MAR 12 1998

Mr. William A. Passetti
Chief, Bureau of Radiological Control
Florida Department of Health
1317 Winewood Boulevard
Tallahassee, FL 32399-0700

Dear Mr. Passetti:

As requested, we have reviewed the proposed regulations, Administrative Code, 64-5, sent to us in a letter dated February 12, 1998. The regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Parts 19, 20, 30, 34, 35 and 61.

As a result of our review, we have no comments. Please note that we have limited our review to regulations required for compatibility and/or health and safety. Under our current procedure, a finding that a State regulation meets the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final State regulation. However, we have determined that if your proposed regulations were adopted without significant change, they would meet the compatibility and health and safety categories established in OSP Internal Procedure B.7.

We request that when the proposed regulations are adopted and published as final regulations, a copy of the "as published" regulations be provided to us for review. As requested in All Agreement States Letter SP-96-027, "Request to Highlight Changes to Agreement State Regulations Submitted to NRC for Compatibility Review" (March 1, 1996), please highlight the final changes and send one copy in a computer readable format, if possible.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me or Dr. Stephen N. Salomon at (301) 415-2326 or by INTERNET: SNS@NRC.GOV.

Sincerely,

Original Signed By:
PAUL H. LOHAUS
Paul H. Lohaus, Deputy Director
Office of State Programs

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CONTROL OF RADIATION HAZARDS

PART I GENERAL PROVISIONS

64E-5.101 Definitions: As used in these rules, these terms have the definitions set forth below. Additional definitions used only in a certain part are defined in that respective part.

(142) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium 233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

(172) "Principal activities" means activities authorized by the license that are essential to achieve the purpose for which the department issued or amended the license. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

Specific Authority 404.051, 404.061, 404.20, 404.22 FS.

Law Implemented 404.031, 404.061(2), 404.20, 404.22, 404.30 FS.

History--New 7-17-85, Amended 4-4-89, 5-12-93, 1-1-94, 5-15-96, Formerly 10D-91.102, Amended _____.

PART II LICENSING OF RADIOACTIVE MATERIAL

SUBPART A LICENSE TYPES AND FEES

64E-5.204 Types of Licenses. Licenses for radioactive materials are of two types: general and specific.

(2) Specific licenses require the submission of an application to the department and the issuance of a licensing document by the department. The licensee is subject to all applicable portions of these regulations as well as any limitations specified in the licensing document. The licensee is subject to the payment of fees as authorized under Section 404.131, Florida Statutes, and as outlined below:

(e) Below is the schedule of fees for specific radioactive materials licenses:

	Application Fee	Annual Fee
1. Source Material.		
a. Licenses for concentration of uranium from phosphate ores for the production of uranium as "yellow cake" or powdered solid;	$6,907 ~~$5,756~~	$11,942 ~~$9,952~~
b. Licenses for concentration of uranium from phosphate ores for the production of "green cake" or equivalent, moist or solid;	$3,768 ~~$3,140~~	$7,439 ~~$6,199~~
c. All other specific source material licenses excluding depleted uranium used as shielding and counterweights.	$544 ~~$453~~	$229 ~~$191~~
2. Special Nuclear Material (SNM).		
a. Licenses for use of SNM in sealed sources contained in devices used in measuring systems;	$653 ~~$544~~	$518 ~~$432~~
b. Licenses for use of SNM not sufficient to form a critical mass, except as in 2.a., above, and 2.c. and 5.e., below;	$1,340 ~~$1,117~~	$1,944 ~~$1,620~~

