REGULATORY GUIDE 6.2

GUIDE FOR THE PREPARATION OF A RADIATION PROTECTION AND SAFETY PROGRAM FOR USE OF RADIATION MACHINES IN THE HEALING ARTS

INTRODUCTION

The purpose of this document is to provide guidance to registrants in preparing a Radiation Protection Program. "Control of Radiation" 180 NAC 4-004.01 requires that each registrant "develop, document, and implement a radiation program sufficient to ensure compliance with the provisions of 180 NAC 4."

The model procedures in this regulatory guide are generalized. You must write procedures that are specific for your facility. By using the section of this guide that apply, you may create your unique set of operating and safety procedures.

The information in this guide may be used as a "checklist" or as a basis on which to formulate a documented Radiation Protection Program for the use of radiation machines in the healing arts. All of the following information may not be applicable to each registrant and therefore, may not be necessary to include it in the Radiation Protection Program. Also, the information listed in this guide may not be all-inclusive for a particular registrant authorized for medical use of x-ray machines and therefore, must be expanded upon so that the Radiation Protection Program is in accordance with 180 NAC 4-004.01.

All components of a Radiation Protection Program do not have to be contained in one consolidated document. However, all components do have to be documented and identified as being part of the Radiation Protection Program. Records of audits and other reviews of the Radiation Protection Program content and implementation must also be maintained for inspection by the Department in accordance with 180 NAC 4-047.

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.

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 radiation.programs@dhhs.ne.gov

Requests for single copies of issued guides (which may be reproduced) should be made in writing to the address above.

GUIDE FOR THE PREPARATION OF OPERATING AND SAFETY PROCEDURES FOR USE OF X-RAY DEVICES IN MEDICAL OFFICES AND CLINICS

I. *Sample* Operating and Safety Procedures:

OPERATING AND SAFETY PROCEDURES FOR : _____
(name of facility)

This guide establishes procedures that will minimize radiation exposure to patients and employees. They are provided to comply with regulations enforced by the Nebraska Health and Human Services Regulation and Licensure (HHS R&L). The regulations require that each x-ray facility be registered with the Department and pay annual renewal fees.

A copy of 180 NAC (Nebraska Regulations for Control of Radiation) is available for your review in/at (http://www.dhhs.ne.gov/reg/t180.htm). (Note: The copy of 180 NAC can be a hard copy, an electronic copy or viewed on the internet at the facility. If the internet is used indicate what facility computer can be used and have the website bookmarked.) [See 180 NAC 10-002]

RADIATION PROTECTION PROGRAM CONTENTS

All registrants will designate a radiation safety officer (RSO). "Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations. This individual should be in charge of implementing the Radiation Protection Program. Direct all your questions or concerns on radiation safety to the RSO for this facility, _____(specify name)_____. [See 180 NAC 2-004.02]

If there are changes in the registration such as change of address or ownership, notice must be sent to the Department within 30 days of the change. Change of ownership requires re-registration with full fees paid by the new owner. New equipment or the replacement of old equipment also needs to be reported. Changes to the registration information may be mailed to: Nebraska Department of Health and Human Services, X-ray Program, P.O. Box 95026, Lincoln, NE 68509-5026

The radiation protection program must be reviewed annually in accordance to 180 NAC 4-004.03. The following items are specific documents, records, procedures, and/or instructions that may be part of a Radiation Protection Program.

A. Operator Safety

1. Licensing Requirement for Operators of X-ray Machines

a. All operators of x-ray machines, including fluoroscopy, must meet the licensing requirements of 180 NAC 16. [For information about operating licensing, contact the Credentialing Division of the Nebraska Health and Human Services Regulation and Licensure at (402)471-2118).]

b. Copies of operator licensing are on file in ___(where the records are kept).

2. Personnel Monitoring Requirements

Any adult who is likely to receive a dose from occupational exposure to radiation in excess of 500 millirem [180 NAC 4-022.01, item 1] in a year or a minor in excess of 100 millirem in a year [180 NAC 4-022.01, item 2] must use an individual monitoring device such as a film badge, thermoluminescent or optically stimulated dosimeter.

