RADIATION PROTECTION PROGRAM (RPP) GUIDANCE

The Colorado *Rules and Regulations Pertaining to Radiation Control*, (6 CCR 1007-1) are the regulations developed by the Colorado Department of Public Health and Environment (the Department) to control and manage sources of ionizing radiation. In accordance with Part 4, Section 4.5, all X-Ray facilities registered with the Department shall have a Radiation Protection Program in place and readily available for a Qualified Inspector to review.

The following pages will review the general regulatory requirements for x-ray facilities. Radiation safety policies and procedures must be developed by the facility pursuant to the Regulations and are part of your Radiation Safety Program. The facility should keep the documents required by the Regulations in a clearly labeled folder or binder for the Qualified Inspector or State Auditor to review at any time. The Regulations require that your Radiation Safety Program be kept current and reviewed at least annually (Part 4, Section 4.5). The individual responsible for the administration of these practices is the Radiation Safety Officer and should be available for any questions the inspector may have. Failure to follow the Regulations will result in a citation by the Qualified Inspector or State Auditor. Failure to correct any violation will result in escalated enforcement by the Department, and may result in non-routine inspection fees and/or civil penalties.

This document will review the general regulatory requirements for x-ray facilities according to the Regulations. The Regulations are separated into several parts, many of which pertain to requirements for using an x-ray machine. Parts 1, 4, 5 and 10 have requirements for both radioactive material licensees and x-ray machine registrants. Parts 2, 6, 8, 9 and 24 have requirements for x-ray machine facilities for medical (Parts 2, 6, and 24) and non-medical uses (Parts 2, 5, 8, and 9). Every facility is expected to abide by the Regulations that pertain to their operation. Throughout this document, the Regulations are referred to as "Section #.#.#". The first number always indicates what Part of the regulations the section is in. For example, Section 2.6.1 is in Part 2 of the Regulations.

Please use the link below to find Radiation Regulations, lists of Qualified Inspectors, Registered Medical Physicists or Service Companies, and other guidance documents:

http://www.colorado.gov/pacific/cdphe/xray

THE X-RAY CERTIFICATION UNIT (XRCU)

The X-Ray Certification Unit (XRCU) is part of the Radiation Control Program of the Hazardous Material and Waste Management Division in the Colorado Department of Public Health and Environment. The XRCU is responsible for writing regulations that ensure the safe use of radiation-producing machines (i.e. x-ray machines) and is also responsible for enforcing those regulations. The Radiation Control Act (Title 25, Article 11 of the Colorado Revised Statutes) authorizes the Department to develop and enforce these regulations. Parts 2, 4, 6, 5, 8, 9, 10 and 24 pertain to radiation machine regulations.

In general, the Regulations require **registration** of all radiation machines and facilities where they are used and the regular **evaluation** of each machine and facility to ensure the safety of the workers and the public from radiation sources. Depending on the type of x-ray machine used, the machine must be evaluated annually, bi-annually, or once every three years. These evaluations are called **"routine inspections"** and are done by registered, private individuals known as Qualified Inspectors (QI's).

There are approximately 80 registered QI's in Colorado and a list is available on our web page. QI's may be limited to the type of x-ray machine they can evaluate, so it is important to choose the correct QI for your facility. Mammography, CT, Fluoroscopic and Therapy systems must be inspected by a QI with approval in the Registered Medical Physicists (RMP's) category. The X-Ray Certification Unit will send courtesy notices (green postcards) to the facility's address on file two months before the x-ray machine is due for inspection.

The XRCU will send notices to the registrant of non-compliance issues such as over-due inspections or when the facility misses a dead-line to submit corrective actions. Failure to correct non-compliances within the designated time frame will result in escalated enforcement actions taken by the XRCU. If no response is received from the facility concerning violations, XRCU staff will perform **non-routine inspections** at a charge of $152 per hour. Continued failure to correct violations may result in penalties and loss of registration approval. The X-Ray Certification personnel listed below do not perform routine inspections, but manage the registration process for facilities, x-ray machines, Qualified Inspectors, Service Companies and certain operators.

X-Ray Certification Staff contact information:

Brian Vamvakias, Supervisor	Brian.Vamvakias@state.co.us	303-692-3427
Susan Guiet, Auditor	Susan.Guiet@state.co.us	303-692-3433
Tracey Luty, Auditor	Tracey.Luty@state.co.us	303-692-3446
Christine Irving, Compliance	Chris.Irving@state.co.us	303-692-3448
Erin Woodd, Administrative	Erin.Woodd@state.co.us	303-692-3443
General E-Mail Box	cdphe.hmxraycomments@state.co.us	

RADIATION PROTECTION PROGRAM

A Radiation Protection Program is required by Part 4, Section 4.5. This Section requires that each licensee or registrant shall "develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Part 4" (See Section 4.41 for recordkeeping requirements relating to these programs). The Radiation Protection Program (RPP) is a written document that contains procedures and policies related to the safe use of radiation machines. The main purpose of the RPP is to keep occupational doses and doses to the members of the public "as low as reasonably achievable". Also, the RPP must be reviewed at least annually by the Radiation Safety Officer.

