COLORADO RADIATION REGULATIONS PRIMER

This document is for information purposes only and is intended to serve as background information for members of the public and others with an interest in better understanding the regulation of sources of radiation in Colorado by the Radiation Program of the Colorado Department of Public Health and Environment (the Department). This document contains both general and specific information that is subject to change based upon changes in federal or state statute or regulations, or the policies of the Department. This document shall not substitute for the specific requirements pertaining to regulating sources of radiation which are contained in state statute and regulation. Links to this information and related websites can be found at the end of this document.

REGULATION OF RADIATION SOURCES IN THE UNITED STATES

Because of their potentially hazardous properties, the use of certain radioactive materials and radiation machines must be closely regulated to protect the health and safety of the public, users, and the environment. Toward that end, the responsibility for regulating the use and handling of these materials and the safe use of radiation machines is shared by the following governmental agencies:

- The U.S. Environmental Protection Agency (EPA) - sets air emission and drinking water standards for radioactive materials;
- The U.S. Food and Drug Administration (FDA) – sets standards for the manufacture and use of x-ray machines and linear accelerators used for any commercial purpose;
- The U.S. Nuclear Regulatory Commission (NRC) – regulates nuclear reactors and the civilian use of radioactive materials for medical, industrial, and research purposes. Authority is granted to the NRC through the Atomic Energy Act of 1954;
- State Governments – regulate the use of specific radioactive materials within its borders through agreements between the governor of a state and the NRC. States may also, through state legislative authority, regulate the use of radiation producing (x-ray) machines.

AGREEMENT STATES

Certain States, known as agreement states, have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source, and small quantities of special nuclear materials, which are used or possessed within the state borders. The Agreement State designation and the federal rule compatibility requirements apply only to radioactive materials and do not apply to radiation producing machines such as x-ray machines. State statute provides the authority and mechanisms to regulate these other sources of radiation, including x-ray machines.

Certain requirements accompany the agreement state designation. Such requirements include establishing the necessary statutory (legal) authority to govern radioactive materials within the state, designating an appropriate agency (or agencies) to regulate the materials use, establishing and maintaining the necessary regulations and staff, and having a sustainable funding source for the regulatory program. Colorado has regulated the possession and use of radioactive materials since becoming an agreement state in 1968. Because Colorado is an agreement state, individuals that seek to work with radioactive materials work with the

Radiation Program within the Hazardous Materials and Waste Management Division at the Colorado Department of Public Health and Environment to obtain a license.

While the authority to regulate radioactive materials is transferred to the agreement state, the NRC reviews the state regulatory programs periodically to ensure continued compatibility and effectiveness. This review process – carried out on a four year cycle – is known as the Integrated Materials Performance Evaluation Program or IMPEP.

Additionally, each statutory and regulatory change pertaining to radioactive materials is also reviewed in draft and final form by the NRC to ensure compatibility with federal rule. Failure to maintain compatibility can result in additional oversight by NRC and potential loss of agreement state status.

While the agreement state designation gives authority to certain states to regulate radioactive materials within its boundaries, other types of radioactive materials use remains under the authority of the NRC. The NRC retains sole regulatory authority over regulation of nuclear reactors for power or research; radioactive materials used at federal facilities or properties; high level radioactive waste facilities; import and export of certain radioactive materials; and distribution of manufactured items to persons who are exempt from the regulations. In these areas, NRC continues to be the regulatory authority. (See https://scp.nrc.gov/ for a current map of the 37 current agreement states).

COLORADO STATUTE (LAW) GOVERNING SOURCES OF RADIATION

The Colorado statute which governs radioactive material and gives authority to the Colorado Department of Public Health and Environment Radiation Program is known as the Colorado Radiation Control Act (RCA). The requirements are contained in Title 25, Article 11 of the Colorado Revised Statutes (CRS). The RCA also gives the authority to the Department – through the Colorado Board of Health - to promulgate rules and regulations to ensure the health and safety of the public while using radioactive materials and radiation producing (x-ray) machines. While the RCA primarily contains broad requirements, other sections of the Act also contain very specific details and requirements pertaining to process and penalties that result from violations of regulatory requirements and the disposal of radioactive waste (including wastes arising from uranium or thorium processing).

COLORADO REGULATORY PROGRAM STRUCTURE

The regulatory program governing radiation machines and radioactive materials in Colorado is known as the Radiation Program. The Radiation Program resides within the Hazardous Materials and Waste Management Division which is part of the Environmental Program at the Colorado Department of Public Health and Environment.

Within the Radiation Program is the Radioactive Materials Unit. This unit is responsible for the regulation of radioactive materials use and carries out its function through the licensing

and inspection of facilities using such materials. The program regulates specifically licensed and generally licensed materials and facilities.

