MINNESOTA DENTAL ASSOCIATION®

RADIATION SAFETY MANUAL

Contributors: Frederick W. Nolting DDS, MS, Scott Lingle DDS, Nate Pedersen DDS, Dave Resch DDS, Scott Wagnild DDS, Hanna Nguyen-Dao, RDH-MDA Regulatory Affairs

Reviewed & Updated: 2023

This manual has been developed to help your office in constructing your own Radiation Safety Manual. Our goal is to make compliance with the statutes and rules as simple as possible and streamline the task of review by your employees and the MDH X-ray Unit.

GETTING STARTED

This guide is arranged to help you organize your Radiation Safety Program. The outline and addendums are made to assist you in implementing your office's program as easily as possible. The sections are divided as follows:

Section I. Office Policies
Section II. Radiation Biology Section
Section III. Employee Training
Section IV. Periodic and Special Documentation Requirements
Section V. Addenda

The examples given for you are to be used as a guide. Modify these to fit your practice. A very good, and simple way to start is to use a 3-ring notebook to organize these documents. This allows flexibility in the order in which you wish to store them. Using clear plastic "sheet protectors" will keep documents clean and securely held in the binder. They can be replaced with new sheets as they become dated. The addenda are also examples which can be modified to fit your practice policies. Be sure that all required information is retained on each addendum when it is modified.

Further guidance from MDH X-Ray Program website can be accessed online from the MDA members portal. In the accompanying outline, commentary is provided to assist you in building your manual.

We hope this Manual provides you with all of the tools to make your Radiology Program successful. It is our intent to help you in every way possible, making the regulatory requirements easily fulfilled.

— Environment and Safety Committee

Registration of Equipment

If you are a new owner of ionizing radiation equipment, prior to first use, and within 30-days you must register your units and pay applicable fees with the Minnesota Department of Health X-ray (MDH X-ray). The registration form is online via the Minnesota Department of Health X-ray Unit. If you are an existing facility and need to add or make changes in information, it can be completed online.

Initial registration, additional x-ray equipment registration, and annual registration renewal information is available on the **MDH Registration** webpage.

All questions regarding to MDH X-Ray registration should be directed to:

- MDH X-ray Unit at 651-201-4545.
- Emails are also welcomed to: **health.xray@state.mn.us.**
  - » This webpage includes all applicable registration information.

Registrations should be kept in your manual, along with all copies of equipment repairs. Annually, registration fees are paid for all x-ray units. MDH emails registration renewal reminders to registrants via email approximately 60-days in advance for annual registration. Annual registration must be completed on the online **X-ray Registration System**. Renewal registration certificates are no longer mailed to the registrant and can be printed off the online X-ray Registration System upon completion of registration renewal.

Any information notices and registrant information are emailed to all registrants to the email address listed on the registrant's registration.

SECTION I OFFICE POLICY

This section contains elements that are required to be in your manual. The items that are followed by two asterisks ** can be copied into your manual verbatim when the item applies to your practice.

Page one of your manual should include:
Practice letterhead and your MDH X-ray Facility registration website and information for your office.

A.L.A.R.A. (As Low As Reasonably Achievable) Statement:
THE OVERRIDING PRINCIPLE OF OUR RADIOLOGY PROGRAM IS TO RECORD ALL THE NECESSARY INFORMATION AND TO ACHIEVE A DIAGNOSIS WITH THE LEAST AMOUNT OF RADIATION EXPOSURE TO OUR PATIENTS. (As Low As Reasonably Achievable). **For background information view, "THE USE OF DENTAL RADIOGRAPHS" (MDH Attachment E).

ROUTINE RADIOGRAPHIC EXAMINATIONS

List all of the routine radiographic examinations performed in your office. List the examination, and include any short hand used to list the examination in your computer/chart.
Example: 2 BW- Two routine bitewing x-rays
PAN- Routine panoramic x-ray

NON-ROUTINE X-RAYS

All routine and non-routine x-ray examinations must include written orders prior to the examination being performed. Standing order for recall patients is allowed in the practice of dentistry when the following requirements are met:

A. The standing orders are in writing;
B. Limited to recall patients;
C. Signed by all the dentists; and
D. The facility establishes a policy that defines the scope of the recall patient standing order.

LEAD PROTECTIVE DEVICE USE (APRONS, GLOVES, THYROID COLLAR, ETC.)

Lead protective aprons and thyroid collars for patient protection is not required in the practice of dentistry. A lead protective apron is required only when the primary x-ray beam is within 2 inches of the gonads. Individuals other than the patient who must remain in the operatory, and are within six (6) feet of the patient or the x-ray tube must wear a lead protective apron of at minimum 0.5 mm lead equivalency.

MDH requires lead integrity testing of all lead aprons that are in use, whether for patient or any individual(s) that must remain in the room.

For practices using lead aprons and/or other shielding devices (i.e. lead lined glove used to help stabilize a patient's head) to protect the patient and/or clinician from radiation exposure, are required to test these devices biennially (i.e. every 24 months). Testing must also be documented and recorded in this section. (See Addendum 1.)

USE OF IMAGE RECEPTOR HOLDERS

The following statement should be recorded in your manual and followed by all personnel and patients:

"Image receptor holders, i.e. bite blocks, hemostats, etc should be used whenever possible, when the quality of the image is not affected by the holder or the holding method. Direct holding of the x-ray film or recording device by dental personnel is prohibited. If dental personnel need to help a patient hold a film or recording device, they can only do so by using a device that assures they will not be exposed by the primary x- ray beam. Patients are allowed to hold the image receptor when the use of image receptor holders is not feasible, as in the case of endodontic procedures." **

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:

- Use appropriate techniques for adults and children
- Place the cone of the x-ray tube as close to the patient's skin as possible to reduce potential exposure to the thyroid, eyes and other radiosensitive areas

Follow image receptor holders and alignment tool procedures for use.

RADIATION SAFETY OFFICER

MDH requires that the registrant keep the information for registration current (4372.0200). List the Radiation Safety Officer for the practice. If the Radiation Safety Officer is not the owner of the practice, include the proper documentation stating the identity and qualifications of the Radiation Safety Officer. Also include a current copy of the agreement between the owner and the Radiation Safety Officer. Both the owner (or owner/management representative) and the Radiation Safety Officer must be listed with their signatures next to their listing. (Addenda #4 and #5)

PREGNANCY

When an employee declares, in writing, that she is pregnant, The Radiation Safety Officer will countersign the written declaration and include it in this section of the manual. The Radiation Safety Officer and the pregnant employee will then review the practice's policy for pregnant employees and institute the policy for the full term of the employee's pregnancy. (Addendum #6)

Stated below is an acceptable policy:
When an Employee declares pregnancy in writing, the Radiation Safety Officer will initiate a review of radiation hygiene. A review of barriers will also be done. Under no circumstances will the pregnant employee be allowed to assist holding a patient or a film for a patient. The employee will be required to stand behind barriers during the exposure of the radiograph(s).