Some elements of a RPP are required by regulation and will be listed below. Some elements are considered good practice and facilities are expected to consider them in their RPP. Not all facilities will have the same RPP. The elements in your RPP depend on the types of radiation machines you use and how you use them. The following is a generic list of RPP elements that is common to most radiation machine users. These elements are divided into "Chapters" in this document to allow you to organize your RPP.

Required elements of the RPP include:
Radiation Safety Officer responsibilities

Facility and Machine registration
- New machine install
- Machine repair/ upgrade
- Machine transfer/disposal

Radiation Machine Evaluation

Facility Shielding Design

Operator Training/Credentialing
- Credential Requirements and Annual Review
- Radiation Machine Manual
- Colorado Regulations
- Special Safety Procedures/Policies

Quality Assurance/Quality Control Procedures

Radiation Safety Procedures

Record Retention

Annual Review

Chapter 1 – Radiation Safety Officer

All facilities that have radiation machines must identify a person as the Radiation Safety Officer (RSO) to be responsible for making sure the facility meets all regulatory requirements of the Regulations. The RSO is responsible for developing and maintaining the Radiation Protection Program discussed in this document. This requirement can be found in Section 2.4.1.1 (3)(a).

The RSO is identified on Form R-4, *Application for Registration Facility/Radiation Machines.* The XRCU must be notified if there are changes to the RSO, as the RSO is your facility's main contact for the XRCU and QI.

Part 2, Appendix 2A lists the qualifications to be an RSO. Typically the RSO is the doctor supervising the use of the x-ray machine(s) at a medical facility or the Safety Officer for an industrial site. The RSO may also be anyone who meets the requirements to be an operator of the radiation machine at the facility, such as a radiologic technologist. Some facilities will contract the RSO duties with a Colorado-registered Qualified Expert or Qualified Inspector. It is a good idea to train at least one x-ray machine operator to act as an "alternate" RSO so that they can meet with the QI during an inspection and be available to answer questions.

The following are typical tasks of the RSO:

- Establishing and overseeing operating and safety procedures that maintain radiation levels using ALARA principles.
- Ensuring that individual monitoring devices are properly used and that records are kept of the monitoring results
- Investigating and reporting to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by the regulations
- Having a thorough knowledge of management policies and administrative procedures of the facility
- Assuming control and having the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;
- Maintaining records as required by the regulations
- Ensuring that personnel are adequately trained and complying with these regulations, the conditions of the certificate of registration, and the operating and safety procedures of the registrant;

The Radiation Safety Officer for this facility is:

_____

Chapter 2 – Registration of Facility and Equipment

Facility and radiation machine registration is required by 6 CCR 1007-1 Part 2, Section 2.4.1.

Each facility is responsible for completing Form R-4, *Application for Registration Facility/Radiation Machines*. The form must be filled out and sent to the XRCU whenever there is a change in the facility name or ownership, a change in address, or any changes to the x-ray machines at the facility (Part 2, Section 2.4.6.4). The facility is required to inform the XRCU of registration information changes within 30 days of the change. This form, and instructions for filling it out, can be found on our website. There is a separate Form R-4 for a Healing Arts Facilities and for Non-healing Arts Facilities.

Starting on March 30, 2015 each registered facility will be required to submit a Form R-4 each year and pay a $50 Facility Registration Annual Fee (Part 2, Section 2.4). The R-4 form does not require machine information unless there has been a change in the facility's inventory.

The facility must maintain a list of employees who operate the x-ray machine(s) at the facility (Section 2.4.1.1(3)(b)). The list does not have to be submitted at the time of registration, but should be readily available for inspection by a QI or the XRCU. Each operator must meet the qualifications of Part 2, Section 2.6.1 before being allowed to operate an x-ray machine. Note that this section is divided into several classifications of use and that most classifications have credential requirements in one of the Part 2 Appendices.

X-ray machine sales, installation, or service may only be done by a registered Service Company (Part 2, Section 2.4.2.1). It is the facility's responsibility to use registered service companies when buying a radiation machine or when having it installed or serviced. A list of registered service companies is kept on the XRCU homepage. For human-use machines, an FDA Form 2579, *Report of Assembly*, shall be completed by the installer when a machine is installed or when a component that affects the radiation output has been replaced or installed. The installer must leave a copy of the 2579 with the registrant, send a copy of the form to the FDA and send a copy of the form to the XRCU. When an industrial use or non-human use (veterinarian) machine is installed, the Colorado Form 2579 or equivalent may be used. The registered Service Company must inform the XRCU of all sales, installations or services performed per the requirements of Section 2.7.2.

When notified by the registered Service Company, the XRCU will notify the facility of the requirement to have a routine inspection for the installed x-ray machine within 90 days (per Section 2.5.1.5). Also, any service to the x-ray machine that affects the radiation output will require a routine inspection within 90 days. See Chapter 4 of this document to read the details on the machine and facility inspection process.

