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

DENTAL X-RAY FACILITIES

April 1, 2015

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INTRODUCTION TO THE REGULATORY GUIDE FOR DENTAL REGISTRANTS

Minnesota Department of Health X-ray Unit Mission
The mission of the Minnesota Department of Health (MDH) X-ray Unit is to protect and promote radiation safety through education, 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 dental 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, instruction sheets, and additional guidance, is available on the MDH website as they are developed.

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

Implementation
The information in this regulatory 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 "Instruction Sheets" 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 e-mail at health.xray@state.mn.us.

Revisions to the MDH Regulatory Guide of Dental X-ray Facilities
MDH X-ray Unit is always striving to better the information that we provide to the dental 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 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 facilities and submitted to MDH. The Initial Registration application process 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 process may be found on our website.

FEES (4732.0210)

Fee Type	Amount
Facility Base Fee: due initially and annually	$100
Dental X-ray Equipment Fee	$40

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 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 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 management to ensure x-ray equipment is used safely, compliance with Minnesota Rules, Chapter 4732 is maintained, and the authority to stop operations that he/she considers unsafe. These responsibilities, the authority, 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 in your RSO.

Additional Radiation Safety Officer Information can be found in Attachment A:

- Typical duties and responsibilities
- Training and experience requirements
- Radiation Safety Officer Delegation Agreement

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

Operators of x-ray equipment in a dental setting must meet the requirements of Minnesota Statute, Chapter 150A for Dentistry. These individuals currently include:

- Licensed Dentists
- Licensed Dental Therapists
- Licensed Dental Hygienists
- Licensed Dental Assistants.

All qualification documentation must be available onsite for review. For specific questions regarding Minnesota Statute, Chapter 150A or the qualification requirements, you must contact the Minnesota Board of Dentistry.

- https://www.revisor.mn.gov/statutes/?id=150A
- https://www.hlb.state.mn.us/mnbod/glsuiteweb/homeframe.aspx

OPERATOR TRAINING

Minnesota Rules, Chapter 4732.0510 requires 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 or when new x-ray equipment is added.

Additional training is required for staff that uses Cone Beam Computed Tomography (CBCT), per Minnesota Rules, Chapter 4732.0865. Additional facility specific training requirement information can be found in Attachment B.

RADIATION SAFETY/QUALITY ASSURANCE PROGRAM (4732.0520)

You are required to have a 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 patients, 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 patients and occupational personnel
- 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 (tests used for routine assessment of an x-ray imaging system specific to the x-ray equipment and processing system(s)
- Training of the operators of x-ray equipment including documentation
- Radiation program audits
- Equipment performance tests, including a listing of the required tests can be found in Attachment D 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 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 staff and the public, and compliance with Minnesota Rule Chapter 4732. It is essential once problems are identified that 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 dental office should include, at minimum, a review of:

- Operating and emergency procedures
- Quality control procedures
- Required training
- Proper use of holding devices and personal protective garments
- Proper use of individual monitoring, if applicable
- Proper use of the technique charts
- Review of standing orders for recall patients
- Performance evaluations of the x-ray equipment
- All required records and the 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 C for questions to consider in an annual audit.

AS LOW AS REASONABLY ACHIEVABLE (ALARA) (4732.0530)

As

Low

As

Reasonably

Achievable

Every reasonable effort should be made to maintain radiation exposures as low as is reasonably achievable (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 dental setting may include:

- Commitment from management and staff
- Implement procedures for holding the patient or image receptor
- The manufacturer's instructions on the proper use of image receptor holding devices
- 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 dental 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 E of this guide.

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

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
- Equivalent procedure for identifying the veterinarian ordering the examination
- Individual monitoring devices
- 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 all individuals are properly protected (see Holding of Patient or Image Receptor and Lead Apron Use)
- All individuals wear a 0.5 mm lead equivalent apron or must be at least 6 feet from the patient or tube during the exam
- The X-ray tube and arm assembly is stable
- There is an unobstructed view of the patient during x-ray exam
- All x-ray equipment must have the following warning label. This label must be located on the control panel and 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 OPERATING 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
- 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

GONAD PROTECTION (4732.0510)

- Gonad protection is only required if the area to be radiographed is within two inches (5.0 cm) of the gonads
- Gonad protection is not required for patients in a dental setting because the area to be radiographed is not within two inches
- These are MDH minimum requirements and your facility may establish additional requirements to ensure patient well-being and protection

THYROID PROTECTION AND EYE PROTECTION (4732.0410)

Thyroid and eye protection are not required for patients in dental setting. MDH rules require 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 dental 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)

Per Minnesota Rules, Chapter 4732, you must have written procedures in place for declared pregnant staff and ensure the dose limits are not exceeded when staff declares a pregnancy in writing. Options are available to registrants for declared pregnant staff.

- Ensure the individual remains outside of the operatory when she is performing x-ray examinations and maintains safe operating procedures
- Remove individual from x-ray area during pregnancy
- Individual should not be in the operatory, 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 Chapter 4732.0440
- Additional information on declared pregnancy and prenatal dose may be found on our Topic Index, click on Prenatal Exposure

Dental x-ray equipment has a defined x-ray field that limits the radiation exposure to the patient's area of interest. When the image receptor, image receptor holder and x-ray equipment are used properly, it can significantly reduce unnecessary radiation exposure to the patient.

This can be done by:

- Using appropriate techniques for adults and children
- Using image receptor holders and alignment tools
- The cone of the intraoral x-ray tube must to be as close to the patient as possible to reduce exposure to the thyroid, eyes and other radiosensitive areas
- Ensuring the diaphragm or other beam limiting device is properly placed and the x-ray tube and image receptor are aligned when performing extraoral imaging

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:

Dental x-rays must be ordered by individuals approved per Minnesota Statute 150A:

1. A licensed dentist
2. A licensed dental hygienist who has a collaborative agreement with a licensed dentist that designates authorization for the services provided by the dental hygienist
3. A licensed dental therapist or advanced dental therapist who has a collaborative agreement with a licensed dentist that designates authorization for the services provided by the dental therapist or advanced dental therapist
4. Other individual specifically authorized in Minnesota Statute, Chapter 150A for Dentistry
5. An order for an examination must be available to the operator of the x-ray equipment at the time of the examination
6. The order must include:
    - Identification of the patient to be radiographed
    - Identification of the approved individual ordering the examination through signature, electronic signature or equivalent procedure