Declared pregnant women who are likely to receive a dose from occupational exposure to radiation in excess of 100 millirem during the entire pregnancy must also use an individual monitoring device. [See 180 NAC 4-022, item 3]

Note: Personnel Monitoring will not be required if there is sufficient documentation that employees are not likely to exceed 10% of the dose limits for adults, minors or declared pregnant women.

a. Individual monitoring devices must be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar). [See 180 NAC 6-003.01, item 1.j.]

b. Additional individual monitoring devices used for monitoring the dose to the embryo/fetus of a declared pregnant woman must be located at the waist under any protective apron being worn by the woman.

c. The individual monitoring device must be assigned to and must be worn only by one individual. Employees who wears a monitor must be provided an annual report of their exposure.

d. Records of employee exposure must be retained, even after the employee has left. Upon departure, each employee must receive a copy of their final monitoring report that shows their exposure for the entire employment period.

e. If more than one device is used and a record is made of the data, each dose must be identified with the area where the device was worn on the body.

f. Individual monitoring devices that are not being worn and the control monitoring device will be stored in an area that is away from rooms where radiation machines are in use. This is in/at ____(specify location)_____.

g. _____(specify name)_____ is responsible for the occupational dose records and exchanging the individual monitoring devices on ____(specify exchange dates)___. The individual monitoring device readings ___(film badge reports)____ are located in/at _____(specify posting or records location)____.

h. If you are working for another employer and receive an occupational dose, you should report that dose to the RSO so that it can be included in your annual record of occupational dose. An employee working for a single employer and working at multiple sites must be assigned only one dosimeter, not one for each location. Employees are responsible for reporting their exposure from each job to each employer. The cumulative exposure from each job is the occupational exposure limit. No employee is allowed to receive more than 50 mSv (5 rem) in a calendar year from all employment during that year.

i. If any employee is pregnant or becomes pregnant, she may voluntarily inform the Radiation Safety Officer (RSO) or employer in writing of the pregnancy. [See 180 NAC 4-012.01]. If the RSO or employer is informed of the pregnancy, the employer must ensure that the dose to the embryo or fetus does not exceed 5 mSv (500 mrem) during the entire pregnancy and no more than 0.5 mSv (50 mrem) in any month. The dose to the monitoring device worn at the waist level is considered to be the fetal dose. If the employee chooses to wear a leaded apron and have dosimetry, two monitors are recommended; one device will be worn at the neck and the second under the apron at the waist level. If an apron is not worn, only one monitor may be assigned and that shall be worn at the waist level.

   If employees do not declare their pregnancy in writing, for radiation safety purposes she is not considered to be pregnant and the 50 mSv (5 Rem) occupational exposure limit applies.

j. Occupational dose limits are found in 180 NAC 4-005.

Top Ten Dosimeter Do's and Don'ts

- **DO WEAR IT** when working. It has no value in your locker or purse.
- **DON'T WEAR IT** when you are receiving x-rays for your own health care.
- **DON'T WEAR IT** away from the workplace.
- **DON'T WEAR IT** under your apron unless you are wearing two dosimeters. Leave your dosimeter in the same place every day when you leave work so you know where it is.
- **DO TURN IT IN** on time. Time gaps make analysis more difficult, less accurate and reduces legal and historical value of the reports.
- **DO PLACE** the control dosimeter in a radiation-safe area; the dose to the control is subtracted from each dosimeter and needs to be accurate.
- **DO REPORT LOST OR DAMAGED** dosimeters immediately. Prevent damage by not leaving your dosimeter in areas of high temperature such as your dashboard or in the clothes dryer.
- **DON'T PLACE** a dosimeter in an area for testing of stray radiation. Additional dosimeters can be assigned for testing.
- **DON'T SHARE** dosimeters. An average for a shared dosimeter is meaningless to each individual.
- **DON'T TAMPER** with your dosimeter or anyone else's. The reports are legal documents and are regarded as real exposures received. Tampering with dosimeters is illegal.