This policy is to be signed by the owner and Radiation Safety Officer. A copy of this policy is to be signed and dated by the Radiation Safety Officer and the pregnant employee, as soon as feasible after the written declaration of pregnancy is received and entered into this manual.

If your office chooses to use radiation monitoring devices, you will be required to keep records of all the employees, devices, results for the required period of time as outlines in MDH X-ray Rule. (**4732.0440 INDIVIDUAL MONITORING**)

SECTION II. RADIATION BIOLOGY

BIOLOGICAL EFFECTS OF RADIATION

1. "Biological Effects of Radiation from Dental Radiography" JADA, Vol. 105, August 1982, pp. 275-281. (Addendum 2)
2. "The Use of Radiographs, Update and Recommendations JADA Vol. 137, Sept 2006,pp. 1304-1311. (Addendum 3)

Have both of these documents in your manual. Use them for training new staff and staff declaring pregnancy in writing.

SECTION III. EMPLOYEE TRAINING

There is no requirement for Annual Training, however it is encouraged, especially in practices with many employees and multiple offices.

New Employees- New employees must be trained in the following areas:

1. Trained in all radiographic procedures performed in the practice.
2. Review of the Radiation Biology section.
3. Review of the Radiation Safety Manual.
4. Review of the developing procedures and dositometry testing (Film).
5. Review of software and hardware procedures (Digital).
6. Review of the emergency operating procedures for the x-ray equipment

New Procedures- All employees must be trained when a new radiographic procedure is begun in a practice. Any documentation for the new procedure such as new software must be included in this manual.

New Equipment- Whenever different x-ray equipment, darkroom equipment, scanning equipment, and/or software is installed, all personnel are required to train with the new equipment/software. The only exception would be a replacement piece of equipment that is identical to another already in use. An example is when an intraoral x-ray machine is replaced with a machine identical to one other already in use in that practice.

All training must be documented. (Addendum 7)

Pregnancy- When an employee declares pregnancy in writing, Review of all radiographic procedures; safety and radiation biology must be done and recorded. (See Section III under “New Employees” 1.-5.)

SECTION IV. PERIODIC AND SPECIAL DOCUMENTATION

OFFICE RELOCATION/CONSTRUCTION/REMODELING & SHIELDING PLANS

Shielding plans are required for extraoral X-ray systems (pan/ceph/CBCT). Shielding plans must be completed and submitted to MDH prior to construction, remodel, or installation in an existing room where the extraoral X-ray system is to be installed. A shielding placard is required to be permanently mounted in the room/area specifying the amount and type of shielding in all walls, doors, partitions and, if occupied, spaces above and/or below the floor and/or ceiling. ***Verification of the shielding must be documented with the documentation made a permanent part of the Radiation Safety Manual***. ALL of this documentation must remain in the Radiation Safety Manual of this practice as long as the practice is in existence or the practice is sold and remains in the same location.

PROOF OF LICENSURE OF X-RAY OPERATORS

A copy of the licenses of all x-ray operators must be in the Radiation Safety Manual. These must be retained until the next MDH x-ray inspection is completed. Proof of all operators must be provided for the time between inspections/audits. i.e. if the previous inspection was performed in 2008 and the new inspection is performed in 2011, all of the licenses of all operators working in the practice between 2008 and 2011 inspections must be in the Radiation Safety Manual. This includes float staff, temporary staff, and staff that are no longer employed. Some operators working during that entire time will have multiple licenses. Proof of licensure of each operator must be kept in the Radiation Safety Manual from the date of the last inspection by MDH until the completion of the next inspection by MDH.

ANNUAL X-RAY AUDIT

The Radiation Safety Officer must complete an annual X-ray audit of all radiographic procedures used, review all documentation pertaining to radiography in the manual, identify and document any remedial actions needed along with the date(s) the remediations were completed. Documentation of all annual audits must be kept in the Radiation Safety Manual from the date of the last inspection by MDH until the completion of the next inspection by MDH. (MDH ATTACHMENT E)

CALIBRATIONS

Whenever any X-ray machine is repaired or relocated a calibration of the x-ray equipment must be performed. All functions must be checked and verified to be working properly. This must be documented in the Radiation Safety Manual. (Addendum 8)

PERFORMANCE TESTING

(Biannual) Performance Testing of Equipment- Biannual testing of equipment must be performed every 24 months. The service Provider is to test all x-ray equipment producing radiation and make sure the Radiation Safety Officer is given written performance documents for all machines including any remedial action(s) that need(s) to be completed. In addition, the Service Provider must show documentation that he/she is registered with the MDH X-ray Unit. This documentation must be kept in the Radiation Safety Manual from the date of the last inspection by MDH until the completion of the next inspection by MDH. Service providers are also required to retain records of inspections for four years.

PROCESSING

The stability of your processor is very important to the diagnostic quality, reproducibility of your patient films and dose to the patient. Unless proper quality control measures are taken, staff may not know they are under developing their patient films. Instead, technique factors are adjusted on the x-ray equipment to compensate for under development. This practice increases unnecessary radiation dose to the patient and sacrifices the image quality.

Two methods of processing quality control currently used in the dental practice that comply with MDH rules are:

The Crabtree test for processing intraoral film
The Stepwedge test for processors used to develop extraoral and intraoral film. Processor quality control testing must be performed on the film that is most sensitive to development conditions.

- When extraoral film is processed
  - » 11-step Step wedge
- When only intraoral film is processed
  - » Crabtree test device

Follow the manufacturer's directions for performing the Crabtree test and guidance for the step wedge test and charts for recording the test results are in Addendum 9.
Results of the test must be documented each day the developing system is used and must be kept in the Radiation Safety Manual from the date of the last inspection by MDH until the completion of the next inspection by MDH (Addendum 9).

Fog Test

The fog test is conducted every six months and whenever a safe light bulb is changed, or safe light filter is changed. Fog test evaluations are required for all darkroom and glovebox conditions used when processing. The results and corrective actions are noted on the log for the fog test. The log and films must be kept in the Radiation Safety Manual from the date of the last inspection by MDH until the completion of the next inspection by MDH.

Two methods for performing the darkroom/glove box fog test currently used in the dental practice that comply with MDH rules are:

- The coin test when only intraoral film is processed
- The step wedge test when extraoral film is processed
- The step wedge test when extraoral and intraoral film is processed under the same conditions in the darkroom or glove box.

Instructions for conducting these tests and a chart to record results are in Addendum 10.

Screen/Film Match
The Speed/Match test verifies that the film being used matches the intensifying screen of the cassette. This test is done every 24 months and must be kept in the Radiation Safety Manual from the date of the last inspection by MDH until the completion of the next inspection by MDH. (Addendum 11).