- Clearly stated clinical indications
- The exact anatomical part to be radiographed
- The examination to be performed

EQUIVALENT PROCEDURE FOR IDENTIFYING THE DENTIST ORDERING THE EXAMINATION

You are responsible for ensuring that all examinations are ordered by a licensed dentist 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 approved individual
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 approved individual to include the information required above, including a signature on the order

STANDING ORDERS FOR RECALL PATIENTS

Standing orders are for recall patients only, and must:

1. Be signed by all approved individuals
2. Be updated when there is any change in the standing orders
3. Have a policy must be in place for the scope of recall exams

Standing orders must also include the following:

- New patient or an emergency patient must be seen by the dentist and x-rays ordered prior to exam
- An approved individual review of the patient chart and ordering of x-rays without seeing the patient is permitted
- All x-ray orders must be documented in the patients chart

INDIVIDUAL MONITORING DEVICES (4732.0400-4732.0440)

Individual monitoring devices are not typically used in a dental 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 Rule, Chapter 4732.0410.

If a registrant chooses to use individual monitoring devices, the requirements of Minnesota Rules, Chapter 4732.0440 must be followed including record retention and reporting requirement, and providing occupational staff with appropriate dosimetry badges. Personnel must wear monitoring devices if:

1. They are likely to receive greater than 10% of the dose limits in Minnesota Rules, Chapter 4732.0410.

Due to the nature of dental imaging, it is unlikely that dental 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
3. Each individual who enters a high radiation area or very high radiation area
    - Highly unlikely in dental 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. It is good practice to maintain staff dosimetry badges with the control dositmetry 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 via email or the dosimtry 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 dental 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

Registrants must perform an evaluation to assess the need for individual monitoring of all occupational workers including dentists, dental hygienists, dental assistants, dental therapists 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 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.
    - Sister clinics
    - Other similar facilities
    - Patient workload
    - General radiography
    - CBCT
    - Fluoroscopy
    - C-arm use
4. All x-ray equipment uses within your 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 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.

The following shielding requirements are for all Dental Extraoral x-ray equipment including:

1. Cephalometric
2. Cone Beam Computed Tomography (CBCT)
3. Panoramic

Note: Dental Intraoral x-ray equipment is exempt from shielding requirements and a shielding plan is not required to be completed or submitted to MDH. You must, however, comply with the dental shielding requirements of Minnesota Rules, Chapter 4732.0365 and the operator protection requirements of Minnesota Rules, Chapter 4732.0880.

If you are a registrant that has extraoral x-ray equipment in rooms/areas that were constructed, structurally remodeled, or placed into use prior to February 2008, you are responsible for compliance with Minnesota Rules, Chapter 4732.0220, subpart 3.

If you are a registrant that has purchased a facility with existing extraoral x-ray equipment in rooms/areas that were constructed, structurally remodeled, or placed into use prior to February 2008, you are responsible for obtaining shielding documentation from the previous owner to ensure compliance with Minnesota Rules, Chapter 4732.0220, subpart 3.

If you are a registrant that has extraoral x-ray equipment in x-ray rooms/areas that were constructed, structurally remodeled, or placed into use after to February 2008, you are required to complete and submit a shielding plan in accordance with Minnesota Rules, Chapter 4732.0360. See Shielding Plans Section on pg. 17 of this guide.

The requirements for a registrant that has extraoral x-ray equipment in x-ray rooms/areas that were constructed, structurally remodeled, or placed into use prior to February 2008 were regulated under Minnesota Rules, Chapter 4730.1670, subpart 1, adopted in 1993. Chapter 4730 required a registrant to perform a radiation survey at the time of initial installation of x-ray equipment and after any change in the facility or equipment which might cause a change in radiation hazard:

Minnesota Rules, Chapter 4730.1670, subpart 1 states: Each registrant conducting diagnostic or therapeutic x-ray procedures must ensure that the radiation safety surveys specified in this part are site-specific and in compliance with this chapter. A survey must be performed at the time of initial installation and after any change in the facility or equipment which might cause a change in radiation hazard. A report of each survey must be prepared, maintained at the facility according to the record requirements in part 4730.1520, and made available to the commissioner on request. The safety survey must include the following:

A. An evaluation of the tube housing integrity;
B. Calibrations;
C. Equipment performance measurements;
D. Maintenance and equipment modifications;and
E. Shielding plans or results from radiation shielding evaluations.

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 registered with MDH 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

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.

3. Calculation to ensure occupational staff and the public do not receive a dose in excess of the following dose limits:
    - 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.

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. Due to the nature of the imaging, dental facilities typically do not incorporate the use of an operator's booth.

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 including: 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

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 plans must be submitted to MDH prior to the new construction, remodel or use in rooms/areas that were not originally designed for x-ray use.
4. 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. You were required to perform a radiation or evaluation of your room/area to ensure that staff and the public are protected from unnecessary radiation and the dose received are not in excess of the limits identified in this guide.

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

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 (4732.0555)

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 guidance documents are provided at the end of the regulatory guide.

You must implement site specific 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 image processing. The required testing and frequency of testing are listed below.

Quality Control Procedures include:

Quality Control Procedure	Rule Part
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
Cone Beam Computed Tomography (CBCT)	Minnesota Rules, Chapter 4732.0865
Dental Intraoral X-ray Equipment	Minnesota Rules, Chapter 4732.1100, subpart 11
Dental Extraoral X-ray Equipment	Minnesota Rules, Chapter 4732.1100, subpart 12

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.

You must ensure that the required testing and frequency of testing listed above is performed for all x-ray equipment, processors, and processing conditions. Corrective actions must be taken and verified to have corrected the out-of-limit parameters prior to using the x-ray equipment or processing patient images.

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

Daily Processor Quality Control Evaluation:

- Processor quality control testing to confirm the stability of your processor or chemistry prior to processing patient films:
    1. Daily prior to processing the first patient films
        - Crabtree test for intraoral processing
        - Step wedge test for extraoral processing
- Registrants processing greater than ten films a week must perform the processing quality control test:
    1. Daily prior to the first patient of the day
- Registrants that process less than ten patient films in a week may perform the processing quality control test:
    1. The first day that films are processed
    2. When greater than ten films are processed in a week, the processor quality control must be performed each day films are processed after the tenth film and prior to the first patient of the day

DARKROOM OR GLOVE BOX FOG TEST

You must ensure films must be processed under conditions that minimize unnecessary film fogging.