3. Use of Protective Devices

a. Use protective devices, such as lead aprons, gloves, and shields, to reduce exposure to radiation and keep radiation exposure as low as reasonably achievable (ALARA). Protective devices must be used or provided in the following situations:
   (i) when it is necessary for an individual other than the patient to remain in the room or hold a patient; [See 180 NAC 6-003.01, item 1. e.]
   (ii) when it is necessary to protect other patients who cannot be moved out of the room (Examples: critical care areas, emergency rooms, or trauma units); [See 180 NAC 6-003.01, item 1. e.] or
   (iii) when the gonads are in or within 5 centimeters of the x-ray beam, shields must be used unless the use of the shield interferes with the diagnostic procedure. [See 180 NAC 6-003.01, item 1. f.]

b. If fluoroscopic procedures are being performed, protective devices (lead drapes, hinged sliding panels) must be in place.

c. Protective device(s) is/are stored in/at __(specify location)_____.

d. Protective devices should be checked annually for defects, such as holes, cracks, or tears. This check can be done by visually inspecting or feeling the protective devices or may also be done by x-raying these items. Appendix C can be used to record the annual check. If a defect is found at the time of the annual check or on any other occasion, notify the RSO and remove the device from service until it can be repaired or replaced.

4. Holding of patients and/or film

a. If a patient or film must be supported during a radiation procedure, use a mechanical holding device when circumstances permit.

b. If it becomes necessary for an individual to hold a patient or film, the holder should not be pregnant. They must wear protective devices and keep out of the direct beam. [See 180 NAC 6-003.01, item 1. h.]

5. Holding of x-ray tubes.

The x-ray tube housing **can not** be held by an individual during any radiographic exposure.

6. Posting Notices, Instructions, and Reports to Workers; and Posting a Radiation Area

a. Read the "Notice to Employees" sign posted in/at __(specify location)___. The NRH –3 “Notice to Employees” form can be printed from the web site at: http://www.dhhs.ne.gov/puh/enh/rad/formdoc.htm

b. The certificate of registration, operating and safety procedures, and any notices of violations involving radiological working conditions are located in/at ____(specify location(s)____. [See 180 NAC 10-002.01]

c. Your rights and obligations as a radiation worker are found in 180 NAC 10-003, 10-004, 10-005, 10-007 and 10-008.

d. Each machine is labeled in a conspicuous manner, which cautions individuals that radiation is produced when it is energized. [180 NAC 4-036.03 and 6-004.01]

e. The RSO will oversee the posting of the above signs.

B. 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 a person licensed to practice healing arts in Nebraska. [See 180 NAC 6-001.02]

A utilization log or chart will be maintained with the patient’s name, type of examination and date of examination. When a patient or film must be provided with human auxiliary support, the name of the human holder must be recorded. [180 NAC 6-003.02]

2. Operator Position During Exposure

a. The operator must be able to continuously view and communicate with the patient. [180 NAC 6-006.02, item 5]

b. The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure must be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent. [See 180 NAC 6-003.01, item 1.e.(2)]

c. During the exposure, the operator must be positioned so that the operator exposure is low as reasonably achievable (ALARA) and/or a lead apron, gloves, or other shielding protection for the operator is used. [180 NAC 6-003.01, item 1.h.(6)]

d. Doors that are an integral part of room shielding will be closed during x-ray procedures. And the door(s) will be posted with a sign saying "Close door during x-ray procedures." [180 NAC 6-003.01, item 1.d.]

3. Use of a Technique Chart

Use of a technique chart is required for systems with adjustable techniques, such as kV, time and mA (x-ray tube current). Use of a technique chart aids in reducing the exposure to the operator and patient by providing a standard technique for a given machine regardless of the operator. Technique charts must be displayed in the vicinity of the control panel of each x-ray machine. [See 180 NAC 6-003.01, item 1.c.]

4. Restriction and Alignment of the Beam

The useful x-ray beam must be restricted to the area of clinical interest [See 180 NAC 6-006.01]. Use the centering and beam limiting devices (collimator) provided on the x-ray machine. [See 180 NAC 6-006.01, item 1.]