Screen Film Contact Test
The contact test is performed every 24 months to verify that the screens and film are evenly in contact. This ensures your radiograph image is not distorted. The record of this test must be kept in the Radiation Safety Manual from the date of the last inspection by MDH until the completion of the next inspection by MDH. (Addendum 12) Specialized test tools are necessary for the screen contact test and screen/film speed match tests, and it is recommended that these tests are performed by your service provider at the same time of your x-ray equipment calibrations or performance evaluations.

DIGITAL SYSTEMS

You must follow the manufacturer's recommendations for quality control of your digital imaging system. A copy of your digital radiograph system software operation manual and sensor information (or scanner/phosphor plate system) must be included in your Radiation Safety Manual. This includes Intraoral, Panoramic, Cephalometric and CBCT systems. These documents provide the information necessary to operate and correct problems encountered within these systems.

If your manual only exists online, record the vendor information and web address below for your Manual reference:

Vendor _____ Website:_____

INTRAORAL, PANORAMIC, and CEPHALOMETRIC SYSTEMS

For Panoramic, Cephalometric, and Intraoral Radiography, your manual must contain the manual for the software, the sensor system, (or scanner/phosphor plate system). These documents provide the information necessary to correct problems encountered with these systems.

COMPUTERIZED TOMOGRAPHY/CONE BEAM SYSTEMS

Performance Evaluations:

Daily and Monthly Performance Evaluations
Daily and monthly evaluations following manufacturer's procedures or the procedures outlined in 4732.1100, including all processing procedures outlined in 4732.0510. A phantom must be used. (Addendum 13)

The CBCT/CT manufacturer is required to provide you with a phantom(s) and instructions on the use of the phantom(s). This requirement is Code of Federal Regulations Section 1020.33 Computed tomography (CT) equipment 1020.33 under (d) Quality assurance.
(d) Quality assurance. The manufacturer of any CT x-ray system shall provide the following with each system. All information required by this subsection shall be provided in a separate section of the user's instructional manual.

(1) A phantom(s) capable of providing an indication of contrast scale, noise, nominal tomographic section thickness, the spatial resolution capability of the system for low and high contrast objects and measuring the mean CT number of water or a reference material.
(2) Instructions on the use of the phantom(s) including a schedule of testing appropriate for the system, allowable variations for the indicated parameters, and a method to store as records, quality assurance data.
(3) Representative images obtained with the phantom(s) using the same processing mode and CT conditions of operation as in paragraph (c)(3) of this section for a properly functioning system of the same model. The representative images shall be of two forms as follows:
(i) Photographic copies of the images obtained from the image display device.
(ii) Images stored in digital form on a storage medium compatible with the CT x-ray system. The CT x-ray system shall be provided with the means to display these images on the image display device.

Reach out to your CBCT/CT manufacturer and verify the required phantom(s) and instructions are provided to you. MDH x-ray will review the above requirements during future inspections to verify compliance (4732.0865, subpart 6).

Bi-annual (24 month) Performance Evaluation
Performance evaluations must be performed by a registered service provider at 24 month intervals or a change/replacement of component(s) that could cause an increase in radiation hazard or could result in the minimum performance criteria not being met. The measurements must be made with a calibrated system traceable to national standards.

Annual Spot Checks
Spot checks must follow all manufacturers' recommendations for performance testing and are to be performed at intervals not exceeding 12 months or an interval specified by the manufacturer, which ever is less. All tests must use a phantom under the same conditions as the biannual performance evaluation. Photographic images or digital images obtained from the spot checks must be retained until a new equipment performance test is completed. The documentation of all tests must be retained from one inspection to the next inspection.

Corrective Actions for CBCT Equipment Problems

A. Correction of the problem must take place and be verified by performing the equipment performance measurements according to:

(1) Code of Federal Regulations, title 21, section 1020;
(2) the manufacturer's specifications; or
(3) part 4732.1100.

B. The equipment must not be used until corrective actions have been taken, verified, and documented, if the equipment performance measurement or spot check of the CT system indicates that a

system operating parameter has exceeded a tolerance established:

(1) in part 4732.1100;
(2) by the manufacturer; or
(3) by a registered service provider.

CBCT software and instructional manual

A copy of your CBCT (cone beam computed tomography) software program operating guide and machine operating guide must be kept in the Radiation Safety Manual. If your manual is online only please record vendor and web address here for reference:

Vendor_____ Website:_____

Further Information
"Operational Principles for Cone Beam Computed Tomography" JADA Vol. 141(10), Oct 2010, pp. 3S-6S. (Addendum 15)

Minnesota Department of Health Inspections
All records including letters, inspection reports, correction orders, and the practice's response to the correction orders of the current inspection must be maintained until the successful closure of the next Minnesota Department of Health inspection.

The Radiation Safety Officer or Registrant must review and sign and date the performance evaluations, with the interval not to exceed 12 months. (Addendum 14)

The Registrant must ensure that the CBCT system is operated by an individual who is qualified and properly trained on that CBCT unit.

The Registrant must ensure that the following information is displayed at the control panel of the CBCT machine:

(1) A current technique chart available at the control panel, which specifies for each routine examination, the CBCT conditions of operation and the number of scans per examination; and
(2) Instructions on the use of the CBCT dosimetry or image quality phantoms including the allowable variations for the indicated parameters.

References

ADA Council on Dental Materials, Instruments and Equipment. (1982). Biological Effects of Radiation from Dental Radiography. JADA, 105, 275-281.

ADA Council on Scientific Affairs. (2006). The Use of Radiographs, Update and Recommendations. JADA, 137, 1304-1311.

Hatcher, D. (2010). Operational Principles for Cone Beam Computed Tomography. JADA,141, 3S-6S.

Minnesota Department of Health. X-Ray Bulletin. CBCT. St. Paul: MDH, 2012. Online. **http://www.health.state.mn.us/divs/eh/radiation/xray/bulletin12apr.pdf**

Given that there is an overlap of clinical skills with patient protection, we have highlighted areas that are primary clinical skills that assist in keeping radiation doses to a minimum.

MDH ATTACHMENTS

A. ALARA Model Program

Minnesota Department of Health
X-ray Unit
625 Robert Street North
PO Box 64975
St. Paul, Minnesota 55164-0975

Information Notice 2007-01
October 2007
MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE USING THE ALARA CONCEPT
(AS LOW AS REASONABLY ACHIEVABLE)

You may use the text as it appears here or if you prefer, you may develop your own ALARA 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 is 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 and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.
- Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been recommended but not implemented, and we will be prepared to describe the reasons for not implementing the changes.
- 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.

Radiation Safety Officer (RSO) Commitment:

Annual review:

- The registrant and/or the radiation safety officer will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.
- The registrant and/or the RSO will review at least quarterly the radiation doses of the workers to determine that the doses are ALARA in accordance with the policy.