A darkroom or glove box fog test must be performed:

- 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:
- Initially prior to first use of the darkroom or glove box
- At intervals not to exceed six months
- Must be performed under all conditions for which film is processed
- Any time there may be a change in the processing conditions (new safelight, new bulb, moving daylight loader to a new location, etc.)

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.

RADIATION PROGRAM AUDIT

A Radiation Program Audit, or review of your quality assurance program, its content and implementation, must be performed every 12 months. See Attachment C for a sample Annual Audit for Dental X-ray Registrants.

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 in addition to:

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.

CONE BEAM COMPUTED TOMOGRAPHY (CBCT) FOR DENTAL USE

Facilities using Cone Beam Computed Tomography (CBCT) must follow the quality control recommendations of the manufacturer in addition to:

1. Initial calibrations of the digital x-ray system prior to first use
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.

CALIBRATIONS/PERFORMANCE EVALUATIONS (4732.0700) (4732.1100)

Calibrations/Performance Evaluations must be performed 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:
    - CBCT 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. Anytime maintenance is performed on the x-ray unit or system that may affect the results of the applicable tests required in 4732.1100

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. Due the minimal exposure risk from scattered radiation to any individual who may be required to wear a lead apron in a dental setting and the burden of performing this evaluation using dental equipment, therefore an evaluation of lead aprons in a dental setting may consist of a visual check to look for obvious tears, cuts, or rips, of the lead material.

The Radiation Safety Officer must review and document any defects in lead aprons, gloves or thyroid collars and consideration should be made as to the location and size of the defect prior to use or removal.

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

- Qualifications of the operators of x-ray equipment and ordering practitioners since the last inspection, including past and present, float, and temporary staff
- Training
- Calibration and performance evaluations
- Quality control testing
- Corrective action for any quality control tests which may have failed
- Radiation safety/quality assurance program audit
- Individual monitoring (where applicable)
- Radiation Safety Officer (RSO) Delegation Agreement
- Registration information
- Shielding information
- Signed Standing Orders

Note: You may be required to maintain records for accreditation purposes or as required by other regulatory agencies at the state or federal level.

HAND-HELD DENTAL X-RAY EQUIPMENT

The use of hand-held x-ray equipment in the state of Minnesota is unauthorized, per Minnesota Rules, Chapter 4732.0306. You must submit a hand-held x-ray equipment request and receive approval from MDH for hand-held x-ray equipment use prior to performing activities requiring the use of the x-ray equipment.

A hand-held x-ray equipment request may be granted only to rule and will not be issued to a non-compliant activity after that activity has taken place. When applying for a request, it must be submitted by the registrant and include the following information.

1. The specific language in the rule or rules from which the hand-held x-ray equipment request is requested
2. The reasons why the rule cannot be met
3. Alternative measures that will be taken to assure a comparable degree of protection to health or the environment
4. The length of time for which the hand-held x-ray equipment request is requested
5. A statement that the party applying for the hand-held x-ray equipment request will comply with the terms of the request, if granted
6. Other relevant information the commissioner determines necessary to properly evaluate the request for the hand-held x-ray equipment

MDH may attach alternative measures or conditions to a hand-held x-ray equipment request approval based on the conditions of use. Examples are listed below (the specific device would replace *"hand-held x-ray equipment"*):

- Operators of the *"hand-held x-ray equipment"* must receive training provided by the manufacturer prior to use
- Operators of the *"hand-held x-ray equipment"* must receive specific radiation safety training for its safe use at each location used
- The *"hand-held x-ray equipment"* must be calibrated
- The backscatter shield must be in place on the *"hand-held x-ray equipment"* during an exposure
- Only individuals necessary for the exam may be in the room during the exam, individuals in the room during the exam must wear 0.5 mm lead equivalent aprons
- Each operator of the *"hand-held x-ray equipment"* must be assigned an individual monitoring device, and it must be worn at the neck level (outside of the apron)
- The *"hand-held x-ray equipment"* must be secured and inaccessible to untrained personnel when not under direct supervision

You are responsible for ensuring your hand-held x-ray equipment request approval is current and you are compliant with the conditions of your approved request alternative measures or conditions, as well as all other applicable rules. You must submit a renewal application for your hand-held x-ray equipment request in writing 30 days before the expiration date. This will ensure that MDH is provided sufficient time to review your renewal application prior to your current expiration date. Renewal requests must contain all the required information, submission of the documentation required within the hand-held x-ray equipment request approval and additional information as requested by MDH to ensure compliance with your request approval and MDH rules.

If MDH does not receive a hand-held x-ray equipment request renewal or it is incomplete, an expiration letter will be sent indicating the termination date of your hand-held x-ray equipment request renewal. Registrants performing activities requiring hand-held x-ray equipment request approval after the specified expiration date may be subject to administrative penalties up to $10,000.

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, and 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 both 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
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

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/CBCT 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:

- 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.
- Students and externs who train within different practices must receive training at each location of practice.
- 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 C
ANNUAL AUDIT FOR DENTAL X-RAY REGISTRANTS
(4732.0540)

Only address those areas that apply to their 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**	☐	☐	☐
Holding procedures in place?	**4732.0510**	☐	☐	☐
Lead aprons in use?	**4732.0510**	☐	☐	☐
Standing orders for recall patients current?	**4732.0560**	☐	☐	☐
Declared pregnant staff?	**4732.0415**	☐	☐	☐
Quality Control Procedures	**4732.0510**	**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 all records been maintained?	**4732.0330**	☐	☐	☐

X-ray Operator Training	4732.0510	N/A	Yes	No
X-ray operators qualified?	**4732.0580**	☐	☐	☐
New x-ray operators received initial training?	**4732.0510**	☐	☐	☐
Training program implemented?	**4732.0510**	☐	☐	☐
Operating procedures?	**4732.0510**	☐	☐	☐
Emergency procedures?	**4732.0510**	☐	☐	☐
Training for changes in program? (new equipment, digital)	**4732.0510**	☐	☐	☐
Individual monitoring device	**4732.0440**	**N/A**	**Yes**	**No**
Are individual monitoring devices in use?	**4732.0440**	☐	☐	☐
Users notified in writing of annual exposure?	**4732.0440**	☐	☐	☐
Reports reviewed quarterly?	**4732.0440**	☐	☐	☐
Reports maintained for 30 years	**4732.0440**	☐	☐	☐
Is the monitoring worn in the proper locations?	**4732.0440**	☐	☐	☐

Summary of findings:

Corrective and preventive actions:

Audit conducted by: _____

Date: _____

ATTACHMENT D
CALIBRATIONS AND PERFORMANCE EVALUATION TESTS
(4732.0280 & 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 Code of Federal Regulations, Title 21, sections 1020.30 and 1020.31. If the manufacturer's specifications are unknown, the x-ray equipment must meet the specification of Minnesota Rules, Chapter 4732 or the Code of Federal Regulations, Title 21, sections 1020.30 and 1020.31.

