

Health Regulations Bureaus and Offices

Health Facilities Licensing and Certification Bureaus

Providing health care involves working within a complex system of state and federal agencies and many community partners. It is important for health care providers to know what is expected of them and which resources are available to assist them in meeting those expectations.

Licensing and certification of health care facilities is critical to ensuring that established standards are met by hospitals, ambulatory surgical centers, hospice programs, and other health care facilities. Rules and regulations are developed to ensure that South Carolinians receive safe, high quality health care.

Health Facilities Licensing Bureau Gwen Thompson, Bureau Chief

The **Licensing** program helps to ensure that individuals receiving care and services from facilities licensed by DHEC receive appropriate levels of care and high quality services. To do this, the program promulgates regulatory standards, evaluates licensed and proposed activities through inspections and investigations based on established standards, and requires activities for facilities based on set standards.

Health Licensing is made up of the following Divisions:

- Facility Safety Oversight (FSO)
- Community Care Oversight (CCO)
- Medical Management Oversight (MMO)
- Operations and Support Team
- Complaint Team
- Quality Management Team

Certification Bureau

Mary Jo Roué, Bureau Chief

The **Certification** program helps to ensure that all residents, patients, and clients of providers that receive Medicaid and Medicare reimbursements receive high quality care. The program conducts onsite surveys of providers to review medical records and facility files, and also interviews residents and staff. Certification activities are done on behalf of the federal government through an annual contract.

The Long Term Care Division surveys health facilities that participate in the Medicare and Medicaid programs, including nursing homes and facilities for persons with intellectual disability. These facilities are surveyed with unannounced site visits. Survey teams include nurses, pharmacists, social workers, dieticians, qualified intellectual disability professionals and generalists.

Health Provider Division conducts Initial surveys, recertification surveys and complaint surveys of Hospitals, Home Health Agencies, Portable X-Ray, Rehabilitation Agencies, Rural Health Clinics, End Stage Renal Disease Facilities, Comprehensive Outpatient Rehabilitation Facilities, Ambulatory Surgery Centers, Hospices, and Swing Bed Units of Hospitals. These surveys are unannounced and are completed by a staff of registered nurses.

Certificate of Need (CON)

Louis Eubank, Director

The Certificate of Need (CON) program authorizes the implementation or expansion of health care facilities and services in South Carolina. A certificate of need is based on a calculation of need for a particular medical service from the South Carolina Health Plan. A CON authorizes a person or facility to provide a portion of that calculated need in a county or service area, which may comprise several counties.

CON program was reinstated in July 2014 after being defunded, since that time it:

- Received over 233 applications since the restart
- Issued over 104 decisions
- Granted over 90 Certificates

Drug Control Bureau,

Lisa Thomson, Bureau Chief

The Drug Control program aims to promote and protect public health through enforcement of South Carolina's Controlled Substances Act. The program administers the state's prescription drug monitoring program (known as SCRIPTS), which tracks the prescribing and dispensing of all Schedule II, III and IV controlled substances by licensed professionals such as doctors, pharmacists, dentists, and veterinarians. The goal is to improve South Carolina's ability to identify and quickly stop illicit distribution and use of prescription drugs.

In addition to monitoring, the program also employs inspectors who conduct onsite inspections and audits of pharmacies, hospitals, and practitioners to make sure they are properly recording, storing, and handling controlled substances. These inspectors are pharmacists who have undergone additional training and become state law enforcement officers. These inspectors respond to complaints and concerns reported to DHEC and, when warranted, make arrests and issue fines.

Emergency Medical Services (EMS) and Trauma Bureau
Robert Wronski, Bureau Chief

The EMS and Trauma program develops and regulates systems for quality emergency medical care in South Carolina. This ensures EMS providers are fully trained and that their medical vehicles are properly equipped. The program conducts scheduled and surprise inspections of EMS agencies, vehicles, and educational programs to check for compliance with statutes and regulations. The program also is responsible for credentialing of trauma centers and expansion of a statewide trauma system, as well as collecting and disseminating trauma related data. This oversight helps to ensure that South Carolina's emergency medical systems are functioning efficiently and effectively.

Radiological Health Bureau
Aaron Gantt, Bureau Chief

Energy emitted from a source is generally referred to as radiation. Radiation exists in the natural environment (e.g., heat and light from the sun), as well as being generated by man-made devices (e.g., X-rays). The Radiological Health program works to protect South Carolinians from unnecessary exposure to radiation, which can come from a variety of sources such as X-ray equipment, radioactive materials, and tanning beds.