Education responsibilities for ALARA program:

- The RSO will schedule briefing and educational sessions as needed to ensure that the workers and other personnel who may be exposed to radiation are instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.

Cooperative efforts for development of ALARA procedures:

- Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow to maintain the ALARA philosophy.
- The RSO will be in close contact with the workers in order to develop ALARA procedures for working with radiation-producing equipment.
- The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
- Workers will be instructed in recourses available if they feel that ALARA is not being promoted and supported on the job.

Reviewing instances of deviation from good ALARA practices:

- The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

Registrant's responsibility to supervised individuals:

- The registrant will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

- The registrant will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices involving time, distance, shielding and appropriate techniques in maintaining exposures ALARA

Addenda

1) Lead Protective Device Biennial Check
2) Article- "Biological Effects of Radiation from Dental Radiography"
3) Article- "The Use of Dental Radiographs"
4) Radiation Safety Officer- Delegation of Authority
5) Job description- Radiation Safety Officer
6) Declaration of Pregnancy Form
7) Training Log
8) Radiology Equipment Safety Check
9) Densitometry Quality Assurance Worksheet
10) Fog Test Semi- Annual Test Records
11) Speed Match Test
12) Screen Film Contact Test
13) CBCT Daily and Monthly Performance Evaluation
14) Annual Spot Check- CBCT
15) Article- Operational Principles for CBCT
16) Information on Incorporating Digital Radiology in Practice
17) Hand-Held

Addendum 1

Lead Protective Device Biennial Check (Apron, Gloves, Etc.)

This test must be done initially and at least once every 24 months.

1. Lay the lead protective apron flat out and make sure that there is no bunching up of the lead or protective material. Perform inspection on other devices also.
2. Look closely for any signs of wear to the devices. Any holes or seams that are unraveling, cracks, or even a discoloration should be evaluated for possible repair or replacement.
3. If there are any questionable findings please notify the Radiation Safety Officer.

Date	Lead Garment Identification/Room	Good Condition?	Device Needs Repair or Replacement(be specific)	RSO Initials

Addenda 2 and 3

Comprised of attached articles:

Addendum 2. ADA Council on Dental Materials, Instruments and Equipment. (1982). Biological Effects of Radiation from Dental Radiography. *JADA*, 105, 275-281.

Placement in Radiation Manual: Addenda **pages 19-25**

Addendum 3. ADA Council on Scientific Affairs. (2006). The Use of Radiographs, Update and Recommendations. *JADA*, 137, 1304-1311.

Placement in Radiation Manual: Addenda **pages 26-34**

Addendum 4

Radiation Safety Officer Delegation of Authority

Dental Practice _____
Practice Manager _____
Contact information _____

The purpose of this form is to state that you have been appointed Radiation Safety Officer for the 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 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.

Your signature below indicates acceptance of the above responsibilities.

Year	RSO Signature	Practice Mgr. Signature
2018	_____	_____
2019	_____	_____
2020	_____	_____
2021	_____	_____
2022	_____	_____
2023	_____	_____
2024	_____	_____
2025	_____	_____
2026	_____	_____
2027	_____	_____
2028	_____	_____

Addendum 5

Job Description for RSO

Title:	Radiation Safety Officer (RSO)
Description:	Manage responsibilities (as noted below) and maintain records related to Radiation Safety. Attend annual continuing education within the dental radiology field and provide training and updates to staff members. Train staff within the practice as needed for assigned tasks. Officer will perform quarterly radiation program inspections that include assessment of unsafe practices, evaluation of products that can enhance the safety and efficacy of dental radiology and providing updates to policies and procedures as needed. All other items as related to Radiation Safety.
Reports To:	
Supervises:	N/A
Responsibilities:	Radiation Safety Officer Minimum Training requirements 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: (1) fundamentals of radiation safety; (2) familiarization with facility's x-ray equipment; (3) film processing, if applicable; (4) digital imaging, if applicable; (5) quality assurance program; (6) audits of the quality assurance program; (7) emergency procedures for x-ray equipment failures; (8) proper use of personal dosimetry, if applicable; (9) requirements of pertinent state rules; and (10) the registrant's written operating and emergency procedures.

Radiation Safety Officer Responsibilities

Understand and support the Radiation Safety program as outlined in the manual.

Radiation Delegation of Authority- included in the RSO section of radiology manual.

Quality assurance tests as noted in the Radiation manual

Crabtree test
Step Wedge test
Quick developer
Processor cleaning
Fog test
Biennial checks:

- Lead apron
- Screen Contact testing of cassettes
- Speed Match testing of cassettes
- Performance evaluations of x-ray equipment
- Maintain technique charts

Maintain "Site Specific for Radiation" for the practice

DDS standing order of X-rays.

Provide x-ray unit information for annual registration as directed

Maintain new equipment & repair records and informing practice manager of new x-ray installations for state registration

Training Records

New employee, flex staff, fill-in staff, temporary agency staff and extern training (sign-off sheets)

Provide site specific training in practice for new employees as related to Radiation Safety

Annual RSO audit- standard audit template provided with manual

Shielding records if required.

Be available for MDH inspections

Addendum 6

Declaration of Pregnancy Form

In accordance with the MDH rule 4732:0415, the pregnancy must be declared in writing.

Declaration of Pregnancy

Upon declaration of pregnancy, I agree to utilize safe operation standards and commit to ALARA when performing x-ray duties.

As always, staff members must stand at a distance of 6 ft from the beam.
An x-ray apron is required if staff must remain in the room and within 6 feet of the x-ray beam or patient
Fetal monitoring is not required unless the declared pregnant worker is likely to receive during the pregnancy a dose in excess of 0.1 Rem (100 millirem).

I _____ (print name) declare that I am pregnant.

Signature: _____ Date: _____

Last 4 digits of employee's Social Security #: _____

Revoking my Declaration of Pregnancy

I _____ (print name) choose to revoke my Declaration of Pregnancy.

Signature: _____ Date: _____

Submit form to Practice Manager _____

Name of the individual who was trained: _____

Addendum 7

Training Log- To be used when there is a new hire, new procedure or new equipment

New employee training documentation must include content, date, and attendee/employee signature.

Date	**Details** (**New employee, new equipment, new procedure**)	**RSO Signature**

Addendum 8

Radiology Equipment Safety Check

Recalibration Following Repair and/or Relocation of X-Ray Unit

Date	Equipment Checked	RSO Signature

*Note any deficiencies/ corrections needed
*Note WNL if check reveals no problems/ corrections needed

Addendum 9

DAILY DENTAL EXPOSURE & DENSITOMETRY
QUALITY ASSURANCE WORKSHEET
SEE SUGGESTED INFORMATION PROVIDED BY MDH.