c. Licenses for use of SNM to be used as calibration and reference sources.	$205 ~~$171~~	$109 ~~$91~~
3. Byproduct, naturally occurring or accelerator produced material.		
a. Licenses for processing or manufacturing for commercial distribution or industrial uses;	$2,923 ~~$2,436~~	$2,802 ~~$2,335~~
b. Licenses for processing or manufacturing and distribution of radiopharmaceuticals. This category includes radiopharmacies.	$2,560 ~~$2,133~~	$3,840 ~~$3,200~~
c. Licenses for industrial radiography performed only in an approved shielded radiography installation,	$1,558 ~~$1,298~~	$2,161 ~~$1,801~~
d. Licenses for industrial radiography performed only at the address indicated in the license, or at temporary job sites of the licensee;	$1,643 ~~$1,369~~	$2,657 ~~$2,214~~
e. Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials where the source is not removed from the shield	$605 ~~$504~~	$605 ~~$504~~

and is less than 10,000 curies;		
f.(I) Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials when the source is not removed from the shield and is greater than 10,000 curies and less than 100,000 curies, or where the source is less than 100,000 curies and is removed from the shield;	$1,414 ~~$1,178~~	$1,630 ~~$1,358~~
(II) Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials when the source is equal to or greater than 100,000 curies;	$3,659 ~~$3,049~~	$3,961 ~~$3,301~~
(III) Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials when the source is greater than 1,000,000 curies;	$9,780 ~~$8,150~~	$4,398 ~~$3,665~~
g. Licenses issued to distribute items containing radioactive materials to persons under a general license;	$1,643 ~~$1,369~~	$2,150 ~~$1,792~~

h. Licenses issued to distribute exempt quantities or items containing naturally occurring or accelerator produced material to persons exempt from licensing;	$1,643 ~~$1,369~~	$2,150 ~~$1,792~~
i. Well logging		
(I) Sealed sources or sub-surface tracer studies	$1,135 ~~$946~~	$1,498 ~~$1,248~~
(II) Sub-surface tracer studies and sealed sources	$1,436 ~~$1,197~~	$1,594 ~~$1,328~~
j. Nuclear Laundry;	$3,200 ~~$2,667~~	$5,651 ~~$4,709~~
k. Industrial or medical research and development;	$1,184 ~~$987~~	$1,474 ~~$1,228~~
l.(I) Fixed and portable gauging devices	$605 ~~$504~~	$966 ~~$805~~
(II) In Vitro and clinical laboratory	$725 ~~$604~~	$918 ~~$765~~
(III) Academic	$978 ~~$815~~	$1,171 ~~$976~~
(IV) Possession of uranium or thorium, or their decay products, as a result of mining or processing	$978 ~~$815~~	$870 ~~$725~~
(V) All other specific licenses except	$725 ~~$604~~	$1,002 ~~$835~~

as otherwise noted		
m. Licenses of broad scope		
(I) Academic	$3,200 ~~$2,667~~	$7,346 ~~$3,673~~
(II) Medical	$3,200 ~~$2,667~~	$5,474 ~~$2,737~~
(III) Industrial or Research and Development	$3,200 ~~$2,667~~	$4,568 ~~$2,284~~
n. Gas chromatography devices;	$434 ~~$362~~	$314 ~~$262~~
o. Reference or calibration sources equal to or less than one millicurie total;	$314 ~~$262~~	$132 ~~$110~~
p. Nuclear service licenses, such as, leak testing, instrument calibration, etc.;	$518 ~~$432~~	$410 ~~$342~~
4. Waste disposal or processing		
a. Commercial waste disposal or treatment facilities, including burial or incineration;	$275,842 ~~$229,868~~	$250,555 ~~$208,796~~
b. All other commercial facilities involving compaction, repackaging, storage or transfer;	$27,084 ~~$22,570~~	$24,971 ~~$20,809~~