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

Note: 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, within 24 months of the previous evaluation and any time there is a change or replacement to the x-ray equipment where applicable. Performance evaluations are to be performed at all clinically used settings.

- **Filtration or Half Value Layer (HVL):** This refers "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 teeth, jaw or soft tissue to reach the patient and produce an image. Lower energy x-rays which cannot penetrate the teeth, jaw or soft tissue add to the patient overall exposure but do does affect the x-ray image.

- **Radiation exposure at the end of cone:** MDH limits the maximum dose at the end of the cone on intraoral x-rays to reduce the patient dose. These maximums are based on the measured kVp of your x-ray unit and the speed of the film or imaging system you use. With proper development of the image, optimal image quality can be obtained using less than the maximums established by your service provider.

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

- **kVp Accuracy:** kVp is the factor which allows the x-rays to penetrate the area of interest and provide the contrast to your images.

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

- **Linearity:** This test is required only if your x-ray unit has multiple mA settings that are used clinically.

- **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:** A dental unit which 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.

- **Beam Size:** The area exposed to radiation must be limited to the area of interest and image receptor. It is very important to obtain the proper placement of the tube and image receptor to reduce the risk of clipping the area of interest and or exposing areas of the patient that is not to be imaged.
    1. Intraoral X-ray units:
    - If you are using a long cone dental unit the x-ray field size can be no larger than 2.75 inches (7cm) at the end of the cone
    - If you are using a short cone dental unit the x-ray field size can be no larger than 2.36 inches (6cm) at the end of the cone

    2. Extraoral X-ray units:
    - If the unit is designed for one image receptor size and has a fixed source to Image distance (SID) the beam size must be no larger than the image receptor
    - All other extraoral x-ray units must have a beam size no greater than 2% of the SID

    Note: These beam size limits allow for the entire image receptor to be exposed when the x-ray tube cone is properly placed at the surface of the skin and perpendicular to the image receptor. All Imaging must be performed with the x-ray tube cone placed as close to the surface of the patient's skin as possible.

ATTACHMENT E
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 additions 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.

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Registrant's Responsibility to Supervised Individuals

- Dental registrants will explain the ALARA concept and the need to maintain exposures as low as reasonably achievable to all staff.
- Dental 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.

Dental registrants will ensure staffs that are subject to occupational radiation exposure are 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 dental facility using x-ray equipment. Included are procedures for the following quality control tests:

Procedures

Dental Intraoral Daily Processor Quality Control
Dental Intraoral Fog Testing
Dental Extraoral Daily Processor Quality Control Step Wedge
Dental Extraoral Fog Testing
Adding or Converting to a PSP or a Digital Imaging System

Note: The following tests must be performed on extraoral film imaging cassettes at the same frequency as the performance evaluations of your x-ray equipment. It may be of value to have the service provider perform these tests for you.

Dental Extraoral Screen Contact Testing
Dental Screen Speed Match Testing

Guidance Documents

Additional Registration Form
Initial Registration Form
Processor Quality Control Crabtree Test
Processor Quality Control Step Wedge Test
Radiation Safety Officer (RSO) Delegation Agreement

PROCEDURES FOR DENTAL INTRAORAL DAILY PROCESSOR QUALITY CONTROL

What is it?
The dental radiographic normalizing and monitoring device, better known as the "Crabtree" test, along with a check of your developer temperature, is simple quality control test which can be used to evaluate the stability of your x-ray film processing conditions.

The stability of your processor is very important to the diagnostic quality and reproducibility of your patient films. Many registrants do not know they are under developing their patient films because they are adjusting the technique factors on the x-ray equipment to compensate for under development. This practice sacrifices the film quality and may increase an unnecessary radiation dose to your patients from under developing or having to repeat films.

An evaluation of your processing conditions must be performed daily prior to processing the first patient film. This test must be performed after the processor has had sufficient warm-up time and the temperature of the chemistry is within the manufacturer's recommendations.

What is the requirement?
Minnesota Rules, Chapter 4732.0555 requires processor quality control testing to be performed:

- Each day prior to any diagnostic films being processed
- Using a dental radiographic normalizing and monitoring device for the processor quality control test when intraoral film is processed
- Using the step wedge test when both intraoral and extraoral films are processed in the same processor

Items needed

- Dental Radiographic Quality Control Device
- Intraoral operatory used routinely for imaging, use the same operatory for your daily quality control testing
- Establish technique factors used for a posterior bite wing examination
- Thermometer, ready light

Procedure

- Designate an intraoral unit to use consistently for performing daily quality control testing.
- Set the technique on the intraoral unit that has been established for an adult posterior bite wing examination.
- Insert an unexposed intraoral film under the copper sleeve of the "Crabtree" device where it has been marked "Insert Film". Place the film in the same manner you would for a patient film with the correct side of the film toward the x-ray tube.
- Position the "Crabtree" device on a flat surface that is close enough to the x-ray tube so the cone of the x-ray tube can be placed on the top of the copper square where the unexposed x-ray film has been placed. This location has been marked by a circle around the copper sleeve.
- Expose the film using the established posterior bitewing setting.
- Before processing the film ensure the processor ready light is on or verify the developer chemistry is at the correct temperature with a thermometer.
- Process the film under the same conditions you would process a patient film.

- Insert the processed “Crabtree” film into the film slot marked “Film Slot” and compare the density of your film with that on the “Crabtree” device.
- The density of your film must be between the density marked 3 and the density marked 5 on the “Crabtree” device.
- Each day’s “Crabtree” film must be evaluated and documented prior to processing any patient films. Evaluation results and corrective actions taken must be saved until the next inspection by the State. The daily “Crabtree” films must be saved for 60 days.