Date **Place a line through the dates below that the clinic is not open.**	Step Reading	Is reading within the Range (3-5)?	Developer temp.	Comments
	Actual reading	Y or N If no, how many steps is it off?	Temp	Corrections if test failed-then must retest
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				

Addendum 10

Fog Test Semi-Annual Test Records

Be certain to date all test films using a black sharpie pen. Films can be taped to the back side of this form.

Clinic: ______________________________ Type of processor: ______________________________

Darkroom or Daylight processor: ____

Technique Used for Extra-oral Fog Test: ____

Two-minutes test: TAPE FILM HERE! Pass or Fail (circle one)

Date Exposed: ________________

Performed by:

Two-minutes test: TAPE FILM HERE! Pass or Fail (circle one)

Date Exposed: ________________

Performed by:

Two-minutes test: TAPE FILM HERE! Pass or Fail (circle one)

Date Exposed: ________________

Performed by:

Two-minutes test: TAPE FILM HERE! Pass or Fail (circle one)

Date Exposed: ________________

Performed by:

Two-minutes test: TAPE FILM HERE! Pass or Fail (circle one)

Date Exposed: ________________

Performed by:

Two-minutes test: TAPE FILM HERE! Pass or Fail (circle one)

Date Exposed: ________________

Performed by:

Addendum 11

Speed Match Test (not to exceed 24 months)

This test is ONLY performed if the office has 2 or more panorex or ceph cassettes. This test should be done "not to exceed 24 months" on the panorex or ceph cassette. Recommend having this test performed at the same time as the x-ray unit calibrations. This test is to be performed when cassettes are put into place as well as when a screen is replaced.

The Radiation Safety person will schedule the testing with their dental radiography service provider. This can generally be arranged with your local dental vendor.
Paperwork from the service provider will show that this has been complete. The service provider will also leave the test films for each cassette. The films should be 3-hole punched and placed in this section of the manual.

Patterson Dental or another vendor will perform this test.

- Both panorex or ceph films will be exposed at the same time.
- Films are processed.
- Processed films are individually placed into the densitometer for a optical density reading.
- Passing tests are + or – 0.10 OD (10%)
- This test determines the effectiveness of the intensifying screen.
- If test falls outside of the + or – 0.10 (10%)-cassette is removed from usage until the screen has been replaced and retested.

Date	Test Results (pass)	Comments

Addendum 12

Screen Film Contact Test (Not to exceed 24 months)

This test, like calibration tests, should be done "Not to exceed 24 months" on the Panorex/Ceph cassette. Recommend having this test performed at the same time as the x-ray unit calibrations. This test is also to be performed when cassettes are put into use as well as when a screen is replaced.

Your service provider will perform this test. The Radiation Safety Officer will schedule the testing. Upon completion of test, your service provider will leave the "test" film and the films can be placed in Radiology Manual.

This test is performed on all flexible and flat cassettes only, not the curved metal cassettes that are present with some Panorex units. There will be a test film for each cassette in the practice.

Date	Test Results (pass)	Comments

Addendum 13

CBCT DAILY AND MONTHLY PERFORMANCE EVALUATIONS

Evaluation and Recalibrations are to be completed following manufacturer's specifications and recommendations. Documentation of Evaluation and Recalibrations are to be included in Radiation Safety Manual.

Sun	Mon	Tue	Wed	Thu	Fri	Sat

-Include Employee Initials and Date
-Note any deficiencies/ corrections needed
-Note WNL if check reveals no problems/ corrections needed

Addendum 14

Annual Spot Check- CBCT Equipment Performance Evaluation

Date	Equipment Checked and Found Safe	RSO Signature

Addendum 15

Comprised of attached article: Hatcher, D. (2010). Operational Principles for Cone Beam Computed Tomography. JADA,141, 3S-6S.

Placement in Radiation Manual: Addenda p.48-52.

THE JOURNAL OF THE AMERICAN DENTAL ASSOCIATION
JADA

Operational Principles for Cone-Beam Computed Tomography
David C. Hatcher
JADA 2010;141;3S-6S

Operational principles for cone-beam computed tomography

David C. Hatcher, DDS, MSc, MRCD(c)

Many of the diagnostic chal- lenges that routinely arise in clinical practices can benefit from imaging investigations. Until recently, dentists were limited to using two-dimensional radio- graphs to assess three-dimensional (3-D) anatomy. Cone-beam computed tomography (CBCT) was introduced into the European market in 1998. In May 2001, QR (Verona, Italy) introduced CBCT, a 3-D digital imaging technology, into the U.S. market. It has been estimated that more than 3,000 CBCT units consisting of more than 30 dif- ferent machines have been installed in the United States (oral communication, Chris Scharff, vice president of sales, Imaging Sciences International, Hatfield, Pa., July 2010).

During a CBCT scan, the scanner (x-ray source and a rigidly coupled sensor) ro- tates, usually 360 degrees, around the head to obtain multiple images (ranging from ap- proximately 150 to 599 unique radio- graph- ic views). The scanning software col- lects the raw image data and reconstructs them into viewable formats. The scan time can range between five and 40 seconds, depend- ing on the unit and protocol setting. The x-ray source emits a low milliampere and a shaped or divergent beam. The beam size is constrained by a circular or rectan- gular collimator to match the sensor size, but in some cases it can be constrained (col- li- mated) further to match the anatomical region of interest. After the scan, the result- tant image set or raw data are subjected to a reconstruction process that results in the production of a digital volume (a cylindri- cal or spherical shape that is composed of volume elements called "voxels" that are stacked in rows and columns) of anatomical

ABSTRACT

Background. Cone-beam computed tomography (CBCT) was introduced into the U.S. market in 2001. Today, there are more than 3,000 installed units in the United States. There are numerous CBCT manufacturers and types of units. To produce the best imaging results, clinicians need to be knowledgeable about the CBCT unit, the clinical issue being investigated and how to optimize the unit's operational parameters. The author identifies the variables that should be considered for each imaging session and addresses the building blocks required to design the appropriate imaging strategy. The remaining arti- cles in this supplement address imaging for orthodontics, the investigation and localization of impacted teeth and implant planning, and customized imaging protocols designed to solve the clinical issues being presented.

Methods. The author addresses CBCT from an operational point of view. An ideal imaging examination answers the clin- ical question while maintaining an acceptable radiation dose and cost. The quality and value of each imaging study is pro- portional to the protocol being used. The author also addresses imaging protocol variables (raw data frames, scan time, voxel size, field of view and milliampere settings) and their effects on the final image quality and radiation dose, as well as CBCT accuracy and the radiation dose.

Results. CBCT can provide image volumes of the maxillofa- cial region and can be useful in clinical dentistry.

Conclusion. CBCT has been shown to be a precise imaging modality and is a valuable tool for use in dental applications.