At any time an x-ray machine is sold to another facility, disposed of, or removed from service, the facility is required to notify the XRCU (Part 2, Section 2.4.6.4). Form R-61, *Storage or Final Disposition of Radiation Machines* must be used and can be located at the XRCU forms web page. An x-ray machine may be put in "storage" to postpone routine inspections only if a

registered Service Company certifies the x-ray machine is disabled by signing off on the R-61 form.

Any deliberate exposure of a human being may only be for medical purposes and must be done under the supervision of a Colorado licensed physician, dentist, podiatrist or chiropractor (Part 6, Section 6.3.3.3). Procedures to expose people for research or health screening purposes (Healing Arts Screening) without a doctor's order must be approved by the XRCU. Form R-300, *Application for Healing Arts Screening,* may be used to apply for approval to do this (Part 2, Section 2.4.1.2).

Chapter 3 - SHIELDING DESIGN REQUIREMENTS

A Shielding Design is an analysis performed by a Qualified Expert that determines the radiation levels in certain areas from the use of an x-ray machine(s) in the facility. The area of concern may be the employee work area, the employee lounge area, or an area that the public has access to, such as a waiting room or a sidewalk. A Qualified Expert (QE) is a person registered with the XRCU and has the proper training and experience to determine radiation levels and calculate the amount of lead shielding required in barriers (walls, glass) surrounding the x-ray machine. Colorado regulations in Part 4, Section 4.6 limit the level of radiation that a worker or member of the general public may receive in a year. Installation of an x-ray machine following the requirements of a Shielding Design ensures the radiation exposure to workers and the general public in the vicinity of the x-ray machine will be below the regulatory limits Only a QE registered with the XCRU is authorized to perform a Shielding Design for a facility in Colorado. A list of registered QE's can be found at the XRCU homepage.

Certain machines and their uses are exempt from the requirements of a shielding design (see Section 6.3.2.4 for Healing Arts facilities). Rooms or areas that only contain the following types of X-ray machines may be exempt from shielding designs:

- Intraoral dental
- Panoramic dental
- Bone densitometry (Dexa or DXA)
- Mini-c-arm fluoroscopic
- Cabinet XRF

A Shielding Design must be completed prior to installation of a radiation machine (See Part 6, Section 6.3.2). A Shielding Design is also required if the facility replaces an x-ray machine with a different model or if the x-ray room or adjacent rooms are remodeled. When the x-ray machine is installed, the service company must follow the room layout diagram in the Shielding Design.

In order to complete a Shielding Design, the facility must send the information required in Appendix 6A in Part 6 to the QE. The type of machine, how often it is used and the occupancy of the rooms surrounding the x-ray room is information used by the QE to determine if the radiation levels in public or work areas will be below the limits in Part 4. If not, the QE will determine which walls will require additional shielding, and how much, so that the facility can safely operate its x-ray machine. For certain machines, the QE will also determine if an operator's booth is necessary (per Appendix 6B). The Shielding Design report from the QE is required to have certain information, including a diagram showing the position and orientation of the x-ray machine, for the installer to follow when they assemble the x-ray machine (per Appendix 6C).

If a room is used for mobile or portable x-ray machines (other than dental, bone densitometry or mini c-arm) it may require a shielding design. Rooms in which portable units are used routinely, regardless of the frequency, will require a shielding design. An example of this is a clinic that uses a portable machine to take x-rays in one or several rooms. Each room is

required to have a shielding design performed by a QE. Intensive Care Units in a hospital are not required to have a shielding design when a portable machine is used in them.

It is recommended that the registrant review Part 6, Section 6.3.2 for further information with reference to shielding analysis/designs for a facility.

Chapter 4- ROUTINE AND NON-ROUTINE INSPECTIONS

Routine Inspections

The registrant is required to have each x-ray machine in use certified by a Qualified Inspector (QI) at the schedule required by Part 2, Section 2.5.1. Certification evaluations are also known as **"routine inspections"**. A list of QI's is maintained on the XRCU web page. QI's are approved for only certain types of radiation machines. The list available on the XCRU web site indicates the types of machines each QI is approved to inspect. QI's are not XCRU employees and their fees are not regulated by the XCRU. Also, XCRU staff does not perform routine x-ray machine inspections. A facility is required to complete each routine inspection process with the QI who started the inspection, unless specific approval is given to the facility from the Department.

The frequency required for inspections depends on the type of machine and its use. Most machines used to expose people for medical purposes (Healing Arts) must be inspected annually. Most dental machines are inspected every three years, except for the hand-held units or the cone-beam units. X-Ray machines used for Veterinary purposes are also inspected every three years. Most industrial use units are inspected every two years. Please review Part 2, Section 2.5.1 for details.

X-ray machine certification is also required whenever a machine is moved (disassembled and reassembled in a different location) or when a major component is repaired or changed. Replacement of a high voltage generator, timer circuits, or image receptor systems (i.e. converting to digital) are examples of service that would require a routine inspection within 90 days.

