Minnesota Department of Health
Radiation Control, X-ray Unit

Protecting, maintaining and improving the health of all Minnesotans by promoting radiation safety through guidance and collaboration with the radiation community

X-RAY
REGULATORY GUIDE

CHIROPRACTIC X-RAY FACILITIES

February 1, 2015

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INTRODUCTION TO THE REGULATORY GUIDE FOR CHIROPRACTIC REGISTRANTS

Minnesota Department of Health Mission, X-ray Program Mission
The mission of the Minnesota Department of Health (MDH) Radiation Control X-ray Unit is to protect and promote radiation safety through guidance and collaboration with the radiation community. Our vision is to reduce unnecessary radiation exposure from the use of ionizing radiation producing equipment.

Introduction
This guide is designed to describe the type and extent of a radiation safety/quality assurance program necessary for the safe use of x-ray equipment and compliance with Minnesota Rules, Chapter 4732 in chiropractic facilities. The information in this guide is not a substitute for radiation safety/quality assurance training or for developing and implementing an effective radiation safety/quality assurance program. You should carefully study this guide and Minnesota Rules, Chapter 4732.

http://www.health.state.mn.us/divs/eh/radiation/xray/rules/index.html

This guidance, instructions, and additional information are available on the X-ray Unit website as they are developed.

http://www.health.state.mn.us/xray

Implementation
The information in this guide is intended to assist in compliance with Minnesota Rules, Chapter 4732. This guide provides one set of methods approved by MDH for meeting the regulations and represents the minimum acceptable standards. MDH has included many useful guidance documents to assist you in creating your radiation safety/quality assurance program and complying with the Minnesota Rules, Chapter 4732. If you have questions, please contact the Radiation Control, X-ray Unit at (651) 201-4545 or email at health.xray@state.mn.us.

Revisions to the MDH Regulatory Guide for Chiropractic X-ray Facilities
MDH X-ray Unit is always striving to better the information that we provide to the chiropractic registrant. This may include additions to the information presented in this guide. There may be occasion for revisions to this guide. These revisions are not changes to Minnesota Rules, Chapter 4732 and are intended to clarify or supplement what is already within the guide.

Any revisions to this guide will be documented in the Summary of Revisions at the end of this guide.

Note: Ionizing radiation producing equipment will be identified as "x-ray equipment" throughout this guidance document.

APPLICATION FOR REGISTRATION (4732.0200)

All facilities or individuals in possession of x-ray equipment must apply for registration using the current application process provided by the commissioner. Registration with payment must be completed by the facility and submitted to MDH. The Initial Registration application may be found on our website.

Note: Your service provider is not responsible for the registration of your facility or x-ray equipment. Service providers are required to notify MDH when they deliver or install x-ray equipment in your facility. This is in addition to your application requirements for registration and notification to MDH.

ADDITIONAL REGISTRATION INFORMATION

- Registrants, who purchase replacement x-ray equipment, must notify MDH within 30 days of obtaining the replacement equipment.
- Registrants who purchase additional x-ray equipment must submit a registration using the current application process provided by the commissioner and submit a fee for each new tube within 30 days of obtaining the equipment and prior to use.
- Registrants must notify MDH when there is a change in ownership or when x-ray equipment is placed in storage or removed from the registrant's physical location. This is to ensure the following:
    1. X-ray equipment is only possessed, used, or controlled by persons who have valid MDH facility registrations
    2. X-ray equipment is properly handled and secured
    3. Public health and safety are not compromised by the unauthorized use of x-ray equipment
- The Additional Registration application may be found on our website.

FEES (4732.0210)

Fee Type	Amount
Facility Base Fee: (due initially and annually only)	$100
X-ray Equipment Fee	$100

Submit your registration online at www.health.state.mn.us/xray or mail to:

Minnesota Department of Health
Radiation Control X-ray Unit
625 Robert Street North
PO Box 64497
St. Paul, Minnesota 55164-0497

INDIVIDUAL RESPONSIBLE FOR THE RADIATION SAFETY/QUALITY ASSURANCE PROGRAM (4732.0500)

You are responsible for x-ray equipment that is under your administrative control and must ensure your site specific radiation safety/quality assurance program, your staff and the use of your x-ray equipment is in compliance with Minnesota Rules, Chapter 4732. To ensure adequate oversight is provided to your site specific radiation safety/quality assurance program, a radiation safety officer must be designated and identified within your radiation safety/quality assurance program.

RADIATION SAFETY OFFICER (RSO) (4732.0500 - 4732.0505)

The Radiation Safety Officer (RSO) is responsible for the day-to-day operations of your radiation safety/quality assurance program. The RSO must receive RSO specific training and has additional responsibilities beyond his/her day to day job duties. The RSO must be provided sufficient time and commitment from your management to stop operations that he/she considers unsafe, ensure x-ray equipment is used safely, and maintain compliance with Minnesota Rules, Chapter 4732. These responsibilities, time and commitment must be delegated in writing from your management to the RSO.

> ***Note: When the registrant is also the RSO, an RSO Delegation Agreement does not have to be completed. You must notify MDH in writing when there is a change to your RSO delegation.***

Additional Radiation Safety Officer Information can be found in Attachment A at the end of this guide:

- Typical duties and responsibilities
- Training and experience requirements
- Radiation Safety Officer Delegation Agreement
- http://www.health.state.mn.us/divs/eh/radiation/xray/rso.html

Radiation Safety Officer Responsibilities

Radiation Safety Officer Responsibilities	
Ensuring the safe use of radiation	Managing the Radiation Protection Program
Identifying x-ray radiation protection problems	Ensuring quality control tests are documented and completed
Recommending and providing corrective actions	Verifying implementation of corrective actions
Stopping unsafe activities	Ensuring compliance with state regulations

OPERATOR QUALIFICATIONS

Individuals who operate x-ray equipment on humans must meet the minimum qualification requirements of Minnesota Statute 144.121. The term operator of x-ray equipment is used when discussing all qualified individuals. This is not to be confused with Minnesota X-ray Operator who was required to meet specific qualification requirements.

The following list includes examples of individuals qualified to operate x-ray equipment on humans:

- Licensed Practitioners of the Healing Arts
- American Registry of Radiologic Technologists (ARRT) Radiologic Technologist
- ARRT Limited Scope X-ray Operator
- American Chiropractic Registered Radiologic Technologist (ACRRT) Radiologic Technologist
- Minnesota X-ray Operator, prior to January 1, 2008 are Grandfathered in

Qualifications must be maintained for all operators of x-ray equipment and available at the time of the inspection. Qualification records for employees who have terminated employment must be maintained until your next inspection by the MDH X-ray Unit.

A complete listing of qualified individuals can be found in Attachment B.

OPERATOR TRAINING

Minnesota Rules, Chapter 4732.0510 require that all individuals operating x-ray equipment must receive initial training in facility specific and system specific safe operating procedures, emergency procedures, quality control procedures, and proper protective shielding. Additional training must be conducted when there is a change to the radiation safety/quality assurance program, when existing x-ray equipment is upgraded, or when new x-ray equipment is added.

Additional training is required for staff that uses:

- Computed Tomography (CT), Minnesota Rules, Chapter 4732.0860
- Fluoroscopic x-ray equipment, Minnesota Rules, Chapter 4732.0825

Additional facility specific training requirement information can be found in Attachment C.

The exposure of an individual for training, instruction, demonstration, or maintenance is prohibited. The use of x-ray equipment for these purposes will result in enforcement action that may include an administrative penalty of up to $10,000.

OPERATION OF X-RAY EQUIPMENT

MDH Statute and Rule require specific qualifications for the operation of x-ray equipment. The qualification requirements are addressed in the Operator Qualifications section. MDH identifies operation of x-ray equipment to include the use, manipulation, or adjustment of any components for the controlled production of x-rays that may affect the dose to the patient, occupational staff, public or the quality of the raw image. This includes minimally x-ray equipment and x-ray system that are defined in Minnesota Rules, Chapter 4732.0110. These components would include:

- X-ray high-voltage generator
- X-ray control
- X-ray tube housing assembly
- X-ray beam-limiting device
- The necessary supporting structures

The following items are examples of operating x-ray equipment:

- Positioning or repositioning of the patient table during activation of the x-ray beam
- Setting or the adjustment of the x-ray control
- Manipulating the image intensifier and x-ray tube
- Manipulating the collimators
- Manipulation or adjustment of any components that may affect the dose to the patient, occupational staff, public or the quality of the raw image
- Making the exposure
- Evaluating quality control tests

The following items are examples of what is not considered "operation" of x-ray equipment and may be performed by individuals who have not met the required operator qualification requirements:

- Movement of the portable x-ray equipment into a room
    1. Make the necessary equipment connections
    2. Plug the x-ray unit in
- Turning on the "power" to the x-ray equipment
- Inputting the patient identification and examination information
- Movement of the x-ray equipment, x-ray table or image receptors prior to the patient being positioned for the examination
- Processing patient films
- Post-processing of the digital images

OPERATION OF FLUOROSCOPIC X-RAY EQUIPMENT

Operation of fluoroscopic x-ray equipment must be performed with a licensed practitioner of the healing arts, physician assistant, registered radiologist assistant, or radiology practitioner assistant physically present in the room, per Minnesota Rules, Chapter 4732.0306.

Note: This does not exempt the operator of x-ray equipment of the qualification requirements in Statute 144.121, and Minnesota Rules, Chapter 4732.0570 through 4732.0590.

Fluoroscopic operation must only be performed by the following individuals who have met the qualification requirements:

- A licensed practitioner of the healing arts defined in Minnesota Rules, Chapter 4732.0110
- An individual who has taken and passed the ARRT registry for radiography
- An individual who has taken and passed the ACRRT registry
- An individual who had taken and passed the X-ray Operator Examination as required in Chapter 4730

Note: Individuals who have taken the ARRT Limited Scope X-ray Operator (LSXO) examination or the ACRRT Minnesota Limited X-ray Operator examination have not met the fluoroscopic x-ray equipment qualification requirements and are not qualified to operate fluoroscopic equipment.

RADIATION SAFETY/QUALITY ASSURANCE PROGRAM (4732.0520)

You are required to have a site specific radiation safety /quality assurance program in place prior to first use of your x-ray equipment. A radiation safety/quality assurance program includes administrative, radiation safety and quality control procedures to ensure:

- Occupational staff, the patient, and the public are protected through the safe operation of x-ray equipment
- Consistent, high-quality images will be produced with a minimum exposure to occupational staff and the public
- Compliance with state regulations

Your radiation safety/quality assurance program must include:

- Radiation Safety procedures for the safe and proper use of the x-ray equipment
- Quality control procedures to include tests used for routine assessment of an x-ray imaging system specific to your x-ray equipment and processing systems
- Training of the operators of x-ray equipment including documentation
- Radiation program audits
- Equipment performance tests, including a list of the required tests, can be found in Attachment E of this guidance document

RADIATION PROGRAM AUDIT (4732.0540)

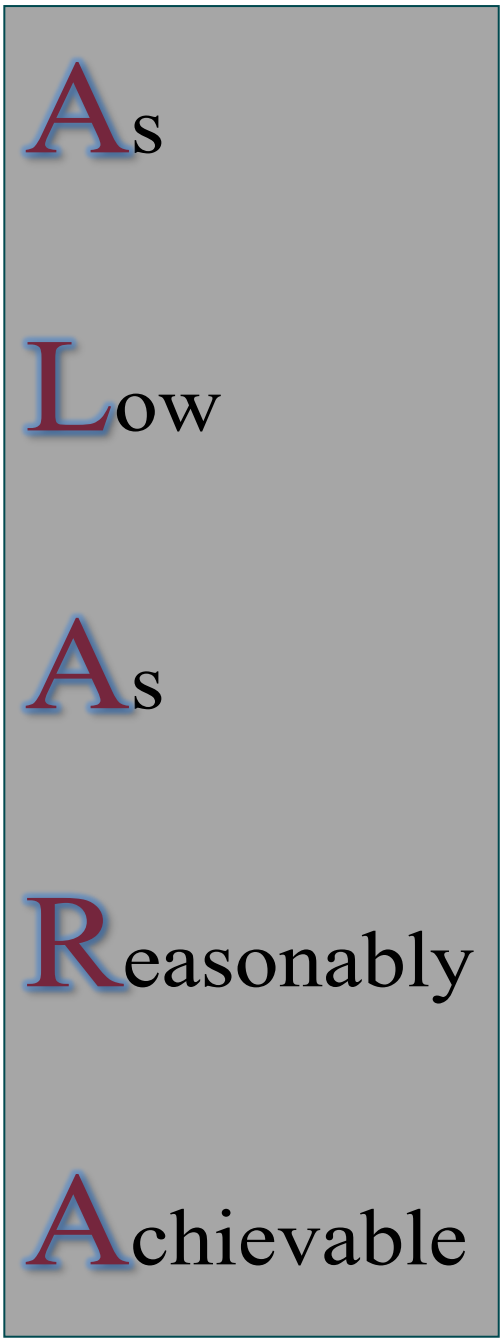
The RSO and management are required to audit your radiation safety/quality assurance program to ensure the continued safe use of chiropractic x-ray equipment at intervals not to exceed 12 months. An audit is a review of your established radiation safety/quality assurance policies, procedures, and their implementation to ensure the safe operation of the x-ray equipment, protection of your staff, your patients, the public, and compliance with Minnesota Rules, Chapter 4732. It is essential once problems are identified they are addressed and corrected promptly and comprehensively. At the time of an MDH inspection, inspection staff will review your radiation safety/quality assurance program audit and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence.

