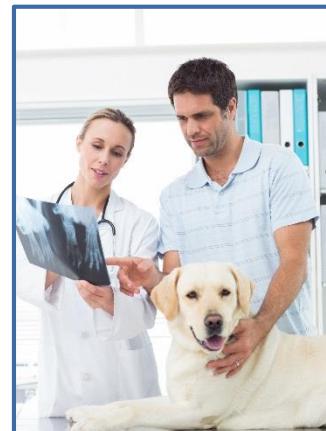
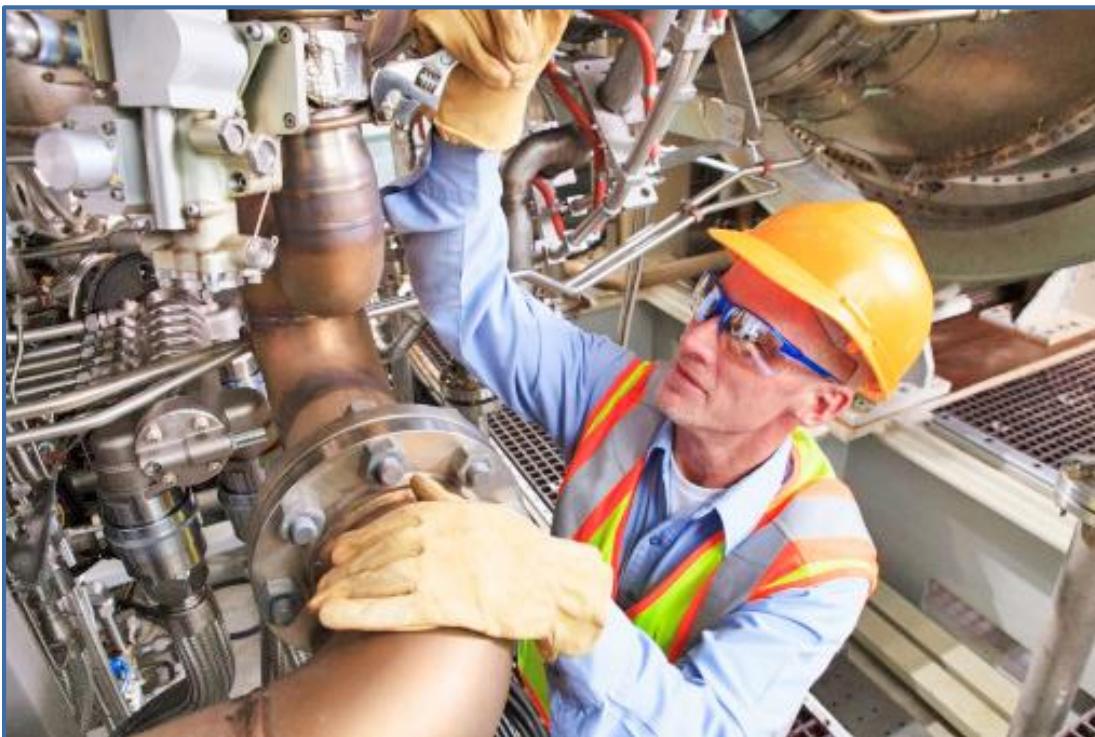


State of Delaware

# Radiation Control Program Annual Report 2017



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DELAWARE HEALTH AND SOCIAL SERVICES  
Division of Public Health

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## The Radiation Control Program

### Executive Summary

This report is issued to make the public aware that there is a radiation control program operating in Delaware, why it exists, what the program regulates, and why it is important to Delawareans. The Office of Radiation Control (ORC) has administered the Radiation Control Program since state legislation was enacted in 1953 to protect the public health and safety at a time when radiation-generating devices were becoming more widespread, with health implications for workers, patients, and members of the general public. In the spirit of open government, this report describes how ionizing radiation is regulated, and by whom at the state and federal level. Data in the form of program metrics are provided that reflect the type and magnitude of population-based public health services delivered by the program. This report also describes how the program partners with state and federal partners to ensure the health and safety of Delawareans.

The ORC's regulatory programs are the registration of x-ray machine facilities, radioactive material facilities, and radiation service providers; and the certification of radiation technologists and technicians who administer ionizing radiation to human patients. The office's oversight contributes directly to essential public health by enforcing laws and regulations that protect health and safety, and ensure a competent public health and personal health care workforce. The radiation control program contributes directly to maintaining the Division's Public Health Accreditation by enforcing public health law. In addition, the program employs scientists who perform technical assessment of simulated radiological emergencies impacting the public.

