

CHAPTER 33-10-23
REGULATION AND LICENSING OF TECHNOLOGICALLY ENHANCED NATURALLY
OCCURRING RADIOACTIVE MATERIAL

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33-10-23-01. Purpose.

This chapter establishes radiation protection standards for technologically enhanced naturally occurring radioactive material (TENORM). These standards include the possession, use, processing, manufacture, distribution, transfer, and disposal of TENORM and of products containing TENORM. This chapter also provides for the licensing of TENORM, including license termination. The provisions of this chapter are in addition to the definitions and applicable requirements of chapters 33-10-01, 33-10-03.1, 33-10-04.2, 33-10-10.1, and 33-10-13.1.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-02. Scope.

1. Except as otherwise provided, this chapter applies to any person who receives, possesses, uses, processes, transfers, distributes, or disposes of TENORM.
2. The manufacture and distribution of products containing TENORM, in which the TENORM's emitted radiation is considered beneficial to the products, are licensed pursuant to the provisions of chapter 33-10-03.1.
3. This chapter addresses the introduction of TENORM into products in which the radiation emitted from the TENORM is not considered to be beneficial to the products.
4. This chapter does not apply to source material and byproduct material as both are defined in the Atomic Energy Act of 1954, as amended [42 U.S.C. 2011 et seq.] and relevant regulations implemented by the United States nuclear regulatory commission.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

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33-10-23-03. Definitions.

The terms used throughout this chapter have the same meaning as in North Dakota Century Code chapter 23-20.1, except:

1. "Applicant" means a person applying for a license under this chapter and includes any individual or entity that owns or controls the applicant.
2. "Beneficial to the product" means that the radioactivity of the TENORM is necessary to the use of the product.
3. "Conditional release" means release by a licensee for a specified use other than release for unrestricted use.
4. "Consumer" means a member of the public exposed to TENORM from final end-use products available on a retail basis.
5. "Consumer or retail product" means any product, article, or component part thereof, produced, distributed or sold for use by a consumer in or around a permanent or temporary household or residence, or for the personal use, consumption, or enjoyment of a consumer, or for use in or around a school or playground.
6. "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

7. "Generator" means any person whose act or process produces TENORM or whose act first causes the TENORM to become subject to regulation.
8. "Purposeful dilution" means a deliberate act of the mixing of clean or unlike materials with contaminated materials for the purpose of changing waste classification or concentration of waste.
9. "Product" means something produced, made, manufactured, refined, or benefited.
10. "Radiation safety officer" means an individual with the responsibility for the overall radiation safety program on behalf of the licensee and who meets the requirements of section 33-10-23-28.
11. "Reasonably maximally exposed individual" means a representative of a population who is exposed to TENORM at the maximum TENORM concentration measured in environmental media found at a site along with reasonable maximum case exposure assumptions. The exposure is determined by using maximum values for one or more of the most sensitive parameters affecting exposure, based on cautious but reasonable assumptions, while leaving the others at their mean value.
12. "Reclaiming" means returning property to a condition or state such that the property no longer presents a health or safety hazard or threat to the environment; the term "reclaiming" includes those activities necessary to decommission the licensed facility (i.e., to remove, as a facility, safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license).
13. "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of chapter 33-10-04.2.
14. "Tank" means a stationary device, other than a container as described in subsection 2 of section 33-10-23-08, designed to contain an accumulation of TENORM waste, which is constructed primarily of nonearthen materials (e.g., wood, concrete, steel or plastic), which provide structural support.
15. "Technologically enhanced naturally occurring radioactive material (TENORM)" means naturally occurring radioactive material whose radionuclide concentrations are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not include "source material" and "byproduct material" as both are defined in the Atomic Energy Act of 1954, as amended [42 U.S.C. 2011 et seq.] and relevant regulations implemented by the United States nuclear regulatory

commission.

16. "Transfer" means the physical relocation of TENORM within a business' operation or between general or specific licensees. This term does not include commercial distribution or a change in legal title to TENORM that does not involve physical movement of those materials.
17. "Total effective dose equivalent" or "TEDE" means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

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General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-04. Exemptions.