c. Commercial treatment of radioactive materials for release to unrestricted areas.	$5,760 ~~$4,800~~	$5,735 ~~$4,779~~
5. Medical use.		
a. Teletherapy or high dose rate remote afterloading devices;	$1,414 ~~$1,178~~	$1,378 ~~$1,148~~
b. Medical institutions including hospitals, except category 5.a. and 5.e.;	$1,643 ~~$1,369~~	$1,908 ~~$1,590~~
c. Private practice physicians except category 5.a. and 5.d.;	$1,184 ~~$987~~	$1,340 ~~$1,117~~
d. Private practice physicians using only strontium 90 eye applicators, materials authorized by 64E-5.531, and materials authorized by 64E-5.630;	$605 ~~$504~~	$748 ~~$623~~
e. Nuclear powered pacemakers;	$434 ~~$362~~	$266 ~~$222~~
f. Mobile nuclear medicine services.	$1,414 ~~$1,178~~	$1,625 ~~$1,354~~
6. Civil defense.	$544 ~~$453~~	$821 ~~$684~~
7. Device, product, or sealed source safety evaluation.		
a. Device evaluation, per device;	$1,208 ~~$805~~	NONE

b. Sealed source design, per source.	~~$528~~ ~~$352~~	NONE

Specific Authority 404.051, 404.061, 404.131 FS.

Law Implemented ~~404.022,~~ 404.031, 404.061, 404.051(1),(4),~~(8),~~ (10),~~(11),~~ 404.131(1) FS.

History--New 7-17-85, Amended 9-9-90, 8-25-91, 5-12-93, 11-6-94, Formerly 10D-91.304, Amended _____.

SUBPART C

SPECIFIC LICENSES

64E-5.213 Specific Terms and Conditions of License.

(7) A licensee shall notify the department in writing within 30 days after a radiation safety officer permanently discontinues performance of radiation safety officer duties.

(8) A licensee shall apply and receive a license amendment or department approval:

(a) Before using radioactive material for a method or type of use not permitted by the license;

(b) Before permitting anyone to use radioactive material as an authorized user as authorized by the license;

(c) Before changing a radiation safety officer;

(d) Before ordering or receiving radioactive material in excess of the amount authorized on the license;

(e) Before adding to or changing the areas of use or

address or addresses of use identified in the application or on the license; and

(f) Before changing statements, representations, and procedures which are incorporated into the license.

Specific Authority: 404.051, 404.061, ~~404.071, 404.081,~~ 404.141, F.S.

Law Implemented: ~~404.022,~~ 404.051(1),(4),~~(9),~~ 404.061(2),(3), 404.081(1), 404.141, F.S.

History: New July 17, 1985, Amended May 12, 1993, Amended August 14, 1996, Formerly 10D-91.315. Amended _____.

64E-5.214 Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.

(1) Except as provided in Part II, each specific license shall expire at the end of the specified day in the month and year stated therein. Each specific license revoked by the department expires at the end of the day on the date of the department's final order revoking the license or on the expiration date stated in the final order.

(2)(a) Each licensee shall notify the department in writing within 60 days of the occurrence of any of the following and either begin decommissioning its site or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release as specified in

these rules or send a notice of a decommissioning plan within 12 months as specified in (4)(c) below and begin decommissioning upon approval of that plan.

1. The license has expired as specified in (1), above.

2. The licensee has ceased principal activities permanently at the entire site or in any separate building or outdoor area.

3. The licensee has conducted no principal activities under the license for 24 months.

4. The licensee has conducted no principal activities for 24 months in any separate building or outdoor area that contains residual radioactivity to the extent that the building or outdoor area is unsuitable for release as specified in these rules.

(b) The notification and request for termination of the license shall include the reports and information specified in (4)(a)4. and 5., below.

~~Each licensee shall notify the department immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive materials authorized under the license. This notification and request for termination of the license must include the reports and information specified in (4)(a)4. and 5., below.~~

(4)(c)1. If detectable levels of residual radioactive contamination attributable to activities conducted under the

license are found or licensee possesses other radioactive materials, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination or possession of radioactive material, until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of (5), below.