The ORC annual report was first issued for 2014, and again for 2015. It was not issued in 2016; however, comparisons in data from the 2015 report, and 2017 are provided in the body of this report. Although federal agencies issue various kinds of annual reports related to radiation protection, the state is the sole agency providing oversight of operational safety within ionizing radiation machine facilities located in Delaware. Accordingly, the metrics are provided to provide a common operating picture for the state program, and how it interacts with state and federal partners with respect to their mission to protect the public.

### Introduction

Federal and state regulations require that radiation source facilities maintain a radiation protection program to assure that radiation devices are installed, operated, and maintained to protect the public, workers, and patients from unnecessary radiation exposure. Health care credentialing organizations require that individuals who administer radiation to human patients meet certification requirements to ensure patient safety, limit radiation dose to levels as low as reasonably achievable (ALARA), and promote positive health outcomes. The regulatory mission for radiation protection is broad and diverse. Key governmental organizations are dedicated to monitoring radiation protection in Delaware.

## **State of Delaware, Authority on Radiation Protection**

Established in 1976, the Delaware Authority on Radiation Protection (the Authority) consists of members appointed by the Governor. This public board has statutory authority to effectively regulate sources of ionizing radiation to protect occupational and public health and safety. The Authority is tasked with establishing a regulatory system within the state that permits maximum utilization of ionizing radiation sources for peaceful purposes consistent with public health and safety. The enabling legislation for the Authority is Delaware Code Title 16, Chapter 74 (Radiation Control), which identifies the Office of Radiation Control as the Administrative Agent for the Authority. The Delaware General Assembly first enacted radiation control legislation in 1953, and last amended it in 2008. The Authority establishes regulations under the Radiation Control Act that reflect a wide array of technologies utilizing ionizing radiation sources for peaceful purposes.

## **Office of Radiation Control, Division of Public Health**

The Office of Radiation Control (ORC) is located in the Division of Public Health (DPH) (the Agency) of the Delaware Department of Health and Social Services (DHSS). ORC carries out the state regulations established by the Authority. ORC annually inspects FDA-certified mammography facilities in Delaware, registers and periodically inspects all registered radiation machine facilities for compliance, and registers radioactive material facilities. ORC also registers radiation service providers (vendors); certifies radiation technologists and technicians who administer radiation to human patients; investigates complaints, reportable events, or incidents involving radiation sources; and provides consultation and coordination with other parties who have an interest in radiation protection in Delaware.

## **Office of Radiation Control Metrics, 2015 and 2017**

This annual program report provides an overview of core operational work flow managed by ORC in calendar year 2017, and compares 2017 metrics to the last time the report was issued, in 2015 (Figure 1). There was no report issued in 2016. Metrics for work carried out in calendar year 2015 reflect full staffing of the ORC program. Metrics for work carried out in calendar year 2017 reflect substantially less staffing, with an inspection workforce less than 50% that of 2015. Accordingly, the number of inspections carried out was far less in 2017 than in 2015. In addition to inspections, in 2017 ORC staff participated in multiple planning, training, and drill activities to prepare for a full-scale, multi-agency Ingestion Pathway Exercise for the state Radiological Emergency Preparedness (REP) Program. The Federal Emergency Management Agency (FEMA) evaluated state agencies during that exercise to determine the degree to which the state could demonstrate an effective response to a simulated nuclear power plant disaster. This three-day exercise evaluates the state's capacity to protect people within 50 miles of a nuclear power plant, and occurs approximately once every eight years. The exercise was very successful, with no findings requiring corrective action, and with commendation given for the performance of the Technical Assessment Center (TAC) team that ORC leads and in which it participates. The TAC is the sole team of governmental scientists in the state with demonstrated capability to assess a radiological emergency, determine projected radiation dose to the population, and justify protective action recommendations. Decisions such as evacuation, sheltering in place, or taking radiation countermeasure (potassium iodide or KI) to reduce radiation exposure to the state's population rely on the TAC's recommendations.