1. Persons who receive, possess, use, process, transfer, distribute, or dispose of TENORM are exempt from the requirements of this chapter with respect to any combination of radium-226 and radium-228 if the materials contain, or are contaminated at, concentrations less than one hundred eighty five becquerel per kilogram [five picocuries per gram (5.0 pCi/g)] excluding natural background. The progeny of the exempt TENORM radium-226 and radium-228 are also exempt.
2. Persons who receive products or materials containing TENORM distributed in accordance with a specific license issued by the department pursuant to subsection 1 of section 33-10-23-11, or to an equivalent license issued by another licensing state, are exempt from this chapter with regard to those products or materials.
3. Persons who receive, possess, use, process, transfer and distribute, including preparation of custom blends for distribution, phosphate or potash ore-based fertilizers containing TENORM are exempt from this chapter.
4. Persons who receive, possess, use, process, transfer, dispose into a permitted landfill, and distribute, including preparation of custom blends for distribution, zirconia, zircon, and products of zirconia and zircon containing TENORM are exempt from this chapter. A facility that manufactures zirconia or zircon from ore is not exempt from this chapter. A facility that chemically processes zirconia or zircon resulting in increased environmental mobility of TENORM is not exempt from this chapter.
5. Persons who possess TENORM waste regulated by the Comprehensive Environmental Response, Compensation and Liability Act, as amended [42 U.S.C. 9601 et seq.] or by the Resource Conservation and Recovery Act, as amended [42 U.S.C. 6901 et seq.] or equivalent state authority are exempt from this chapter for the TENORM waste regulated by either of these federal acts.

6. Other persons who possess or use TENORM shall be exempt when the department makes a determination, upon its own initiative or upon request for such determination, that the reasonably maximally exposed individual will not receive a public dose with a total effective dose equivalent (TEDE) of more than one millisievert [one hundred millirem] in one year from all licensed or registered sources of radiation including TENORM.
7. Persons who possess TENORM in the form of coal combustion residuals (i.e., fly ash waste, bottom ash waste, slag waste and flue gas emission control waste) from energy conversion facilities are exempt from this chapter.

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General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-05. Standards for radiation protection for members of the public.

1. All licensees shall conduct operations with TENORM so that individual members of the public will not exceed one millisievert [one hundred millirem] TEDE in a year, exclusive of the dose contributions from background radiation, from all licensed or registered sources of radiation, including TENORM. Doses from inhalation of indoor radon and its short half-life (less than one hour) progeny shall not be included in calculations of the TEDE, except when the dose is due to releases from licensed operations involving the handling or processing of TENORM.
2. Persons subject to a specific or general license under this chapter shall comply with chapter 33-10-04.2's radiation protection standards.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-06. Protection of workers during operations.

Each person subject to a specific or general license under this chapter shall conduct operations so that protection of workers complies with chapter 33-10-04.2 and 33-10-10.1's radiation protection standards.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-07. Unrestricted use and conditional release.

Each general or specific licensee shall, no less than thirty days before vacating or relinquishing possession or control of premises which may have been contaminated with

TENORM as a result of the licensee's activities, notify the department in writing of intent to vacate. When deemed necessary by the department, the licensee shall decontaminate the premises in accordance with the following or in such other manner as the department may specify.

1. Each licensee before vacating or transferring any premises shall permanently decontaminate the premises to meet the criteria for decommissioning in 10 CFR part 20, subpart E. The licensee shall make a survey after the decontamination and provide a copy to the department and any landlord, subsequent tenant or transferee. The premises may not be vacated, sold, or transferred until the department verifies and accepts the decontamination survey.
2. No machinery, instruments, laboratory equipment, or any other property used in contact with, or close proximity to TENORM at a licensed premise may be assigned, sold, leased, or transferred to an unlicensed person unless such property has been permanently decontaminated below or equal to the standards specified in table 4.2-07.1 of chapter 33-10-04.2. The licensee shall make a survey after the decontamination and provide a copy to the department and subsequent transferee or owner. The equipment may not be assigned, sold, leased, or transferred until the department verifies and accepts the decontamination survey.
3. Persons with a specific license shall comply also with the requirements of subdivisions f and g of subsection 1 of section 33-10-23-17 and section 33-10-23-18 that are applicable to remediation and license termination.
4. Persons with a general license shall notify the department in writing before beginning activities to reclaim the site. Decontamination activities require a specific license under section 33-10-23-11.
5. Notification of site or area closure. When the general licensee has permanently ceased use of radioactive materials at a site or portion of a site or facility or when an area has not been used for a period of two years, the licensee shall, within sixty days, provide the following information in writing to the department:
 - a. The location of the site or area; and
 - b. The plan for reclaiming or decontaminating the site or area.
6. Actions taken to confine TENORM on site or to remediate sites shall be based on expected longevity-related controls for one thousand years or longer.
7. Conditional release of metal for recycle. Conditionally released metal for recycle shall be done only under the condition that metal contaminated with TENORM does not exceed a maximum exposure level of fifty microroentgens per hour, including background radiation, at any accessible location of the metal surface prior to release from the site.
8. Equipment not released for unrestricted use. Equipment contaminated with

