



REGULATORY GUIDE 21.0 GUIDE FOR DENTAL FACILITIES USING DENTAL RADIOGRAPHIC EQUIPMENT

Introduction

Operating and safety procedures are required by 180 NAC 21. The model procedures in this regulatory guide are generic. You must write procedures that are specific for your facility. By using the sections of this guide that apply, you may create your unique set of operating and safety procedures. This guide may also be used to develop operating and safety procedures for facilities with mobile services. Although other operating and safety procedure formats are acceptable, at least the information contained in 180 NAC 21-007.03 must be included in your operating and safety procedures.

These operating and safety procedures should be reviewed annually for content and implementation. These procedures must be made available to each individual operating dental x-ray machines [see Appendix A]. Individuals who are sole practitioners and sole operators and who are the only occupationally exposed individuals are exempt from 180 NAC 21-007.03 and do not have to maintain operating and safety procedures.

NEBRASKA DEPARTMENT OF HEALTH & HUMAN SERVICES (DHHS), REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public acceptable methods of implementing specific parts of Title 180 NAC Nebraska regulations, "Control of Radiation," to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants, licensees, or registrants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the DHHS, Division of Public Health, Office of Radiological Health, to make necessary determination to issue or continue a license or certificate of registration.

Reg. Guide 21.0

Comments and suggestions for improvements in these Regulatory Guides are encouraged at all times and they will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to the DHHS, Division of Public Health, Office of Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 69509-5026. OR DHHS.Radiation.Programs@nebraska.gov

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I. <u>Sample Operating and Safety Procedures</u>

OPERATING AND SAFETY PROCEDURES FOR

(name of facility)

These are procedures that will minimize radiation exposure to patients and employees. They are provided to comply with rules enforced by the Nebraska Department of Health and Human Services (DHHS), Office of Radiological Health. The certificate of registration contains conditions and restrictions that apply to the use of the x-ray machines in this facility. These rules are available for your review at <u>(specify location)</u> [See 180 NAC 21-007.05B].

The Radiation Safety Officer (RSO) for this facility is <u>(specify name)</u>. The RSO has the responsibility and authority for assuring safe radiation practices and serves as the contact person between this facility and DHHS. Direct all your questions or concerns on radiation safety to the RSO [See 180 NAC 21-007.01B].

A. Operator and Patient Safety

1. Credentialing Requirements for Operators of Dental X-ray Machines

Individuals who operate dental x-ray systems are authorized under Neb. Rev. Stat. § 38-1130 and 38-1131 to practice as dental hygienists and dental assistants who meet the requirements of Neb. Rev. Stat. § 38-1135.

Licenses for dentists and dental hygienists can be found at (specify location).

Documentation of x-ray training for dental assistants can be found at (specify location).

2. Individual Monitoring Requirements

Individuals who operate only dental x-ray machines are exempt from individual monitoring requirements [See 180 NAC 21-003.06].

- 3. Holding of Patients and/or Film
 - a. Film holding devices must be used when techniques permit. [See 180 NAC 21-007.09E].
 - b. Do not hold the tube housing and the support housing during an exposure [See 180 NAC 21-007.09d].
 - c. If it becomes necessary for an individual to hold a patient or film, the holder should not be pregnant. They should wear protective devices (e.g., lead aprons) and keep out of the direct beam.

- 4. Posting Notices and Instructions to Workers
 - a. Read the "Notice to Employees" sign, NRH-3D. This notice is posted (specify location).
 - b. The certificate of registration, operating and safety procedures, and any notices of violations involving radiological working conditions are located at <u>(specify location)</u>. [See180 NAC 21-007.05B]
 - c. Your rights and obligations as a radiation worker are found in <u>(specify location)</u>. [See 180 NAC 21-007.04C and 180 NAC 21-009]
- 5. Notification and Reports to Individuals

If applicable, radiation exposure data for individuals must be reported to the individual. [See 180 NAC 21-008.02D]

- B. Dose to Operators
 - 1. Occupational dose limits are found in180 NAC 21-007.04A.
 - 2. If any employee is pregnant or becomes pregnant, she may voluntarily inform the RSO in writing of the pregnancy [See 180 NAC 21-007.04A2]. If the RSO is informed of the pregnancy, the facility must ensure that the dose to the embryo/fetus does not exceed 0.5 rem (5 mSv) during the entire pregnancy [See 180 NAC 21-007.04A2].
 - 3. Radiation Incident or Overexposure

If you suspect there has been an excessive exposure or a radiation incident, immediately notify the RSO [See 180 NAC 21-007.04C, item 3].

- C. Operation of the X-ray Machine and Film Processing
 - 1. Ordering of X-ray Exams

No x-ray exams shall be taken unless ordered by <u>name of dentist(s)</u> [See 180 NAC 21-007.01A4].

- 2. Operator Position during Exposure [See 180 NAC 21-007.09C]
 - a. The operator must be able to continuously see, hear, and communicate with the patient.
 - b. During the exposure, the operator must stand at least six feet from the useful beam or behind a protective barrier.
- 3. Use of a Technique Chart [see Appendix B]

Use of a technique chart aids in reducing the exposure to the operator and patient and it must be used for all exposures. The technique charts are displayed in the vicinity of the control panel of each x-ray machine and are posted or displayed electronically. [See 180 NAC 21-007.01A, item 3]