An audit program for a chiropractic office should include, at minimum, a review of:

- Operating and emergency procedures
- Quality control procedures
- Operator qualifications and required training
- Proper use of holding devices and personal protective garments
- Proper use of individual monitoring (if applicable)
- Proper use of technique charts
- Quarterly Retake/Reject analysis
- Performance evaluations of the x-ray equipment
- All required records and maintenance of these records

You are responsible for the content and implementation of your radiation safety and quality assurance program and for all actions of your employees. Each registrant must create a site specific audit and audit form. See Attachment D for questions to consider in an annual audit.

AS LOW AS REASONABLY ACHIEVABLE (ALARA) (4732.0530)



Every reasonable effort should be made to maintain radiation exposures ALARA. You are required to consider the ALARA philosophy in establishing your radiation safety/quality assurance program involving the use of your x-ray equipment.

A typical ALARA program in a chiropractic setting may include:

- Commitment from management and staff
- Implement procedures for holding the patient or image receptor
- The manufacturer's instructions for proper image development
- Implementing site specific radiation safety procedures
- Implementing site specific quality control procedures

Operating and emergency procedures must be developed, implemented, and maintained to ensure that chiropractic x-ray equipment is used only as designed, control and accountability are maintained, and radiation doses received by occupational workers and members of the public are ALARA and below the regulatory dose limits.

The success of an ALARA program depends on the cooperation of each person at your facility. Management must make a formal procedure to ensure commitment to the ALARA philosophy and implement that commitment with adequate resources. A model ALARA management program is contained in Attachment F of this guide.

OPERATING AND EMERGENCY PROCEDURES (4732.0500's) (4732.0800's)

Establishing and implementing operating and emergency procedures promotes good radiation safety practices to reduce the unnecessary radiation exposure received by the patient, occupational staff, individuals who must remain in the room during the x-ray examination, and the public. The registrant must implement site specific operating and emergency procedures including, but not limited to:

- The safe use of x-ray equipment
- Emergency operating procedures
- Holding of patient or image receptor and lead apron use
- Declaring pregnant staff
- Thyroid and eye protection
- Ordering of x-ray exams and equivalent procedure for identifying the individual ordering the examination
- Individual monitoring devices and assessing the need for individual monitoring

THE SAFE USE OF X-RAY EQUIPMENT

- Develop a technique chart to ensure a proper and consistent exposure for the anatomical region to be imaged
- Properly set the line voltage adjustment prior to the examination (if applicable)
- Proper use of mechanical holding devices
- Ensuring only qualified and trained operators operate x-ray equipment
- Ensuring a physician is in the room during fluoroscopy procedures
- Ensuring all individuals are properly protected (see Holding of Patient or Image Receptor and Lead Apron Use)
- Ensuring there is an unobstructed view of the patient and all entrances into the room during x-ray exam
- All x-ray equipment must have the following warning label and it must be located on the control panel, be legible and accessible to view

WARNING

This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed

EMERGENCY PROCEDURES (4732.0510)

You must have procedures in place in the event of an x-ray equipment malfunction, including:

- Switching off the power by turning off main power on the control panel or unplugging the x-ray equipment according to manufacturer's specifications
- Remove the patient from the exam room
- Remove the x-ray equipment from service
- Contact the RSO
- Contact the service provider, when necessary
- Ensure x-ray equipment is functioning properly before next use

HOLDING OF PATIENT OR IMAGE RECEPTOR AND LEAD APRON USE (4732.0510)

Individuals must not hold patients or image receptors, unless protected by a 0.5 millimeter lead equivalent apron. Only individuals necessary for the exam may be allowed in the room during an x-ray exam.

- 0.5 millimeter lead equivalent apron use is required for any individual that must remain in the x-ray operatory
- 0.5 mm lead equivalent gloves must be worn when the hands are in the primary x-ray beam
- Collimate the primary x-ray beam to the area of interest

Individuals may not routinely be used to hold the patient or imaging receptor.

- Staff must be rotated
- Pregnant staff *should not* be used to hold the patient or image receptor

Equipment Type	Patient Apron Required?	0.5 mm Lead Apron Required for Others in the Room?
Dental	No	If within 6' of patient or tube
Bone Densitometry	If Primary Beam within 2" of the gonads	If within 6' of patient or tube
Portable Radiography	If Primary Beam within 2" of the gonads	If within 6' of patient or tube
General Use Radiographic	If Primary Beam within 2" of the gonads	All personnel in room must wear an apron
Fluoroscopic	If Primary Beam within 2" of the gonads	All personnel in room must wear an apron
Computed Tomography	If Primary Beam within 2" of the gonads	All personnel in room must wear an apron

THYROID PROTECTION AND EYE PROTECTION (4732.0410)

Eye and thyroid protection must be worn if the potential exposure to the individual would exceed the dose limits of Minnesota Rules, Chapter 4732.0410, including: dose to the lens of the eye exceeding 5 Rem, and dose to the thyroid exceeding 50 Rem. Though exceeding these dose limits in diagnostic chiropractic imaging is highly unlikely, you and your staff must be aware of the potential exposures to the eyes and thyroid and take precautions as needed.

DECLARED PREGNANT STAFF (4732.0415) (4732.0440)

You must have written procedures in place for declared pregnant staff and ensure the dose limits in are not exceeded when staff declares pregnancy in writing. Options are available to registrants for declared pregnant staff.

- Ensure the individual remains outside of the x-ray room/area when performing x-ray examinations and maintains safe operating procedures
- Remove individual from x-ray area during pregnancy
- Individual should not be in the x-ray room/area, hold the patient or image receptor during the x-ray exam
- Provide individual with fetal monitoring, when necessary, in accordance with Minnesota Rules, Chapter 4732.0415 and 4732.0440
- Additional information on declared pregnancy and prenatal dose may be found on our Topic Index, click on Prenatal Exposure.

ORDERING OF X-RAY EXAMS (4732.0560)

Minnesota Rules, Chapter 4732.0560 establishes minimum requirements on who must order x-ray examinations and what must be included in an x-ray order:

1. X-rays must be ordered by an individual identified in Minnesota Rules, Chapter 4732.0560
   a. Licensed Practitioner of the Healing arts as defined in Minnesota Rules, Chapter 4732.0110
   b. Certified Clinical Nurse Specialist
   c. Certified Nurse Midwife
   d. Certified Nurse Practitioner
   e. Licensed Physician Assistant with a current written physician-physician assistant agreement showing eligibility to order radiographic procedures
2. The operator may not carry out an examination unless ordered by an individual listed in item 1 above
3. An order for an examination must be available to the operator of the x-ray equipment at the time of the examination
4. The order must include:
   a. Identification of the patient to be radiographed
   b. Identification of the chiropractor ordering the examination through a signature, electronic signature, or equivalent procedure listed below
   c. Clearly stated clinical indications
   d. The exact anatomical part to be radiographed
   e. The examination to be performed

EQUIVALENT PROCEDURE FOR IDENTIFYING THE CHIROPRACTOR ORDERING THE EXAMINATION

You are responsible for ensuring that all examinations are ordered by a licensed chiropractor and the order is available to personnel at the time of the examination.

1. The order must be available to the individual performing the examination when the order is not given directly to the operator of the x-ray equipment by the chiropractor
2. The order may be in a hardcopy format to include the information required above
3. The order may be in an electronic format to include the information required above
4. The order may be verbally given to the operator of the x-ray equipment by the ordering chiropractor to include the information required in item 4 above, Ordering Radiographic Exams

INDIVIDUAL MONITORING DEVICES (4732.0400 - 4732.0440)

Note: Individual monitoring device will be identified as "dosimetry badge" throughout this guide.

You must have written procedures in place for dosimetry badge use. Dosimetry badges are not typically used in a Chiropractic setting as the operators of x-ray equipment are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits as specified in Minnesota Rules, Chapter 4732.0410.

If a registrant chooses to use dosimetry badges, the requirements of Minnesota Rules, Chapter 4732.0440 must be followed including record retention and reporting requirements.

Minnesota Rules, Chapter 4732.0440 requires you to provide occupational staff with appropriate dosimetry badges and require personnel to wear the dosimetry badges if:

1. Personnel are likely to receive greater than 10% of the dose limits in Minnesota Rules, Chapter 4732.0410. See Assessing the Need for Individual Monitoring.

> ***Due to the nature of chiropractic imaging, it is unlikely that chiropractic occupational staff have the potential to receive greater than the 10% (500 millirem). However, you must perform an evaluation based on your individual practice to assess the need for individual monitoring.***

2. A declared pregnant women is likely to receive during the entire pregnancy a dose in excess of 0.1 rem (100 millirem)
    - Facilities may remove pregnant staff from performing or assisting in any x-ray imaging during the pregnancy. See Declared Pregnant Staff.
3. Each individual who enters a high radiation area or very high radiation area
    - Highly unlikely in diagnostic chiropractic imaging
4. A minor likely to receive in one year a dose in excess of 0.1 rem (100 millirem).