TENORM in excess of levels specified in section 33-10-23-26 may be transferred pursuant to subsection 4 of section 33-10-23-10.

9. Other transfers of TENORM. Other transfers of TENORM shall be in accordance with sections 33-10-23-08, 33-10-23-10, or 33-10-23-11.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-08. Disposal and transfer of waste for disposal.

1. Each person subject to this chapter's general and specific licensing requirements shall manage and dispose of wastes containing TENORM:
 - a. By transfer of the wastes for storage, treatment, or disposal at a facility authorized to accept wastes containing TENORM by the department or other applicable state or federal agency;
 - b. By transfer for disposal in another state as otherwise approved by the applicable governmental authority; or
 - c. In accordance with alternate methods authorized by the department or other applicable state or federal agency.
2. Containers:
 - a. TENORM waste shall be kept in a leak-proof container.
 - b. The licensee shall use a container made of, or lined with, materials that will not react with, or be incompatible with the TENORM waste to be stored so that the ability of the container to contain the waste is not impaired or compromised.
 - c. A container containing TENORM waste shall always be closed or covered to prevent loss of material and entrance of outside elements during storage or while in transport, except when it is necessary to add or remove waste.
 - d. A container containing TENORM waste shall not be opened, handled, or stored in a manner that may rupture the container or cause it to leak.
 - e. At least quarterly, the licensee shall inspect areas where containers of TENORM waste are stored, looking for leaking or deteriorating containers or containment systems.
 - f. All containers of TENORM waste shall be stacked in such a manner that each container identification label can be read from the access aisle or

area.

- g. Each container of TENORM waste shall be labeled with the following information prior to storage:
 - (1) Name and address of generator.
 - (2) Type of material (e.g., sludge, scale, dirt, scrap metal, et cetera).
 - (3) Date stored.
 - (4) Labeled as radioactive material.
- h. Records of inspections shall be maintained by the licensee for inspection by the department for five years.

3. Tanks containing TENORM.

- a. The licensee shall develop a schedule and procedure for assessing the condition of each tank containing TENORM waste. The schedule and procedure must be adequate to detect cracks, leaks, corrosion and erosion that may lead to cracks, leaks, or wall thinning to less than the required thickness to maintain vessel integrity. Procedures for emptying a tank to allow entry, procedures for personnel protection, and inspection of the interior must be established when necessary to detect corrosion of the tank sides and bottom. The frequency of these inspections shall be performed at intervals not to exceed 12 months. Records shall be maintained for a period of 5 years.

4. Each shipment of TENORM shall be accompanied by a manifest containing all of the following information prior to leaving the licensee's site:

- a. The licensee's (generator's) name, physical site address and telephone number;
- b. The name, address, telephone number and radioactive material license number of each transporter;
- c. The name, address and telephone number of the designated disposal facility;
- d. The description of the waste material; and
- e. The total quantity of all TENORM waste by units of weight in tons or cubic yards and the number and type of containers.

5. The following certification must appear on the manifest and be signed and dated

by the licensee as follows:

"I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name and are classified, packed, marked, and labeled, and are in all respects in proper condition for transport according to applicable international and national government regulations."