If the daily test result is less than 3 or greater than 5 your processing is not within the range of stability and you must not process any patient films until corrective actions are taken and a follow-up “Crabtree” test has confirmed that processing is within established limits.

When performing this test it is very important that as many variables that may affect the results of this testing are removed. For this reason, once you have established an intraoral unit to use for quality control testing, document the room #, technique setting used and make sure these are used each time you perform the “Crabtree” test. A change in any of these conditions will affect the results of your testing.

Follow the Trouble-shooting Guide on the “Crabtree” device to identify what may be the cause of the test failing and what corrective actions you should take.

Helpful Hints

If your daily “Crabtree” test fails, repeat the test, confirming that all the procedures are followed:

- Same operatory
- Same technique setting (adult posterior bitewing established for the operatory used)
- Developer at the correct temperature
- Use the same view box or viewing conditions
- Maintain a record of your corrective action for future evaluations

If the second test fails you must perform corrective action and repeat the “Crabtree” test to verify your corrective actions have brought your processing within range of the established standard.

PROCEDURES FOR DENTAL INTRAORAL FOG TEST

What is it?
The darkroom/glove box (daylight processor) fog test is meant to determine and minimize the amount of unwanted light within the darkroom or glove box.

Why is it important?
Improper safelights and unwanted light in the darkroom or glove box 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 or glove box conditions that may introduce 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 to 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 the outline of a coin on the intraoral film

Items Needed
Timer
Coin
Unexposed Intraoral Film Packet (Fastest film in use)

Procedure
1. Set the timer for two minutes
2. Place all of the items needed for this test in the darkroom or glove box.
3. Ensure the darkroom or glove box is performed using the same processing conditions that are used for processing patient films: safelight on/off, cracks under door covered/uncovered, glove box filters open/closed
4. Under the conditions addressed above unwrap the film from the film packet and place the film in the typical work area of the darkroom or glove box (see Figure 1 for the glove box).
5. Place the coin on the film.
6. Start the 2 minute timer.
7. In the darkroom, stand back from the film to ensure your body is not shadowing it. Take the time to look around the darkroom for any potential light leaks or sources of unwanted light.
8. In a glove box, keep your hands in the cuffs and lean from the viewing window to ensure your body is not shadowing it. Evaluate the condition of the cuffs and any seals for potential light leaks.
9. When the timer goes off, process the film as usual.

10. Review the film to ensure it passes:
    - Figure 2 shows a passing fog test.
    - Figure 3 shows a failing fog test. If any difference between the covered and uncovered portions is seen, it may indicate the presence of darkroom fog. See corrective actions on the next page.
11. If the fog test fails, corrective action must be taken and another fog test must performed to verify the corrective action was acceptable.
12. Record the date, the results of the test (pass/fail), and save the film for state inspection.

Figure 1 – Intraoral Fog Test Set-up in a Glove box

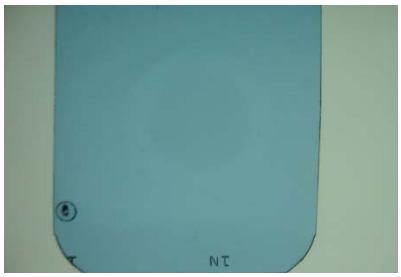


Figure 2 – Passing Fog Test

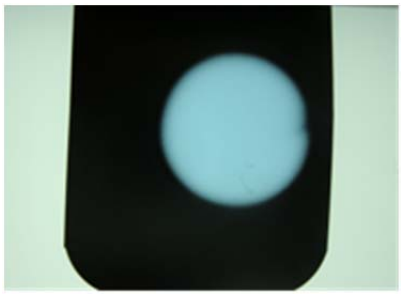


Figure 3 – Failing Fog Test

Helpful Hints
Common conditions why the fog test may fail.

Glove box:
- Placed under direct fluorescent lights
- Glove box cuffs are worn and fit loosely around the wrists
- Filter cover may be damaged or is not compatible with film used
- Seal between the glove box and processor are bad

Darkroom:
- Safelight/filter:
    1. Not compatible with the film being used
    2. Bulb in the safelight is too high a wattage
    3. Cracks
    4. Filter emulsion flaking off

- Electronic equipment indicator lights
- Glow in the dark stickers or toothbrushes
- Ceiling tiles that are not installed correctly
- Light leaks around ceiling fixtures
- Light leaks around the door

Corrective Actions

Glove boxes:

- If a daylight processor glove box fog test fails, try covering the viewing window filter when redoing the fog test to see if this is the source of fog. If that is the case, moving the processor to a different location or changing surrounding lighting conditions may help to remove the fogging conditions.
- Replace cuffs that are loose fitting.
- Glove boxes attached to table top processors may not seal properly. Place a flashlight in the glove box, close the cover and see if any light is coming out through the seal between the glove box and processor. If there is, light is also getting in during film processing.

Darkroom:

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 that 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 DENTAL EXTRAORAL DAILY PROCESSOR QUALITY CONTROL STEP WEDGE

What is it?
The step wedge test, along with a check of your developer temperature, is simple quality control test which can be used to evaluate the stability of your x-ray film processing conditions.

Why is it important?
The stability of your processor is very important to the diagnostic quality and reproducibility of your patient films. Many registrants do not know they are under developing their patient films because they are adjusting the technique factors on the x-ray equipment to compensate for under development. This practice sacrifices the film quality and may increase an unnecessary radiation dose to your patients from under developing or having to repeat films.

When is it performed?
An evaluation of your processing conditions must be performed daily prior to processing the first patient film. This test must be performed after the processor has had sufficient warm-up time and the temperature of the chemistry is within the manufacturer's recommendations.

What is the requirement?
Minnesota Rules, Chapter 4732.0555 requires processor quality control testing be performed:

- Each day prior to any diagnostic films being processed
- Using a dental radiographic normalizing and monitoring device for the processor quality control test when intraoral film is processed
- Using the step wedge test when both intraoral and extraoral films are processed in the same processor

Items needed

- Aluminum step wedge with at least 11 steps
- Loaded panoramic/cephalometric cassette
- Intraoral operatory used routinely for imaging, use the same operatory for your daily quality control testing
- Establish technique factors for the step wedge test, in the range of a posterior bite wing
- Tape measure or yard stick
- Thermometer, ready light

Procedure

1. Load a pan or cephalometric cassette under your normal Darkroom/glove box conditions.
2. Take the loaded pan or cephalometric cassette into an intraoral room that has been designated to use consistently for performing daily quality control testing.
3. Place the cassette on the floor.
4. Place step wedge on top of the cassette. Make sure you know which direction the step wedge is placed, along the long or short axis of the cassette. This will be important in the next steps.
5. 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 step wedge.
6. Expose the step wedge and cassette using your established setting.
7. Take the cassette into the darkroom and process the film under your normal processing conditions including the developer temperature.