When dosimetry badges are used, you are responsible, through the RSO, to ensure:

- Dosimetry badges are worn and cared for properly
- Minnesota Rules, Chapter 4732.0440, subpart 2 and subpart 3, states that dosimetry badges are for each individual and must not to be shared
- The specific locations for wearing dosimetry badges are as follows:
    1. When a protective apron is not worn, on the trunk of the body or at the unshielded location of the whole body likely to receive the highest exposure
    2. When wearing a protective apron and a single dosimeter is worn:
        - Outside of the protective apron at the collar
        - Declared pregnant staff must wear the dosimeter at the abdomen and under the protective apron
    3. When wearing a protective apron on and two dosimeters are worn:
        - Outside of the protective apron at the collar
        - At the waist under the protective apron
- A control dosimetry badge should be included each time a new shipment of dosimetry badges is received. The control badge accompanies staff dosimetry badges and monitors any radiation received on the staff dosimetry badges during shipment.
    1. The control badge must be kept in an area of natural background radiation at the facility between shipments
    2. Dosimetry badges should be stored with the control dosimetry badge when not in use
    3. The control badge must be shipped back to the dosimetry provider each time staff dosimetry badges are sent in for reading
- Dosimetry Badge reports are reviewed according to Minnesota Rules, Chapter 4732.0505, subpart E:
    1. The RSO is responsible to ensure individual monitors are returned to the dosimetry provider for evaluation at the established frequency, typically on a monthly or quarterly frequency
    2. Dosimetry badge reports are reviewed to ensure staff are maintaining individual

exposure levels as low as possible

- Dosimetry Badge records are maintained according to Minnesota Rules, Chapter 4732.0440, subpart 13 and subpart 14:
    1. Records must be maintained for 30 years after termination or the lifetime of the individual
    2. Staff must receive a written notification of occupational dose received annually (not to exceed 12 months), as a hardcopy, or softcopy via email or the dosimetry provider's website
- Terminated staff must receive a written report of their occupational dose received within 30 days of registrant's receipt of dosimetry badge report from the dosimetry provider
- Attempt to obtain previous dose records for new employees
    1. Obtain information from the individual (termination exposure record)
    2. If you are unable to obtain pre-employment occupational dose records, you must reduce the individual's annual limit by 1.25 rem (1250 milllirem) for each quarter exposure records are unavailable

Example: You hire an individual in July and this individual is unable to provide you with any previous occupational dose history from a previous employer where dosimetry badges were required:

1. ***You are to assume the new employee received an occupational exposure of:***
    - ***1.25 rem (1250 millirem) for the first quarter (Jan-March)***
    - ***1.25 rem for the second quarter (April-June***
2. ***This total of 2.5 rem (2500 millirem) must be reduced from the annual limit of 5.0 rem (5000 millirem)***
3. ***For the next two quarters employed by you, the employee must not receive an occupational dose of greater than 2.5 rem***

Note: This is a conservative calculation and diagnostic chiropractic occupational staff is unlikely to receive an exposure of 2.5 rem over two quarters. This should not affect the occupational duties of the employee regarding the use of x-ray equipment.

ASSESSING THE NEED FOR INDIVIDUAL MONITORING

Chiropractic registrants must perform an evaluation to assess the need for individual monitoring of all occupational workers including chiropractic assistants, chiropractors, and other individuals assisting in the x-ray examinations. Minnesota Rules, Chapter 4732 does not exempt a registrant, individual or x-ray equipment use from the individual monitoring requirements of Minnesota Rules, Chapter 4732.0440.

The evaluation process may be different for each registrant and must include a review of your entire radiation safety program and how it is implemented. This review may include:

1. An evaluation of previous dose history records.

> ***Past dosimetry reports are the easiest way for chiropractic registrants to verify and document the likelihood of receiving greater than 10% of the dose limits of Minnesota Rules, Chapter 4732.0410.***

2. Provide individual monitoring to staff for a designated time, from 3 to 6 months.
    - Dosimetry badges can be submitted to the dosimetry provider on a monthly or quarterly basis
    - Designated time must be representative of the typical volume and type of imaging performed
    - Maintain records according to Minnesota Rules, Chapter 4732.0330 and Minnesota Rules, Chapter 4732.0415
3. Review similar practices and procedures representative of the typical volume and type of imaging being performed at your facility.
    - Other similar facilities
    - Patient workload
    - General radiography
    - CT
    - Fluoroscopy
    - C-arm use
4. All x-ray equipment uses within your chiropractic practice must be included in the overall evaluation process.
5. Individuals who perform specific duties that include more extensive use of the x-ray equipment than other staff should be evaluated independently to ensure they are not likely to exceed the 10% annual dose. Examples include:
    - Individuals hired exclusively to perform fluoroscopic x-ray examinations
    - Individuals hired exclusively to perform portable x-ray examinations
    - Individuals who routinely work with compromised patients when assistance during imaging is necessary
6. You must retain records of the evaluation process used to determine that dosimetry badges are not necessary.

SHIELDING REQUIREMENTS

You are responsible for protecting your staff, your patients and the public from unnecessary radiation. MDH has requirements for the design of an x-ray room/area to ensure that you have met the minimum protection requirements.

Minnesota Rules, Chapter 4732.0220, subpart 3 requires all registrants to maintain documentation of the radiation shielding installed in their facility. The documentation must include:

1. A blue print or architectural drawing indicating installed shielding.
2. A shielding plan that was completed by a service provider or an appropriate radiological physicist.
   - The actual structural composition and thickness or lead equivalent of all walls, doors, partitions, and, if occupied spaces above or below, the floor and ceiling of the rooms concerned
   - Shielding plans must be completed by a service provider registered in Minnesota or by a radiological physicist

3. Calculations to ensure occupational staff and the public do not receive a dose in excess of the dose limits found in:
   - Occupational, Minnesota Rules, Chapter 4732.0410
   - Embryo or Fetus, Minnesota Rules, Chapter 4732.0415
   - Exposure to minors, Minnesota Rules, Chapter 4732.0420
   - Members of the public, Minnesota Rules, Chapter 4732.0430

OR

4. If shielding compliance can't be verified by all the above, a detailed radiation survey covering the radiation levels at the operator position and at pertinent points outside the room during normal operation must be completed.
5. If you have purchased an existing facility and radiation shielding information is not available, you must perform a radiation survey or radiation shielding evaluation of your room/area to ensure that staff and the public are protected from necessary radiation.

As defined in Minnesota Rules, Chapter 4732.0110, "Survey" or "radiation survey" means an evaluation of the radiological conditions and potential hazards incident to the use of radiation-producing equipment. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation.

Minnesota Rules, Chapter 4732.0355 establishes general shielding and operator booth requirements of the x-ray equipment. Facilities that possess computed tomography (CT) equipment must have a control booth in the design of the room. See Shielding Plan Requirements for CT.

SHIELDING PLANS

MDH does not develop or approve radiation shielding plans. MDH does verify the following at the time of inspection:

1. A post construction radiation evaluation has been completed to ensure the room/area has been constructed according to the submitted shielding plan and MDH shielding

requirements to include: Room/area design, operator's booth design requirements, viewing conditions, and shielding calculations

2. Corrective actions are taken when a post construction radiation evaluation or subsequent analysis of operating conditions indicate:
    - The possibility of individuals receiving a dose in excess of the dose limits prescribed in Minnesota Rules, Chapters 4732.0410 - 4732.0430
    - Non-compliance with the design of the room/area
3. Permanent Placards are in place

Note: Shielding plans completed by any other individual will be not be accepted by MDH and do not comply with the shielding plan submission requirements.

Minnesota Rules, Chapter 4732.0360 establishes requirements for shielding plans to be completed and submitted to MDH after February 5, 2008 for the following:

1. New construction of an x-ray room/area.
    - This includes rooms/areas that were not originally designed for x-ray use and are now used routinely or permanently
2. Structural remodel of an existing x-ray room/area.
    - Removal or remodeling of existing exterior walls, ceiling, floor, or control booth of a room or area
3. Shielding plan forms and additional information may be found on the MDH X-ray website in the Topic Index, under Shielding.

If your x-ray room/area was constructed prior to February 5, 2008, you were not required to submit a shielding plan to MDH. However, you were required to perform a radiation survey or radiation shielding evaluation of your room/area to ensure that staff and the public are protected from unnecessary radiation.

When a shielding plan has been completed and submitted, a permanent placard must be mounted in the room/area identifying the amount and type of shielding in the room/area. See Permanent Placard Requirements.

SHIELDING REQUIREMENTS FOR CT

Minnesota Rules, Chapter 4732.0860, subparts 2 through 5 establish design, viewing, and radiation survey requirements for rooms where computed tomography (CT) equipment is used.

Subpart 2	Requires the operator to remain in a permanently protected area and must meet the design requirements of Minnesota Rules, Chapter 4732.0355, subpart 4
Subpart 3	Requires that the operator must have a means to continuously observe the patient from the control panel during the examination
Subpart 4	Requires the operator to have two way communication with the patient from the operator control panel

Subpart 5	Requires that all existing CT systems, and CT systems installed after February 5, 2008 must have a radiation survey performed to identify the radiation levels, at the control panel where the operator is located, and exterior rooms and locations outside of the CT room/area

PERMANENT PLACARD REQUIREMENTS

A placard must be mounted in the room/area specifying the amount and type of shielding in all walls, doors, partitions, and, if occupied, spaces above or below the floor and ceiling.

- If mounting the shielding information is not practical, you may post a notice in the room/area that describes the document and states where it may be examined
- The placard is to remain in the room/area until the room/area is destroyed or remodeled at which time a new shielding plan must be competed and submitted if the room/area is to be used for x-ray purposes
- The placard must be mounted in a manner that the placard cannot easily be removed, defaced or destroyed
- In the event the placard is removed, defaced or destroyed, you must replace the placard

1. Example placard when shielding information is placed directly on the placard.

Radiation Shielding for Room 101
Control Room Wall contains 1/16 inch lead
North Wall contains 1/16 inch lead
East Wall contains 1/32 inch lead
South Wall contains 1/32 inch lead
West Wall contains 1/32 inch lead
Ceiling contains 4 inches concrete on metal deck
Floor is concrete on slab (unoccupied)

2. Example placard where it may be impractical to place the shielding information directly on the placard.

Radiation shielding information for Room 101 is maintained in the radiation safety manual located in the Radiation Safety office. This information is available for review by contacting (provide the name of your RSO and contact number).

QUALITY CONTROL PROCEDURES

Routinely evaluating and maintaining your x-ray equipment, imaging system, image processing, darkroom and other associated components is important for maintaining the quality and stability of your x-ray imaging. In an effort to assist in understanding of the quality control tests required by MDH, quality control instruction documents are provided at the end of this guide.

You must implement a site specific quality assurance program and implement quality control procedures to monitor the x-ray system on a routine basis to ensure stable and reliable performance of the x-ray equipment, imaging system and the imaging conditions.

Quality Control Procedures include:

Retake/Reject Analysis Program	Minnesota Rules, Chapter 4732.0535
Processing Equipment	Minnesota Rules, Chapter 4732.0555, subpart 1
Darkroom or Glove Box Fog Tests	Minnesota Rules, Chapter 4732.0555, subpart 3
Outdated Film	Minnesota Rules, Chapter 4732.0555, subpart 4
X-ray Equipment Calibrations and Corrective Actions	Minnesota Rules, Chapter 4732.0700
Computed Tomography (CT)	Minnesota Rules, Chapter 4732.0860 Minnesota Rules, Chapter 4732.1100, subpart 9
Radiographic X-ray Equipment	Minnesota Rules, Chapter 4732.1100, subpart 5
Fluoroscopic X-ray Equipment	Minnesota Rules, Chapter 4732.1100, subpart 6

Note: Minnesota Rules, Chapter 4732.0275 requires individuals who are not employed by you that assemble, install, repair, or replace components of your x-ray equipment, perform installation calibrations or equipment performance evaluations on your x-ray equipment, need to be registered as service providers with the State of Minnesota prior to providing these services.

FILM OR FILM/SCREEN COMBINATIONS

You must ensure that films are developed according to the film and chemistry manufacturer's recommendations. Minnesota Rules, Chapter 4732.0555 has specific requirements depending on your processing method:

Manual Processing:

- Films must be developed according to the film and chemistry manufacturer's time-temperature recommendations
- Films must be developed according to the time-temperature requirements listed in Minnesota Rules, Chapter 4732.0555 subpart 1 when the manufacturer's recommendations are not available
- The temperature of the developer must be checked prior to developing each set of films

Automatic Processing:

- Films must be developed according to the film and chemistry manufacturers' time-temperature recommendations

- The developer must be checked daily when the processor does not have a developer temperature readout or a "ready light" indicating the developer temperature is within range
- The developer must be checked weekly when a processor has a developer temperature readout or a "ready light" indicating the developer temperature is within range

DARKROOM FOG TEST

You must ensure films are processed under conditions that minimize unnecessary film fogging. See Procedures for Fog Testing at the end of this guide.