Another primary function of the radiation program is to regulate radiation machines. The X-Ray Certification Unit regulates radiation producing (x-ray) machines through registration of facilities using radiation machines. This unit also ensures - through an evaluation and registration process - those individuals who perform certain functions related to radiation machines, including individuals who perform the period inspection of machines (known as Qualified Inspectors), and those who sell, install or service radiation machines. The unit also establishes the qualifications necessary to register certain individuals to operate radiation machines.

Non-regulatory activities within the radiation program include a public outreach and education program pertaining to radon in buildings. This work group also provides grants to local government and other entities to provide information and education about radon hazards and mitigation.

RADIATION ADVISORY COMMITTEE

The RCA (Section 25-11-105, CRS) establishes a requirement for the Radiation Advisory Committee (RAC), a governor appointed body of nine volunteer members of the regulated community who represent industry, healing arts (medicine), and higher education. Members serve a four year term, at the discretion of the Governor. Although the RAC advises the Program on matters related to radiation safety, the RAC does not have the authority to oversee or direct the Program, and does not involve itself in matters relating to licensing, registration, or compliance for any given facility. A key function of the committee is to review and comment on proposed new regulations and regulatory changes, and to provide feedback and advice on current issues faced by the Program. The RAC meets four to six times per year. The meeting dates for the RAC are published on the radiation program website. All RAC meetings are open to the public.

COLORADO'S RADIATION REGULATIONS

OVERVIEW OF THE REGULATIONS

Colorado's radiation regulations provide the specific details on how sources of radiation (including radioactive materials and x-ray machines) are to be controlled and used to ensure the health, safety, and security of the public, environment, and employees of facilities using radiation devices or radioactive materials. The radiation regulations, are contained in Code of Colorado Regulations (CCR), 6 CCR 1007-1.The radiation rules are comprised of 22 "parts" labeled 1 through 24 (excluding parts 21 and 23 which are currently unused). Some radiation regulatory parts are specific to a particular use or topic such as radioactive materials in medicine or uranium processing while others apply to all types of uses and sources. Similarly, some regulatory parts may only apply to radiation producing (x-ray) machines and others may

apply only to use of radioactive materials. For example, 6 CCR 1007-1, Part 1, contains definitions used throughout other regulatory parts and 6 CCR 1007-1, Part 3 has requirements related to the licensing of radioactive material. Entities regulated under the radiation regulations are commonly required to follow the requirements of more than one regulatory part.

CHANGES TO COLORADO'S RADIATION REGULATIONS

Colorado's radiation regulations may be modified periodically for a variety of reasons, including changes to state law, changes to federal regulations, and changes in department or programmatic processes or program needs. For radioactive materials, the majority of regulatory changes are driven by changes to the federal rules of the NRC. As an agreement state, Colorado radiation regulations must be consistent with the NRC regulations necessary for compatibility and typically must be updated within a three year period following issuance of federal regulation changes. Such federal rule changes are tracked through the NRC Regulatory Action Tracking System, or RATS. When applicable, proposed Colorado regulatory changes typically reference the specific NRC RATS item driving the change. While there are different levels of compatibility specified by the NRC for any given regulation or requirement, most regulations promulgated by the NRC have little flexibility in the language or requirements and therefore, state requirements may not deviate much from these requirements.

The Radiation Control Act dictates that Colorado's radiation regulations be consistent with the Conference of Radiation Control Program Directors, Inc. (CRCPD) Suggested State Regulations for Control of Radiation. The CRCPD in conjunction with member states, periodically develops and updates model regulations on a voluntary basis for use by state radiation programs. While the intent is to maintain these model regulations consistent with federal rule changes in a timely manner, there are often delays in issuing updated or new model regulations by this organization. To comply with the NRC requirements, agreement states often make changes to their rules without the benefit of a current model regulation available.

Rulemaking is a multi-step process involving a variety of activities. The process typically begins by evaluating the drivers behind any potential rule change whether it is state, federal, or programmatic. Regulatory staff of the radiation program will begin developing a draft based on these changes or needs. The initial draft is reviewed and discussed with staff as well as the Radiation Advisory Committee.

ENGAGING STAKEHOLDERS

When the new rule language is developed, the draft rule is distributed so the public and stakeholders can review and comment. The comment period is typically 30-60 days. Stakeholder meetings may or may not be held, depending upon the magnitude of the proposed changes. For radioactive materials regulations, the NRC is typically provided a copy

of the draft rule for review and comment. Once the stakeholder process is completed and comments are submitted, they are reviewed for possible incorporation.

