

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



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Vision: To be the Healthiest State in the Nation

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**Bureau of Radiation Control
Radioactive Materials and Radiation Machine Sections
Information Notice 2017-01**

**Revision 15 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” Rules 64E-5.502, 64E-5.511, F.A.C., Rules 64E-5.801 and 64E-5.1602, F.A.C., which became effective March 21, 2016 (Revision 15). **These changes are indicated as Revision 15 in the margin.** Official versions of regulations may be found at the Florida Department of State website www.flrules.org/

These rules provides an exemption for nonmedical use of certain X-Ray Security Scanners in jails or penal institutions for detainees using certain scanners in specific situations (Additional details below).

**This rule SUPERSEDES all previous variances authorizing this activity.
Variances not address by this rule are still in effect.**

These instructions apply to the complete version (brown cover) of Chapter 64E-5, F.A.C. Be sure that Revisions 1 through 14 changes have been inserted before making these changes. This may be verified by checking page iv of the index. Visit our website at <http://www.floridahealth.gov/environmental-health/radiation-control/> to download R15 pages to replace. The replacement pages are formatted to be printed on both sides to conserve paper. A complete copy of R15 is also available on the 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 xvi	i through xvi
Part V (R15) X-Rays In The Healing Arts	Part V Index Part V Pages 9/10, 11/12, 13/14, 15/16, 59/60, 61/62	Part V Index Part V Pages 9/10a, NEW 10b/10c , 11/12, 13/14, 15/16, , 59/60, 61/62)

Part VIII (R15) Radiation Safety Requirements for Analytical particle Accelerators	Part VII Index Part VII pages 1/2	Part VII Index Part VII pages 1/2
Part VX1 (R15) Electronic Brachytherapy	Part XVI Index Part XVI pages 1/2, 3/4	Part XVI Index Part XVI pages 1/2, 3/4

Brief Summary

Rule 64E-5.502 provides the exemption requirements for the security scanners and Rule 64E-5.511 updates the machine registration form for both manufacturers and registrants. The jail or penal institution SHALL register each and every device owned or under the control of the institution and SHALL register them prior to use and within 30 days of taking possession. The current designation is IN Industrial at \$47 for the first tube and \$23 for each additional tube. Fees are subject to change. Rules 64E-5.802 and 64E-5.1602 are only changed to reflect the new machine registration form and does not apply to any substantive change for these registrants. Table 1 below lists the requirements of the rules.

Table 1: Requirements Specified in Rule 64E-5.502

Rule	Requirements	Comments
64E-5.502(1)(a) 2.	<ul style="list-style-type: none"> X-Ray Operator MUST receive instruction on System use: AND. X-Ray System Operator must be competent in safe use of x-ray system 	
64E-5.502(1)(a) 7.	Provides exemption from medical purposes only for Security Screening in the following specific cases and if requirements are met.	
64E-5.502(1)(a) 7.a.	<ul style="list-style-type: none"> System installed AND used only in a jail or penal institution; AND System is stationary: AND System is non-mobile 	A portable system within a facility is not permitted under the exemption and is not allowed by rule.
64E-5.502(1)(a) 7.b	<ul style="list-style-type: none"> System is ONLY used on Legal Detainees in a jail or penal institution System is NEVER Used on anyone except Legal Detainees. 	<p>System may only be used to screen legal detainees.</p> <p>System may not be used to screen ANY other person.</p> <p>(Use on anyone but a legal detainees is specifically prohibited no matter what the reason or purpose.)</p>
64E-5.502(1)(a) 7.c	Most Restrictive Standard found in ANSI/HPS N43.17-2009 "Radiation Safety	See ANSI/HPS N43.17-2009 "Radiation Safety for Personnel Security Screening

