



REGULATORY GUIDE 20

GUIDE FOR THE PREPARATION OF OPERATING AND SAFETY PROCEDURES FOR THERAPEUTIC RADIATION MACHINES

INTRODUCTION

The purpose of this document is to provide guidance to registrants in preparing a Radiation Protection Program. Nebraska Regulations for Control of Radiation-Ionizing 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".

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 Agency in accordance with 180 NAC 4-047.

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 therapeutic radiation facilities. 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 therapeutic radiation facilities and therefore, must be expanded upon so that the Radiation Protection Program is in accordance with 180 NAC 4-004.01.

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The model procedures in this regulatory guide are generalized. 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

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.

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 68509-5026. 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.

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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 Agency and pay annual renewal fees.

A copy of 180 NAC (Nebraska Regulations for Control of Radiation) is available for your review in/at (location of 180 NAC). (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 on what 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 2-004.01, item 2].

Written safety procedures and rules must be developed by a radiological Medical Physicist and must be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator must be able to demonstrate familiarity with these rules.[See 180 NAC 20-003.06]

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

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. Credential Requirement of Radiation Therapists

- a. Individual who will be operating a therapeutic radiation machine for medical use must be American Registry of Radiologic Technologists (ARRT) Registered Radiation Therapy Technologists. Individual who are not ARRT Registered Radiation Therapy technologists must submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology.
- b. Copies of credentials 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, optically stimulated or thermoluminescent 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 4-022.01, item 3]

Note: Personnel Monitoring will not be required if there is sufficient document 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).
- 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 _____ (filmbadge 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 an employee does not declare their pregnancy in writing, for radiation safety purposes they are 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

3. 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/radio/nrh-3.pdf>
- 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]
- e. The RSO will oversee the posting of the above signs.

B. Operation of the Therapy Units

1. Operator Position During Exposure

- a. The operator must be able to continuously view and communicate with the patient. For therapeutic radiation machines capable of operating in the Range 50 kV to 500 KV [180 NAC 20-006.14]

For therapeutic radiation machines capable of operating above 500 KV [180 NAC 20-008.17, item 3 and 4].
- b. Two-way verbal/aural communication between the patient and the operator at the control panel is established by means of (name method, i.e., intercoms, etc.).
- c. (name system used, ie., windows, mirrors, or closed-circuit television) must be provided for continual observation of the patient. The therapeutic radiation machine must not be used for patient irradiation unless at least one viewing system is operational.

C. Quality Management Program

Each therapeutic radiation facility must develop a quality management program to provide high confidence, that radiation will be administer as directed by the user. [180 NAC 20-005]

- 1. **Training** All individuals associated with the operation of a therapeutic radiation machine must be instructed in and must comply with the provisions of the quality management program. [180 NAC 20-003.08] This instruction will be provided by (how will the individual be provided training).

2. **Written directives**

- a. A written directive must be dated and signed by a user prior to the administration of radiation. The directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and the name of fractions. [180 NAC 20-005.01, item 1.b.]
- b. The registrant must develop, implement, and maintain written procedures for administration of radiation treatments. [180 NAC 20-005.01, item 2]
 - (1) Prior to administration of each course of radiation treatments, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive; by (what means will be used to identify the individual).
 - (2) Each administration is in accordance with the written directive;
 - (3) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by:
 - (a) Checking both manual and computer generated calculations to verify they are correct and in accordance with the written directive;
 - (b) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units.
 - (c) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken.

3. **Radiation Incidents, Overexposures, and therapy events (misadministrations)** The following incidents, overexposures, or misadministrations should immediately be reported to the RSO.

- a. Stolen, lost, or missing radiation machines
- b. Overexposures [180 NAC 20-005.02, item 1]; and
- b. Therapy events (misadministrations) [180 NAC 20-005.02, item 1].
- c. All therapeutic radiation 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 to be kept on file at _____ (location of record).
- d. The therapeutic radiation equipment will be serviced and calibrated by ___(service provider(s)).

D. Inspections and Documentation

X-ray therapeutic 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 5-003.01, item 2]

E. Recordkeeping

- 1. The registrant must maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Agency: [180 NAC 20-003.9]
 - a. Report of acceptance testing;
 - b. Records of all surveys, calibration and periodic quality assurance checks of the therapeutic radiation machine, as well as the name(s) of person(s) who performed such activities;

- c. Records of maintenance and/or modifications performed on the therapeutic radiation machine, as well as the name(s) of person(s) who performed such services;
 - d. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.
2. All records required by 180 NAC 20 must be retained until disposal is authorized by the Agency unless another retention period is specifically authorized in 180 NAC 20. [180 NAC 20-003.10]
 3. 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	Shielding and safety design requirements	180 NAC 20.009.02
II	Copy of all correspondence with Agency regarding the therapeutic radiation machine	180 NAC 20-003.10
III	Receipt, Transfer, and Disposal of Each Radiation Machine Possessed	180 NAC 1-004
IV	Current Operating and Safety Procedures	180 NAC 20-003.06.& 180 NAC 10-002.01, item 3
V	Current 180 NAC	180 NAC 10-002.01, item 1
VI	Current Certificate of Registration (NRH-4)	180 NAC 10-002.01, item 2
VII	Notice of Violation From Last Inspection	180 NAC 10-002.01, item 3
VIII	Dosimetry system calibration,	180 NAC 20-004.03D
IX	Written directive	180 NAC 20-005.01, item 1.d.
X	Acceptance testing	180 NAC 20-003.09, item 1
XI	Records of surveys, calibrations and periodic quality assurance checks	180 NAC 20-003.09,item 2
XII	Records of maintenance performed on therapeutic radiation machines	180 NAC 20-003.09
XIII	Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair or upgrade.	180 NAC 20-003.09, item 4
XIV	Procedures for administration	180 NAC 20-005.01, item 2.
XV	Misadministrations	180 NAC 20-005.03
XVI	Documentation of Corrections of any Violations	180 NAC 10-002.01, item 4
XVII	Outside verification of calibration	180 NAC 20.006.16, item 2

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 therapeutic operator should be familiar with the limitations of movement and safe positioning of the 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 radiation therapy equipment on the date(s) indicated. [180 NAC 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)

(Signature of Equipment Operator) (Date)

(Signature of Equipment Operator) (Date)

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