RULEMAKING PROCESS

Once the stakeholder process is completed, the rule will move forward through the Board of Health rulemaking process. The State Board of Health is an independent board that reviews and approves changes to Colorado's radiation regulations. Radiation program staff will go before the Board (known as a request for rulemaking) to present and explain the initial rule changes and request that a future rulemaking hearing be set. If the request is approved by the Board, a rulemaking hearing is set, typically 60 days from the request for rulemaking. Notice of the rulemaking hearing is provided to stakeholders and is published in the Colorado Register. While public testimony or comments are not allowed during a request for rulemaking, written and oral testimony is permitted at the rulemaking hearing. If approved by the Board at the rulemaking hearing, the final rule becomes effective within approximately 60 days of the hearing, unless a different date is requested by the Division promulgating the regulation.

REGULATORY AGENDA AND REGULATORY REVIEW

As required by Executive Order D 2012-002 , Sections 2-7-202, 2-7-203 and 24-4-103.3(4), CRS, each state agency must establish the Regulatory Agenda or "schedule" of regulatory changes for the coming calendar year for regulations. The Regulatory Agenda is established in the fall and is published on the Department website each November for the following calendar year. The agenda outlines what regulations are planned for modification. There are instances where the need for rulemaking arises after the agenda is published or a rulemaking that was planned is withdrawn. The Radiation Control and Board of Health websites and the Colorado Register have updated information pertaining to rulemaking.

Executive order D 2012-002, and Section 24-4-103.3(4), CRS, require a periodic review of regulations by each state agency, to ensure that each regulation is still applicable, and efficient, and does not duplicate other regulations. Similar to the Regulatory Agenda, the schedule of regulation review (Regulatory Plan) is posted on the Department website for the coming calendar year. While the review is typically an internal process, individual programs may seek out and hold stakeholder processes or other activities to obtain feedback from the community. Members of the public or regulated community are encouraged to submit suggestions for changes to the rules. The Regulatory Plan can be amended throughout the year.

RADIATION PRODUCING MACHINES ("X-RAY MACHINES")

Radiation machines are considered to be devices which emit ionizing radiation as a result or product from the acceleration of subatomic particles (e.g., electrons) into a target within the machine. Such machines do not emit radiation once the power or electricity to the device is eliminated. Such x-ray machines are not radioactive. Examples of radiation producing

machines include: X-ray machines such as those used for security, medicine, dentistry, chiropractic, veterinary medicine, and industry; computed tomography (or CT or "CAT" scanner) machines; fluoroscopy machines used primarily in diagnostic medicine; and linear accelerators used for radiation therapy in medicine.

The regulations pertaining to X-ray machines are not governed by NRC requirements and the NRC does not review or comment on radiation machine regulations. Because explicit provision by provision compatibility is not required, the department has more discretion when modifying the x-ray regulations.

Other types of machines - used primarily for diagnostic imaging purposes - do not produce ionizing radiation and are not x-ray machines. Such machines include ultrasound imaging devices, and magnetic resonance imaging (or "MRI") machines. As these specific devices do not produce ionizing radiation, the Department does not regulate these machines in any way.

RADIOACTIVE MATERIALS

Radioactive materials are those elements which emit ionizing radiation spontaneously and continuously and without the addition of any external force or action. A few examples of radioactive materials which occur in nature include Uranium, Thorium, Radium, and Radon. There are many other radioactive materials which occur in nature. Other radioactive materials do not occur in nature but are produced artificially through direct exposure to other radiations, such as exposure in a nuclear reactor or accelerator. Such materials that are produced in such a way are broadly defined as "byproduct material", although through federal legislation, this definition has been expanded somewhat. (Refer to radiation regulations Part 1 for the regulatory definition of byproduct material).

Radioactive materials may be used in many forms, shapes, or quantities. Radioactive materials may be used or processed in their "raw" or natural forms, such as during uranium milling operations or for such purposes as research. Other radioactive materials (that are fully encapsulated) may used inside or outside of machines or devices.

Radioactive materials are used in many fields for many different purposes including industry, health, and research. For further information on the use of radioactive materials, refer to the NRC website at www.nrc.gov

LICENSING OF RADIOACTIVE MATERIALS

The licensing of radioactive materials in Colorado (and other agreement states and the NRC states) generally follows what one might call a "3 tiered" approach. Radioactive materials are either specifically licensed, generally licensed, or are exempt from all or some regulatory requirements.

SPECIFIC LICENSING

Specific licensing is the most restrictive level of licensing. A specific license for radioactive materials requires that an applicant apply for a license with the department and submit the necessary documentation (such as radiation safety procedures, training documents, etc.) for review before a license can be issued and before radioactive materials can be received. The applicant must demonstrate they have the adequate education, training, experience, facilities and equipment to safely use and store radioactive materials.

Once issued by the Department, the specific license contains details on what types and quantities of radioactive materials may be used, how and in what devices the radioactive materials can be used, who may use the materials, and where the materials can be used. Other more broad requirements are also contained in the license.