Rule	Requirements	Comments
	for Personnel Security Screening Systems Using X-Ray or Gamma Radiation” FOR <ul style="list-style-type: none"> ❖ Manufactured in accordance with MOST RESTRICTIVE ANSI standard ❖ Maintained in accordance with MOST RESTRICTIVE ANSI standard ❖ Operated solely for security screening purposes in accordance with MOST RESTRICTIVE ANSI standard 	Systems Using X-Ray or Gamma Radiation” Requirements for details
64E-5.502(1)(a) 7.d	Institution shall track radiation dose for each detainee in accordance with ANSI/HPS N43.17-2009 “Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation”	See ANSI/HPS N43.17-2009 “Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation” Requirements for details
64E-5.511 (2)(a), (b), (c)	<ul style="list-style-type: none"> • Facility must apply for registration using Form DH 1107 10/15 • Facility must designate an individual who is responsible for radiation protection • Facility must prohibit anyone who is not registered with the department from providing radiation machine servicing • Facility must apply for registration within 30 days of acquisition and before use (Currently IN Industrial at \$47 for the first tube and \$23 for each additional tube. Fees are subject to change.) 	Contact the Department if you have any questions on how to complete Form DH 1107 10/15
64E-5.511 (4), (5)	<ul style="list-style-type: none"> • Any changes to information provided on Form DH 1107 10/15 must be reported in writing within 30 days. • Any assembler who relocates, assembles, install or disposes of the security scanners or major components of the scanners must notify the Department within 15 days on Form DH 1114 10/15. 	The report must include the name, address of installation change, receipt, wale, transfer or disposal of the security scanner or major component. Contact the Department if you have any questions on how to complete Form DH 1114 10/15

ANSI/HPS N43.17-2009 "Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation" has requirements regarding dose limitations, operating procedures, record keeping requirements, personnel training requirements (includes topics and proficiency demonstrated), refresher training every 12 months, preventative maintenance and radiation surveys, etc. This publication may be purchased on line at <http://hps.org/#> (Search term N43.17-2009)

Below is brief summary and location in the ANSI document for a "**General Use Systems**", "**Class A**" (**Full Body Scanner**). This list is not intended to be inclusive of the requirements, it is recommended that you review the ANSI document for details.

Note: Other and additional standards are required of "General Use Systems" Class B (Partial Body Scanner) and "Limited Use Systems" both for "Class A" and "Class B".

"General Use Systems", "Class A" (Full Body Scanner) Only (partial requirements list)

Dose limits (Section 6.1.1.1)

the maximum dose per screening is 0.25 microSv or 25 microRem per screening AND 250 microSv or 25 millirem over a 12 month period.

The 0.25 microSv/screening means that an individual can only be screened twice per day every day for 12 months. (See ANSI Table for weekly, monthly frequencies)

Operating Procedures (Section 8.1.3)

Facility must have documented operating procedures that includes multiple topics listed in Section 7.5 "Information to be provided to the End User" AND

Individual shall inform person screened the system emits radiation (Section 8.1.4) which as a minimum includes effective dose less than 25 microrem and an example comparing dose to common know radiation sources (example ~1 hour from background radiation) and screening is in compliance with the ANSI standards.

Personnel Training (Section 8.1.5)

Operator must receive training to comply with ANSI standard. Nine topics listed in the ANSI standard, AND

Proficiency demonstrated at conclusion of training, AND

Refresher training provided at least once every 12 months.

Preventive Maintenance (Section 8.1.6)

Institution must follow the manufacturer's recommended maintenance schedule and any maintenance shall be performed by qualified personnel

Radiation Surveys (Section 8.1.7)

Survey must verify reference dose, radiation leakage, inspection zone and any other parameters specified by the manufacturer. Surveys must be performed at installation, at least once every 12 months, after maintenance affection shielding, shutter or other radiation production components, and after any incident that may have damaged the system.

Records and Documentation (Section 8.1.9)

The following records must be kept and maintained on site for at least 5 years:

Each operating training records including information to show compliance with Section 8.1.5; upgrades, modification, maintenance and repair records shall be kept for the life of the system; radiation surveys required in Section 8.1.7; the number of scans conducted; AND

Complete set of operating procedures required in section 8.1.3 "Operating Procedures" shall be readily available the operator of each system; AND

the current name and contact information of responsible individual (section 8.1.1) "Responsible Individual" (also 64E-5.511(2))(a)2.).