6. The licensee shall:
 - a. Sign and date the manifest upon initial transporter acceptance of the waste material;
 - b. Obtain the signature of the initial transporter and date of the acceptance of the manifest;
 - c. Retain one copy for a period of not less than 3 years;
 - d. Provide the initial transporter the remaining copies of the manifest; and
 - e. Receive the fully signed copy of the manifest from the designated disposal facility within forty-five days from the delivery to the initial transporter. In the event the licensee does not receive the signed manifest within this period, the licensee shall:
 - (1) Notify the department within seven days;
 - (2) Conduct an investigation into the reason the manifest was not received; and
 - (3) Report the results of the investigation to the department within thirty (30) days.
7. The licensee shall file with the department a quarterly summary report stating the date, type and total quantity by weight in tons or cubic yards, generator and final disposal facility of each TENORM transferred. Each report shall be filed within thirty days of the end of each quarter. If no transfers of TENORM have been made during the reporting period, the report must so indicate. Quarterly summary reports shall be maintained for a period of 3 years.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-09. Prohibition - purposeful dilution.

Purposeful dilution to render TENORM exempt shall not be performed without prior department approval.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-10. General licenses.

1. A general license is hereby issued to possess, use, transfer, distribute or dispose of TENORM without regard to quantity, except for those activities requiring a specific license.
2. Employees or contractors under control and supervision of a general licensee may perform routine maintenance on equipment, facilities, and land owned or controlled by the general licensee. Maintenance that provides a pathway for exposure different from that found in periodic maintenance operations and that increases the potential for additional exposure is not considered routine maintenance. The decontamination of equipment, facilities, and land shall be performed only by persons specifically licensed by the department, an agreement state, or another licensing agency to conduct such work.
3. Any person subject to the general license issued under this section shall notify the department within sixty days of the effective date of this chapter or of becoming subject to the general license. The notification shall include the following:
 - a. Name and address of the licensee;
 - b. Location and description of the facility, facilities, or portion of a facility where the TENORM is situated; and
 - c. Description of the TENORM including estimates of the amount and extent of TENORM.
4. Transfer of material, equipment or real property.
 - a. The transfer of TENORM, not exempt from article 33-10, from one general licensee to another general licensee is authorized if:
 - (1) The equipment and facilities contaminated with TENORM are to be used by the recipient for a similar purpose, provided that no member of the public shall receive a dose in excess of that allowed under subsection 1 of section 33-10-23-05; or
 - (2) The transfer of control or ownership of land contaminated with TENORM includes an annotation of the deed records to indicate the presence of TENORM.

- b. For transfers not made in accordance with subdivision a, the transferor shall obtain the department's prior written approval for the transfer.
 - c. For transfers made under subdivision a, the transferor shall assess the amount and extent of TENORM contamination or material present, inform the general licensee receiving the TENORM of these assessments prior to such transfer, and maintain records that include:
 - (1) The date, recipient name and location;
 - (2) A description and quantity of the material; and
 - (3) A description of the procedures and mechanisms used to ensure that material will not be released in another manner, such as an unrestricted release.
 - d. A general licensee intending to transfer material or real property for unrestricted use shall document compliance with the requirements of section 33-10-23-07. Records of such compliance shall be maintained for ten years.
5. Distribution of TENORM products between general licensees. The distribution of TENORM products from one general licensee to another general licensee is authorized provided the product is accompanied by labels or manifests which identify the type and amount of TENORM.
6. The department may, by written notice, require any person authorized by a general license to apply for and obtain a specific license if the department determines that specific licensure is necessary to ensure that exposures do not exceed the criteria of sections 33-10-23-05 and 33-10-23-06. The notice shall state the reason or reasons for requiring a specific license.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-11. Specific licenses.

- 1. A specific license is required to manufacture and distribute any consumer or retail product containing TENORM unless the manufacture and distribution are:
 - a. Authorized as specified by section 33-10-23-10;
 - b. Licensed under the provisions of chapter 33-10-03.1; or
 - c. Otherwise exempt in accordance with another chapter of article 33-10.

2. A specific license is required to decontaminate equipment or land not exempted under the provisions of section 33-10-23-04 or to decontaminate facilities contaminated with TENORM in excess of the levels in section 33-10-23-07. For purposes of this subsection, the term "decontaminate" shall not include routine maintenance which results in the incidental removal of contamination.
3. A specific license is required to receive TENORM from other persons for storage.
4. A specific license is required to possess or use TENORM for the purposes of processing, treatment or disposal.
5. A specific license is required to transport TENORM upon public roadways.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-12. Application and background review for specific licenses.