Examples of specifically licensed uses include hospitals or medical facilities that use radioactive materials for human diagnosis or therapy; universities performing research using radioactive materials or sources; industrial entities using devices containing radioactive materials to measure or monitor flow, fill, density, or thickness of materials or that are used to image high density materials, or to characterize materials in the earth; and licenses for facilities that refine and process naturally occurring uranium or thorium for the purpose of recovering such materials.

Specific licenses are most commonly issued for 5 year periods, although the Department has flexibility with the issuance period. Once issued, the specific licensee is required to pay an annual licensing fee. The application and licensing fees help to sustain the regulatory program and provide for regulatory oversight and compliance activities.

As of early 2016, Colorado had approximately 325 active specific licensees.

GENERAL LICENSING

Some types of radioactive materials or devices containing radioactive materials may present a lower risk to the end user and may require a lesser degree of training and little to no specialized equipment or facilities for their use. Such devices are considered to be generally licensed devices or materials. Examples of generally licensed devices include certain exit signs containing (radioactive) tritium; certain fixed gauges; devices used to measure lead paint in materials or on surfaces; and some commercial smoke detectors with larger amounts of radioactive materials.

The general license designation applies only to the end user of such materials or devices. Any entity wishing to manufacture or initially distribute materials or devices containing radioactive materials to persons who are generally licensed must be specifically licensed to do so. An agreement state such as Colorado has the authority to issue specific licenses for such manufacturing and distributing of generally licensed devices.

As of early 2016, Colorado had approximately 1,012 entities registered as general licensees.

EXEMPT MATERIALS

Some quantities and types of radioactive materials, or devices containing radioactive materials are exempt from regulatory control once they are produced or manufactured. The concept with exempt materials is that they present a very low risk to the end user and that risk is comparable to other daily or "life" risks, and that they require no special training or qualifications to use them. Some common examples of exempt devices are smoke detectors (which contain small amounts of radioactivity) sold at hardware and home supply stores; lenses or mirrors coated with radioactive materials used in scientific, military, space, or other applications; ceramic glazing found on older pottery or ceramics known as "fiestaware"; and small "button" or check sources used by first responders and others to check radiation survey instrument response. There are limitations relating to exempt material including a prohibition on gathering a number of exempt sources and installing them in a device to in essence make a larger source. Similarly, persons wishing to manufacture devices for exempt distribution and use must be specifically licensed.

The exempt designation applies only to the end user of such materials or devices. Any entity wishing to manufacture or initially distribute materials or devices containing radioactive materials to persons who are exempt from the regulations must be specifically licensed to do so. The distribution of materials or devices to exempt persons requires a license from the NRC. It also will require a specific license from an agreement state for possession and use of the material in an agreement state.

For further information on the regulation of radiation at the Colorado Department of Public Health and Environment, visit the radiation program website.

USEFUL LINKS AND WEBSITES

CDPHE RADIATION ADVISORY COMMITTEE:
https://www.colorado.gov/pacific/cdphe/radiation-advisory-committee

CDPHE RADIATION PROGRAM: https://www.colorado.gov/pacific/cdphe/categories/services-and-information/environment/radiation-management

CDPHE RADIOACTIVE MATERIALS (RADIATION MANAGEMENT) UNIT
https://www.colorado.gov/pacific/cdphe/radioactive-materials-management

CDPHE X-RAY CERTIFICATION UNIT: https://www.colorado.gov/pacific/cdphe/xray

CDPHE RADON PROGRAM: www.colorado.gov/cdphe/radon

COLORADO BOARD OF HEALTH
https://www.colorado.gov/pacific/cdphe/boh

COLORADO RADIATION CONTROL ACT (RCA)
https://www.colorado.gov/cdphe/radregs

COLORADO RADIATION REGULATIONS (CURRENT AND PROPOSED):
https://www.colorado.gov/cdphe/radregs

COLORADO REGISTER
http://www.sos.state.co.us/CCR/RegisterHome.do

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS (CRCPD):
Main website: http://www.crcpd.org/
Suggested State Regulations for Control of Radiation (SSRCR's):
http://crcpd.org/SSRCRs/default.aspx

ORGANIZATION OF AGREEMENT STATES (OAS): http://www.agreementstates.org/

U.S. NUCLEAR REGULATORY COMMISSION (NRC)
Main website: http://www.nrc.gov/
Regulations: http://www.nrc.gov/reading-rm/doc-collections/cfr/
NRC State and Tribal Programs: https://scp.nrc.gov/
State of Colorado Agreement: https://scp.nrc.gov/special/regs/coagreements.pdf
Amendment to Agreement: https://scp.nrc.gov/special/regs/co_agreements.pdf