See Part 2, Sections 2.6.2, 2.6.3 and 2.6.4 (pages 2-17 to 2-18) for specific regulations pertaining to the inspection process. The QI will complete the forms 59-1, *X-Ray Machine Certification Evaluation Report* and 59-2 *X-ray Facility Compliance* to report the findings of the inspection. The QI, Service Company and Facility are required to follow the instructions provided on these forms (Section 2.6.2).

The QI will complete Form 59-1, *X-Ray Machine Certification Evaluation Report* for each machine inspected at the facility. The top (white) copy will be sent to the Department to verify the machine has met all regulatory requirements. The green copy (or equivalent) is the facility's copy to be kept on file. If machine performance violations are found, the QI must notify the facility immediately and the facility must have the machine repaired by a registered Service Company within 30 days (per Section 2.6.3.1). The service engineer that performed the service must sign Section III, Service Repair Certification on the R-59-1 form, certifying that repairs or corrections to the equipment have been completed and the machine meets regulatory requirements (per Section 2.7.4). After the violations have been corrected, the inspector will complete the R-59-1 form and issue a certification label for the x-ray machine (Section 2.5.2.4). The white (top) copy of this form shall be sent to the Department to document the corrective action. The green copy (or equivalent) must be kept in the facility's files.

The blue, metallic, certification label issued by the QI must be affixed to the radiation machine so that both the operator and patient (if applicable) can see it (Section 2.5.2.4(3)). The label shows the facility registration number, the QI number, and the expiration date for that machine certification. It is the facility's responsibility to schedule a QI to complete the machine inspection before the last day of the month of the expiration date is past.

If the QI finds violations that are not related to machine performance (i.e. facility violations), the QI will leave a copy of Form 59-2, *X-ray Facility Non-Compliance Certification Evaluation* listing each violation found. When facility violations are cited, the registrant must correct each violation listed on the form and then sign the top (white) copy at the bottom (Section 2.6.4). The registrant must send the white copy (or equivalent) along with documentation of corrective actions to the Department within 30 days of the inspection. The registrant must keep the green copy for their records and have them available for inspection by a QI or XRCU inspector.

If corrective actions are not received by the XRCU in a timely manner, the registrant may be subject to a **non-routine inspection** by XRCU staff. An inspection fee of $152 per hour may be charged to the registrant if violations are found during a non-routine inspection (Section 2.9).

XRCU Staff may perform audits of facilities to determine if facilities, QI's or Service Companies are compliant with the Regulations. If the audit determines that regulations were not followed, the facility, the QI, or the Service Company may be charged for a non-routine inspection.

Chapter 5 – OPERATOR TRAINING / CREDENTIALS

Credential Requirements

Different credentials are required for different radiation machine operators as described in Section 2.6.1. Appendices 2D through 2N lists the specific requirements for operators of certain types of machine uses. Facilities using x-ray machines for Medical, Chiropractic, Dental, Podiatric or Veterinary purposes are considered "Healing Arts" facilities. Facilities using x-ray machines for nondestructive testing, material analysis, package scanning, etc that do not involve the deliberate exposure of humans are considered "Industrial" facilities.

Each facility shall keep x-ray machine operator credentials on file and document that there is verification of the credentials at time of hire and annually. The verification must be "primary source verification" meaning that you must be able to determine the validity of the credentials with the issuing organization. Fraudulent credentials provided by x-ray machine operators to facilities will be investigated to the extent of the law and will be prosecuted with fines and penalties.

Any Colorado-licensed physician, dentist, chiropractor or podiatrist is considered adequately trained to operate an x-ray machine in the course of their practice. Physician Assistants and Nurses may not operate x-ray machines in a medical practice even under supervision unless they meet the requirements in Section 2.6.1. In the healing arts facilities, the term "operator" refers to the person(s) involved in the complete radiographic process including patient positioning, technique selection and machine operation. This means that a person involved with any part of the radiographic process must meet the credentialing requirements of Section 2.6.1.

An individual currently registered with the American Registry of Radiologic Technologist (ARRT) as a Radiologic Technologist is considered adequately trained to operate diagnostic x-ray equipment. An individual who is registered with the XRCU as a Limited Scope Operator (LSO) may operate general diagnostic x-ray machines, but is not allowed to operate fluoroscopic (including c-arms and mini c-arms), computed tomography, mammography, or bone densitometry machines. See Section 2.6.1 for details.

Fluoroscopy
Operators of, and doctors supervising the use of, fluoroscopic radiation machines on humans are required to have additional training related to radiation safety of fluoroscopy (see Section 2.6.1.5). Fluoroscopic machines include c-arms, o-arms and mini c-arms. These machines have a potential to cause severe radiation damage to both the patient and operator.
The fluoroscopy training by itself will not be considered sufficient training to operate a fluoroscopy machine. The fluoroscopy training must be in addition to the training required in Section 2.6.1. This additional training is required once before operating or supervising the use of a fluoroscopic system.