Clinical Implications. CBCT can be used for diagnosis and treatment planning for all of the dental specialties.

Key Words. Cone-beam computed tomography; cone-beam imaging; radiation risk.

JADA 2010;141(10 suppl):3S-6S.

Dr. Hatcher is a clinical professor, College of Dental Medicine, University of Southern Nevada, Henderson, and an adjunct associate clinical profes- sor, Arthur A. Dugoni School of Dentistry, University of the Pacific, San Francisco, and he maintains a private practice in oral and maxillofacial radiology. Address reprint requests to Dr. Hatcher at 99 Scripps Drive, Suite 101, Sacramento, Calif. 95825, e-mail "David@ddicenters.com".

Figure. Visualization options for a cone-beam computed tomography volume. A. Visualization of the full data volume by means of a shaded surface display method with thresholds set to show the soft tissues. B. Visualization of the full data volume by means of a shaded surface display with the threshold set to show hard tissues (bone and teeth) only. C. The volume rendering method. The data attenuation values corresponding to the soft tissues were made partially transparent, allowing for visualization of the underlying skeleton and teeth.

data that can be visualized with specialized soft- ware. Voxels are the smallest subunit of a digital volume. CBCT voxels generally are isotropic (that is, X, Y and Z dimensions are equal) and range in size from approximately 0.07 to 0.40 millimeters per side. Each voxel is assigned a gray-scale value that approximates the attenuation value of the rep- resented tissue or space. The latest generation of CBCT units produces 12- or 14-bit images in which 12 bits is 212 (4,096) shades of gray and 14 bits is 2^{14} (16,384) shades of gray. Computer monitors used to visualize the 12- or 14-bit digital or voxel volume can display only eight bits (256 shades) of gray at a time. The software uses a technique called "windowing and leveling" that allows the operator to access and visualize all of the data. Windowing allows the data to be scrolled through, thus visual- izing eight bits at a time with air and soft tissues (low-attenuation structures) at one end of the spec- trum and bone and teeth (high-attenuation struc- tures) at the other end of the spectrum. Once the optimum window level has been achieved, the con- trast and brightness (leveling) are adjusted by the clinician for optimal viewing. The small isotropic voxel size along with the large number of gray levels have contributed to accuracy and precision when clinicians measure the dimensions of anatomical structures and visualize anatomical form.[1-4]

The diagnostic value of an imaging study needs to be balanced against the risk to the patient and the cost of service. The trend for CBCT use has been to apply it clinically and then validate its utility scientifically. CBCT technology has several beneficial applications in the clinical setting. The articles in this supplement address the benefits of using CBCT for investigations in orthodontics, impactions and implants. The authors of these articles discuss the coordinated effort required by clinicians in the investigative process to achieve successful imaging outcomes that meet the clin- ical objectives. The authors also define clinical objectives and associated imaging goals, imaging protocols, diagnostic portfolios and value proposi- tion. When possible, the authors attempt to blend clinical applications using CBCT technology with the appropriate scholarly validation.

CBCT imaging sessions are based on a process designed to answer specific clinical questions.

This design process results in the development of imaging goals, a customized or case-specific imaging protocol and an imaging portfolio. It may require input from several people, including the clinician ordering the scan, the radiology technol- ogist and the reviewing radiologist. An ideal imaging session provides answers to the clinical question via a precise display of relevant anatom- ical information that can aid the clinician, the radiologist and the patient. An illustration of the levels of decision making in the imaging process are provided as online supplemental data to this article (available at "http://jada.ada.org").

ABBREVIATION KEY. **CBCT:** Cone beam computed tomography. **E**1990: Effective dose calculations using 1990 tissue-weighting factors. **E**2007: Effective dose calculations using 2007 tissue-weighting factors. **FOV**: Field of view. FOVMand: 6-centimeter field of view, mandible. FOVMax: 6-cm field of view, maxilla. **PSP:** Photostimulable phos- phor. **TLDs:** Thermoluminescent dosimeters. **3-D:** Three-dimensional.

Imaging protocol variables include field of view (FOV), voxel size, scan time, mA setting and patient immobilization. Clinicians select imaging protocol vari- ables to investigate a patient's condi- tion on the basis of their knowledge about image sensor responses or con- version of the analog signal to a digital signal. There are many options clini- cians can use to visualize the digital volume. The diagnostic portfolio includes the visualization options clini- cians can use to provide a customized image set that is relevant to the clinical issue being addressed.

IMAGE QUALITY

Images acquired by CBCT are con- verted to a voxel volume and stored digitally on computers. The image quality or feature detection ability can be related to physical characteristics of digital images represented by Nyquist- Shannon sampling theorem, volume averaging, dynamic range, modulation transfer function and signal-to-noise ratio. The effects of these variables are provided as online supplemental data to this article (available at "http:// jada.ada.org").

Data visualization. The recon- structed volumes can be viewed using specialized software. The smallest subunit in a CBCT volume is the voxel. The voxels created from a CBCT generally are isotropic. The voxels are stacked in rows and columns. Information (for example, dimension, 3-D location and value) for each voxel is stored in the computer.

The voxel volume can be retrieved and viewed by using a range of viewing options. Visualization options include multiplanar or orthogonal (that is, coronal, axial, sagittal) viewing angles. The data can be sliced into a single row or column of voxels. Multiple voxel layers can be combined to create a slab. Clinicians can produce and visualize oblique and curved slices or slabs, and they can render and visualize the entire volume from any angle.

There are several techniques for visualizing a volume, including shaded surface display and volume rendering (Figure). Illustrations of addi- tional visualization options are provided as online supplemental data to this article (available at "http://jada.ada.org"). Shaded surface display is a software technique that allows the user to set a threshold range for the data on the basis of an attenuation value. The data with an attenuation value outside the selected range will not be visible. The shaded surface display creates a 3-D object of the anatomy that can be visualized from any selected angle. It is common to use shaded surface display technique to visualize soft tissue or bone surfaces. Volume rendering is a method that uses all of the voxels but allows the operator to assign transparency values to voxels on the basis of their attenuation values.