## **Radiation Control Regulations – Partnering with the Authority and the Office of Radiation Control**

The ORC carries out the state regulations established by the Authority. By Delaware Code, the ORC Administrator serves as the Authority's administrative agent and plans, organizes, and facilitates periodic review and revisions to the regulations so they are in concert with current health care and industry standards, and closely aligned with current state administrative code and federal requirements. The radiation control regulations apply to any facility or person that receives, possesses, uses, transfers, sells, owns, or acquires ionizing radiation sources, or provides radiation services to such radiation source facilities, operates radiation machines in industry, research and development or veterinary practice, or administers machine-generated radiation to human patients in the healing arts. There are 14 chapters of radiation control regulations (Title 16, Delaware Administrative Code, DHSS, DPH, Health Systems Protection Section, 4465) and one chapter regulating professional certification of radiation technologists and technicians, (Title 16, Delaware Administrative Code, DHSS, DPH, Health Systems Protection Section, 4466). The entire set of regulations was reviewed and amended in 2002. Since then, the Authority has reviewed and revised groups of regulations in phases. In 2018, the Authority plans to publish a final rule affecting several chapters, and to develop a proposed rule addressing review of the last four of 14 radiation control chapters. A table detailing review of radiation control regulations is provided in Figure 2.

**Figure 1. Office of Radiation Control Program Metrics, January 1 – December 31, 2017.**

<b>Radiation Machine Facility Operations</b>	<b>2017</b>	<b>2015</b>
Facilities holding registration permits	713	721
Facility permits amended or renewed	616	826
New permits issued	32	14
Radiation machine facilities inspected	145	357
Inspection violations issued	7	96
Administrative penalty letters issued	0	0
X-ray Devices (tubes) inspected	406	941
Number of web hits: Office home page	15,712	10,558

<b>Radiation Technologist/Technician Certification</b>	<b>2017</b>	<b>2015</b>
Individuals holding certificates	2,466	2,539
New certificates issued	323	346
Existing certificates renewed	704	398
Certificates sanctioned	2	1

<b>Radioactive Material Facility Registration</b>	<b>2017</b>	<b>2015</b>
Facilities holding registration permits	100	100
Facility permits amended or renewed	129	95
New permits issued	3	5

<b>Radiation Service Provider Registration</b>	<b>2017</b>	<b>2015</b>
Companies/persons holding permits	219	128
Provider permits amended or renewed	74	48
New permits issued	13	16

<b>Radiological Emergency Preparedness (REP) Operations</b>	<b>2017</b>	<b>2015</b>
Public health staff assigned	5	6
Number of REP events: planning, training, drills, graded exercises, and public outreach events	20	15
DPH staff hours expended on REP events: planning, training, drills, graded exercises, and public outreach events	800	430

<b>Authority on Radiation Protection, Administrative Agent Duties</b>	<b>2017</b>	<b>2015</b>
Quarterly public board meetings	4	4
Proclamations/Tributes	1	4
Public hearings	1	1

Source: Delaware Department of Health and Social Services, Division of Public Health, Delaware Office of Radiation Control, March 2018.

**Figure 2. Delaware Radiation Control Regulations, Executive Order 36 Review Status, January 1 – December 31, 2017.**

Amended Regulation Effective Date	Proposed Rule Publication Target Date	Current Delaware Regulation DDRT	Title
5/11/2014		4465 Part A <sup>1</sup>	General Provisions
5/11/2014		4465 Part B	Registration of Radiation Source Facilities and Services
6/11/2013		4465 Part C	Licensing of Radioactive Material
8/1/2015		4465 Part D <sup>2</sup>	Standards for Protection Against Radiation
	TBD	4465 Part E <sup>3</sup>	Radiation Safety Requirements for Industrial Radiographic Operations
6/11/2013	5/1/2018	4465 Part F <sup>4</sup>	Use of Diagnostic Imaging in the Healing Arts
6/11/2013		4465 Part G	Use of Radionuclides in the Healing Arts
	5/1/2018	4465 Part H <sup>5</sup>	Radiation Safety Requirements for Analytical X-Ray Equipment
	TBD	4465 Part I	Radiation Safety Requirements for Particle Accelerators
8/1/2015		4465 Part J	Notices, Instructions, and Reports to Workers; Inspections
6/11/2013	TBD	4465 Part K	Compliance Procedures
	TBD	4465 Part T	Transportation
6/11/2013		4465 Part X	Therapeutic Radiation Machines
5/11/2014		4466	Certification of Radiation Technologists/Technicians

Source: Delaware Authority on Radiation Protection, March 2018.

<sup>1</sup> As of May 2014, eight chapters of radiation control regulations (4465 Parts A, B, C, F, G, K, X and 4466) were published as final rule in the Register of Regulations.

