and experience requirement changed to be listed on a license as a physician authorized users, authorized medical physicists (AMP), authorized nuclear pharmacists (ANP), Radiation Safety Officer (RSO). Recentness of training expanded from 5 to 7 years, Grandfathering of existing uses expanded to include RSO's, medical physicists, nuclear pharmacists currently listed on a medical use license (certain restrictions apply). Requirements for the medical use of remote afterloaders and gamma knife added. Definitions added to support this use. Concept of visiting authorized user expanded to include authorized medical physicists and RSO, expanded duties for RSO's, expanded duties for and requirements to have a Radiation Safety Committee, higher possession limits for calibration, reference and transmission sources, DIS half-life isotopes increased from 90 to 120 days, acceptance testing required on treatment planning systems for therapy-related computer systems, brachytherapy inventory frequency expanded from 3 months to 6 months, and the RSO must agree in writing to the licensee to accept RSO duties and responsibilities for implementation of the radiation safety program, use of I-123 does not require a written directive as long as its use is listed in the diagnostic clinical procedures manual signed off on by all the authorized users. Authorized Users and Authorized Medical Physicists at High Dose Rate Remote Afterloader facilities and Gamma Stereotactic Radiosurgery facilities have very specific new rules requiring their physical presence during the treatment.

Part XIII: Tritium and Iodine 125/131 bioassay requirements are specified.

Visit our website at www.doh.state.fl.us/environment/radiation/ to download pages to replace in your "brown cover" version of the "Control of Radiation Hazard Regulations", 64E-5, F.A.C. or to download a complete copy of 64E-5, F.A.C.

No specific actions nor written response is required to this information notice. However, we urge you to carefully review those changes applicable to your license and procedures. It may be necessary for you to revise your procedures to be compliant with the rule changes. If you have any questions or need additional information, please call us at (850) 245-4545.