(5) Each licensee who possesses ~~residual~~ radioactive material under (4)(c), above, following the expiration date specified in the license shall:

(a) Limit actions involving radioactive material to those related to decontamination, decommissioning, and other activities related to preparation for release for unrestricted use; and

(b) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Department notifies the licensee, in writing, that the license is terminated.

Specific Authority 404.051, 404.061, ~~404.071,~~ 404.081, 404.141 FS.

Law Implemented ~~404.022,~~ 404.051(1), (4), (9), 404.061(2), 404.081(1), 404.141 FS.

History--New 7-17-85, Amended 5-12-93, Formerly 10D-91.315. Amended _____.

PART III

STANDARDS FOR PROTECTION AGAINST RADIATION

SUBPART G

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

64E-5.319 Use of Individual Respiratory Protection Equipment.

(1) If the licensee uses respiratory protection equipment to limit intakes as specified in 64E-5.318:

(c) The licensee shall implement and maintain a respiratory program that includes:

5. Determination by a physician prior to initial fitting of respirators and either every 12 months ~~annually~~ thereafter or periodically at a frequency determined by a physician that the individual user is medically ~~physically able~~ fit to use the respiratory protection equipment.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: ~~404.022,~~ 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.452. Amended _____.

SUBPART J

WASTE MANAGEMENT

64E-5.332 Transfer for Disposal and Manifests.

(1) The requirements of this section, Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifest, July 1997, hereafter referred to as "Requirements for Low-Level Radioactive Waste Disposal," which is herein incorporated by reference and which is available from the department, and Part XV are designed to control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in Requirements for Low-Level Radioactive Waste Disposal, who ships low-level waste directly or indirectly through a waste collector or waste processor to a licensed low-level waste land disposal facility as defined in Requirements for Low-Level Radioactive Waste Disposal, ~~intended for disposal at a licensed low-level radioactive waste disposal facility~~, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes. Requirements for Low-Level Radioactive Waste Disposal incorporates NRC Form 540(3-95), Uniform Low-Level Radioactive Waste Manifest - Shipping Paper; NRC Form 541 (11-96), Uniform Low-Level Radioactive Waste Manifest - Container and Waste Description; and NRC Form 542 (3-95), Uniform Low-Level Radioactive Waste Manifest - Manifest Index and Regional Compact

Tabulation.

(2) Prior to March 1, 1998, each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in 64E-5.333(12). Beginning March 1, 1998, any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility shall document the information required on forms specified in Requirements for Low-Level Radioactive Waste Disposal and transfer this recorded information to the intended consignee as specified in Requirements for Low-Level Radioactive Waste Disposal.

(3) Prior to March 1, 1998, each shipment manifest shall include a certification by the waste generator as specified in 64E-5.333(12). Beginning March 1, 1998, each shipment manifest shall include a certification by the waste generator as specified in Requirements for Low-Level Radioactive Waste Disposal.

(4) Prior to March 1, 1998, each person involved in the transfer of waste for disposal, including the waste generator, waste collector, ~~and~~ waste processor~~,~~ and disposal facility operator, shall comply with the requirements specified in ~~Section III, of~~ 64E-5.333(12). Beginning March 1, 1998, each person participating in the transfer of waste for disposal, including the waste generator, waste collector, waste processor and

disposal facility operator, shall comply with the requirements specified in Requirements for Low-Level Radioactive Waste Disposal.

Specific Authority: 404.051, 404.081, 404.20, F.S.

Law Implemented: ~~404.022,~~ 404.051(1),(4), 404.081, 404.20, F.S.

History: New 1-1-94, Formerly 10D-91.466. Amended _____.

64E-5.333 Classification and Characteristics of Low-Level Radioactive Waste for Near-Surface Land Disposal, Labeling and Manifest Requirements.

(13) Beginning March 1, 1998, all licensees shall comply with Requirements for Low-Level Radioactive Waste Disposal. Prior to March 1, 1998, a low-level waste disposal facility operator or its regulatory authority can require the shipper to use requirements specified in (12), above.

