

The purpose of the following pages is to assist in providing information relating to the DRAFT-NOTICE OF INSPECTION from the RI Department of Health. The Rules and Regulations for the Control of Radiation (Revised 2007) is a 480 pages document which is available online at the Secretary of State Website:

<http://sos.ri.gov/documents/archives/regdogs/released/pdf/DOH/4864.pdf>

A google of RI Rules and Regulations for the Control of Radiation will also bring you to the document.

The following few pages are formatted as follows:

Page 1- Draft-NOTICE OF INSPECTION: If a notice is received, it may look similar to this

Pages 2-3- Details the referenced sections as listed on Page 1, with full explanation

Pages 4-7- Details the subsets (sub sections) that are located within the sections (with special attention to section A.6.4), and thus are not in strict numerical sequence, rather, they follow the order of appearance within the document.

A.5.1 Radiation Monitoring and Surveys

A.6.4 Notification and Reports to Individuals, with following sub-sets

A.5.7 Record of Individual Monitoring Results

A.6 Notices, Instructions and Reports to Workers; Inspections

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F.2.3 Names and Qualifications of Operators of the X-ray Equipment (CDH, CDA, Dentist, etc.)

F.2.5 Written Safety Procedures

F.2.13 Information and X-ray Maintenance Records (X-ray equipment, X-ray film processor, etc.)

F.2.14 X-ray Patient Log



****DRAFT****
NOTICE OF INSPECTION

**STATE OF RHODE ISLAND
DEPARTMENT OF HEALTH
CENTER FOR HEALTH FACILITIES AND REGULATIONS
3 CAPITOL HILL - ROOM 306
PROVIDENCE, RI 02908-5097
(401) 222-2566**

TO: **Dental Facility Name** REGISTRATION NO.: DEF XXXX
Dental Facility Street Address, Suite #
City, State, Zip Code DATE ISSUED: Month, day, year

ATTN: (Name of Facility Supervisor) INSPECTOR: **RI DOH Inspector Name**
ISSUING OFFICER: **RadHealth Supervisor**

Pursuant to Title 23, Chapter 23-1.3, Section 23-1.3-4 of the general laws entitled "Health and Safety", as amended, the Radiation Control Agency, under the provisions of Subpart A.6 and Section A.1.6 of the Rules and Regulations for the Control of Radiation, is hereby providing notice that the Agency's Administrator or her duly authorized representative will inspect your X-ray facility as specified below for compliance with said rules and regulations. A response is requested within two weeks of the date issued for scheduling purposes:

1. Facility Requested Inspection Date:
 - a. month, day, year, time (AM or PM) OR
 - b. month, day, year, time (AM or PM) OR
 - c. month, day, year, time (AM or PM)
2. Approximate Duration: ## - ## Hours
4. The presence of the Facility Supervisor or his/her designee is required.
5. The presence of the Individual Responsible for Radiation Protection is requested.
6. The inspection will include, but not be limited to, review of the following records as contained in Rhode Island Rules and Regulations for the Control of Radiation:

<u>Reference:</u>	<u>Medical Diagnostic Radiology</u>
A.5.1	Radiation Monitoring and Surveys
A.6.4	Notification and Reports to individuals (Radiation Badge Monitoring Reports)
F.2.3	Names and qualifications of operators of the X-ray equipment (CDH, CDA, Dentist, etc)
F.2.5	Written Safety Procedures
F.2.13	Information and Maintenance Records (X-ray equipment, film processor, etc.)
F.2.14	X-ray Patient Log

Please e-mail the Agency at doh.radhealth@health.ri.gov with three dates and times that would be convenient for the inspection to be performed at your facility over the next 6-8 weeks (from the date of this notice). Your cooperation and assistance are required in order for the inspection to be of maximum benefit to the health and safety of all parties.
Rev. (7/2016)

A.5.1 General Provisions.

(a) Each licensee or registrant shall use the SI units 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.

(b) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Part (e.g., total effective dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, committed effective dose equivalent).

A.6.4 Notifications and Reports to Individuals.

(a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to Agency regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to A.5.7. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number; include the individual's exposure information; and contain the following statement:

"This report is furnished to you under the provisions of Rhode Island Rules and Regulations for the Control of Radiation, Subpart A.6. You should preserve this report for further reference."

(b) Each licensee or registrant shall advise each worker annually of the worker's dose as shown in records maintained by the licensee or registrant pursuant to A.5.7.

(c) Each licensee or registrant shall furnish to each worker and, upon request, to each former worker engaged in activities controlled by the licensee or registrant a report of the worker's exposure to sources of radiation. The report shall include the dose record for each year the worker was required to be monitored pursuant to A.3.3. Such report shall be furnished within 30 days from the date of request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(d) When a licensee or registrant is required pursuant to A.5.14 to report to the Agency any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Agency.