Dental
Dental practices licensed under the Colorado State Board of Dental Examiners are required to document training required in 3 CCR 709-1, Rule X, "Minimum Standards for Qualifications, training and Education for Unlicensed Personnel Exposing Patients to Ionizing Radiation". At this time, that Board requires that dental x-ray machine operators have 8 hours of training to include dental nomenclature, machine operation exposure factors, operator and patient safety, practical or clinical experience in intra/extra - oral techniques for exposing radiographs, appropriate film handling and storage, appropriate processing procedures, and appropriate patient record documentation for radiographs. This training may be provided by the licensed dentist or dental hygienist as long as the training module is approved by the Dental Board. New operators must be trained within 3 months of employment. Please contact the Colorado Dental Association at 303-740-6900 to get an approved training program.

Chiropractic
Chiropractic practices licensed under the Colorado State Chiropractic Board are required to document the requirements in 3 CCR 707-1, Rule 19, "Safety training for Unlicensed Chiropractic Personnel. At this time, that Board requires that chiropractic x-ray machine operators have 24 hours of training to include basic radiological guidelines, operator and patient safety, and practical and clinical experience in radiographic production, beam imaging formation, density, contrast, filtration, collimation, processing techniques, chart selection, positioning, examinations, high speed film selection, film marking, film storage, and darkroom procedures. The Chiropractic Board regulations require that the training be done through a Board-approved program.

Veterinary
Veterinary practices licensed under the Colorado Board of Veterinary Medicine are required to follow the requirements of 4 CCR 727-1. At this time, that Board does not specify requirements for Veterinary technicians or assistants who operate x-ray machines. However, Radiation Regulations Section 6.3.3 requires training on basic radiation safety principles for each x-ray machine operator. See Chapter 8 of this document for information on required radiation safety practices that all x-ray machine facilities must follow.

Podiatry
Podiatry practices licensed under the State of Colorado Podiatry Board shall have documentation of training required by 3 CCR 712-9, Rule 700 for those individuals operating x-ray machines. At this time, that Board requires that podiatric x-ray machine operators have at least eight hours of educational instruction or supervised training in each of the following areas, podiatric nomenclature, machine operation exposure factor, operator and patient safety, and practical or clinical experience in foot and ankle techniques for exposing radiographs, film handling and storage, processing procedures, and patient record documentation for radiographs.

Industrial
Operators of industrial radiation machines must meet the requirements of Appendix 2N in Part 2. These training requirements are intended to be commensurate with the radiation

hazards of the radiation machine in use. For example, only one hour of training is required for an analytical cabinet-style unit or a security package scanning machine because the construction of these machines greatly reduces the risk of radiation exposure to operators and the public. All operators must be trained on the operator's manual and the safety features of the unit such as interlocks and "emergency off" switches. Please be aware that Industrial Radiography operators must meet the training requirements of Part 5.

The facility RSO must ensure the training of each operator on procedures and safety issues that are specific to the machine(s) used in the facility. In addition to initial training requirements, most operators of machines used in the healing arts must show continuing education in their field.

CREDENTIALS OF X-RAY OPERATORS

The following is a list of each radiation machine operator at this facility. Each operator listed below has credentials necessary to meet the requirements of Part 2, Section 2.6.1, inclusive. These credentials will be verified each year during the review of this radiation protection program.

Employee Name	Date Hired/ Terminated	Credential Verification

Chapter 6 - Employee Notification

The Regulations require communication of potential radiation hazards to workers at facilities where radiation producing machines are operated. The operator must be aware of how to safely operate the radiation machines.

Part 10, Section 10.2 lists requirements all facilities must meet including:

- The regulations in Part 10 and Part 4 must be made available to all workers.
- The Facility Registration information must be made available to all workers.
- Any procedures dealing with the operation of the radiation machines at the facility must be made available to workers.
- Any notice of violations and/or corrective actions must be made available to all workers.
- Each facility/registrant is required to post a current copy of the "Notice to Employees", Form OR-RH-15. This form can be found on our website.

These documents can be posted in a common work or lounge area or a notice can be posted to inform the workers where this information can be found. Posting must be in sufficient areas so that all employees are made aware of this information.

Inspection reports or notices of violations are to be posted for at least five working days or until corrective actions are completed, whichever is longer.

Operator Manuals

All facilities that use radiation machines in their operation are required to use adequately trained individuals as radiation machine operators (Section 2.6.1). For facilities using radiation machines in the healing arts, Section 6.3.1.9 also requires that operators are adequately trained. In addition to radiologic imaging and basic radiation safety knowledge, operators must read the operator's manual for the x-ray machine they are using.

Facilities are required to have a manual for each type of x-ray machine in the facility available to the x-ray machine operators (Section 2.6.5.3). If a manual is not available, the facility must create a manual that meets the regulatory requirements. This operator's manual must be kept on site and shall be made available to all those operating or servicing the x-ray machines.

Special Procedures

It is important that the facility keep their employees informed of changes to the work area that affect their radiation safety. Employees must be trained on any special procedures the facility develops for x-ray machine use. Many of these special procedures involve the use of safety equipment such as lead aprons or portable shields. Chapter 8 of this document discusses the procedures many facilities must use to keep radiation exposure to employees and the public as low as possible.