<sup>2</sup> As of August 2015, two chapters of radiation control regulations (4465 Parts D & J) were published as final rule in the Register of Regulations.

<sup>3</sup> As of February 2016, four remaining chapters of radiation control regulations last amended in 2002 require review (4465 Parts E, H, I, & T). The timeframe for review of this set of regulations is under review by the Authority on Radiation Protection in 2016.

<sup>4,5</sup> As of March 2018, two chapters of radiation control regulations (4465 Parts F & H) are in progress for publication of proposed rule (previously published for public comment June 1, 2017.)

## Federal Partners

### U.S. Food & Drug Administration

The Radiation Control for Health and Safety Act of 1968 (the Act) authorized the U.S. Food and Drug Administration (FDA) to set federal radiation standards for electronic radiation emitting devices, and to monitor compliance and conduct research. The FDA's Bureau of Radiological Health administered the Act, and promptly called a meeting of the states to discuss implementation following passage of the Act, focusing on the growing public health problem of exposure to radiation. Sections 356 and 357 of the Act emphasized the importance of state involvement in its implementation, and identified measures and assistance needed to strengthen state radiation control programs. Implementation of the federal Act resulted in enactment of state radiation control statutes nationwide. Recognizing state resource challenges, in 1968 the FDA provided funding and consultation to establish the non-profit, non-governmental organization called the Conference of Radiation Control Program Directors (CRCPD) to develop peer-reviewed state model regulations and promote a more consistent national approach to operational safety and health protection in radiation machine facilities. CRCPD continues to operate with partial funding from the FDA and other federal partners, the U.S. Nuclear Regulatory Commission (NRC), Environmental Protection Agency (EPA), FEMA, and Department of Energy (DOE), as well as professional societies such as the American Association of Physicists in Medicine (AAPM), American College of Radiology (ACR), American Society of Radiation Oncology (ASTRO), and Health Physics Society (HPS).

The Mammography Quality Standards Act (MQSA) of 1992 authorized FDA to certify and inspect mammography facilities to establish and monitor minimum standards for radiation machine parameters, quality assurance, and professional training and experience for mammography device operators. Under the MQSA Act administered by the FDA Bureau of Radiological Health, the FDA contracts with state radiation control programs to provide annual, onsite inspections of accredited mammography facilities within their jurisdiction, and identify violations for follow-up and enforcement by the FDA.

### U.S. Nuclear Regulatory Commission and Federal Emergency Management Agency

The Atomic Energy Act of 1954 was amended in 1970 to organize governing authority for oversight of nuclear materials in the defense sector to the U.S. Department of Energy. The amended law specifies governing authority for oversight of radioactive materials in the civilian sector to the NRC. The Energy Policy Act of 2005 further amended the Atomic Energy Act to expand federal authority for licensure and enforcement of civilian radiation sources, and to expand accountability and safeguarding of radiation sources for homeland security purposes. Under the Energy Policy Act of 2005, additional requirements were implemented for radiation source tracking, vetting authorized users of safeguarded sources, and critical infrastructure protection in the nuclear sector. The Delaware ORC is the lead state agency for civilian radioactive material source regulation, with licensing and enforcement of radioactive material facilities carried out by the NRC Region 1 office in King of Prussia, Pennsylvania.

### **U.S. Nuclear Regulatory Commission and Federal Emergency Management Agency (*cont.*)**

The NRC issues operating licenses to corporations that own or operate commercial nuclear reactors used to generate electrical power and to research reactors used to generate radioactive materials for biomedical or pharmaceutical purposes. For public health and safety, the NRC provides on-site inspections and monitoring of such reactor facilities. FEMA establishes standards for emergency preparedness and response capabilities that must be maintained by nuclear power utilities and off-site response organizations (state/local governments). FEMA periodically evaluates response and recovery capabilities utilizing full-scale, multi-agency exercises that simulate radiological emergencies resulting in releases of radioactivity to the environment. Exercise evaluation criteria include the development of protective actions that prevent or limit radiation dose to the public. The Delaware Emergency Management Agency is the lead state agency for the Delaware REP program and works closely with the FEMA Region 3 office in Philadelphia, Pennsylvania.

Copies of this report are available by contacting the ORC at 302-744-4546, or by visiting the ORC website at <http://www.dhss.delaware.gov/dhss/dph/hsp/orc.html>.

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