A darkroom fog test must be performed:

1. To confirm the correct safelight filters and safelight filter placement, visible white light leaks, and any other conditions are corrected which may cause film fogging
2. Initially prior to first use of the darkroom or glove box, and at intervals not to exceed six months
3. For all processing conditions, including:
    - General chiropractic images
    - Any time there may be a change in the processing conditions, such as: a new safelight or a new safelight bulb.

Note: Corrective actions must be taken and verified to have corrected the out-of-limit parameters prior to using the darkroom or processing patient images.

DIGITAL IMAGING

Minnesota Rules, Chapter 4732.0835 states that you must follow the quality control recommendations of the manufacturer for the image receptor(s) when you have a computed radiography (CR), direct radiography (DR) or a photostimulable storage phosphor (PSP) system.

1. Calibrations of the digital x-ray system must be performed if this digital system includes new or replacement x-ray equipment.
2. Performance evaluations of your x-ray equipment must be performed at the appropriate interval listed in Calibrations/Performance Evaluations or anytime maintenance is performed on the x-ray unit or system.
3. Review your digital technical manuals very carefully. Maintenance and quality control testing of the image receptors must be performed according to manufacturer's specifications and be maintained onsite.

COMPUTED TOMOGRAPHY (CT)

In addition to the general requirements, facilities using CT must comply with the specific requirements found in Minnesota Rules, Chapter 4732.0860 and 4732.1100, subpart 9.

- Performance evaluations of your x-ray equipment must be performed at the appropriate interval listed in Calibrations/Performance Evaluations or anytime maintenance is performed on the x-ray unit or system
- Spot checks and measurements performed by the CT operator according to the required frequencies

CALIBRATIONS/PERFORMANCE EVALUATIONS (4732.0280) (4732.0700) (4732.1100)

Calibrations must be performed at installation or receipt, prior to first use of your x-ray equipment, and anytime maintenance is performed on the x-ray unit or system.

Performance evaluation of your x-ray equipment must be performed:

1. At intervals not to exceed 24 months for the following:
    - Radiographic x-ray equipment
    - Dental x-ray equipment
    - Screen contact (one or more cassettes)
    - Speed match testing with two or more cassettes and cassettes of the same speed/type
2. At intervals not to exceed 12 months for the following:
    - Fluoroscopic x-ray equipment
    - Computed Tomography x-ray equipment
3. Anytime maintenance is performed on the x-ray equipment or system

A listing of the required tests can be found in Minnesota Rules, Chapter 4732.1100.

Note: Individuals that assemble, install, repair or replace components of your x-ray equipment, perform calibrations, or performance evaluations on your x-ray equipment must be registered as a service provider with the state of Minnesota prior to providing these services per Minnesota Rules, Chapter 4732.0275.

LEAD APRON/PROTECTIVE GARMENTS INTEGRITY EVALUATIONS (4732.0550)

Lead aprons must be monitored for integrity initially and at intervals not to exceed 24 months. This requirement is to ensure the radiation protection quality of the lead within the apron has not been compromised. See a guidance document on Lead Apron/Protective Garments Integrity Evaluations at the end of this document.

UTILIZATION LOG (4732.0545)

Registrants must maintain a daily utilization log for all radiographic procedures performed. The utilization log must contain the following information:

1. Patient identification, including name, patient id, and other means to identify the patient
2. Type of procedure(s) performed on the patient
3. The number of images taken (including retakes)
4. The date the procedure was performed
5. The name of the individual performing the procedure
6. The name(s) of individuals required to hold the patient or image receptor during the examination
7. Fluoroscopic on time for fluoroscopy procedures over 5 minutes

See a sample Utilization Log at the end of this guide.

RETAKE/REJECT ANALYSIS (4732.0535)

You must perform a quarterly analysis of all radiographic images, including dental imaging, retaken or rejected. The quarterly results must be reviewed during the annual audit. A retake/reject analysis is a valuable tool for reducing unnecessary radiation dose to occupational staff, improving image quality and providing important information about existing and reoccurring imaging issues.

An analysis may indicate the need for:

- Corrective action for x-ray equipment failures
- Corrective action to processing issues
- Additional staff training
- Adjustment to procedures and or techniques
- The need for specialized devices to assist in imaging

See a sample Repeat Reject Analysis Worksheet at the end of this guide.

RECORD RETENTION (4732.0330)

MDH X-ray Unit record retention requirements are limited to the use of x-ray equipment, operator of x-ray equipment qualifications, training, registration, and those records associated with the establishment and implementation of a radiation safety and quality assurance program.

You must, at a minimum, maintain all records for review between MDH X-ray Unit inspections. This would include:

- Qualifications and training of the operators of x-ray equipment since the last inspection including present, float, and temporary staff
- Calibration/Performance Evaluation reports including the numerical results and corrective actions for deficiencies
- Quality control testing, procedures located at the end of this guide
- Corrective action for any quality control tests which may have failed
- Procedures for the Radiation safety/quality assurance program audit
- Radiation safety/quality assurance program audit
- Utilization log
- Quarterly Retake and Reject Analysis
- Evaluation for assessing the need for individual monitoring
- Individual monitoring (where applicable)
- Radiation Safety Officer Delegation Agreement
- Registration and disposition of equipment
- Shielding plan documentation

INSPECTIONS

MDH X-ray Unit inspection staff is responsible to perform inspections of facility operations to ensure the safe use of your x-ray equipment and compliance with Minnesota Rules, Chapter 4732. During an inspection, inspection staff may perform confirmatory testing of your x-ray equipment, interview you and your staff, and review your radiation safety procedures, quality assurance procedures, and records. At the completion of the inspection, the inspector will perform an exit interview with you, your administrator, radiation safety officer, or registrant designee to discuss potential findings or concerns. The exit interview is to ensure the inspector's review of your program is complete and accurate, and that there are no misunderstandings with

potential findings or violations you may receive.

Inspections may be conducted initially for new registrants to review your radiation safety and quality assurance procedures and at the below subsequent inspection intervals.

Registrant	Inspection Interval
Chiropractic	Every 4 years
Computed Tomography (CT)	Every 3 years
Dental	Every 4 years
Industrial	Every 4 years
Medical (general and fluoroscopic)	Every 4 years
Radiation Therapy	Every 2 years
Veterinary	Every 4 years

Inspections may be performed at an increased frequency based on previous enforcement history, failure to respond to corrective actions, or if MDH receives a call of concern regarding a registrant's x-ray operations.

Registrants must allow MDH X-ray Unit inspection staff, during reasonable hours of operation, the opportunity to inspect the premises, x-ray equipment and records.

ATTACHMENT A
RADIATION SAFETY OFFICER

Radiation Safety Officer Training Requirements (4732.0500)

The individual designated as a radiation safety officer must be either a licensed practitioner of the healing arts; or an individual who has completed training in the following items:

- Fundamentals of radiation safety
- Familiarization with facility's radiation-producing equipment
- Film processing, if applicable
- Digital imaging, if applicable
- Quality assurance program
- Audits of the quality assurance program
- Emergency procedures for radiation-producing equipment failures
- Proper use of personal dosimetry, if applicable
- Requirements of pertinent Minnesota Rules, Chapter 4732
- Registrants 's written operating and emergency procedures

Typical Duties and Responsibilities of the Radiation Safety Officer (4732.0505)

The RSO's duties and responsibilities include ensuring radiological safety and compliance with Minnesota Rules, Chapter 4732 and the conditions of the radiation safety/quality assurance program. Typically, the RSO's duties and responsibilities include and are not limited to:

- Establishing a radiation safety/quality assurance program
- Maintenance, and implementation of up-to-date operating and emergency procedures
- Ensure initial site specific training has been performed for safe operating procedures, emergency procedures and quality control procedures
- Radiation Safety/Quality Assurance program audits are performed at intervals not to exceed 12 months
- Identifying radiation protection problems and developing, implementing, and documenting timely corrective actions
- Stopping unsafe activities using x-ray equipment
- Ensuring compliance with regulations
- Ensuring that radiation exposures are ALARA

ATTACHMENT B
OPERATION OF X-RAY EQUIPMENT QUALIFICATIONS

Minnesota Statute 144.121 has specific requirements for operators of x-ray equipment. The term operator of x-ray equipment is used when discussing all qualified individuals. This is not to be confused with the X-ray Operators who were required to meet specific qualification requirements.

The governing licensing boards allow for the operation of x-ray equipment and Minnesota Rules, Chapter 4732.0570 exempts Licensed Practitioners of the Healing Arts. Specifically those listed below:

1. Board of Medical Practice, Minnesota Statute 147
2. Physician Assistant, Registration, Minnesota Statute 147A
3. Dentistry, Minnesota Statute 150A
   a. Licensed Dentist
   b. Licensed Dental Therapist
   c. Licensed Dental Hygienist
   d. Licensed Dental Assistant
4. Podiatry, Minnesota Statute 153
5. Chiropractic, Minnesota Statute 148.06

Minnesota Statute 144.121 states operators of x-ray equipment requirements are specific to the use on humans. Veterinary use and non-human research use of x-ray equipment must meet the specific training requirements of Minnesota Rules, Chapter 4732.

X-ray Operator Examination

The x-ray operator examination was provided December 1996 through December 2007 and is grandfathered into Minnesota Statute 144.121.

1. The tests were provided by the following:
   a. Evalcor
   b. Diane Harayda
   c. Health Activations
2. X-ray operators may perform radiographic procedures including:
   a. Fluoroscopy, specific training under Minnesota Rules, Chapter 4732.0825
   b. Computed Tomography, specific training under Minnesota Rules, Chapter 4732.0860
   c. Bone Densitometry
3. X-ray operators may not perform
   a. Mammography
4. X-ray operators must provide documentation of passing the X-ray Operator Examination:
   a. MDH certificate
   b. Letter from the test provider documenting a passing score
   c. Letter from MDH verifying passing of the X-ray Operator Exam

Limited Scope X-ray Operator Examination

The Limited Scope X-ray Operator Examination replaced the X-ray Operator Examination and has been a qualification requirement since January 1, 2008.

1. Must have passed the Core Exam which includes:
   - Radiation Protection

- Equipment Operation and Quality Control
- Image Production and Evaluation
- Patient Care and Education

2. Must have passed at least one of the following anatomical modules in addition to the Core Exam:
   - Chest
   - Extremities
   - Skull/Sinus
   - Spine
   - Podiatric Radiography
3. May perform only radiographic procedures related to the modules passed
4. May not perform the following exams:
   - Computed Tomography (CT)
   - Exams using contrast media
   - Fluoroscopic
   - Mammography (MQSA)
5. Documentation required:
   - MDH documentation of the Core Exam and anatomical modalities passed
   - MDH documentation of the passed Bone Densitometry Exam

If a Limited Scope X-ray Operator has passed the Core Exam and Spine Module, they are not qualified to perform extremity images.

Bone Densitometry Operators

Bone Densitometry Operators must have taken and passed one of the following:

- Bone Densitometry Equipment Operators exam
- Limited Scope X-ray Operators Examination, including Core Exam, Spine Module, and Extremities Module

Examinations Approved By the Commissioner of Health

1. American Registry of Radiologic Technologists
   - May perform any radiographic procedure within the scope of a Radiologic Technologist
2. American Registry of Chiropractic Radiography Technologists
   - Limited to spines and extremities after January 1, 2008, per Minnesota Statute 144.121
3. Equivalent examinations approved by MDH from another state
   - May only perform those exams limited by the equivalent state certification, per 2008 Minnesota Statute
   - Equivalent examinations approved by the commissioner
4. Documentation required as proof of passing one of the approved exams:
   - Record of passing test results
   - Registration
   - State certificate
   - State license
   - Equivalency approval letter from MDH

SPECT/CT and PET/CT Qualification Requirements

Because some commercial models allow each imaging modality to be used separately, MDH has made a determination regarding the operator requirements for operating this dual imaging device. If you are a registrant utilizing PET/CT or SPECT/CT technology combining a nuclear medicine imaging device and a radiologic imaging device into one unit for CT adhering to the qualifications listed below is required.