Specific Authority: 404.051, 404.061, 404.20, F.S.

Law Implemented: ~~404.022,~~ 404.051(1),(4), 404.061(2), 404.20(1), F.S.

History: New January 1, 1994, Amended May 15, 1996, Formerly 10D-91.468. Amended _____.

SUBPART K

RECORDS

64E-5.334 General Provisions.

(1) Each licensee or registrant shall use the SI unit becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this part. The information on shipping manifests, specified in 64E-5.332(2) shall be recorded in SI units or in SI units and special units curie, rad, rem and roentgen.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: ~~404.022,~~ 404.051(1)(4), 404.081, F.S.

History: New 1-1-94, Formerly 10D-91.469. Amended _____.

SUBPART L

REPORTS

64E-5.347 Notifications and Reports to Individuals.

(2) When a licensee or registrant is required by 64E-5.345, 64E-5.346 or 64E-5.347 to report to the department any occupational exposure of an individual or an identified member of the public to radiation or radioactive material, the licensee or registrant shall also provide a copy of the report submitted to the department to the individual ~~notify the individual~~. Such notice shall be transmitted no later than the transmittal to the department, and shall comply with the provisions of Part IX.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: ~~404.022,~~ 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.484, Amended _____

_____.

PART IV

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

SUBPART A

EQUIPMENT CONTROL

64E-5.402 Performance Requirements for Radiography Equipment. Radiographic exposure devices, source changers, and associated equipment manufactured after the effective date of these regulations shall meet the following minimum criteria:

(7) (a) Each radiographic exposure device and all associated equipment shall meet the requirements specified in American National Standards Institute N432-1980, "Radiological Safety for Design and Construction of Apparatus for Gamma Radiography," published as National Bureau of Standards NBS Handbook 136, January 1981, which is herein incorporated by reference and which is available from the department. A license applicant or licensee can submit engineering analyses that demonstrate that the radiography equipment components are equivalent as an acceptable alternative to actual testing of the

component.

(b) Equipment used in industrial radiographic operations need not comply with section 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980 if the prototype equipment has been tested using a torque value representative of the torque value that an individual using the radiography equipment realistically can exert on the lever or crankshaft of the drive mechanism.

Specific Authority: 404.051, F.S.

Law Implemented: ~~404.022,~~ 404.051(1),(4),(6), F.S.

History: New January 1, 1994, Formerly 10D-91.5031, Amended _____.

PART V

X-RAYS IN THE HEALING ARTS

64E-5.502 General Requirements.

(1) Administrative Controls.

(a) Registrant. The registrant shall be responsible for directing the operation of the x-ray systems which are subject to registration as described in 64E-5.511. The registrant or the registrant's agent shall assure that the following requirements are met in the operation of the x-ray system.

10. Healing arts self-referral. Only healing arts self-referral programs for mammography screening will be authorized by

the Department. ~~Persons conducting a mammography screening healing arts self-referral program must:~~

~~a. Meet the requirements of 64E-5.510;~~

~~b. Perform mammography screening procedures only on self-referred patients who meet the guidelines of the American Cancer Society, the American College of Radiology, or the National Institutes of Health, which are herein incorporated by reference and which are available from the department.~~

Specific Authority 404.051, 404.081, 404.141, 404.22 FS.

Law Implemented ~~404.022,~~ 404.051(1),(4),(5),(6),~~(8),~~ 404.081(1), 404.141, 404.22(1),(2),(3), FS.

History--New 7-17-85, Amended 4-4-89, 1-1-94, 11-20-94, Formerly 10D-91.603, Amended _____.

64E-5.504 Fluoroscopic X-Ray Systems. All fluoroscopic x-ray systems shall meet the following requirements:

(1) Limitation of the Useful Beam.

(d) Limitation to the Imaging Surface.