1. Applications for specific licenses shall be in English and filed in a manner and on a form prescribed by the department.
2. The department may at any time after the filing of the original application, and before the termination of the license, require further statements in order to enable the department to determine whether the application shall be granted or denied or whether a license shall be modified or revoked.
3. An applicant must provide information required by the department to complete an environmental compliance background review, including:
 - a. Consent to a criminal history check under North Dakota Century Code section 12-60-24.
 - b. Disclosure of personal and business information on a form provided by the department, executed under oath or affirmation, which includes:
 - (1) The person's name and address;
 - (2) A description of the person's experience in managing the type of TENORM that will be managed under the license;
 - (3) A description of every civil and administrative complaint against the person for the violation of any state or federal environmental protection law which has resulted in a fine or penalty of more than ten thousand dollars within five years before the date of the submission of the application;

- (4) A description of every settlement agreement entered into by the person with a federal or state agency to resolve any alleged violation of any state or federal environmental protection law which has resulted in a payment of more than ten thousand dollars within five years before the date of the submission of the application;
- (5) A description of every pending notice of violation, civil complaint, administrative complaint, or criminal complaint alleging the violation of any state or federal environmental protection law;
- (6) A description of every judgment of criminal conviction entered against the applicant within five years before the date of submission of the application for the violation of any state or federal environmental protection law;
- (7) A description of every judgment of criminal conviction of a felony constituting a crime involving fraud or misrepresentation under the laws of any state or of the United States which has been entered against the applicant within five years before the date of submission of the application; and
- (8) Any other information the department deems relevant.

c. In addition to the applicant, the following related individuals and entities may be required to submit personal and business disclosure information:

- (1) Each entity that is, or is proposed to be:
 - (a) A partner;
 - (b) An entity contracted with the applicant to operate, manage or supervise the facility or activities for which approval is being sought;
 - (c) An entity holding of 10% or more of the applicant's debt;
 - (d) An entity holding 10% or more of the applicant's equity;
 - (e) The parent corporation, holding corporation, and any other entity that exercises control over the facility or activities for which approval is being sought.
- (2) Each individual which has, or is proposed to have, any of the following relationships with the applicant:
 - (a) Director;

- (b) Partner;
 - (c) Officer;
 - (d) All individuals having managerial or supervisory or substantial decision-making authority and responsibility for the management of operations involving TENORM;
 - (e) Holder of 10% or more of the applicant's debt;
 - (f) Holder of 10% or more of the applicant's equity.
- 4. The department may deny an application for the issuance, renewal, transfer, or major modification based on its environmental compliance background review.
 - a. Circumstances justifying denial include:
 - (1) The applicant has intentionally misrepresented or concealed any material fact in a statement required under this section;
 - (2) The applicant or related individual or entity has been convicted of a felony or pleaded guilty or nolo contendere to a felony involving the laws of any state or the federal government within five years preceding the application for the license;
 - (3) The applicant or related individual or entity has been adjudicated in contempt of an order of any court enforcing the laws of this state or any other state or the federal government within five years preceding the application for the license; or
 - (4) The applicant or related individual or entity has repeatedly violated any state or federal environmental protection laws.
 - b. The department shall consider the relevance of the offense to the business to which the license is issued, the nature and seriousness of the offense, the circumstances under which the offense occurred, the date of the offense, and the ownership and management structure in place at the time of the offense.
- 5. Each application shall be signed by the applicant or a person duly authorized to act for and on the applicant's behalf.
- 6. An application for a license may include a request for a license authorizing one or more activities.
- 7. Each application for a specific license shall be accompanied by the fee prescribed in chapter 33-10-11.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-13. Requirements for the issuance of specific licenses.