1. When a unit is operated as a nuclear medicine imaging device, the operator must be a nuclear medicine technologist.
2. When the unit is operated as a radiologic imaging device, the operator must have passed an x-ray operator examination or equivalent.
    - The daily quality control must only be performed by an individual registered with ARRT for Radiologist Technologists or has passed the Minnesota x-ray Operators examination.
3. When the unit is operated as a dual imaging device, it is considered a nuclear medicine technology procedure rather than a radiologic technology procedure for the following reasons:
    - Radiopharmaceuticals are injected.
    - The device may use radioactive material as point sources in transmission scanning and attenuation correction.
    - The nuclear medicine procedure involves a greater potential for radiation safety problems (including dose to the patient, employees, and the public) as well as potential contamination of areas within the facility.

ATTACHMENT C
FACILITY SPECIFIC TRAINING (4732.0510)

Facility Specific Training

Each operator must be instructed initially in site-specific and system specific procedures including:

- Safe operating and Emergency procedures
- Quality control procedures for all imaging receptors, film and digital
- The use of proper protective shielding for staff
- Additional training must be conducted at the time of any change to the quality assurance program or change in radiation output. Examples include, but are not limited to:
    - Changing from film/screen to Computed Radiography (CR) or Direct Radiography (DR)
    - Replacement of or addition of a new x-ray unit
    - Upgrades to existing x-ray equipment

If your facility is in possession and uses fluoroscopic, cone beam computed tomography (CBCT), or computed tomography (CT) x-ray equipment, your staff must receive system specific training.

1. Fluoroscopic training must include:
    - X-ray generation and control§
    - X-ray dosimetry
    - Image formation
    - Image acquisition
    - Image processing and management
    - Radiation effects
    - Dose-management fundamentals
    - Staff radiation safety
    - Professional standards and regulatory requirements
    - Other miscellaneous items appropriate to site-specific use§
2. CT training must include:
    - Training by the manufacturer or equivalent
    - Training in appropriate CT positioning and anatomy for procedures performed at the facility

Training requirements for students, float staff, externs and temporary staff include:

1. Students, externs, and float staff are required to perform the initial training at only one location if they remain within a system that has an established radiation safety/quality assurance program for all sites.
2. Students and externs who train within different practices must receive training at each location of practice.
3. Temporary staff working within different practices must receive training at each location of practice.

Record Retention Training

Documentation of training must be available onsite at each registered location, either in electronic or hard copy.

- Training records must include site specific and modality specific: date of training, topics covered and names/signature of trained individuals

ATTACHMENT D
ANNUAL AUDIT FOR CHIROPRACTIC X-RAY REGISTRANTS
(4732.0540)

Only address those areas that apply to your activities and activities that have not occurred since the last audit.

Audit History	4732.0540	N/A	Yes	No
Date of the previous audit:				
Were previous audits conducted annually?	**4732.0540**	☐	☐	☐
Are records of previous audits maintained?	**4732.0540**		☐	☐
Deficiencies identified?	**4732.0540**	☐	☐	☐
Were the deficiencies corrected?	**4732.0540**		☐	☐
Organization and Scope of Program		**N/A**	**Yes**	**No**
Is the Radiation Safety Officer identified	**4732.0500**		☐	☐
Does the RSO meet MDH training requirements?	**4732.0500**		☐	☐
Is RSO fulfilling all duties?	**4732.0500**		☐	☐
Is the written agreement in place for the RSO?	**4732.0500**	☐	☐	☐
All x-ray equipment registered with the MDH?	**4732.0200**		☐	☐
Changes in program since the last audit?	**4732.0520**	☐	☐	☐
Operating and Emergency Procedures		**N/A**	**Yes**	**No**
Are the procedures current?	**4732.0520**		☐	☐
Technique charts completed and in place?	**4732.0550**		☐	☐
Patient/Image receptor holding procedures in place?	**4732.0510**	☐	☐	☐
Lead apron procedures in place, and in use?	**4732.0510**	☐	☐	☐
Declared pregnant staff procedures in place?	**4732.0415**		☐	☐
Quality Control Procedures		**N/A**	**Yes**	**No**
Are the procedures current?	**4732.0520**		☐	☐
Processor quality control tests performed?	**4732.0555**		☐	☐
Darkroom quality controls tests performed?	**4732.0555**		☐	☐
Equipment evaluations performed?	**4732.1100**		☐	☐
All quality control tests performed at the required frequency?	**4732.1100**		☐	☐

Digital manufacturer's quality control procedures followed?	**4732.1100**	☐	☐	☐
Have records been maintained?	**4732.0330**		☐	☐
X-ray Operator Qualifications	**4732.0570**	**N/A**	**Yes**	**No**
X-ray operators qualified to perform examinations	**4732.0570**	☐	☐	☐
Limited Scope X-ray Operators performing only those examinations within the modules passed?	**4732.0570**	☐	☐	☐
Students/Externs in an approved course?	**4732.0590**	☐	☐	☐
Performing only those examinations within the scope of training?	**4732.0590**		☐	☐
X-ray Operator Training	**4732.0510**	**N/A**	**Yes**	**No**
X-ray operators received initial training?	**4732.0510**		☐	☐
Training program implemented?	**4732.0510**		☐	☐
Operating procedures?	**4732.0510**		☐	☐
Emergency procedures?	**4732.0510**		☐	☐
Fluoroscopic specific training performed	**4732.0825**	☐	☐	☐
CT specific training performed	**4732.0860**	☐	☐	☐
Training for changes in program? (new equipment, image receptors)	**4732.0510**	☐	☐	☐
Individual Monitoring Device	**4732.0440**	**N/A**	**Yes**	**No**
Are individual monitoring devices in use?	**4732.0440**	☐	☐	☐
Individual monitoring evaluation performed?	**4732.0440**		☐	☐
Users notified in writing of annual exposure?	**4732.0440**		☐	☐
Dosimetry reports reviewed quarterly by the RSO?	**4732.0440**		☐	☐
Reports maintained for 30 years	**4732.0440**		☐	☐
Is the individual monitoring worn in the proper locations?	**4732.0440**		☐	☐

Summary of findings:

Corrective and preventive actions:

Comments:	
Audit conducted by: _____	**Date:** _____

ATTACHMENT E
CALIBRATIONS AND PERFORMANCE EVALUATION TESTS (4732.1100)

Calibrations and performance evaluations are required in order for you to ensure your x-ray equipment is functioning in accordance with the specifications of the manufacturer, Minnesota Rules, Chapter 4732 or the following Code of Federal Regulations, title 21, sections:

- Diagnostic X-ray Systems - 1020.30
- Radiographic Equipment - 1020.31
- Fluoroscopic Equipment - 1020.32
- Computed Tomography Equipment - 1020.33

If the manufacturer's specifications are unknown the x-ray equipment must meet the specification of Minnesota Rules, Chapter 4732 or the respective Code of Federal Regulations, title 21, sections.

Calibrations and performance evaluations must be performed by a service provider who is currently registered with the MDH and the following information must be included on a calibration or performance evaluation report:

- The name and registration information of the service provider
- The numerical results for each test where applicable, and any test images
- Written recommendations necessary to bring x-ray equipment failures into compliance
- The date the equipment performance tests were completed
- The serial number of the equipment, room number, or name, if applicable

If the service provider is using the manufacturer's specifications for compliance, the manufacturer's specifications must be available onsite for review.

The following tests are required at initial installation of the x-ray equipment, at the required intervals and anytime there is a change or replacement to the x-ray equipment. Performance evaluations are to be performed at all clinically used settings.

General Radiographic

- **Filtration or Half Value Layer (HVL):** This refers to "hardening" of the x-ray beam by filtering out the lower energy x-rays to allow for only the higher energy x-rays which are able to penetrate the bony structure and soft tissue to reach the patient and produce an image. Lower energy x-rays which cannot penetrate the bony structure or soft tissue add to the patient overall exposure but do not affect the x-ray image.

- **Timer Accuracy:** Ensures the radiation exposure is consistent with the time that is set on the x-ray control. Timer setting sets the duration of the radiation exposure.

- **Timer Reproducibility:** This verifies the x-ray unit timer settings are accurate and will provide a reproducible exposure (density) of your image.

- **kVp accuracy:** Ensures the Kilovoltage Peak (kVp) set is consistent with the kVp that is set on the x-ray control. KVp controls the speed and energy of the x-rays and is the factor which allows the x-rays to penetrate the area of interest and provide the contrast to your images.

- **Reproducibility:** This verifies that the technique factors set (kVp, mA and timer setting) provide a reproducible exposure of your image.

- **Linearity:** This test is required only if your x-ray unit has multiple milliamperage (mA) settings that are used clinically. Milliamperage controls the quantity of electrons and with the timer setting the quantity of x-rays.

- **Dead man exposure switch:** When the x-ray exposure button is released the x-ray unit must stop producing an x-ray.

- **Audible and visible indication of an x-ray exposure:** There must be an audible and visible indication during the x-ray exposure.

- **Tube head stability:** The x-ray tube must remain stable during an x-ray exposure without the assistance of an individual or holding device.

- **Multiple tubes with one control:** An x-ray control console that operates more than one tube must have an indication on the x-ray control and on or near the tube housing assembly which has been selected.

- **SID Indicator Accuracy:** Ensures the actual distance at which the examination is performed is consistent with the distance noted on the technique chart.

- **X-ray to Light Field Alignment:** Ensures the area to be exposed to the x-ray field is congruent and the same size of the light field that is used to collimate to the patient area of interest.

- **X-ray to Image receptor Alignment:** Ensures the x-ray field is centered to the image receptor.

Fluoroscopic, Cone Beam Computed Tomography (CBCT) and Computed Tomography (CT)

Due to the greater risk of unnecessary exposure, fluoroscopic, CBCT and CT x-ray equipment should be calibrated and evaluated only by registered service providers that are specifically trained on the x-ray equipment being tested.

If you have questions regarding calibrations or performance evaluations that have been performed for you, please contact your registered service provider.

ATTACHMENT F
MODEL PROGRAM FOR MAINTAINING RADIATION EXPOSURE USING THE ALARA CONCEPT (4732.0530)

You may include the text as it appears here or if you prefer or you may develop your own ALARA (As Low as Reasonably Achievable) program for MDH review at the time of an inspection.

Management Commitment

- We, the management of this facility, are committed to the program described herein for keeping individual and collective doses As Low as Reasonably Achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a radiation safety officer.

- We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures, past dose records (if applicable), inspections, etc., and any modifications to operating and maintenance procedures or to x-ray equipment and facilities will be reviewed and include consultations with the radiation safety staff or outside consultants.

- In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level.

Registrant's Responsibility to Supervised Individuals

- Registrants will explain the ALARA concept and the need to maintain exposures as low as reasonably achievable to all staff.
- Registrants will ensure that the supervised individuals who are subject to occupational radiation exposure are trained and educated in safe radiation practices involving time, distance, shielding, and appropriate techniques in maintaining exposures.

Registrants will ensure staff that is subject to occupational radiation exposure is trained and educated in practices involving time, distance, shielding and appropriate techniques in maintaining exposures ALARA.

QUALITY CONTROL (QC)
PROCEDURES AND GUIDANCE DOCUMENTS

In this section, you will find suggested methods for performing the applicable quality control testing required in a chiropractic facility using x-ray equipment. Included are procedures and guidance documents for the following quality control tests:

Procedures

Repeat and Reject Analysis
Fog Testing
Film/Screen Contact Testing
Screen Speed Match Testing
Adding or Converting to a Digital Imaging System
Lead Apron Integrity Evaluation
Processor Quality Control

Guidance Documents

Crossover Worksheet
Initial Registration Form
Additional Registration Form
Sample Radiation Safety Officer (RSO) Delegation Agreement
Patient Utilization Log
Repeat/Reject Analysis Worksheet

PROCEDURES FOR REPEAT AND REJECT ANALYSIS

What is it?
Repeat and Reject Analysis is a mechanism for tracking and evaluating images that have to be repeated or are rejected.