Table 1

Effective dose for i-CAT Classic* cone-beam computed tomography.†‡

CONE-BEAM COMPUTED TOMOGRAPHY	E_{1990}§		E_{2007}¶	
	Standard	High Resolution	Standard	High Resolution
22cm FOV	92.8 µSv#	NA**	206.2 µSv	NA
13cm FOV	39.5 µSv	NA	133.9 µSv	NA
6cm FOV_{Mand}††	23.9 µSv	47.2 µSv	96.2 µSv	118.5 µSv
6cm FOV_{Max} ‡‡	9.7 µSv	18.5 µSv	58.9 µSv	93.3 µSv

* i-CAT Classic is manufactured by Imaging Sciences International (Hatfield, Pa.).
† Source: Roberts and colleagues.[6]
‡ The data shown in this table are calculations of the effective dose using the 1990 and 2007 International Commission on Radiological Protection tissue-weighting factors for the i-CAT Classic cone-beam computed tomography machine with a flat panel sensor (amorphous silicon)[7] using a field of view (FOV) of 22, 13 and 6 centimeters and time settings of 20 and 40 seconds. This unit captures angular images (raw data) at 15 images per second. A 20-second rotation around the head (standard resolution) creates 300 images. High-resolution scans are produced by increasing scan time to 40 seconds at 15 images per second for 599 or 600 images. The 22-cm scan requires two 20-second rotations. The effective dose for Next Generation i-CAT (Imaging Sciences International) in landscape mode (standard resolution) was 87 microsieverts.[8]
§ E_{1990}: Effective dose calculations using 1990 tissue-weighting factors.
¶ E_{2007}: Effective dose calculations using 2007 tissue-weighting factors.
# µSv: Microsieverts.
** NA: Not available.
†† FOV_{Mand}: 6-centimeter field of view, mandible.
‡‡ FOV_{Max}: 6-cm field of view, maxilla.

Table 2

Effective dose for two-dimensional techniques.*†

TWO-DIMENSIONAL IMAGING	ROUND COLLIMATION		RECTANGULAR COLLIMATION
	PSP/ F-Speed Film	D-Speed Film	PSP/ F-Speed Film
Complete Series of Radiographs	170.7 µSv‡	388.0 µSv	34.9 µSv

* Source: Ludlow and colleagues.[9]
† The data shown in this table are calculations of the effective dose using the 2007 International Commission on Radiological Protection tissue-weighting factors for common two-dimensional maxillofacial intraoral and extraoral techniques. For intraoral imaging, the sensors were F- and D-speed film and photostimulable phosphor (PSP) storage using round or rectangular collimation.
‡ µSv: Microsieverts.

Table 3

Effective dose for two-dimensional extraoral imaging.*

TWO-DIMENSIONAL IMAGING	EFFECTIVE DOSE
Panoramic (Charge-Coupled Device)	14.2-24.3 µSv†
Cephalometric (Photostimulable Phosphor)	5.1-5.6 µSv

* Source: Ludlow and colleagues.[9]
† µSv: Microsieverts.

For example, if the superficial soft tissues were assigned a 70 percent trans- parency value, then the underlying skeleton could be visualized through the soft tissues. All CBCT units include viewing software, but third-party software also is available for general viewing or specialized applications, such as implant planning and assessment for orthodontic treatment.

Dose. Radiation dose studies allow clinicians to assess risk and use a calculation method that helps clinicians compare risk between disparate imaging devices. The dose calculations are expressed as an effective dose in microsieverts.5,6 Dose studies generally use a dosimetry phantom (human skull encased in a soft tissue–equivalent material). The phantoms are sliced into multiple layers along the axial plane to allow access to internal anatomy. For each study session, cali- brated thermoluminescent dosimeters (TLDs) are placed on the radiosensitive anatomy to be tested (for example, ramus, thyroid gland, salivary gland, bone marrow). The phantoms are imaged with selected variables including unit type, FOV, scan time, mA setting and voxel size. To obtain the effective dose, the absorbed dose from the TLDs is weighted by the 1990 or 2007 Interna- tional Commission on Radiological Protection tissue-weighting factors. There are distinct effec- tive dose variations among CBCT units, which can be attributed to factors including FOV, mA set- ting, kilovolt (peak), scan time (including pulsed versus continuous dose), sensor sensitivity and the number of image captures.

The operator can control the FOV, the mA set- ting and the scan time settings, which relate directly to the effective dose. Matching the FOV to the area of interest can optimize the effective dose. Having shorter scan times, reducing the mA setting or both can reduce the dose, but doing so also can decrease the signal and therefore image quality (Tables 1,6-8 29 and 39).

CONCLUSIONS

Diagnostic imaging investigations are processes that begin with designing an imaging protocol to address specific individual clinical goals.

Selecting the optimum technique begins by determining the imaging goals. Clinicians need to determine precisely what information needs to be revealed during the imaging study; this will allow them to determine what imaging modalities can fulfill the imaging goals. The optimum imaging modality fulfills the imaging goals, has the lowest radiation dose and has an acceptable cost.

The articles in this supplement outline the utility of CBCT for specific clinical investigations. The authors discuss specific clinical objectives, imaging goals, imaging protocols and appropriate image portfolios.

Disclosure. Dr. Hatcher did not report any disclosures.

1. Honey OB, Scarfe WC, Hilgers M, et al. Accuracy of cone-beam computed tomography imaging of the temporomandibular joint: com- parisons with panoramic radiology and linear tomography. Am J Orthod Dentofacial Orthop 2007;132(4):429-438.
2. Ludlow JB, Gubler M, Cevidanes L, Mol A. Precision of cephalo- metric landmark identification: cone-beam computed tomography vs conventional cephalometric views. Am J Orthod Dentofacial Orthop 2009;136(3):312.e1-e10.
3. Lagravere MO, Gordon JM, Guedes IH, et al. Reliability of tradi- tional cephalometric landmarks as seen in three-dimensional analysis in maxillary expansion treatments. Angle Orthod 2009;79(6):
1047-1056.
4. Chung RR, Lagravere MO, Flores-Mir C, Heo G, Carey JP, Major PW. A comparative analysis of angular cephalometric values between CBCT generated lateral cephalograms versus digitized conventional lateral cephalograms. Int Orthod 2009;7(4):308-321.
5. Yamashina A, Tanimoto K, Sutthiprapaporn P, Hayakawa Y. The reliability of computed tomography (CT) values and dimensional mea- surements of the oropharyngeal region using cone beam CT: com- parison with multidetector CT. Dentomaxillofac Radiol 2008;37(5): 245-251.
6. Roberts JA, Drage NA, Davies J, Thomas DW. Effective dose from cone beam CT examinations in dentistry. Br J Radiol 2009;82(973):
35-40.
7. Baba R, Ueda K, Okabe M. Using a flat-panel detector in high res- olution cone beam CT for dental imaging. Dentomaxillofac Radiol 2004;33(5):285-290.
8. Ludlow JB, Ivanovic M. Comparative dosimetry of dental CBCT devices and 64-slice CT for oral and maxillofacial radiology. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2008;106(1):106-114.
9. Ludlow JB, Davies-Ludlow LE, White SC. Patient risk related to common dental radiographic examinations: the impact of 2007 Interna- tional Commission on Radiological Protection recommendations regarding dose calculation. JADA 2008;139(9):1237-1243.

Addendum 16

PROCEDURES FOR ADDING OR CONVERTING TO PSP OR DIGITAL IMAGING SYSTEM TO A DENTAL OFFICE

What is it?