2. The longitudinal and transverse dimensions of the x-ray field produced by image-intensified fluoroscopic equipment shall not extend beyond the corresponding dimensions of the visible area of the image receptor by more than 3 percent of the SID in either dimension in the plane of the image receptor and the sum of the excess shall be no greater than 4 percent of the SID. ~~The~~

~~following criteria shall be applied in determining the applicable image receptor.~~

~~a.~~ If the ~~fluoroscopic system was installed after September 19, 1972, and~~ collimation is automatically accomplished between the tube and patient, the x-ray field dimension criteria ~~in (1)(d)2., above,~~ shall apply to all film sizes and portions thereof that the spot film device accommodates and to the dimensions of the input phosphor, as appropriate. If collimation is not automatic, the x-ray field dimension criteria shall apply to the input phosphor.

~~b. If the fluoroscopic system was installed prior to September 20, 1972, the x-ray field dimension criteria in (1)(d)2.a., above, shall apply to the largest image receptor that the system accommodates, which includes the input phosphor. The determination shall be made at a point 35 centimeters from the tabletop.~~

(3) ~~Allowable Entrance Exposure Rate Limits for Fluoroscopic Equipment Manufactured Before June, 1995.~~

~~(a) The exposure rate measured at the point where the center of the useful beam enters the patient shall not exceed 10 roentgens (2.58 mC per kg) per minute, except during recording of fluoroscopic images.~~

~~(b) When provided with optional high level control, the equipment shall not be operable at any combination of the tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC per kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. The exposure rate shall not exceed 10 roentgens (2.58 mC per kg) per minute at the point where the center of the useful beam enters the patient when the high level control is activated.~~

~~1. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use.~~

~~2. A continuous signal audible to the fluoroscopist shall indicate when the high level control is being employed.~~

~~(c) Measuring Compliance of Entrance Exposure Rate Limits. Compliance with this subsection shall be determined as follows.~~

~~1. Movable grids and compression devices shall be removed from the useful beam during the measurement.~~

~~2. If the source is below the table, the exposure rate shall be measured at least 1 centimeter above the tabletop or cradle, and corrected for distance to show the actual entrance exposure rate.~~

~~3. If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam limiting device or spacer assembly positioned as close as possible to the point of measurement.~~

~~4. In the case of a C arm type fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.~~

~~5. X ray systems that incorporate automatic exposure controls, such as automatic brightness control, shall have sufficient lead or lead equivalent placed in the useful beam to produce the maximum output of the x ray system.~~

~~6. X ray systems that do not incorporate automatic exposure control shall utilize the maximum combination of current and potential to produce the highest output. Attenuating materials shall be placed in the useful beam to protect the imaging system.~~

~~(d) Periodic Measurement of Entrance Exposure Rate Limits. The entrance exposure rate shall be measured prior to use on humans after the completion of any initial or subsequent installation and after any maintenance of the system which might affect the exposure rate.~~

~~(e) For cinefluoroscopy, the maximum exposure at the face of the input phosphor with the grid removed and with an attenuation block in the beam shall not exceed 40 microroentgens~~

~~(0.010 μC per kg) per frame. The maximum exposure shall be measured prior to use on humans after the completion of any initial or subsequent installation and after any maintenance of the system which might affect the maximum exposure.~~

~~(f) Barrier Transmitted Radiation Rate Limits.~~

~~1. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516 μC per kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.~~

~~2. Measuring Compliance with Barrier Transmission Limits.~~

~~a. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area no greater than 100 square centimeters with no linear dimension greater than 20 centimeters.~~

~~b. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.~~

~~c. If the source is above the tabletop and the SID is~~

~~variable, the measurement shall be made with the end of the beam limiting device or spacer assembly as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.~~

~~d. Movable grids and compression devices shall be removed from the useful beam during the measurement.~~

~~e. The attenuation block shall be positioned in the useful beam 10 centimeters toward the input surface of the imaging assembly from the point at which the entrance exposure rate was measured.~~

~~f. The maximum beam size shall be used during measurements.~~

~~(4)~~ Allowable Entrance Exposure Rate Limits for Fluoroscopic Equipment ~~Manufactured After June, 1995~~.