Why is it important?
It is a tool for improving image quality and reducing unnecessary occupational and patient dose by tracking and evaluating poor images that may be caused by, for example:

- Malfunctioning x-ray equipment
- Changes in procedures
- Staff that require additional training
- The need for specialized devices to assist in imaging

When is it performed?
Repeat and Reject Analysis is an ongoing process where the repeated or rejected images are tracked on your daily utilization log with an analysis performed quarterly. An annual review of your repeat and reject analysis must also be reviewed by the RSO during the annual audit.

What is the requirement?
Minnesota Rules, Chapter 4732.0535 requires the repeat and reject analysis be:

- Performed at least quarterly
- Include the overall retake or reject rate and a summary of the causes for the retakes or rejects
- A review of your repeats and rejects during the annual audit
- Develop written facility specific procedures for the retake and reject analysis
- Maintain records according to Minnesota Rules, Chapter 4732.0330

Items needed

- Utilization log from the previous quarter
- Repeat and Reject analysis form

Procedure

1. Review your daily utilization log for the previous quarter
2. Document on your Repeat and Reject Analysis Form the number of repeated or rejected films corresponding to the reason for the repeat or reject
3. Calculate the total number of repeated or rejected images
4. Calculate the total number of images taken in the quarter
5. Use the one of the following formulas for calculating the repeat or reject rate:

$$\text{Repeat Rate} \quad \frac{\text{Total Number Repeats for the Quarter}}{\text{Total Number of Films Taken}}$$

$$\text{Repeat Rate} \quad \frac{\text{Total Number Repeats for a specific exam in the Quarter}}{\text{Total Number of Films Taken}}$$

Corrective Actions
MDH does not have a maximum percentage rate for the repeat and reject analysis. It is the RSO's responsibility to review these rates and determine what, if any, corrective action should be taken. All corrective actions must be documented and retained in your Radiation Safety/Quality Assurance Manual for future reference. Changes in staffing, x-ray equipment or from film to digital imaging are examples where the repeat and reject rate may be higher than what is typically seen at your facility.

PROCEDURES FOR FOG TESTING

The darkroom fog test is not required for digital imaging systems

What is it?
The darkroom fog test is meant to determine and minimize the amount of unwanted light within the darkroom.

Why is it important?
Improper safelights and unwanted light in the darkroom can compromise the quality of your radiographs by reducing contrast and darkening the image. This can jeopardize image quality to the point of repeating the image or misdiagnosis.

When is it performed?
Fog testing must be performed initially, at intervals not to exceed 6 months, and any time there is a change in the darkroom conditions that may have the potential for unnecessary light to affect the quality of your images.

What is the requirement?
Minnesota Rules, Chapter 4732.0555 requires the darkroom/glove box test be performed:

- Initially and at intervals not to exceed six (6) months
- Anytime fog is suspected
- Anytime there is a filter or bulb change
- Any other change in darkroom conditions

The amount of fog for a two-minute test must not allow visualization of a density difference between the covered and uncovered side of the fog test film. Minnesota Rules, Chapter 4732.0330 requires records be maintained for review by the X-ray unit.

Items needed

- Loaded imaging cassette (preferably the smallest cassette used in your practice)
- Your x-ray unit
- Established technique factors for the darkroom fog test
- Timer set at 2 minutes
- Densitometer

Procedure

1. Load the cassette with unexposed film under your normal darkroom conditions
2. Take the loaded cassette into your x-ray room and place on the patient table
3. Set a distance typically used for imaging, 40 inches to table top or the cassette tray
4. Collimate to about a 6” by 8” field size on the cassette
5. Set a technique that would be used for a small finger:

- For example 50 kvp at 1 mAs
- You will have to adjust your techniques according to you specific film system
- The processed film should have a density that is light enough to visualize the writing on a newspaper, and yet dark enough to make the writing difficult to read. Approximately an optical density (O.D.) of 1.0 when read with a densitometer.

6. Take the cassette into the darkroom and under the same conditions that would be used for processing patient films
7. Place the cassette in the location most used for unloading and loading during processing
8. Remove the film from the cassette and cover half of the film lengthwise with something that is light opaque. A cassette works well.
9. Etch a line in the film along the edge of the light opaque object
10. Start the 2 minute timer
11. Stand back from the film to ensure your body is not shadowing the fog test film. Take time to look around the darkroom for any potential light leaks or sources of unwanted light.
12. When the timer goes off, process the film as usual.
13. Take the processed film to a view box and review the density on the side of the film that was covered with the density on the side of the film that was uncovered.
14. If the densities between the covered and uncovered side are greater than 0.08 O.D., your fog test evaluation fails
15. Corrective action must be taken and another fog test must be performed to verify the corrective action was acceptable
16. Record the date, the results of the test as pass/fail, and save the film for state inspection

Helpful Hints

Below are some common conditions as to why the fog test may fail.

Safelight/filter:

- Not compatible with the film being used
- Bulb in the safelight is too high a wattage
- Cracks in the filter
- Filter emulsion flaking off

Electronic equipment indicator lights:

- Radio
- Internet modems
- Phone

Additional conditions:

- Flames from boilers, water heaters or furnaces
- Ceiling tiles that are not installed correctly
- Light leaks around ceiling fixtures or doors

Corrective Actions

Repeating a fog test without the safelight on and the fog is removed, the safelight may need to be replaced or moved further away from the processor. Any light other than what is from the safelight can potentially fog your patient films. Remove or completely cover any of these sources of unwanted light:

- Close cupboards or place items behind a curtain
- Place a curtain covering the entire darkroom door entrance and use a curtain rod or hooks to move the curtain out of the way when film processing is not being performed
- Tape around light leaks in the ceiling
- Attach weather stripping around the darkroom door

PROCEDURES FOR FILM/SCREEN CONTACT TEST

The film/screen contact test is not required for digital imaging systems

What is it?
The screen contact test is used to confirm there is good contact between the screens and the film inside of the x-ray cassette and must be performed on all x-ray cassettes used clinically. Repeated expose to x-rays does not cause x-ray screens to wear out. Typically the cause for poor contact requiring replacement of the screen(s) is due to improper maintenance and handling. Be sure to follow the manufacturer's recommendations for cleaning and care.

Why is it important?
Poor contact between the screen and the film inside of an x-ray cassette can cause an x-ray image to look blurred, density fluctuations throughout the film, and artifacts which may reduce the diagnostic quality of your patient films and add unnecessary radiation dose to your patients if the films must be repeated.

When is it performed?
The screen contact test must be performed initially prior to patient use, at intervals not to exceed twenty four (24) months and any time there has been a change to the cassette that may affect the film/screen contact including new hinges, felt padding or screen(s). This is the same frequency as the calibration/performance evaluations of your x-ray equipment and it may be of value to have the service provider perform this test for you.

What is the requirement?
Minnesota Rules, Chapter 4732.1100 requires the screen contact test to be performed:

- Initially (new) and at intervals not to exceed twenty four (24) months
- Anytime screen damage is suspected
- Minnesota Rules, Chapter 4732.0330 requires records be maintained for review by the X-ray unit

Items Needed

- 8 wire/inch mesh test tool or 7 holes per inch test tool
- All imaging cassettes. Each cassette must be identified along with the respective test film.
- View box

Procedure

1. Load with film each imaging cassette under your normal darkroom/glove box conditions allowing them to sit for at least 15 minutes after loading. This will give any air trapped in the cassettes time to dissipate.
2. Take the loaded imaging cassette into the x-ray room.
3. Rotate the x-ray tube so that the x-ray beam is pointed towards the floor.
4. Place the cassette on the floor or flat surface underneath the x-ray tube.
5. Place the screen contact test tool on top of the cassette.
6. The cassette should be placed on the floor with the tube at a distance of at least 40". This will provide enough distance from the tube to the cassette to allow the x-ray field to cover the entire cassette.
7. Expose the test tool and cassette using approximately the same setting you used for your fog test evaluation, Optical Density (O.D.) of approximately 1.0.

8. Take each cassette into the darkroom and process the film under your normal processing conditions.
9. View each processed film on a view box in a dimly lit room from a distance of approximately six feet or more.
10. Look for areas that are darker and/or more blurry than the rest of the film. This indicates poor contact.
11. If there is an area of poor contact located in an area of interest on a film, remove the cassette from service.

Helpful Hints

Some common causes of poor screen-film contact:

- Worn felt behind the screen(s)
- Loose, bent or broken hinges or latches
- Warped screens or cassettes
- Sprung or cracked cassette frame
- Foreign matter under the screen

X-ray cassettes and screen will last indefinitely when they are properly handled and maintained by following the manufacturer's recommendations.

What the test tool looks like…

What your films may look like…

PROCEDURES FOR SCREEN SPEED MATCH TESTING

The screen speed match test is not required for digital imaging systems

What is it?
The screen speed match test is performed to confirm there is a consistent image density from one cassette to another and must be performed on all x-ray cassettes used clinically.

Why is it important?
The screen speed match test is used to ensure that the effective film density remains consistent from one cassette to another at a given technique. If you use a number of cassettes interchangeably, you need to be aware of the density for the combination of film and screen that you are using and you need to perform a proper speed match test to make sure that each of the interchangeable cassettes produces the same effective density. An adjustment in the technique may be required for cassettes that do not provide a similar density.

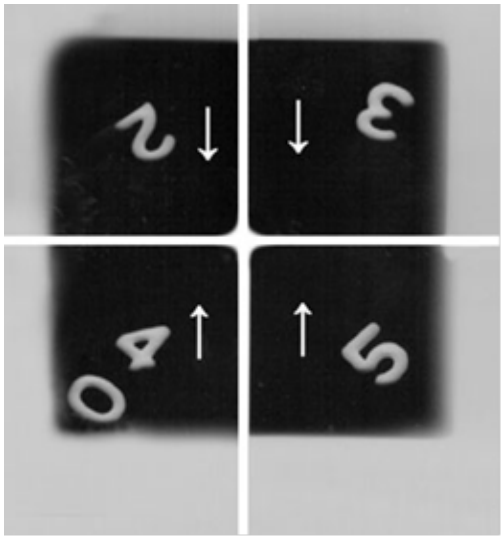
When is it performed?
The screen speed match test must be performed initially prior to patient use, at intervals not to exceed twenty four (24) months and any time there has been a change to the cassette that may affect the screen speed. This is the same frequency as the calibration/performance evaluations of your x-ray equipment and it may be of value to have the service provider perform this test for you.

What is the requirement?
Minnesota Rules, Chapter 4732.1100 requires the screen speed match test to be performed:
- Initially (new) and at intervals not to exceed twenty four (24) months
- Anytime screen damage is suspected

Minnesota Rules, Chapter 4732.0330 requires records be maintained for review by the X-ray unit.