8. Take the processed film and place a newspaper behind the step wedge image on the film. The darkest step at which you can see the newspaper print clearly will be your "standard density and step" to use for your evaluation. Tape a paper clip or other marker on this step. This will be your standard step on your step wedge film to compare with each of the daily step wedge films. ***Do not dispose of this film***. This film is your "standard" film which you compare your daily step wedge film to.
9. Compare the marked step on your standard with the same step on your daily step test film. The density of the marked step on your daily film must be within ± 1 step of the marked step of your standard.
10. Each day's step wedge film must be evaluated and documented prior to processing any patient films. Evaluation results including corrective actions taken for failed tests must be saved until the next inspection by the State. The daily step wedge films must be saved for 60 days.

If the daily test result is greater than ± 1 step from the standard step, your processing is not within the range of stability and you must not process any patient films until corrective actions are taken and a follow-up step wedge test has confirmed that your processing within established limits.

When performing this test it is very important that as many variables that may affect the results of this testing are removed. For this reason, once you have established a "standard film" using the procedures above, document the room #, technique setting used, the distance at which you performed the test and make sure these are used each time you perform the step wedge test. A change in any of these conditions will affect the results of your testing.

Helpful Hints

If your daily step wedge test fails, repeat the test, confirming that all the procedures are followed.

- Same operatory
- Same technique setting (kVp, mA and time)
- Same distance
- Developer at the correct temperature
- Use the same view box or viewing conditions

If the second test fails you must perform corrective action and repeat the step wedge test to verify your corrective actions have brought your processing within range of the established standard.

You may need to establish a new standard when:

- The x-ray unit used has been calibrated or replaced with a new x-ray unit
- New brand of film or chemistry
- New processor
- Using a different operatory for the step wedge testing
- Film used as the standard has degraded or lost

For any of these reasons you would need to follow the procedures above to establish a new standard film. Adding fresh chemistry or purchasing a new box of the same brand of film would not require you to establish a new standard.

Remove the excess film around the standard film and the daily test film. This will make it easier to perform a visual comparison of the density steps.

PROCEDURES FOR DENTAL EXTRAORAL FOG TESTING

What is it?
The darkroom/glove box (daylight processor) fog test is meant to determine and minimize the amount of unwanted light within the darkroom or glove box. *This test is not required for CR, DR, or PSP imaging systems.*

Why is it important?
Improper safelights and unwanted light in the darkroom or glove box 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 or glove box conditions that may introduce 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 the outline of a coin on the intraoral film

Items needed

- Aluminum step wedge with at least 11 steps
- Loaded pan/ceph cassette
- A currently calibrated intraoral operatory
- Establish technique factors for the step wedge test, in the range of a posterior bite wing
- Tape measure or yard stick
- Timer

Procedure

1. Load a panoramic or cephalometric cassette under your normal Darkroom/glove box conditions.
2. Take the loaded panoramic or cephalometric cassette into an intraoral room that is used routinely.
3. Place the cassette on the floor.
4. Place step wedge on top of the cassette. Make sure you know which direction the step wedge is placed, along the long or short axis of the cassette. This will be important in the next steps.
5. 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 step wedge.
6. Note the orientation of the step wedge to the film and expose the step wedge and cassette using your established setting.
7. Take the cassette into the darkroom or place in the glove box and use the same conditions that would be used for processing patient films.
8. Remove the film from the cassette and cover half of the film lengthwise on the step wedge image with something that is light opaque. Start the 2 minute timer.

9. In the darkroom: Stand back from the film to ensure your body is not shadowing the fog test film. Take the time to look around the darkroom for any potential light leaks or sources of unwanted light.
10. In the glove box test keep your hands in the cuffs and lean from the viewing window to ensure your body is not shadowing the viewing window. Evaluate the condition of the cuffs and any seals for potential light leaks.
11. When the timer goes off, process the film as usual.
12. Take the processed film and place a newspaper behind the step wedge image. Using the step you have established as your standard for the step wedge evaluation, review the density on the side of the film that was covered with the density on the side of the film that was uncovered.
    - The difference in densities between the covered and uncovered side must be less than a one-step density difference.
13. If the density is greater than one-step your fog test fails corrective action must be taken and another fog test must performed to verify the corrective action was acceptable.
14. Record the date, the results of the test (pass/fail), and save the film for state inspection.

Helpful Hints

Common conditions why the fog test may fail:

Glove box:

- Placed under direct fluorescent lights
- Glove box cuffs are worn and fit loosely around the wrists
- Filter cover may be damaged or is not compatible with film used
- Seal between the glove box and processor are bad

Darkroom:

- Safelight/filter:
    1. Not compatible with the film being used
    2. Bulb in the safelight is too high a wattage
    3. Cracks
    4. Filter emulsion flaking off
- Electronic equipment indicator lights
- Glow in the dark stickers or toothbrushes
- Ceiling tiles that are not installed correctly
- Light leaks around ceiling fixtures
- Light leaks around the door

Corrective Actions

Glove boxes:

- If a daylight processor glove box fog test fails, try covering the viewing window filter when redoing the fog test to see if this is the source of fog. If that is the case, moving the processor to a different location or changing surrounding lighting conditions may help to remove the fogging conditions.
- Replace cuffs that are loose fitting.
- Glove boxes attached to table top processors may not seal properly. Place a flashlight in the glove box, close the cover and see if any light is coming out through the seal between the glove box and processor. If there is, light is also getting in during film processing.

Darkroom:
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 that 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 ADDING OR CONVERTING TO A PSP OR DIGITAL IMAGING SYSTEM IN A DENTAL OFFICE

What is it?