Chapter 7 – RECORD RETENTION REQUIREMENTS

There are certain records that a facility is required to maintain according to the Regulations (see Section 2.6.5). These records deal with operator training, radiation machine maintenance, facility registration, and patient images (when applicable). The facility is required to keep these records on file at the facility. The QI will review these records during the inspection. It is recommended these files be kept in the same binder or file as the items for ALARA program and other policies and procedures, however, the facility should be aware of HIPAA restrictions regarding patient identification security.

Operator Training:

- Section 2.6.1.1 requires that the facility document the evaluation of each operator's credentials and keep a list of operators. The page following Chapter 5 of this document may be used for that purpose.
- This section also requires that the records include any certifications that prove the operator meets applicable requirements. These records must be kept current and be available for review by the QI.
- Note that if the facility uses fluoroscopy machines on humans, the facility must show additional training for fluoroscopy operators and those doctors supervising the use of fluoroscopy machines.

Radiation Machine Records

- Facilities must keep complete records of x-ray machine service and repair. Certain service or repair of an x-ray machine may require it to be re-certified by a QI.
- Records of x-ray machine inspections and facility inspections are covered in Chapter 4 of this document. Facilities must keep copies of Forms 59-1 and 59-2 for review by the QI and the XRCU.
- The facility is required to maintain service and repair reports, and radiation machine inspection reports for three years (six years for a facility or machine inspected only every three years such as Dental, Podiatry, or Veterinary machines).
- Healing Arts facilities must maintain records of each patient's exam, to include the patient's identification, the operator's name, and the type and date of the exam.

Facility Registration:

- See Section 2.6.5 and Section 6.3.4 for regulations on retention of facility records.
- The facility is required to maintain the shielding design report, including the facility diagram and survey readings, for review by the QI. This report must be kept with the facility, even if the ownership changes. Once the shielding design is completed, the registrant must keep the design/report on file permanently. See Sections 2.6.5.2 and 6.3.2.3.
- If a facility is cited for either a machine of facility violation, the facility is required to keep that notice of violation for three years (six years for a facility or machine inspected only every three years).

Chapter 8 – RADIATION SAFETY PROCEDURES

The following Chapter discusses the typical radiation safety procedures that are either required by regulations or are present in nationally accepted guidance documents. The National Council on Radiation Protection and Measurements (NCRP) publishes reports on a variety of radiation protection issues in medical and industrial uses. Many times, the content of these reports become the basis for regulation.

- The facility is required to adopt written policies and procedures that address radiation protection practices for radiation workers (Section 4.5.1). Radiation Workers are defined as employees who operate x-ray machines or are exposed to x-ray radiation during their work duties. These policies and procedures must address each paragraph under Section 6.3. These policies and procedures are commonly known as the "ALARA" Policy for As Low As Reasonably Achievable.

- Training on these procedures must be documented for each employee who operates an x-ray machine or is exposed to ionizing radiation during their work duties.

- Each employee must review these policies and related procedures on an annual basis.

Items to be included in the ALARA Policy

Occupational Dose Monitoring

- Employees must be at least 18 years of age to operate x-ray machines or be exposed to radiation during their work duties.

- The facility must determine if the x-ray machine operator has received radiation exposure from a previous or current employer in the calendar year. All radiation exposure received from other employers must be considered when comparing the employee's exposure to the limits in Section 4.6.1.

- The occupational dose for the whole body must not exceed 50 mSv (5000 mrem) per year. Occupational dose limits are defined in Section 4.6.1.1 of the Regulations.

- Facilities are required to monitor the radiation exposure for each radiation worker (Section 4.18). Radiation workers may not share dosimetry badges and the facility is responsible to ensure that dosimetry badges are secure to prevent accidental or deceptive exposure (Section 4.17.4).

- The dosimetry service must be accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) A link to a list of vendors at the NVLAP web site is available on our website. A vendor will provide you with a dosimetry monitoring program appropriate for the types of x-ray machines used at your facility.

- Results of the badge monitoring must be kept on file at the facility and reviewed at least annually with each employee who is monitored. The review of the dosimetry monitoring reports with each employee must be documented (Section 4.18.3.2(2)).

- Control badges shall be kept in an area away from radiation sources. This badge is used to subtract exposure to the employee dosimetry badges during the mailing process.

- A dosimetry badge shall be kept for each individual radiation worker. Dosimetry badges cannot be shared. Dosimetry badges must be worn during work activities when an exposure to radiation is possible.

- Employee dosimetry badges shall be stored in an area free of radiation when not worn. Employee badges should also be kept secure so that a badge is not exposed to a deceptive or erroneous dose (Section 4.17.4).

- Workers who are "Declared Pregnant" must be monitored according to the requirements of Section 4.13.

- Any questions about radiation dose monitoring or overexposure should be referred to the XRCU or your QI. Section 4.52 lists reporting requirements for certain overexposure conditions.

- Proper care and usage of dosimetry badges should be reviewed with every employee annually.

