To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



John H. Armstrong, MD, FACS State Surgeon General & Secretary

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Bureau of Radiation Control RADIOACTIVE MATERIALS SECTION Information Notice 2014-01

Revision 12 Filing Instructions: Changes to Chapter 64E-5, Florida Administrative Code (F.A.C.)

Changes to "Control of Radiation Hazard Regulations," Part V "X-Ray in the Healing Arts" Rule 64E-5.504, F.A.C., became effective May 8, 2013 (Revision 11) and changes to the radioactive materials regulations became effective December 26, 2013. **These changes are indicated as Revision 11 or 12 or (R11) (R12) in the margin.** Official versions of regulations may be found at the Florida Department of State website www.flrules.org/

These instructions apply to the complete version (brown cover) of Chapter 64E-5, F.A.C. Be sure that Revisions 1 through 10 changes have been inserted before making these changes. This may be verified by checking page ii of the index. Visit our website at http://www.floridahealth.gov/radiation to download R12 pages to replace. (Includes R11 changes.)

Due to the large number of pages to be replaced, you may want to obtain a complete electronic copy of the chapter. This pdf file is also available on our website.

A brief summary of the changes is listed below the page replacement table.

PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
Cover	Cover	Cover
Index	i through xii	i through xvii
Part I (R11 & R12) General Provisions Part II (R12) Licensing of Radioactive Materials	Part I Index Part I Pages 1-27 (all) Part II Index Part II Pages 1-96 (all)	Part I Index Part I Pages 1-29 Part II Index Part II Pages 1-110
Part III (R12) Standards for Protection Against Radiation	Part III Index Part III Pages 3/4, 5/6, 11/12, 13/14, 21/22, 23/24, 25/26, 41/42, 43/44a, 47/48, 49/50, 51/52	Part III Index Part III Pages 3/4, 5/6, 11/12, 13/14, 21/22, 23/24, 25/26, 41/42, 43/44a, 47/48, 49/50, 51/52

PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
Part V (R11) X-Ray in the Healing Arts	Part III Index 23/24, 25/26, 27/28, 29/30	Part III Index 23/24, 25/26, 27/28, 29/30
Part VI (R12) Use of Radionuclides in the Healing Arts	Part VI Index Part VI Pages 3/4, 5/6, 11/13, 13/14, 15/16, 19/20, 21/22, 33/34, 35/36, 37/38, 41/42, 43/44, 45/46, 57/58, 59/60, 61/62, 63/64, 65/66, 67/68, 71/72, 73/74, 75/76, 77/78, 79/80, 81/82, 85/86, 87/88, 89/90, 91/92, 93/94	Part XV Index Part VI Pages 3/4, 5/6, 11/13, 13/14, 15/16, 19/20, 21/22, 33/34, 35/36, 37/38, 41/42, 43/44, 45/46, 57/58, 59/60, 61/62, 63/64, 65/66, 67/68, 71/72, 73/74, 75/76, 77/78, 79/80, 81/82, 85/86, 87/88, 89/90, 91/92, 93/94
Part XI (R12)	Part XI Index Pages 9/10	Part XI Index Pages 9/10
Part XIII (R12) Radiation Safety Requirements for Possession and Use of Sealed or Unsealed Sources of Radioactive Materials	Part XIII Index Part XIII Pages 9/10	Part XIII Index Part XIII Pages 9/10)
Part XIV (R12) Licensing and Radiation Safety Requirements for irradiators	Part XIV Index Pages 19/20	Part XIV Index Pages 19/20
Part XV (R12) Transportation of Radioactive Materials	Part XV Index Pages 1a/1b, 1c/2	Part XV Index Pages 1a/1b, 1c/1d(new), 1e(new)/2

The majority of changes are due to the changes to the Energy Policy Act of 2005 where the U.S. Nuclear Regulatory Commission (NRC) obtained authority to regulate accelerator produced radioactive materials (NARM) and discrete radium and also NRC identified other changes needed for Florida to be compatible with NRC regulations.

The table below provides a brief summary of the changes in each rule and not all changes are listed. You must read the rule changes and make appropriate adjustments if needed. If you have any questions, please contact us at 850-245-4545

Rule Number(s)	Brief Summary of Changes
64E-5.101	New ALI/DAC tables are incorporated by reference to include NARM and discrete radium. Changes to definitions of Byproduct material, Medical Event, Dose, TEDE and new definitions for Discrete Source, PET, Consortium, and Waste. The changes are not new to the industry and have been used at the federal level since 2005.
64E-5.203	NRC retained the authority to regulate exempt items, quantities and concentrations of radioactive materials. This rule deletes obsolete exemptions and adds numerous new exemptions for certain isotopes and quantities of radioactive materials to include discrete radium sources.

Rule Number(s)	Brief Summary of Changes
64E-5.204	License category descriptions for medical use of HDR was clarified to include low, medium and pulsed rate remote dose afterloaders. The license fees were not changes and remain at the same level established in 2007.
64E-5.206	Relaxing the transfer requirements of generally licensed devices if certain criteria is met. Links to the forms for In Vivo and in Vitro use of radioactive materials under a general license are provided.
64E-5.210	Requirement for distributors of certain generally and specifically licensed radioactive materials are listed and links to existing documents incorporated by reference are provided.
64E-5.213	Requirement to follow the manufacturer's safety procedures identified in a national registry for the use of radioactive sources and devices and clarifying the requirement that one must maintain a fixed facility in the state to obtain a radioactive materials license.
64E-5.216	Clarifies that licenses operating under reciprocal recognition of an out of state radioactive materials license must transfer or dispose of radioactive materials to those licensed.
64E-5.304	Clarifies that when external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the department.
64E-5.304, 64E-5.306, 64E-5.307, 64E-5.313. 64E-5.315, 64E-5.326, 64E-5.330, 64E-5.629, 64E-5.810, 64E-5.1115, 64E-5.1317, 64E-5.1419, 64E-5.1420	All reference the new ALI/DAC document incorporate by reference in 64E-5.101.
64E-5.504	Requirements for the use of X-ray fluoroscopic systems is listed.
64E-5 Part 6 Medical Use or Radioactive Materials	Majority of changes are those identified by NRC as needed for compatibility. The changes include revised cross references and to accept those listed on an NRC license to qualify as an authorized user.
64E-5.6422	Clarifies gamma knife spot checks that are to be performed only on a monthly basis and NOT before the first use of the unit on days of use.

Attachments – R12 page replacements (288 pages) (Includes R11 changes to Part 5).