5. Use of Fluoroscopic Machines

a. Only a licensed practitioner can perform interpretative fluoroscopic procedures.[See 180 NAC 6-005.11, item 2]

b. All imaging formed by the use of fluoroscopic x-ray systems must be under to direction of and interpreted by a licensed practitioner of the healing arts. [See 180 NAC 6-005.11, item 1]

c. Reset the 5-minute cumulative timing device before each fluoroscopic procedure. [See 180 NAC 6-005.07, item 1]

d. For mobile fluoroscopy (i.e. C-arm) units, a 30-centimeter (cm) source-to-skin distance (SSD) spacer must be used. [See 180 NAC 6-005.06, item 3]

6. 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. [180 NAC 6-002 – X-ray equipment]

b. Portable or mobile x-ray equipment must be used only for examinations where it is not feasible to transfer the patient(s) to a stationary x-ray installation. [180 NAC 6-003.01, item 1.i.(3)]

c. During the exposure the operator:
   (a) must be positioned so that his/her exposure is as low as reasonably achievable (ALARA)[180 NAC 4-004.02];
   (b) must wear lead apron, gloves if necessary, or be protected by other shielding; [See 180 NAC 6-003.01, item 1.] and
   (c) should never be in line with the direct beam.

7. Patient Safety

Patient radiation safety practices include:

a. Using the lowest possible radiation exposure for each exam by using the fastest film speed and the shortest exposure time based on a technique chart, [180 NAC 6-003.01, item 1.i.(1)]

b. Position patient such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent, [180 NAC 6-003.01, item 1.e.(1)]

c. Provide gonad reproductive organ protection for patients of child bearing age unless

the shield interferes with the exam, [180 NAC 6-003.01, item 1.f.] and

.

d. Ask each female patient of child-bearing age if she may be pregnant and to notify the Doctor if she indicates yes.

8. Film Processing [See Appendix B]

a. Unexposed film is stored __(describe location and procedures for storage) . Unexposed film should be stored according to the film manufacturer instructions. This is usually in a temperature and humidity controlled location. [180 NAC 6-003.04, item 2.a. and b.]

b. Films must be developed by the time and temperature recommended by the x-ray film manufacturer. These specifications are posted in/at __(specify location)__ . [See 180 NAC 6-003.04. item 1]

(i) Check the temperature at the beginning of the work day. Do not process films unless the developer temperature is __(specify temperature).

(ii) Manual processing temperature should be checked throughout the work day.

(iii) For automatic processors, run blank films through the processor at the beginning of the work day and perform the QC test prior to processing patient films or at least once a week.

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__ (specify name) according to the manufacturer's or chemical supplier's recommended interval, which is___ (specify frequency) , [See 180 NAC 6-003.04 item 2.e.]

e. Safe light(s) in the film processing/loading area is/are provided under these conditions: [See 180 NAC 6-003.04, item 2. a.].
Safe Light 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.

9. Alternative Processing Systems

Users of daylight processing systems, laser processors, self-processing (Polaroid) film units, or other alternative processing systems must develop procedures following manufacturer's recommendations for image/film processing [See 180 NAC 6-003.04, item 1.b.].

10. Darkroom

The darkroom needs to be light tight and ventilated. Ventilation is especially important if the control panel is located in the darkroom. Corrosive fumes can destroy the electronics in the control panel unless the fumes are vented out of the building. If the control panel is located in the darkroom, other requirements for patient communication also apply.

11. 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 the be kept on file at _____(location of record). [180 NAC 6-003.01, item 2.c.]

b. The x-ray generating equipment will be serviced and calibrated by __(service provider(s).

c. Screens in the cassettes and the type of film must be compatible. Never use green sensitive film with blue light emitting screens or vice versa.

d. Film cassettes and intensifying screens must be inspected periodically and must be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality. [180 NAC 6-003.04, item 2.c.]

e. The darkroom must be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed must not suffer an increase in density greater than 0.1 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes must preclude fogging of the film. [180 NAC 6-003.04, item 2.a.]

f. Film in open packages must be stored in a light tight container. [180 NAC 6-003.04, item 2.b.]

g. Outdated x-ray film must not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations. [180 NAC 6-003.04, item 2.d.]

h. Film developing solutions must be prepared in accordance with the directions given by the manufacturer, and must be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer. [180 NAC 6-003.04, item 2.e.]