PSP imaging and Digital imaging are the manner 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 or Digital imaging system may only replace the film with a sensor. Panoramic, Cephalometric and Cone Beam CT 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 is a photostimulable storage phosphor: After the exposure, the imaging sensor must be or placed within an image reader to obtain the x-ray image. Digital imaging: 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 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 intraoral, extraoral or a combination of both. Retain this letter 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 or Digital), 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 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 PSP and Digital 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 PSP or Digital imaging.

Additional Resources for Video

Provided by MDH

1. **Dental Intra- Oral Fog Test**
2. **Dental Extra- Oral Fog Test**
3. **Procedures for Extra-oral Daily Processor Quality Control (Step Wedge)**
4. **Procedures for Dental Extra-oral Screen Contact Test**

We would like to extend a special thank you to Craig Verke, Radiation Specialist from the Minnesota Department of Health X-ray Unit for agreeing to provide instruction for the video. We would also like to thank Barbara Butts- Williams, wife of the late Dr. John Williams DDS and staff members; Tracie Donnell- Walker and Carla McMorris for allowing us to utilize clinic space and providing materials for the video.

Clarification: In the video, the term "glove box" refers to a daylight loader glove box that may be used in some clinics for processing in lieu of processor within a dark room.

1. 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.

Items Needed:

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

What is the requirement?
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; and
- 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.

Chapter 4732.0330 requires records be maintained for review by the X-ray unit

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. (i.e., safelight on/off, cracks under door covered/uncovered, glove box filters open/closed, etc.)
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. Start the 2-minute timer.
6. 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.
7. 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.

When the timer goes off, process the film as usual. 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.

If the fog test fails, corrective action must be taken, and another fog test must performed to verify the corrective action was acceptable.

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

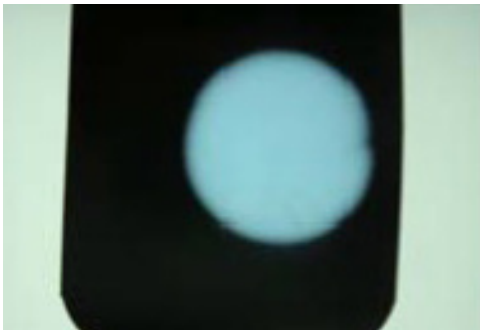

Figure 3 – Failing Fog Test

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 :
    - Not compatible with the film being used.
    - Bulb in the safelight is too high a wattage.
    - Cracks
    - 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 tabletop 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.

2. Dental Extraoral Fog Testing Instruction and Information

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.

Items needed:

- Aluminum medical 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 pan or cephalometric cassette under your normal Darkroom/glove box conditions.
2. Take the loaded pan 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.
9. Start the 2-minute timer.
10. 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.
11. 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.
12. When the timer goes off, process the film as usual.
13. 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.
14. If the density is greater than one-step your fog test fails corrective action must be taken and another fog test must be performed to verify the corrective action was acceptable.
15. 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:
    - · Not compatible with the film being used.
    - · Bulb in the safelight is too high a wattage.
    - · Cracks
    - · 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 tabletop 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.

3. Procedures for 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.

Items needed:

- Aluminum medical 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
- 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 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. 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 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.

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.

4. Procedures for Dental Extraoral 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 curved metal 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.

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.

What is the requirement?
- Chapter 4732.1100 requires that an extraoral screen contact test be performed on new cassettes and at intervals not to exceed 24 months.
- Chapter 4732.0330 requires records be maintained for review by the X-ray unit.

Items needed:
- 8 wire/inch mesh test tool; or
  7 hole per inch test tool
- All pan/cephalometric cassettes (Each cassette must be identified along with the test film)
- Intraoral x-ray unit
  View box

Procedure:
1. Load with film each pan 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 pan 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 approximately six feet or more.
9. Look for areas that are darker and/or blurrier 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 following the manufacturer's recommendations.

Hand-Held Dental X-ray Systems

Registrants need to review Minnesota Statutes 144.1215 regarding Handheld Dental X-Ray Equipment. Registration, maintenance and training are to be followed prior to use. Any questions regarding to hand-held and/or the hand-held variance, reach out and contact MDH X-Ray unit.

Attachments:

- MN Statutes 144.1215 Handheld Dental Statutes
- MDH X-ray Information Notice regarding to Handheld Dental Xray Equipment
- MDH X-Ray Information for Lead Apron Requirement and Variance Request

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.

History: *1Sp2017 c 6 art 10 s 58*

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.

Minnesota Department of Health
Radiation Control, X-ray Unit
PO Box 64975
St. Paul, MN 55164-0975
651-201-4545
health.xray@state.mn.us
www.health.state.mn.us/xray

07/01/2017

To obtain this information in a different format, call: 651-201-4545.

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.

Environmental Health Division
Minnesota Department of Health
PO Box 64975
St. Paul, MN 5516-0975
651-201-4545
x-rayrules@state.mn.us
www.health.state.mn.us

06/16/2017

To obtain this information in a different format, call: 651-201-4545. Printed on recycled paper.

DEPARTMENT OF HEALTH

X-ray Variance

MDH authority

MDH has the authority to grant a variance to various Division of Environmental Health rules as described in Minnesota Rules, parts 4717.7000 through 4717.7050 [LINK https://www.revisor.mn.gov/rules/?id=4717.7000].

Variance request

A Variance Request must:

- Be granted from MDH prior to performing or implementing any activities requested in the variance.
- Be submitted by a facility registered with the X-ray Unit and will not be reviewed until the facility has registered with MDH.
- Include a signature from the administrator and radiation safety officer.
- Be requested by a registrant, not through a manufacturer, seller, distributor, or service representative on behalf of a registrant.

A variance request must contain the following items:

1. The rule citation (e.g. Minnesota Rules, part 4732.XXXX, item X, ...) and the specific language in the rules from which you wish to vary.
2. The reasons why the requirements in the rule cannot be met. NOTE: Expense is not a reason to request a variance.
3. The alternative measures or procedures that you will take to provide a comparable degree of protection to the public health or the environment if a variance is granted.
4. The length of time for which the variance is requested.
5. A statement that you will comply with the terms of the variance, if granted.
6. Other relevant information which is necessary for MDH to evaluate your request. This should include photos, diagrams or other documents that indicate the location, and type.

All sections of the request must be completed or your submittal will be returned. Incomplete requests will not be reviewed and will be returned to the registrant.

- Variance Request (PDF) [LINK http://www.health.state.mn.us/communities/environment/radiation/docs/varreqform.pdf]

Alternative measures

In granting a variance, alternative measures or conditions attached to a variance, have the force and effect of MDH Chapter 4732, X-ray Rules. If the variance conditions are violated, the registrant is subject to enforcement actions and penalties the same as if you violated the MDH Chapter 4732, X-ray Rules.

Last Updated: 08/22/2023