1. A license application will be approved if the department determines that:
 - a. The applicant is qualified by reason of training and experience to use the TENORM in question for the purpose requested in accordance with article 33-10 in such a manner as to protect the public health and safety or property;
 - b. The applicant's proposed equipment, facilities, and procedures are adequate to protect the public health and safety or property;
 - c. The issuance of the license will not constitute a significant risk to the health and safety of the public;
 - d. The applicant satisfied all applicable special requirements in this chapter;
 - e. The applicant has met the financial assurance requirements of section 33-10-23-25;
 - f. The applicant has adequately addressed the following items in the application:
 - (1) Procedures and equipment for monitoring and protecting workers;
 - (2) An evaluation of the radiation levels and concentrations of contamination expected during normal operations;
 - (3) Operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and
 - (4) A method for managing the radioactive material removed from contaminated equipment, facilities, and land.
 - g. For each location to be listed on the license as an authorized use location, the applicant shall submit either:
 - (1) A statement that the applicant owns the facility where radioactive material is to be used or stored; or
 - (2) A statement verifying that the facility owner has been informed, in

writing, of the use or storage of radioactive material at the facility, and that the use of such material is subject to the rules of the department.

2. An application for a specific license to transfer or manufacture or distribute consumer or retail products containing TENORM to persons exempted from this chapter under subsection 2 of section 33-10-23-04 will be approved if:
 - a. The applicant satisfies the general requirements specified in subsection 1;
 - b. The TENORM is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being; and
 - c. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the TENORM product to demonstrate that the product will meet the safety criteria set forth in section 33-10-23-14. The information shall include:
 - (1) A description of the product and its intended use or uses;
 - (2) The type, quantity, and concentration of TENORM in each product;
 - (3) The chemical and physical form of the TENORM in the product, and changes in chemical and physical form that may occur during the useful life of the product;
 - (4) An analysis of the solubility in water and body fluids of the radionuclides in the product;
 - (5) The details of manufacture and design of the product relating to containment and shielding of the TENORM and other safety features under normal and severe conditions of handling, storage, use, reuse, and disposal of the product;
 - (6) The degree of access of human beings to the TENORM product during normal handling, use, and disposal;
 - (7) The total quantity of TENORM expected to be distributed annually in the product;
 - (8) The expected useful life of the product;
 - (9) The proposed method of labeling or marking each unit of the product with identification of the manufacturer or initial transferor of the product and the radionuclides and quantity of TENORM in the

product;

- (10) The procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, reuse, and disposal;
- (11) The results of the prototype testing of the product, including any change in the form of the TENORM contained in it, the extent to which the TENORM may be released to the environment, any change in radiation levels, and any other changes in safety features;
- (12) The estimated external radiation doses and committed dose equivalent relevant to the safety criteria in section 33-10-23-14 and the basis for such estimates;
- (13) A determination that the probabilities with respect to doses referred to in section 33-10-23-14 meet the safety criteria;
- (14) The quality control procedures to be followed in the processing of production lots of the product, and the quality control standards the product will be required to meet; and
- (15) Any additional information, including experimental studies and tests, required by the department to facilitate a determination of the radiation safety of the product.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-14. Safety criteria for consumer and retail products.

An applicant for a license under subsection 2 of section 33-10-23-13 shall demonstrate that the product is designed and will be manufactured so that:

- 1. In normal use and disposal of a single exempt item, and in normal handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the dose in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the doses in column I of section 33-10-23-15.
- 2. In use and disposal of a single exempt item and in handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the

containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or committed dose equivalent in excess of the dose to the appropriate part of the body as specified in column II of section 33-10-23-15 and the probability is negligible that a person would receive an external radiation dose or committed dose equivalent in excess of the dose to the appropriate part of the body as specified in column III of section 33-10-23-15.

3. It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-15. Table of doses.

The dose limits in this section are the doses above background from the product.

1. Column I doses are:
 - a. For the whole body; head and trunk; active blood-forming organs; gonads; or lens of eye - fifty microsieverts [five millirem].
 - b. For the hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter - seven hundred fifty microsieverts [seventy five millirem].
 - c. For other organs - one hundred fifty microsieverts [fifteen millirem].
2. Column II doses are:
 - a. For the whole body; head and trunk; active blood-forming organs; gonads; or lens of eye - five millisieverts [five hundred millirem].
 - b. For the hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter - seventy five millisieverts [seven thousand five hundred millirem].
 - c. For other organs - fifteen millisieverts [one thousand five hundred millirem].
3. Column III doses are:
 - a. For the whole body; head and trunk; active blood-forming organs; gonads; or lens of eye - one hundred fifty millisieverts [fifteen rem].

- b. For ankles and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter - two thousand millisieverts [two hundred rem].
- c. For other organs - five hundred millisieverts [fifty rem].