Quality Assurance and Quality Control Program

- Healing Arts Facilities involving exposure of human patients shall monitor all radiographic processing equipment by establishing an ongoing quality assurance (QA) program. Very often the operator manual will list the manufacturer's quality control testing procedures.

- Section 6.3.5 shall be reviewed by every facility to determine the Quality Assurance program for their equipment and facility. If a facility has any questions, they should contact the XRCU or a Registered Medical Physicist. See Chapter 9 for more details.

General Employee Safety

Utilization of Time, Distance and Shielding Policy

- Three radiation safety factors should be incorporated in the ALARA policy that all employees should follow:

    - **Time**: The shorter the time of the exposure, the lower the total radiation dose received.

- **Distance**: The effect of radiation exposure decreases by ¼ if the distance is doubled.

- **Shielding**: Protection from the radiation source will reduce the dose. Whenever possible, lead protective equipment shall be worn by the patient and staff to reduce dose from the useful beam and scatter radiation, respectively.

    - Check condition of lead apparel for tears and holes periodically and document evaluations.

Patient Holding Policy

- Patients shall not be routinely held by staff during x-ray exposures. Mechanical or other devices shall be utilized whenever possible. Section 6.3.3.8 should be reviewed when developing the facility policy.

- Only the patient being radiographed and necessary staff should be in the room during an exposure.

- When staff or ancillary personnel are required to be in the room during exposures, they are required to wear protective aprons made of at least .25 mm lead equivalent material or be at least 2 meters from the tube head.

- If the procedure causes the exposure of facility staff to the direct beam, the exposed area shall be protected by at least 0.5 mm lead-equivalent material.

Pregnancy Policy for Employees

- Employees may declare their pregnancy in writing to the designated Radiation Safety Officer or doctor in charge.
- Once pregnancy is declared, the Radiation Safety Office must determine the estimated dose to the fetus since conception. Dose monitoring badges must be supplied to the pregnant employee during the gestation period. One badge is worn at the employee's collar to measure dose to the employee and one badge is worn at the employee's waist (under the lead apron) to measure dose to the fetus.
- It is not necessary to place work restrictions on the employee during pregnancy unless the fetus could receive more than the limit of 50 mrem per month. Dose limits for the pregnant employee are outlined in Section 4.13 with the limit to the fetus during pregnancy to be no more than 5 mSv (500 mrem) total.

General Patient Safety

- Only individuals who have been adequately trained in operating x-ray machines will perform an x-ray procedure.

- Collimation of the x-ray beam shall be done, whenever possible, without compromising the area of interest (Section 6.3.3.1(3)(b)).

- Facilities must use a documented protocol for technique factors when exposing human patients. Technical factors that are computerized and can be selected on the control at the x-ray machine will be sufficient as long as the staff follow the protocols.

Gonad and Thyroid Shielding Policy

- Shielding of patients is outlined in Part 6, Section 6.3.3.5 and 6.3.3.6. Gonad shielding of at least 0.5 mm lead-equivalent will be used when the patient's reproductive organs are in the direct beam except when it interferes with the image procedure.

- Thyroid shielding of at least 0.25 mm lead equivalent will be used when the thyroid is within the direct beam unless the shielding interferes with the image procedure.

Pregnancy Policy for Patients

- Signs should be posted in areas such as dressing rooms, exam rooms or at the reception desk that say, for example, "If you think you are pregnant, please tell your doctor, hygienist, technologist or assistant."

ANNUAL RADIATION REVIEW FOR RADIATION WORKERS

As part of the ALARA Policy of the facility, all personnel shall review the radiation safety practices annually.

Employee Name	Review Date

Chapter 9 – QUALITY ASSURANCE/QUALITY CONTROL FOR RADIOGRAPHIC EQUIPMENT USED IN THE HEALING ARTS

Both x-ray machines and the systems to generate a radiographic image require regular testing and to ensure that they are working properly so that the best possible image is obtained. The Quality Assurance (QA) program for x-ray machines includes the preventative maintenance suggested by the manufacturer, the quality control tests listed in the operator's manual, and the performance evaluation (i.e. inspection) done by a QI or RMP. Systems that generate the radiographic image must also have a documented QA program to ensure a high-quality image. Sub-standard images in the healing arts could result in improper diagnosis and the need for repeat images which increases the patient's risk of harm from radiation exposure. Both are serious liabilities that can be prevented by a sound QA program.

A typical QA program lists Quality Control (QC) tests and the frequency the tests are to be performed. Quality control tests may be described in your x-ray machine operator's manual or provided by a Registered Medical Physicist. There are also quality control tests for the image processing systems (laser printers or digital monitors). It is very important that all QC test results are documented.

Part 6, Sections 6.3.5.1 - 6.3.5.9 identifies the specific QA requirements based on the type of the image processing method. In general, all facilities must follow the manufacturer's recommendations for quality testing to ensure a high quality radiographic image. If the manufacturer does not specify procedures to test image quality, the facility should consult with a medical physicist to develop an appropriate program. There are also guidance documents that suggest standard quality control tests for the various imaging systems. National organizations that publish guidance documents on QA procedures are the American Association of Physicist in Medicine (AAPM) and the Conference of Radiation Control Program Directors (CRCPD).