Division of Radioactive Materials Licensing and Compliance

The Division of Radioactive Material Licensing and Compliance is currently responsible for the licensing and inspection of 325 specific radioactive material licensees and about 600 general licensees. Licensing includes a review of all operating facility design and construction. Facilities are inspected according to a priority schedule ranging from one year to every five years depending on facility type. South Carolina, as an Agreement State, has entered into a partnership with the U. S. Nuclear Regulatory Commission (NRC) that allows the State to regulate the use of radioactive material at these facilities. The Division operates its program statewide from the central office of DHEC in Columbia. Each licensed facility must use radioactive material in accordance with Department Regulation 61-63, Radioactive Materials (Title A), which outlines the regulatory requirement for the possession and use of these materials. The Division also performs Increased Controls (enhanced security controls) inspections for licensees that possess quantities of radioactive material above Table 1 values.

There are 25 categories of licenses ranging from Medical Institutions to Industrial Gauges. Radioactive materials are used in the health professions for both diagnostic and therapeutic purposes. Industrial uses range from product sterilization to the level and density measurements of various construction materials. The Division is also responsible for maintaining a 24 hour Emergency Response Assistance Team capable of responding to any incidents involving radioactive material.

The Division is subject to an Integrated Materials Performance Evaluation Program review every four years conducted by a team of NRC personnel. All aspects of the South Carolina Agreement State Program are reviewed and evaluated for compatibility and consistency with the Nuclear Regulatory Commission's program.

Division of Electronic Products

The Division of Electronic Products, within the Bureau of Radiological Health, derives its authority from the Atomic Energy and Radiation Control Act. The Division is responsible for regulating the use of sources of electronically produced ionizing and non-ionizing radiation. The regulatory activities consist of both a registration and an inspection/enforcement program.

The requirements for operating x-ray equipment in South Carolina can be found in Regulation 61-64 (Title B). The Division has approximately 3,600 x-ray facilities with over 6,000 pieces of x-ray equipment registered in South Carolina. Prior to operating x-ray equipment, facilities must receive facility registration approval. This includes a review of the operating procedures, radiation protection program, quality control program, and shielding design. The shielding approval process requires a review of the architectural blueprint, an analysis of the type and number of x-rays performed, and a determination of the room and surrounding area occupancy rate. Facilities are inspected according to a priority schedule ranging from annually to once every four years depending on the facility type. Inspections help ensure that the citizens of the state of South Carolina receive quality radiographs, therefore, improving the accuracy of diagnosis and treatment.

The Division also consists of a Mammography Program. Under a grant from DHEC's Center for Health Promotion, we inspect and consult with mammography facilities to insure quality mammograms for low-income women. The Division also inspects and certifies all mammography providers in the state under the federal Mammography Quality Standards Act. The MQSA is mandated by the U.S. FDA. South Carolina is one of only four states in the nation that has been approved by the FDA to act as a Mammography certifying body. The Division is subject to several audits annually by the FDA.

The Division of Electronic Products operates a calibration facility for calibrating radiation detection and measurement instruments for radiation control programs nationwide. This laboratory will be accredited by the Conference of Radiation Control Program Directors, and will be one of only two accredited labs in the nation run by state radiation control programs. The lab will be certified for both x-ray and gamma ray calibrations. With the ever increasing need for radiation detection instrument calibrations the South Carolina Regional Calibration Laboratory has modernized and updated their facility. These upgrades have significantly improved the overall calibration process. Recently, the laboratory completed their proficiency test which provides traceability to a national standard. The test was conducted by the National Institute of Standards and Technology (NIST).

Construction, Fire and Life Safety Division
William McCallum, Director

The Construction, Fire and Life Safety program reviews plans, specifications, and construction for health care facilities licensed by the state. The program also conducts periodic fire and life safety surveys of facilities to ensure continued compliance with appropriate codes, standards, and regulations.

Legislative and Regulatory Affairs Office
Bentley White, Director

This office coordinates and assists the Bureaus in the development and amendment of policies and regulations; conducts outreach; and collaborates with the regulated community, stakeholders, health care providers and other interested parties. Staff monitor pending legislation and collaborate with DHEC's legislative team to handle legislative initiatives that impact Health Regulations.