(a) Fluoroscopic equipment manufactured after June, 1995, operable at any combination of tube potential and current that results in an exposure rate greater than 5 roentgens (1.29×10^{-3} C per kg) per minute at the point where the center of the useful beam enters the patient shall be equipped with automatic exposure control. Provision for manual selection of technique factors can be provided.

(f) Periodic Measurement of Entrance Exposure Rates. The entrance exposure rate shall be measured before use on humans

after the completion of any initial or subsequent installation and after any maintenance of the system that might affect the exposure rate.

(g) For cinefluoroscopy, the maximum exposure at the face of the input phosphor with the grid removed and with an attenuation block in the beam shall not exceed 40 microroentgens (0.010 μC per kg) per frame. The maximum exposure shall be measured before use on humans after the completion of any initial or subsequent installation and after any maintenance of the system which might affect the maximum exposure.

(4) Barrier Transmitted Radiation Rate Limits.

(a) The exposure rate due to transmission through the primary protective barrier and frame assembly with the attenuation block in the useful beam combined with radiation from the image intensifier if provided shall not exceed 2 milliroentgens (0.516 μC per kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(b) Measuring Compliance with Barrier Transmission Limits.

1. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image

intensifier shall be determined by measurements averaged over an area no greater than 100 square centimeters with no linear dimension greater than 20 centimeters.

2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

3. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam limiting device or spacer assembly as close to the tabletop as it can be placed but not closer than 30 centimeters.

4. Movable grids and compression devices shall be removed from the useful beam during the measurement.

5. The attenuation block shall be positioned in the useful beam 10 centimeters toward the input surface of the imaging assembly from the point at which the entrance exposure rate was measured.

6. The maximum beam size shall be used during measurements.

~~(5) Transmission Through Frame Around Imaging Assembly. With an attenuation block in the useful beam, the exposure rate 10 centimeters above the frame surrounding the primary barrier shall not exceed the exposure rate 10 centimeters above the primary barrier under any condition of use.~~

(5) ~~(6)~~ No change.

(6) ~~(7)~~ No change.

(7) ~~(8)~~ No change.

(8) ~~(9)~~ No change.

(9) ~~(10)~~ No change.

(10) ~~(11)~~ No change.

(11) ~~(12)~~ No change.

Specific Authority 404.051, 404.22 FS.

Law Implemented ~~404.022,~~ 404.051(1)(4) ~~(6)~~, 404.22(1)(3) FS.

History--New 7-17-85, Amended 4-4-89, 3-17-92, 1-1-95, Formerly 10D-91.605, Amended _____.

64E-5.510 Mammographic Systems.

(12) The following requirements apply to personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities.

(c) 1. Prior to April 28, 1999, a medical physicist qualified to conduct surveys of mammography facilities and provide oversight of the facility quality assurance program shall ~~system performance monitoring and evaluation must~~ meet the criteria specified in a. ~~1.~~ and b. ~~2.~~ and c., below:

~~1.~~ a. Licensed in Florida as a medical physicist as specified in Chapter 483, F.S.; and

~~Is certified by the American Board of Radiology in Diagnostic Radiological Physics or Radiological Physics or is certified by another certifying body approved by the U.S. Food and Drug Administration in an equivalent area; or, until October 27, 1997,~~

b.(I) Holds a Master of Science, Master of Arts, or a higher degree in an appropriate field from an accredited institution. Appropriate fields include physics, applied physics, radiological physics, biophysics, health physics, engineering, and public health when the Bachelor's degree is in a physical science; and

(II) Has had training in biological sciences; and

(III) Has had at least 1 year of training in medical physics in the area of diagnostic radiological physics; and

(IV) Has had at least 2 years of experience conducting mammography equipment performance evaluations.

c.~~2.~~ Has received or taught at least an average of 5 hours of documented continuing education related to mammography per year.