- General Requirements
    - Speed of the imaging system shall be the fastest speed or speed equivalent consistent the diagnostic objective of the examination (Section 6.3.3.9).
    - A log or schedule of patients shall be kept to identify the imaging procedure and the operator who exposed the patient (Section 6.3.4.4).
    - Facilities must review reasons for repeated or rejected images (Repeat/Reject Analysis) and apply corrective actions to avoid their occurrence (Section 6.6.5.2).
    - Expired film and processor chemicals shall not be used.
    - Film cassette screens shall be cleaned according to the manufacturer's recommendations. Film cassettes will be in good working order.
    - Facilities shall investigate QC tests that fall outside of the control range.

- Automatic Processors using liquid chemistry
    - The facility shall keep logs of processor temperature and sensitometric monitoring as recommended by the manufacturer (Section 6.3.5.3).

    - Darkroom fog shall be checked at least annually and corrective actions shall be taken if the requirements of Section 6.3.5.5 are not met.
    - Processing chemicals changed and routine cleaning done on a regular basis or according to manufacturer guidelines

- Computed Radiography (Section 6.3.5.8)
    - CR Cassettes shall be erased and maintained according to the manufacturer's specifications.

- Monitor QC requirements (Section 6.3.5.7)
    - Follow the monitor manufacturer's recommended QC processes.

- Laser Printer QC requirements (Section 6.3.5.2)
    - Measurement of low, medium and high optical density steps produced on a periodic frequency based on manufacturer's recommendations. The measured optical densities should be consistent.
    - If the printer's manufacturer does not have procedures for sensitometric testing, the facility may consult with a medical physicist or follow procedures from a national organization such as the AAPM or CRCPD.

- Darkroom (Section 6.3.5.6)
    - Film storage and pass boxes must not allow light into the darkroom and undeveloped film storage in the darkroom must be shielded from radiation sources.

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Radiation Safety Check List

Yes/No/NA	
1. **Facility/ X-Ray Machine Registration** –	
	An R-4 Form has been submitted to the XRCU
	Any change in the company name, address, RSO, or radiation machines have been submitted to the XRCU on Form R-4.
	All radiation machines have been registered using the R-4 Form.
	A Form R-61 has been submitted for any radiation machine recycled, sold to another facility or otherwise transferred from this facility. Machines kept in storage have been disabled by a Colorado-registered service company.
	All installations of radiation machines have been performed by a Colorado registered service company.
	Annual Registration Fee has been paid.
2. Facility/ X-Ray Machine Inspection	
	All radiation machine installations or re-assemblies have been inspected within 90 days of installation.
	Each machine that was converted to digital or had a major component replacement has been inspected within 90 days.
	Each radiation machine has been inspected by the expiration date stated on the blue, metallic certification label.
	Inspection violations have been corrected within 30 days.
	Signed white copies (or equivalent) have been sent to the XRCU.
	All repair or service to the radiation machine has been done by a Colorado-registered service company.
3. Shielding Design	
	The shielding design for each x-ray room has been done, if required, and is filed with the RPP.
	A new shielding design has been developed for any changes to the radiation machine, its orientation, the room construction or the use of the surrounding rooms.
4. Operator Training/Credentialing	
	Operators meet the applicable training requirements of Section 2.6.1
	Operator's manual is available and understood by operators
	Operators are trained on the safety policies of the facility
	Operators are trained on the applicable regulations
5. Postings	
	Current Notice to Employees
	Current Regulations
	Any Violations and Corrective Actions
6. Record Retention	
	Shielding Design/Analysis
	Report of Assembly for each x-ray machine

	Equipment Service Manuals/Tube Rating Charts
	X-Ray machine service reports
	Correspondence from the Department
	Records of x-ray machine inspection
	Dosimetry Badge Monitoring Records
7. Dosimetry Monitoring	
	Each operator and radiation worker has a unique badge
	Dosimetry badges are exchanged according to the facility policy
	"Control Badges" are shielded from radiation until shipment
	Worker's badges are secure from tampering and kept in a low radiation area when not in use.
8. Healing Arts Screening Requirements	
	All exposures involving human patients are ordered by a Physician, Dentist, Chiropractor, or Podiatrist
	Radiographic exams not ordered by a doctor are approved by the Department as part of a Healing Arts Screening Program.

ANNUAL REVIEW FOR RADIATION SAFETY

(Facility Name)

As the Radiation Safety Officer, I have determined that all requirements as outlined in the 6 CCR 1007-1, Colorado *Rules and Regulations Pertaining to Radiation Control* have been met and are being monitored. The review of the policies and procedures for this facility are updated and reviewed annually. Revisions to our Radiation Protection Program will be the responsibility of the Radiation Safety Officer to meet the requirements of the Colorado *Rules and Regulations Pertaining to Radiation Control*.

Signed and dated for each review.

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