- 4. Use of Mobile or Portable Machines
 - a. Mobile x-ray equipment is mounted on a permanent base with wheels and/or casters for moving while completely assembled. Portable x-ray equipment is designed to be hand carried [See 180 NAC 21-002].
 - b. During the exposure the operator:
 - Must be positioned so that his/her exposure is as low as reasonably achievable (ALARA) (e.g. 6 feet or more away) [See 180 NAC 21-007.02]; and
 - (ii) Should never be in line with the direct beam.
- 5. Film Processing [See Appendix B]
 - a. Unexposed film is stored (describe location and procedures for storage)
 - b. Films shall be developed by the time and temperature recommended by the x-ray film manufacturer. These specifications are posted at <u>(specify location)</u> [See 180 NAC 21-007.12A]
 - Check the temperature at the beginning of the work day. Do not process films unless the developer temperature is <u>(specify temperature)</u>. Manual processing temperature should be checked throughout the work day.
 - (ii) For automatic processors, run blank films through the processor at the beginning of the work day.
 - c. Expiration dates on film and chemicals should be checked periodically. New film or chemicals should be rotated so the oldest are used first. Do not use films or chemicals after the expiration date.
 - d. Chemicals will be replaced by <u>(specify name)</u>. Chemicals should be replaced every <u>(indicate frequency)</u> or no longer than every three months [See180 NAC 21-007.12B].
 - e. Lighting in the film processing/loading area is provided under these conditions and should not be changed without authorization from the RSO:

Filter type	
Bulb wattage	
Distance from work surfaces	

- f. If you see light leaks around doors, ceilings, or other openings in the darkroom, notify the RSO.
- 7. Alternative Processing Systems

Our facility uses <u>(state alternative processing system)</u>. Processing will be done according to the manufacturer's recommendations, which are located in <u>(specify location)</u> [See 180 NAC 21-007.12D].

- 8. Quality Control
 - a. All radiographic equipment is to be maintained in good working order. It is the responsibility of each operator to report to the RSO any repairs needed to maintain the equipment in good working order. Repairs are to be made as soon as possible. Records of repairs are kept (location of records).
 - b. Equipment performance evaluations [See 180 NAC 21-007.10]
 - (i) Tests will be performed every five years by (name of service provider).
 - (ii) Records of the test results are located at <u>(location of records)</u>.
- D. Inventory List [See Appendix D and 21-006.04F]

An annual inventory of all radiation machines is maintained by <u>(name of individual)</u>. The records and manuals are located at <u>(specify location)</u>.

Name of Records/Document	Regulation Cross-Reference	Time Interval
Inventory of all Dental Radiation Generating Equipment Possessed	180 NAC 21-006.04F	5 Years after records is made
Receipt, Transfer, and Disposal of Each Radiation Machine Possessed	180 NAC 21-006.04D	Until termination of registration
Current Operating and Safety Procedures	180 NAC 21-007.03	Until termination of registration
Current 180 NAC 21	180 NAC 21-007.05B	Until termination of registration
Current Certificate of Registration (NRH-4)	180 NAC 21-007.05B	Until termination of registration
Notice of Violation From Last Inspection	180 NAC 21-007.05B	Until next on-site inspection
Documentation of Corrections of any Violations	180 NAC 21-007.05B	Until next on-site inspection
Equipment Performance Evaluation Tests	180 NAC 21-007.10B	Unit next on-site inspection
Automatic and Manual Film Processing Records	180 NAC 21-007.12	1 Year
Alternative Film Processing Records	180 NAC 21-007.13	1 Year
United States Food and Drug Administration Variance	180 NAC 21-007.06R	Until transfer of machine or termination of registration

APPENDIX A

SAMPLE RECORD FOR INSTRUCTION OF INDIVIDUALS IN OPERATING AND SAFETY PROCEDURES FOR

(name of facility)

These procedures have been made available to each individual who operates the x-ray equipment on the date(s) indicated [See 180 NAC 21-007.03].

(Signature of RSO)

(Date)

Equipment Operator Statement:

I have read these procedures and agree to follow them.

(Signature of Equipment Operator)	(Date)
 (Signature of Equipment Operator)	(Date)

APPENDIX B

SAMPLE DARKROOM REQUIREMENTS LOG FOR CALENDER YEAR _____

Automatic processor (Model # , OR Manual processing	•		
Developer temperature			
Chemicals replaced (manufacturer's or chemical supplier's recommendations or every 3 months)	(initials)(date)	(initials)(date)	
	(initials)(date)	(initials)(date)	
Darkroom light leak tests perfo (every 6 months)		te) (initials)(date)	
Lighting checked in film proces	ssing/loading area:		
filter type bulb wattage distance from wo	 ork surfaces		
	(initials)(date) (init	tials)(date)	
Light leaks or related deficienc	ies noted(initials	s)(date)	
	(initials	s)(date)	
Corrections of light leaks	or related deficiencie (initials)(date)	ies (or attach service/work orders	5)
	(initials)(date)		

Appendix C

SAMPLE DENTAL TECHNIQUE CHART

CEPHALOMETRIC

PATIENT SIZE	kVp	mA	TIME	SID	FILM/SCREEN
Small					
Medium					
Large					

PANORAMIC

PATIENT SIZE	kVp	mA	TIME	SID	FILM/SCREEN
Small					
Medium					
Large					

INTRAORAL

ADULT	kVp	mA	TIME	SSD	FILM/SCREEN
Anterior Region					
Posterior Region					
Bite Wing					
CHILDREN					
Anterior Region					
Posterior Region					
Bite Wing					

APPENDIX D

SAMPLE EQUIPMENT INVENTORY LIST

ANNUAL INVENTORY DATE: _____

PAGE ____ OF ____

FACILITY NAME: (name of facility)

REGISTRATION NO.: XXX-XXXX

MANUFACTURER	MODEL NUMBER	SERIAL NUMBER	LOCATION (EX. : ROOM NO.)
BENNETT	HFQ-450	ABC-123	123