Items needed
- All cassettes used clinically
- Identifier for each cassette and processed film, such as paperclips or lead markers
- Technique used for your darkroom fog test evaluation, Optical Density (O.D.) of approximately 1.0
- Densitometer
- View box

Procedure
1. Select a small cassette to be used as a "master" cassette. Make a note of the cassette number or some other identifier for the master cassette, and record it. *Ex: Cassette #40 is the master.*
2. Load the master cassette and all other cassettes with film from the same box of film. Place the film in the corner that will be exposed on larger cassettes. Remember what corner of the large cassette the film is in.
3. Set a distance of 40" to the floor or a flat surface
4. Place three cassettes including your master cassette on the floor or a flat surface so that one corner of



each cassette touches each other making sure the film is in the corner you select on the larger cassettes
5. Center the x-ray field to the center where the four cassette corners meet and come down so that you are exposing an area of approximately 4 inches by 4 inches on each cassette. *See arrows on the picture.*
6. Make an exposure using a similar technique that you use for your darkroom fog test evaluation.
7. Take the cassettes into the darkroom and process the films under your normal processing conditions.
8. Place the processed films on a viewbox similar to how the cassettes were placed on the floor or a flat surface.
9. Visually inspect the films for significant density differences between the films.
10. If a film shows a density difference of greater than 0.10 Optical Density, remove the respective cassette from service.
11. If you have more than four cassettes, you must repeat steps 2 through 9 using the same master cassette with the additional cassettes. *Ex: Cassette #40.*
12. Save all associated films and documentation until the next inspection by the state.

Helpful Hints

Some common causes of screen speed match failures:

- Tested cassette screens are not of the same speed
- Film and screens are not compatible
- Incorrect cleaner used on screens

X-ray cassettes and screens can have a long service life as long as they are properly handled and maintained following the manufacturer's recommendations.

PROCEDURES FOR ADDING OR CONVERTING TO A DIGITAL IMAGING SYSTEM

The exposure of an individual for training, instruction, demonstration, or maintenance is prohibited. The use of x-ray equipment for these purposes will result in enforcement action that may include an administrative penalty of up to $10,000.

What is it?

Computed Radiography (CR), Direct Radiography (DR) and Photostimulable Storage Phosphor (PSP) imaging are the manner in which the x-rays are received and processed to provide for a diagnostic image.

- Many registrants converting x-ray units to a CR or PSP imaging system may only replace the film imaging cassettes with CR or PSP imaging cassettes.
- Regardless of the imaging system an x-ray tube is necessary and the patient must receive radiation in order to generate the image.
- CR and PSP imaging systems require the imaging cassette to be placed in an image reader to obtain the x-ray image.
- For digital imaging systems, the x-ray image is obtained directly from the sensor and received on the computer monitor without the need for an image reader.

Why is it important?

1. Digital imaging does not require processing of the image in the same manner as film.
2. Dose reduction is not an "automatic" when converting to digital imaging.
    - Film/screen imaging is not forgiving, what you see is what you get
    - Digital imaging allows for manipulation of the raw image to enhance the final image
3. Doses may be higher during the transitional stages from film to digital imaging.
4. The "dose creep" phenomenon or the theory that "this technique works for everyone" is the tendency to overexpose a patient in order to maintain the ability to manipulate the raw image.
    - Overexposing allows for the ability to enhance the images through adjustment of the window and level post exposure
    - Underexposing does not allow for the ability to enhance the images and increases the noise of the images
    - Proper exposure allows for the enhancement of the images while maintain the dose as low as reasonable
    - Exposure is reduced with the use of Automatic Exposure Control (AEC)

What you must do?

- Submit an email to the X-ray Unit health.xray@state.mn.us stating that you have gone digital.
- Retain the email for your records.
- When installing new x-ray equipment in your digital conversion, the service provider must complete an installation calibration.
- Work closely with the service provider to give you the best image quality and maintain the patient dose as low as possible and adjust your technique charts accordingly.
- Ensure you have updated your techniques for all imaging receptors in use.
- The service provider or you must adjust the preprogrammed techniques if they are to be used.
- Review your digital technical manuals very carefully, including:

  1. Manufacturer's specifications for maintenance and quality control of the digital imaging system

must be maintained onsite
2. Maintenance and quality control testing of the digital imaging system must be performed according to manufacturer's specifications

- Training must be done at the time of conversion and documented for all those who operate the digital system to ensure staff is aware of new exposure techniques, proper equipment usage, including use of holders, and equipment maintenance and quality control requirements.
- Update your Radiation Safety/Quality Assurance Manual to include procedures for the use digital imaging.
- Ensure you have updated your techniques for all imaging receptors in use.

PROCEDURES FOR LEAD APRON INTEGRITY EVALUATION

What is it?
The Lead Apron Integrity Evaluation is an evaluation of the lead inside of the lead aprons, half-aprons, gloves and thyroid collars has maintained its protective characteristics.

Why is it important?
Lead aprons, half-aprons, gloves, and thyroid collars protect the staff and the public, when needed, from unnecessary radiation exposure during radiology procedures. The Lead Apron Integrity Evaluation ensures that lead aprons, half-aprons, gloves, and thyroid collars provide an ideal level of protection against radiation exposure.

When is it performed?
The Lead Apron Integrity Evaluation must be performed initially prior to use and at intervals not to exceed twenty four (24) months.

What is the requirement?
Minnesota Rules, Chapter 4732.0550 requires lead apron integrity evaluations to be performed

- Initially and at intervals not to exceed twenty four months
- Anytime damage is suspected
- Minnesota Rules, Chapter 4732.0330 requires records be maintained for review by the X-ray unit

Note: Lead apron integrity evaluation must be performed for all personal protective garments regardless of the shielding material they are made of. The following procedures specify personal protective garments made with lead, but may be used for the different types of shielding material.

Items Needed

- All lead aprons, half-aprons, gloves and thyroid collars in use
- Identifier for each personal protective garment in use
- Technique of ~ 70 kVp and 10 mAs

Procedure
Film and CR Imaging (The same method may be used for DR imaging replacing the cassette with the digital imaging plate)

1. Lay the lead apron as flat as possible on the table top lengthwise. Remove any wrinkles.
2. Place a loaded 14" X17" cassette crosswise in the table bucky (cassette tray) and position the cassette and x-ray field over the chest area of the lead apron.
3. Collimate to the cassette.
4. Setting a technique of approximately 70 kVp and 10 mAs, make an exposure.
5. Using a second loaded cassette place it lengthwise and position the cassette and x-ray field over the abdomen and pelvis area of the lead apron.
6. Make another exposure.
7. Process the images as normal.
8. Repeat this process for all the lead aprons. Be sure to evaluate the front and back sides of a wrap-around apron.

9. Repeat this process for all half-aprons, lead gloves, and thyroid collars using an adequate sized cassette to evaluate the entire half-apron, lead glove and thyroid collar.
10. Review all images on a view box or monitor for pinholes, cracks, and tears in the shielding material. Tears in the vinyl or cloth outer covering does not necessarily compromise the integrity of the shielding material.
11. Any defects such as pinholes, cracks, and tears within the shielding material will show up as dark areas.
12. Any lead apron, glove or thyroid collar that fails the Lead Apron Integrity Evaluation must be removed from service. See Helpful hints below for failure criteria.
13. Save all associated images and evaluation documentation until the next inspection by the state.

Lead apron integrity evaluations may be performed using fluoroscopy. When using fluoroscopy you must:

- Perform steps 1 through 10, excluding steps 2 through 6
- Use auto mode, when imaging the protective garments for holes, cracks or tears in the protective lining
- Any defects such as pinholes, cracks, and tears within the shielding material will show up as bright and/or white areas on the monitor
- Document the name of the individual who performed and evaluated the lead aprons, gloves and thyroid collars

The Radiation Safety Officer (RSO) should review any defects in lead aprons, half-aprons, gloves or thyroid collars and consideration should be made as to the location and size of the defect prior to use or removal. MDH does not have rule requirements for what is considered a failure in lead integrity, although nationally recognized guidelines are provided below:

- Lead aprons with a defect >15 mm^2 over vital organs
- Lead aprons with a defect >670 mm^2 over non vital areas
- Lead gloves and thyroid collars with a defect >11mm^2

Lead aprons, can have a long service life as long as they are properly handled and maintained following the manufacturer's recommendations.

Helpful Hints

Some common causes of lead apron integrity failures:

- Lead aprons are folded and the leaded material is creased causing a crack
- Lead aprons and gloves are ripped or torn from repetitive use, improper handling and storage

Lead aprons, gloves and thyroid collars are hazardous to the environment and must be recycled and disposed of properly. A link to disposal services is available on our website Topic List page, X-ray Disposal.

PROCEDURES FOR PROCESSOR QUALITY CONTROL (QC)

What is it?
Daily processor quality control is used to verify consistency with the film processor and processor chemistry.

Why is it important?
There are three important pieces to reducing unnecessary patient dose and maintaining image quality. Well maintained and functioning x-ray equipment, qualified and well trained operators, and good consistent image processing. Under processing (developing of images) plays a significant factor in increased unnecessary patient dose through the need for increased exposure technique factors to compensate for the under processing, and in repeated examinations due to poor image quality.

When is it performed?
Registrants that process 10 or more films a week:

- Daily processor QC must be performed daily prior to processing the first patient films

Registrants that process less than 10 films in a week:

- Processor QC may be performed on the first day of the week prior to processing the first patient films
- When a registrant who routinely processes less than 10 films in a week and happens to process 10 or more patient films in a given week, processor QC must be performed daily prior to processing the first patient films after the 10th film is processed

What is the requirement?
Minnesota Rules, Chapter 4732.0550 requires films to be processed according to manufacturer's recommendations and quality control to be performed daily prior to processing the first patient films. *You must not process patient films when your daily QC evaluation is outside of your established control levels.*

Items Needed

- Calibrated Sensitometer
- Calibrated Densitometer
- Thermometer
- Quality Control Chart (A sample is provided at the end of this procedure sheet)
- Film

BASELINE PROCESSOR PROCEDURE

You must establish baseline processor operating levels when you initially set-up your processor or make significant changes in your film processing. Examples listed at the end of this document. These baseline processor operating levels are the levels that you compare with your daily processor QC evaluation to verify that your processing conditions to ensure your processing conditions are stable. Any time you perform processor QC you must ensure:

1. The darkroom environment has been evaluated and a darkroom fog test performed before establishing the processor quality control operating levels. If the darkroom fog evaluation does not meet the minimum requirements, darkroom fog must be addressed and corrected first.
2. The developer temperature is within the specified operating temperature of the manufacturer.
3. You have a calibrated sensitometer and densitometer and each is function according to the manufacturer's recommendations.

Procedure for establishing your baseline operating levels

1. Select the fastest film used at the facility. Those facilities that only have large film sizes; you may wish to cut these into smaller sizes to use for your daily quality control. Ensure that these cut films are cared for in the same manner as your other film. *Note: the emulsion number/lot of the box of film on the remarks section of the control chart.*
2. Using your sensitometer, expose and immediately process the film under the same conditions that you process patient films. Repeat this procedure once each day for 5 consecutive days.
3. Using your densitometer, read and record the densities of each step on the film, including an area of processed film that has not been exposed by the sensitometer. The densities of the steps should be measured in the center of each step.
4. Determine the average of the densities for each step using the densities for that step from the five films done on the 5 consecutive days.
5. Determine which step has an average density closest to but not less than 1.20. Designate this step the mid-density (MD) step. This step is often referred to as the speed point, speed index, or speed step.
6. Identify and record the step number and average density on the centerline of the processor control chart labeled mid-density.
7. Determine which step has average density closest to but not greater than 2.20 and which step has an average density closest to but not less than 0.45. Designate these steps the high-density (HD) and low-density (LD) steps. The difference in densities between these two steps should be designated the density difference (DD).
8. Identify and record these step numbers and the average density (DD) on the centerline of the processor control chart labeled density difference.
9. Determine the average of the densities from any unexposed area of the 5 films, measuring the same area consistently. This density will be designated as the base-plug-fog level (B+F) of the film. Record this value on the centerline of the processor control chart.
10. The numerical values for and each step number must be identified for the MD (including the HD and LD), DD, and the numerical value for the B+F must be recorded in the appropriate areas of the control chart. These are the baseline operating levels for the processor. You are allowed a range (Control Limits) of operation for your processing conditions. The control limits for your daily QC evaluation are as follows:

    ± 0.15 from the standard for MD and DD

    +0.03 from the standard for B+F
11. Record the upper and lower control limits for MD, DD, and B+F on the daily control chart. All daily quality control evaluation results are to be documented on this quality control chart.