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

- Many registrants converting intraoral x-ray units to a PSP, CR, or DR imaging system may only replace the film with a sensor.
- Panoramic, Cephalometric and Cone Beam CT (CBCT) units are generally replaced as a whole unit. Regardless of the imaging system an x-ray tube is necessary and the patient must receive radiation in order to generate the image.
- PSP, CR: After the exposure, the imaging sensor must be placed within an image reader to obtain the x-ray image.
- DR: 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?

PSP, CR, and Digital imaging do not require processing of the image in the same manner as film. This may reduce the patient dose from ½ to ¼ of conventional film imaging depending on the film speed in use.

What you must do?

- Submit a letter or email to the X-ray unit stating that you have gone digital whether it is be intraoral, extraoral or a combination of both.
- Retain this letter for your records.
- When installing new x-ray equipment in your digital conversion, the service provider must complete an installation calibration.
- When replacing only the image receptor (Film to PSP, CR, or DR sensors), new maximum posterior bitewing techniques must be developed.
- The maximum posterior bitewing doses must be at or below the following:
  - Digital imaging with a maximum dose below 120 mR
  - PSP, CR imaging with a maximum dose below 170 mR
- 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.
- The service provider or registrant must adjust the preprogrammed techniques if they are to be used
- Review your digital imaging technical manuals very carefully. Maintenance and quality control testing of the image receptors must be performed according to manufacturer’s specifications.
- Training will need to be done at the time of conversion and documented for all those who attend training to ensure staff is aware of new exposure techniques, proper equipment usage, including use of holders, and equipment maintenance and quality control requirements. All employees must have training documented.
- Update your Radiation Safety/Quality Assurance Manual to include procedures for the use of digital imaging.

PROCEDURES FOR DENTAL EXTRAORAL FILM / SCREEN CONTACT TEST

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 causes for poor contact which requires replacement are due to improper maintenance and handling. Be sure and follow the manufacturer's recommendations for cleaning and care.

Note: The metal curved cassettes are exempt from the screen contact evaluation.

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, fluctuations in the density 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. (Examples may be new hinges, felt padding or screen)

The screen contact test is required to be performed at 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.

Items needed
- 8 wire/inch mesh test tool or 7 hole per inch test tool
- All panoramic/cephalometric cassettes, each cassette must be identified along with the test film
- Intraoral x-ray unit
- View box

Procedure
1. Load with film each panoramic and cephalometric 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 to dissipate.
2. Take the loaded panoramic or cephalometric cassette into an intraoral room that is used routinely.
3. Place the cassette on the floor.
4. Place the screen contact test tool on top of the cassette.
5. 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.
6. Expose the test tool and cassette using half the timer setting used for your daily step wedge testing.
7. Take each cassette into the darkroom and process the film under your normal processing conditions.
8. View each film on a view box in a dimly lit room from a distance of approximately six feet or more.
9. Look for areas that are darker and/or more blurry than the rest of the film. This indicates poor contact.

10. If there is an area of poor contact and it may be 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
- Loose, bent or broken latches
- Warped screens
- Warped cassette front
- 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 DENTAL SCREEN SPEED MATCH TESTING

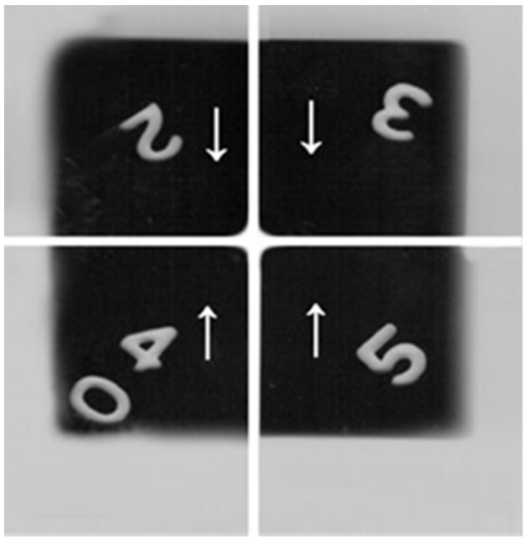
What is it?
The screen speed match test is performed to confirm there is a consistent image density from one cassette to another and must be performed on all x-ray cassettes used clinically.

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're 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.

Items needed
- All cassettes used clinically
- Identifier for each cassette and processed film *(paperclips, lead markers)*
- Technique used for your darkroom fog test evaluation
- 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 *(Example: 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 table top.
4. Place three cassettes including your master cassette on your x-ray table so that one corner of each cassette touches each other, f*or the larger cassettes make sure the film is in the corner you select.*
5. Center the x-ray field to the center where the four cassette corners meet *(arrows on the picture)* and cone down so that you are exposing an area of approximately 4 inches by 4 inches on each cassette.
6. Make an exposure using a similar technique that you use for your darkroom fog test evaluation, *a paw or carpus technique on a small animal.*
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 table top.
9. Visually inspect the films for significant density differences between the films.
10. If a film shows a significant density difference, remove the associated cassette from service. If you are reading the difference with a densitometer, the difference must be less than 0.10 Optical Density.
11. If you have more than four cassettes, you must repeat steps 2 through 9 using the same master cassette *(Example: cassette #40)* with the additional cassettes.
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.

SUMMARY OF REVISIONS TO THE X-RAY REGULATORY GUIDE OF DENTAL 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
04/01/15	Formatting	Throughout Regulatory Guide	Formatting changes were made to be consistent with other modality guidance documents that are available
04/01/15	Addition of dosimetry	Operation and Emergency Procedures	Requirements for the use of dosimetry, proper placement and record keeping
04/01/15	Addition of Shielding	Shielding Requirements	Requirements for shielding and shielding plans when extraoral x-ray equipment is in use
06/30/17	Hand-held Dental	Hand-held Dental X-ray	Revision effective July 1, 2017 per MN Statute 144.1215. Information Notice attached.

Minnesota Department of Health
Radiation Control, X-ray Unit

Processor Quality Control/Crabtree Test

Room #/Name _____ (always use same room)

Adult Molar Bitewing Technique: mA_____ Time _____ kVp_____ Distance _____

Date	Temperature	Crabtree Result	Staff Initial		Date	Temperature	Crabtree Result	Staff Initial

Crabtree results must be 3, 4 or 5. If not in this range, corrective actions must be taken showing passing score prior to using processor.