C. Compliance with Dose Limits to the Public

An x-ray protection survey report was performed __(when report was preformed). The report concluded that from the measurements made, the installation is adequate to shield the adjacent area to the level required by 180 NAC 4-014.02 for the expected workload. A copy of this report is available at ____(where report is located).

D. Inspections and Documentation

X-ray facilities are subject to inspections by the Nebraska Health and Human Services Regulation and Licensure's X-ray Program.

All records are to be maintained and made available for such inspection. Documentation of all inspections will be kept on file. [180 NAC 6-003.01, item 2.]

E. Recordkeeping

The records will be maintained by (name of individual). The records and manuals will be kept in (location of records).

	Name of Records/Document	Regulation Cross-Reference
I	Model and serial number of all certifiable components	180 NAC 6-003.01, item 2.a.
II	User's manuals for x-ray components	180 NAC 6-003.01, item 2.a
III	Tube rating charts and cooling curves	180 NAC 6-003.01, item 2.b.
IV	Surveys, calibrations, maintenance, and modifications performed on x-ray systems	180 NAC 6-003.01, item 2.c.
V	Scale drawing of room with x-ray system and areas adjacent to room and estimation of occupancy	180 NAC 6-003.01, item 2.d.
VI	Copy of all correspondence with Department regarding the x-ray system	180 NAC 6-003.01, item 2.e.
VII	Receipt, Transfer, and Disposal of Each Radiation Machine Possessed	180 NAC 1-004
VIII	Current Operating and Safety Procedures	180 NAC 6-003.01, item 1.d.& 180 NAC 10-002.01, item 3
IX	Current 180 NAC 10 and 180 NAC 4	180 NAC 10-002.01, item 1
X	Current Certificate of Registration (NRH-4)	180 NAC 10-002.01, item 2
XI	Notice of Violation From Last Inspection	180 NAC 10-002.01, item 4
XII	Documentation of Corrections of any Violations	180 NAC 10-002.01, item 4
XIII	X-ray Utilization Log or chart	180 NAC 6-003.02

F. General Safety

1. In the event of fire, the facility should be evacuated in an orderly fashion. The nearest fire extinguisher is __(location of fire extinguisher.)

2. Cautions on the movement and positioning of x-ray equipment.
The x-ray operator should be familiar with the limitations of movement and safe positioning of the x-ray equipment.

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 6-003.01, item 1.d. and 10-002.01, item 3]

_____
(Signature of RSO) (Date)

Equipment Operator Statement:

I have read these procedures and agree to abide by them.

_____
(Signature of Equipment Operator) (Date)

_____
(Signature of Equipment Operator) (Date)

_____
(Signature of Equipment Operator) (Date)

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(Signature of Equipment Operator) (Date)

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(Signature of Equipment Operator) (Date)

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(Signature of Equipment Operator) (Date)

APPENDIX B
SAMPLE DARKROOM REQUIREMENTS LOG
FOR CALENDAR YEAR _____

Automatic processor (Model #, Serial #)_____
OR
Manual processing_____

Developer temperature_____

Chemicals replaced _____ _____ (manufacturer's or chemical suppliers recommendation) (initials)(date) (initials)(date)

Darkroom light leak tests performed _____ _____
(initials)(date) (initials)(date)

Lighting checked in film processing/loading area:

filter type _____
bulb wattage _____
distance from work surfaces _____

_____ _____
(initials)(date) (initials)(date)

Light leaks or related deficiencies noted_____
(initials)(date)

_____
(initials)(date)

Corrections of light leaks or related deficiencies (or attach service/work orders)

_____
(initials)(date)

_____
(initials)(date)

APPENDIX C

SAMPLE PROTECTIVE DEVICES SURVEY
(LEAD APRONS, GLOVES, THYROID SHIELDS,
GONADAL SHIELDS)

ID# of shield	LIST DEFECTS(tears, holes, etc)	INITIAL of person	DATE of test