Procedure for performing the QC daily once you have established your baseline standards

1. Ensure you are using the same film (emulsion/batch number) that was used to establish your baseline operating levels.
2. Check and document the developer temperature for each day that you process film to ensure the developer temperature is within the manufacturer's recommended temperature range.
3. Using a sensitometer, expose the film and immediately process the film under the same conditions that you process patient films. It is important to expose the film at the time the sensitometric strips will be processed.
4. After processing, use your densitometer to read the densities of each step that you have established as your baseline steps for MD (HD - LD), DD, and B+F
5. Document and graph the MD, DD and B+F on the chart.
6. If the MD, DD and B+F values are within the control limits, your processing is stable and may process patient films.

7. If the values are outside of the control limits, you must not process patient films until corrective action is performed and another daily QC evaluation is performed to ensure your processing is within the control limits.
8. When you are running low on the film (same emulsion/batch number) that you use to perform the daily QC with, you need to ensure that you perform a control film crossover.

CONTROL FILM CROSSOVER

Control film crossover and establishment of new operating levels should not be used:

- To correct problems in the processing system
- When replacing chemistry (same brand/type)
- When cleaning of processor as part of routine preventative maintenance

Radiographic film is produced in batches. Consequently, there may be slight variations in the characteristics of film between batches. In addition, film aging and storage conditions can affect the sensitometric characteristics of the film. Whenever a new box of film (different lot/emulsion number) is opened for QC purposes it is necessary to perform a "crossover" with the old film.

Procedures for performing Control Film Crossover

1. While there are at least five sheets of the old QC film remaining, select a new box of film for the processor QC. *Note: The emulsion number/lot of the new box of film on the remarks section of the control chart.*
2. Ensure you are performing the control film crossover according to conditions A-C under Procedures above.
3. Processor QC should be performed at the same time each day and before the first patient films are processed.
4. Expose and immediately process 5 sensitometric films each from the old and new boxes of film. The data calculations may be done at a later time if necessary.
5. Determine the new average of the steps identified for processor QC for MD, DD, and B+F from 5 films from the old box and from the 5 films from the new box.
6. Determine the difference in the average values between the new and old boxes of film, as shown in the example.
7. Adjust the old operating levels for MD, DD, and B+F by this difference to establish the new operating levels. If the difference (new – old) is a positive, the new operating level is increased. If the difference (new – old) is a negative, the new operating level is decreased.
8. Record the new operating levels and their new control limits on a new control chart.
9. Note the date the crossover was performed in the remarks section of the processing quality control chart.
10. A crossover worksheet and x-ray processing control chart are at the end of this Processor sheet and available on our website.

Helpful Hints

Below are some common conditions as to your processor QC evaluation may fail:

- Processor temperature is not within manufacturers' recommendations
- Water has been turned off to the processor and public water system has been recently flushed
- Replenishment rates have been changed
- Sensitometer or Densitometer is out of calibration
- Chemistry has been contaminated
- Chemistry is oxidized

Corrective Actions

The best way to initiate corrective actions is verify the above items are within operating limits:

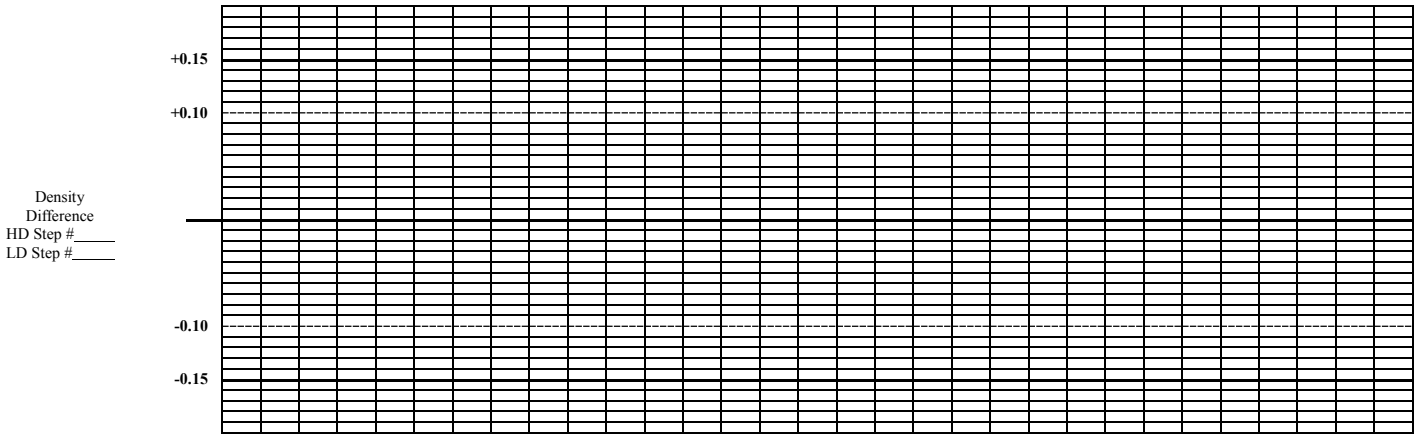
- Repeat the daily QC evaluation to ensure any corrective actions you performed have brought your processing QC within your established control levels
- If your corrective action is does not bring your processor within the control levels, you may need to contact your film and chemistry service provider

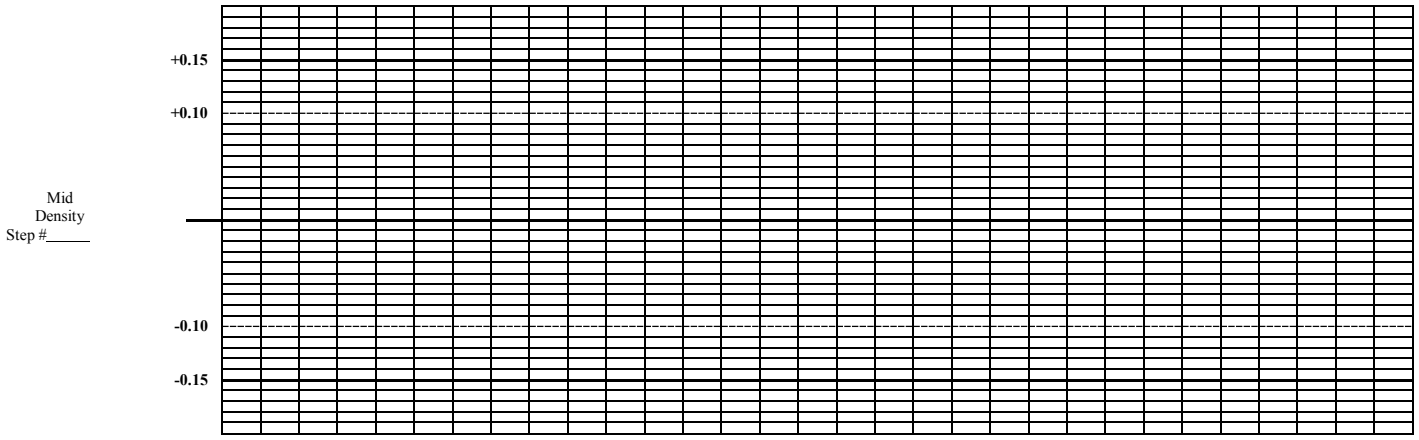
X-RAY PROCESSING CONTROL CHART

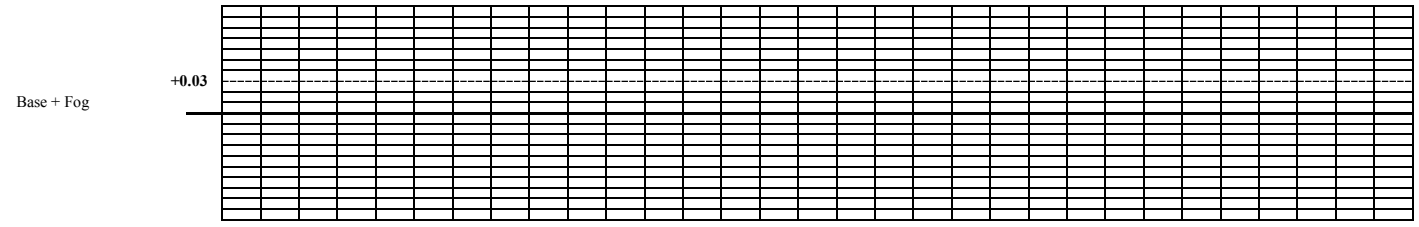
Processor:_____ Film:_____ Emul#_____ Month_____ Year_____

Month:

Date:







REPLENISHMENT RATE

Date	Developer	Fixer	Date	Developer	Fixer

TEMPERATURE

Date	Developer	Wash	Date	Developer	Wash

X-RAY PROCESSING CONTROL CHART

Remarks

Date	Action

SUMMARY OF REVISIONS
REVISIONS TO THE X-RAY REGULATORY GUIDE OF CHIROPRACTIC X-RAY FACILITIES

MDH X-ray Unit is always striving to better the information that we provide to registrants. This may include additions to the information presented in this guide. There may be occasion for revisions to this guide. **THESE REVISIONS ARE NOT CHANGES TO MINNESOTA RULES, CHAPTER 4732** and are intended to clarify or supplement what is already within the guide. Any revisions to this guide will be documented in the **SUMMARY OF REVISIONS.**

Date	Revision	Section	Description

Radiation Control, X-ray Unit
625 North Robert Street
P.O. Box 64497
St. Paul, Minnesota 55164-0497
651-201-4545
www.health.state.mn.us/xray

Delegation of Authority for a Radiation Safety Officer for an X-ray Facility
(Please retain for your records)

Facility Name: _____

Facility Registration Number: _____

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer for our x-ray department. You are responsible for ensuring the safe use of radiation. Your responsibilities include managing the radiation protection program, identifying x-ray radiation protection problems, ensuring quality control tests are completed and documented, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with state regulations.

You are hereby delegated the time and authority necessary to meet those responsibilities, including prohibiting the use of radiation-producing equipment by employees who do not meet the necessary requirements and shutting down operations where radiation safety is compromised. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Minnesota Department of Health at any time.

It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Your signature below indicates acceptance of the above responsibilities.

Name of Radiation Safety Officer	Name of Management Representative
_____	_____
Signature of Radiation Safety Officer	Signature of Management Representative
_____	_____
Date	Date
_____	_____

cc: Department Heads

Minnesota Department of Health
Radiation Control, X-ray Unit

Repeat/Reject Analysis Worksheet

Time Period: _____ **to** _____

Total # Films Used: _____

Cause	Number of Films	Total Number	Total Percentage
Film - Black			
Film - Dark			
Film - Good			
Film - Light			
Fog - Cassette			
Fog - Darkroom			
Mechanical			
Other			
Patient Motion			
Positioning			
Static			

The analysis must include at a minimum the overall retake or reject rate, and a summary of causes for the retakes. Include corrective actions if needed.

$$\text{Repeat Rate} = \frac{\text{Total Number Repeats}}{\text{Total Films Taken}} \times 100$$

Quarterly Repeat Rate _____

Optional: Individual Cause Repeat Rate = $\frac{\text{Total Number Repeats for That Cause}}{\text{Total Number of Repeats}}$

MINNESOTA MDH DEPARTMENT OF HEALTH

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625 North Robert Street
PO Box 64497
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651-201-4545
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health.xray@state.mn.us

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Patient Utilization Log

Date	Patient Identifier	Exam	# of Films	# of Retakes	Retake Reason	Operators	Holding Assistants

Retake Reason:

1 = Positioning
2 = Technique
3 = Too light
4 = Too dark
5 = Motion
6 = Jewelry
7 = Artifact
8 = Mechanical
9 = Static
10 = Fog

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