2. After April 28, 1999, the medical physicist must meet the criteria specified in 1.a. and 1.b.(I), above, and the qualifications and experience specified in 21CFR 900.12(a)(3)(i), (iii), and (iv), which is herein incorporated by reference and

which is available from the department.

(13) Documentation, records and surveys. Each facility shall maintain records, policies, procedures and documentation to demonstrate compliance with these requirements, including corrective actions taken.

(c) Surveys. A medical physicist who meets the qualifications specified in (12), above, and who establishes, monitors, evaluates, and directs the equipment quality control program must perform an on-site ~~a~~ survey of the facility to assure that it meets quality control and equipment standards. These surveys shall be performed at least annually and shall be available for inspection by the department. Each survey report shall be retained by the facility until the next annual survey is completed satisfactorily.

(d) Medical records.

1. Each facility shall maintain mammograms and associated records in a permanent medical record of the patient as follows:

a. For at least 5 years, or, if no additional mammograms of the patient are performed at the facility, for at least 10 years; or

b. Until the records are transferred as requested by the patient to a medical institution, to a physician of the patient, or to the patient. ~~; or~~

~~c. As specified in Chapters 61F6 or 61F9, Florida Administrative Code, if the licensed practitioner dies or the facility closes or relocates and is no longer available to patients.~~

Specific Authority 404.051, ~~404.141,~~ 404.22 FS.

Law Implemented ~~404.022,~~ 404.051(1),(4),~~(6),~~ 404.141, 404.22(1),(3),(6) FS.

History--New 3-17-92, amended 1-1-94, 11-20-94, Formerly 10D-91.611, Amended _____.

PART VI

USE OF RADIONUCLIDES IN THE HEALING ARTS

64E-5.617 Authorization for Calibration and Reference Sources. Any person authorized by 64E-5.601 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

(2) Samarium 153 and any radioactive material listed in 64E-5.626 or 64E-5.627 with a half-life of 100 days or less in individual amounts not to exceed 15 millicuries (555 MBq) each;

Specific Authority ~~404.022,~~ 404.051, 404.061, ~~404.071, 404.081,~~ 404.141 FS.

Law Implemented ~~404.022,~~ 404.051(1), (4), ~~(5),~~ (6), ~~(8), (9),~~ (10), ~~(11),~~ 404.061(2), ~~(3), 404.071(1), 404.081,~~ 404.141 FS.

History--New 8-25-91, Formerly 10D-91.723, Amended _____.

PART IX

NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

64E-5.902 Instructions to Workers.

(1) All individuals who in the course of employment are likely to receive an occupational dose in excess or 100 millirem (1 mSv) in a year ~~engaged in licensed or registered activities which involve exposure to sources of radiation~~:

(a) Shall be kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's facility;

(b) Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material, in precautions or procedures to minimize exposures, and in the purposes and functions of protective devices employed;

(c) Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of these regulations and licenses for the protection of personnel from exposures to radiation or radioactive material;

(d) Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these regulations, and licenses or unnecessary exposure to radiation or

radioactive material;

(e) Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

(f) Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to 64E-5.903.

(2) In determining those individuals subject to the requirements of (1) above, licensees or registrants shall consider assigned activities during normal and abnormal situations involving exposure to sources of radiation or radioactive material that reasonably can be expected to occur during the life of the licensee's or registrant's facility. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

Specific Authority: 404.051, 404.061, 404.081, F.S.

Law Implemented: ~~404.022,~~ 404.051(1),(4), 404.061(2), 404.081~~(1)~~, F.S.

History: New 7-17-85, Amended 1-1-94, Formerly 10D-91.1003.

Amended _____

NAME OF PERSON ORIGINATING PROPOSED RULE: William A. Passetti

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Lyle E. Jerrett, Ph.D.