MINNESOTA MDH DEPARTMENT OF HEALTH

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

Minnesota Department of Health
Radiation Control, X-ray Unit

Processor Quality Control/Step Wedge Test

Room #/Name _____ (always use same room)

Step Wedge Technique: mA_____ Time _____ kVp_____ Distance_____

Date	Temperature	-1	0	+1	Initial	Date	Temperature	-1	0	+1	Initial

If Step Wedge Test is off by two steps (+ or -), corrective actions must be taken showing passing score prior to using processor.

Standard step_____.

MINNESOTA MDH DEPARTMENT OF HEALTH

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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

X-ray Unit Information Notice

HAND-HELD DENTAL X-RAY EQUIPMENT

Date: July 1, 2017

To: Dental Registrants in Minnesota

From: Teresa Purrington, BS, RT (R) (CT), Supervisor, X-ray Program

Subject: Hand-Held Dental X-ray Equipment

The Minnesota Department of Health (MDH) is issuing this Information Notice (IN) to inform dental registrants of recent law changes involving the use of hand-held dental x-ray equipment for human use. The 2017 Legislature authorized the use of hand-held dental x-ray equipment beginning July 1, 2017. *See* Laws 2017, 1st special session, Chapter 6, Article 10, Section 58.

Minnesota Statutes, section 144.1215 [new] specifies hand-held dental x-ray equipment requirements and operators who are authorized according to Minnesota Statutes, Chapter 150A. In addition to these statutory requirements, a registrant must also comply with applicable Minnesota Rules, Chapter 4732.

Minnesota Rules, Chapter 4732

Applicable rules required for hand-held dental x-ray equipment registrants.

- Registration requirements listed under part 4732.0200. Hand-held dental x-ray equipment must be maintained at the registrant's facility with the person having administrative control of the x-ray equipment.
- Registration fees under part 4732.0210.
- General requirements under part 4732.0220, Subp.1 & 2.
- Reciprocity use outlined in part 4732.0250.
- Exemptions listed in part 4732.0300.
- Applicable prohibited uses listed in 4732.0305.
- Unauthorized requirements listed in part 4732.0306, Items B, D, & E.
- General administration requirements under parts 4732.0308, 4732.0310, 4732.0315, and 4732.0320.
- Record requirements under part 4732.0330.

  A registrant who currently has a variance to use hand-held dental x-ray equipment in Minnesota must complete records required under the variance through June 30, 2017 and must maintain the records for review at the registrant's next inspection.

- Inspection and enforcement requirements in parts 4732.0335 and 4732.0340.
- Radiation dose levels and individuals monitoring requirements of parts 4732.0400 through parts 4732.0440. Dosimetry is required for individuals who are likely to receive greater than 500 mRem occupational dose in a year.

- Safety and radiation safety officer responsibilities in parts 4732.0500 and 4732.0505. A registrant must identify a radiation safety officer and the individual is responsible for the operation of the hand-held dental x-ray equipment under the registrant's administrative control.
- Procedures and safety instructions under part 4732.0510.
- Quality assurance and ALARA program requirements under parts 4732.0520 and 4732.0530.
- Annually review a registrant program with a program audit listed in part 4732.0540.
- Requirements under parts 4732.0550 for radiographic practice standards, 4732.0555 for x-ray equipment processing, 4732.0560 for ordering of radiographic procedures, and 4732.0580, Item C.
- A registrant must report and notify to MDH immediately after the theft of the hand-held dental x-ray equipment is known according to part 4732.0600.
- Calibration requirements under parts 4732.0700, Subparts 1, 3, & 4.
- General equipment requirements listed in part 4732.0800, excluding Subpart 2, Item B.
- Requirements for intraoral dental radiographic systems listed in part 4732.0880, excluding Subpart 2, Item C. An individual who is operating the hand-held dental x-ray equipment must be protected by a personal protective garment.
- Hand-held dental x-ray equipment must be calibrated according to parts 4732.1100, Subparts 1, 2 & 11.

For specific questions related to hand-held dental x-ray equipment use, please contact Craig Verke at (651) 201-4533 or Teresa Purrington at (651) 201-4519.

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2017 Handheld Dental X-ray Legislation

Laws 2017, 1st special session, Chapter 6, Article 10, Section 58

Sec. 58. [144.1215] AUTHORIZATION TO USE HANDHELD DENTAL X-RAY EQUIPMENT.

Subdivision 1. Definition; handheld dental x-ray equipment. For purposes of this section, "handheld dental x-ray equipment" means x-ray equipment that is used to take dental radiographs, is designed to be handheld during operation, and is operated by an individual authorized to take dental radiographs under chapter 150A.

Subd. 2. Use authorized. (a) Handheld dental x-ray equipment may be used if the equipment:

(1) has been approved for human use by the United States Food and Drug Administration and is being used in a manner consistent with that approval; and

(2) utilizes a backscatter shield that:

(i) is composed of a leaded polymer or a substance with a substantially equivalent protective capacity;

(ii) has at least 0.25 millimeters of lead or lead-shielding equivalent; and

(iii) is permanently affixed to the handheld dental x-ray equipment.

(b) The use of handheld dental x-ray equipment is prohibited if the equipment's backscatter shield is broken or not permanently affixed to the system.

(c) The use of handheld dental x-ray equipment shall not be limited to situations in which it is impractical to transfer the patient to a stationary x-ray system.

(d) Handheld dental x-ray equipment must be stored when not in use, by being secured in a restricted, locked area of the facility.

(e) Handheld dental x-ray equipment must be calibrated initially and at intervals that must not exceed 24 months. Calibration must include the test specified in Minnesota Rules, part 4732.1100, subpart 11.

(f) Notwithstanding Minnesota Rules, part 4732.0880, subpart 2, item C, the tube housing and the position-indicating device of handheld dental x-ray equipment may be handheld during an exposure.

Subd. 3. Exemptions from certain shielding requirements. Handheld dental x-ray equipment used according to this section and according to manufacturer instructions is exempt from the following requirements for the equipment:

(1) shielding requirements in Minnesota Rules, part 4732.0365, item B; and

(2) requirements for the location of the x-ray control console or utilization of a protective barrier in Minnesota Rules, part 4732.0800, subpart 2, item B, subitems (2) and (3), provided the equipment utilizes a backscatter shield that satisfies the requirements in subdivision 2, paragraph (a), clause (2).

Subd. 4. Compliance with rules. A registrant using handheld dental x-ray equipment shall otherwise comply with Minnesota Rules, chapter 4732.

Effective July 1, 2017.

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