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-16. Issuance of specific licenses.

- 1. Upon a determination that an application meets the requirements of article 33-10, the department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.
- 2. The department may incorporate in any license at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of TENORM subject to this chapter as it deems appropriate or necessary in order to:
 - a. Protect public health and safety or property;
 - b. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and
 - c. Prevent loss, theft, or loss of control of TENORM subject to this chapter.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-17. Conditions of specific licenses.

- 1. General terms and conditions.
 - a. Each specific license issued under this chapter shall be subject to all the provisions of North Dakota Century Code chapters 23-20, 23-20.1, 23-20.2, and 23-20.5, now or hereafter in effect, and to all rules and orders of the department.
 - b. No specific license issued or granted under this chapter and no right to possess or utilize TENORM granted by any license issued under this chapter shall be transferred, assigned, or in any manner disposed of, either

voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the department shall, after securing full information, find that the transfer is in accordance with the provisions of North Dakota Century Code chapters 23-20, 23-20.1, 23-20.2, and 23-20.5, and shall give its consent in writing.

- c. Each person specifically licensed under this chapter shall confine use and possession of the TENORM licensed to the locations and purposes authorized in the specific license.

- d. Transfer of control.

Within thirty (30) days of the existence of any new controlling individual or entity, the licensee shall submit to the department the name of the controlling individual or entity and a statement signed by the controlling individual or entity in which the controlling individual or entity agrees to accept responsibility for the license. The controlling individual or entity must undergo an environmental compliance background review under section 33-10-23-12.

- e. Notification of bankruptcy.

- (1) Each licensee shall notify the department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapters of Title 11 (Bankruptcy) of the United States Code by or against:

- (a) The licensee;

- (b) An entity [as that term is defined in 11 U.S.C. 101(15)] controlling a licensee or listing the license or licensee as property of the estate; or

- (c) An affiliate [as that term is defined in 11 U.S.C. 101(2)] of the licensee.

- (2) This notification shall indicate:

- (a) The bankruptcy court in which the petition for bankruptcy was filed; and

- (b) The date of the filing of the petition.

- f. Each licensee shall notify the department in writing prior to commencing activities to reclaim the licensed facility and site.

- g. Notification of site or area closure. When a licensee has permanently

ceased use of radioactive materials at a site or portion of a facility and the licensee has not decontaminated the area, or when an area has not been used for a period of two years, the licensee shall, within sixty days, provide the following information in writing to the department:

- (1) The location of the facility, site, or area;
- (2) The plan for reclaiming or decontaminating the facility, site or area; and
- (3) An evaluation of any changes to the financial assurance submitted in accordance with section 33-10-23-25.

h. Temporary jobsites.

- (1) When temporary jobsites are authorized on a specific license, TENORM may be used at temporary jobsites throughout North Dakota in accordance with the reciprocal recognition provisions of section 33-10-23-24 or chapter 33-10-19, in areas not under exclusive federal jurisdiction.
- (2) Before TENORM can be used at a temporary jobsite at any federal facility within North Dakota, the jurisdictional status of the jobsite shall be determined as it pertains to the TENORM. Authorization for use of TENORM at jobsites under exclusive federal jurisdiction shall be obtained from the applicable federal agency.

2. Quality control, labeling, and reports of transfer. Each person licensed under subsection 2 of section 33-10-23-13 shall:

- a. Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the department;
- b. Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the product and the TENORM in the product can be identified; and
- c. Maintain records identifying, by name and address, each person to whom TENORM is transferred for use under subsection 2 of section 33-10-23-04 or the equivalent rules of another licensing state, and stating the kinds, quantities, and uses of TENORM transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the department. Each report shall cover the year ending December 31, and shall be filed within ninety days thereafter. If no transfers of TENORM have been made pursuant to subsection 2 of section 33-10-23-13 during the reporting period, the report shall so indicate.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-18. Expiration and termination of specific licenses.