A.6.4(e) At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

F.2.3 (a) Individuals who will be operating the X-ray systems for healing arts use shall possess a current license in accordance with the Rules and Regulations for the Licensure of Radiographers, Nuclear Medicine Technologists and Radiation Therapists [R5-68-RAD] of the Rhode Island Department of Health, unless the individual is specifically exempted from licensure by said regulations. Individuals who will be operating the X-ray systems and who are not subject to licensure under R5-68-RAD shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. As a minimum, such instruction shall consist of subjects outlined in Appendix B of this part.

F.2.5 The registrant of a facility shall create and make available to X-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these

procedures.

F.2.13 Information and Maintenance Record and Associated Information. The registrant shall maintain the following information in a separate file or package in chronological order for each X-ray system, for inspection by the Agency:

- (a) Maximum rating of technique factors;
- (b) Model and serial numbers of all major components, and user's manuals for those components;
- (c) Aluminum equivalent filtration in the useful beam, including any routine variation;
- (d) Tube rating charts and cooling curves;
- (e) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s) after 2 June 1978 with the names of persons who performed such services;
- (f) A scale drawing of the room in which a stationary X-ray system is located with such drawing indicating the current use of areas adjacent to the room and an estimate of the extent of occupancy by an individual in such areas. In addition, the drawing shall include the results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or the type and thickness of materials, or lead equivalency, of each protective barrier.
- (g) A copy of all correspondence with this Agency regarding that X-ray system.

F.2.14 X-Ray Utilization Log.

(a) Except for veterinary facilities, each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed. The record shall also include the following information:

- (1) Name of the licensed practitioner of the healing arts ordering the examination.
- (2) Name(s) of individuals who performed the examination.
- (3) Any deviation from the standard procedure as specified on the technique chart, including all repeat exposures.
- (4) When applicable, the cumulative fluoro on-time.
- (5) When applicable, the X-ray system used.
- (6) When the patient or film must be provided with human auxiliary support, the name of the human holder.

(b) X-ray utilization logs shall be maintained for a minimum of five (5) years following the examination or treatment of adult patients. Records of examination or treatment of minors shall be maintained for a minimum of five (5) years beyond the age of majority.

(c) If X-ray utilization logs are stored electronically, records shall be maintained in a manner that will allow retrieval of records for any specified time period.

A.5.7 Records of Individual Monitoring Results.

(a) **Recordkeeping Requirement.** Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to A.3.3, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before 1 January 1994 need not be changed. These records shall include, when applicable:

- (1) The deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and
- (2) The estimated intake of radionuclides [See A.2.4]; and
- (3) The committed effective dose equivalent assigned to the intake of radionuclides; and
- (4) The specific information used to assess the committed effective dose equivalent pursuant to A.2.6(a) and (c), and when required by A.3.3; and
- (5) The total effective dose equivalent when required by A.2.4; and A.5.7(a)(6)
- (6) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

(b) **Recordkeeping Frequency.** The licensee or registrant shall make entries of the records specified in A.5.7(a) at intervals not to exceed 1 year.

(c) **Recordkeeping Format.** The licensee or registrant shall maintain the records specified in A.5.7(a) on Agency Form RCA-3, in accordance with the instructions for Agency Form RCA-3, or in clear and legible records containing all the information required by Agency Form RCA-3.

(d) The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

(e) The licensee or registrant shall retain each required form or record until the Agency terminates each pertinent license or registration requiring the record.

(f) Upon termination of the license or registration, the licensee or registrant shall make arrangements, satisfactory to the Agency, for permanent storage of records contained on Agency Form RCA-2 or equivalent.

A.6 NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

A.6.1 Purpose and Scope. This subpart establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in work under a license or registration and options available to such individuals in connection with Agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, licenses and certificates of registration issued thereunder regarding radiological working conditions. The regulations in this subpart apply to all persons who receive, possess, use, own or transfer radiation sources licensed by or registered with the Agency pursuant to these regulations.

A.6.2 Posting of Notices to Workers.

(a) Each licensee or registrant shall post current copies of the following documents:

- (1) The regulations in this part;
- (2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;
- (3) The operating procedures applicable to work under the license or registration;
- (4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to the Act, and any response from the licensee or registrant.

(b) If posting of a document specified in A.6.2(a)(1), (2), or (3) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(c) Agency Form RCA-1 "Notice to Employees" shall be posted by each licensee or registrant as required by these regulations.

(d) Documents, notices or forms posted pursuant to this section shall appear in a sufficient number of

places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(e) Agency documents posted pursuant to A.6.2(a)(4) shall be posted within 5 working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within 2 working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

A.6.3 Instructions to Workers.

(a) All individuals who in the course of employment are likely to receive an annual occupational dose in excess of 1 mSv (100 mrem) shall be:

- (1) Kept informed of the storage, transfer, or use of radiation or radioactive material;
- (2) Instructed in the health protection problems associated with exposure to radiation or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;
- (3) Instructed in, and required 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;

A.6.3(a)(4)

(4) 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;

(5) 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

(6) Advised as to the radiation exposure reports which workers shall be furnished pursuant to A.6.4.

(b) In determining those individuals subject to the requirements of Paragraph A.6.3(a), licensees and registrants shall take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed or registered facility. The extent of these instructions shall be commensurate with the potential radiological health protection problems present in the work place.

(c) **Use of Latex Gloves.** Persons, firms or corporations licensed or registered by the Agency that utilize latex gloves are subject to Rules And Regulations Pertaining To The Use Of Latex Gloves By Health Care Workers, In Licensed Health Care Facilities, And By Other Persons, Firms, Or Corporations Licensed Or Registered By The Department [R23-73-LAT], and the posting and employee notification requirements contained therein.

A.3.3

A.3.3 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this Part. As a minimum:

(a) Each licensee or registrant shall monitor occupational exposure to radiation from licensed, registered, unlicensed and unregistered radiation sources under the control of the licensee or registrant and shall supply and require the use of individual monitoring devices by:

(1) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in A.2.3(a); and

(2) Minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem), a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of 5 mSv (0.5 rem).

- (3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem)¹⁰; and
- (4) Individuals entering a high or very high radiation area; and
- (b) Each licensee or registrant shall monitor, to determine compliance with A.2.6, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:
 - (1) Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B to this Part; and
 - (2) Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 1 mSv (0.1 rem); and
 - (3) Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 1 mSv (0.1 rem).
- (c) Individuals wearing a protective apron, when personnel monitoring is otherwise required by these regulations, shall position their individual monitoring devices as follows:
 - (1) An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to A.2.10(a), shall be located under the protective apron at the waist¹¹.
 - (2) An individual monitoring device used for eye dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.

¹⁰ All of the occupational doses in Sec. A.2.3 continue to be applicable to the declared pregnant worker as long as the embryo/ fetus dose limit is not exceeded.

¹¹ It is recognized that, in the specific work environment of medical fluoroscopic equipment, the dose to the embryo/fetus is overestimated by the individual monitoring device because of the overlying tissue of the pregnant individual. A medical physicist who is registered with the Agency pursuant to B.4 as a Provider of Diagnostic XRay Physics Services should be consulted to determine the dose to the embryo/fetus for the rare occasion in which this individual monitoring device has a monthly reported dose equivalent value in excess of 0.5 mSv (50 mrem). Therefore, for purposes of these regulations, the value to be used for determining the dose to an embryo/fetus pursuant to A.2.10(c)(1) for occupational exposure to radiation from medical fluoroscopic equipment may be the value reported by the individual monitoring device worn at the waist underneath the protective apron which has been corrected for the particular individual and her work environment by the above referenced medical physicist.

A.3.3(c)(3)

(3) When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to A.2.3(c)(2), it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

(d) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with A.2.3(a)(2)(ii), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

A.5.14 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.

(a) **Reportable Events.** In addition to the notification required by A.5.13, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

- (1) Incidents for which notification is required by A.5.13; or
- (2) Doses in excess of any of the following:
 - (i) The occupational dose limits for adults in A.2.3; or
 - (ii) The occupational dose limits for a minor in A.2.9; or
 - (iii) The limits for an embryo/fetus of a declared pregnant woman in A.2.10; or
 - (iv) The limits for an individual member of the public in A.2.11; or
 - (v) Any applicable limit in the license or registration; or
 - (v) The ALARA constraints for air emissions established under A.2.2(d); or

(3) Levels of radiation or concentrations of radioactive material in:

- (i) A restricted area in excess of applicable limits in the license or registration; or
- (ii) An unrestricted area in excess of 10 times the applicable limit set forth in Part A or in the license or registration, whether or not involving exposure of any individual in excess of the limits in A.2.11; or

(4) For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(b) Contents of Reports.

(1) Each report required by A.5.14(a) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

- (i) Estimates of each individual's dose; and
- (ii) The levels of radiation, concentrations of radioactive material, and the isotopes, quantities, and chemical and physical form of the licensed material involved; and
- (iii) The cause of the elevated exposures, dose rates, or concentrations; and
- (iv) A description of the event including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned; and
- (v) The exact location, date and time of the event; and
- (vi) Corrective actions, including the results of any evaluations or assessments, taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license or registration conditions.

(2) Each report filed pursuant to A.5.14(a) shall include for each individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in A.2.10, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

A.5.14(c)

(c) All licensees or registrants who make reports pursuant to A.5.14(a) shall submit the report in writing to the Agency.