1. Except as provided in subsection 2 of section 33-10-23-19, the authority to engage in licensed activities as specified in the specific license shall expire at the end of the specified day in the month and year stated therein. Any expiration date on a specific license applies only to the authority to engage in licensed activities. Expiration of a specific license shall not relieve the licensee of responsibility for decommissioning its facility and terminating the specific license.
2. Each licensee shall notify the department immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive materials authorized under the license. This notification and request for termination shall include the documents required by subsection 4 and shall otherwise substantiate that the licensee has met all of subsection 4's requirements.
3. No less than thirty days before the expiration date specified in a specific license, the licensee shall either:
 - a. Submit an application for license renewal pursuant to section 33-10-23-19; or
 - b. Notify the department, in writing, if the licensee decides not to renew the license. The licensee requesting termination of a license shall comply with the requirements of subsection 4;
4. Termination of licenses.
 - a. If a licensee does not submit a complete application for license renewal pursuant to section 33-10-23-19, the licensee shall, on or before the expiration date specified in the license:
 - (1) Terminate use of the TENORM specified in the license;
 - (2) Remove radioactive contamination to the level outlined in section 33-10-23-07, to the extent practicable;
 - (3) Properly dispose of the TENORM specified in the license;
 - (4) Submit a completed department form "certificate: disposition of radioactive material" (SFN 18941); and

- (5) Submit a radiation monitoring report to confirm the absence of TENORM specified in the license or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner acceptable to the department. The radiation monitoring report shall specify the instrumentation used and certify that each instrument was properly calibrated and tested. The licensee shall, as applicable, report levels or quantities of:
 - (a) Beta and gamma radiation at one centimeter from surfaces in units, multiples, or subunits of sieverts or rem per hour or microroentgens per hour;
 - (b) Gamma radiation at one meter from surfaces in units, multiples, or subunits of sieverts or rem per hour or microroentgens per hour;
 - (c) Removable radioactivity on surfaces in units, multiples, or subunits of becquerels or curies per one hundred square centimeters of surface area or in disintegrations (transformations) per minute per one hundred square centimeters of surface area;
 - (d) Fixed radioactivity on surfaces in units, multiples, or subunits of becquerels or curies per one hundred square centimeters of surface area or in disintegrations (transformations) per minute per one hundred square centimeters of surface area;
 - (e) Radioactivity in contaminated liquids such as water, oils or solvents in units, multiples, or subunits of becquerels or curies per milliliter of volume or per gram of liquid; and
 - (f) Radioactivity in contaminated solids such as soils or concrete in units, multiples, or subunits of becquerels or curies per gram of solid.
- b. If levels of residual radioactive contamination attributable to activities conducted under the license are less than those established in section 33-10-23-07, the licensee shall so certify. If the department determines that this certification and the information submitted under subdivision a is adequate and monitoring confirms the findings, then the department will notify the licensee, in writing, of the termination of the license.
- c. If residual radioactive contamination attributable to activities conducted under the license are not in conformance with criteria established in section 33-10-23-07:

- (1) The license continues in effect beyond the expiration date, if necessary, with respect to possession of residual TENORM present as contamination until the department notifies the licensee in writing that the license is terminated. During this time the licensee is subject to the provisions of subsection 5.
 - (2) In addition to the information submitted under subdivision a of subsection 4, the licensee shall submit a plan for decontamination and disposal, if required, as regards residual TENORM contamination remaining at the time the license expires.
5. Each licensee who possesses TENORM under subdivision c of subsection 4, following the expiration date specified in the license, shall:
 - a. Limit actions involving TENORM as specified in the license to those related to decontamination and other activities related to preparation for release for unrestricted use; and
 - b. Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the department notifies the licensee in writing that the license is terminated.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-19. Renewal of specific licenses.

1. Applications for renewal of specific licenses shall be filed in accordance with section 33-10-23-12.
2. In any case in which a licensee, not less than thirty days prior to expiration of an existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, the existing license shall not expire until final action by the department.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-20. Amendment of specific licenses at request of licensee.

Applications for amendment of a license shall be filed in accordance with section 33-10-23-12 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

History: Effective January 1, 2016.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-21. Department action on applications to renew and amend specific licenses.

In considering an application by a licensee to renew or amend the license, the department will apply the criteria set forth in section 33-10-23-13.

History: Effective January 1, 2016.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-22. Modification and revocation of specific licenses.

1. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to North Dakota Century Code chapters 23-20, 23-20.1, 23-20.2, or 23-20.5, or by reason of rules and orders issued by the department.
2. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or because of conditions revealed by such application or any report, record, or inspection or other means which would warrant the department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of North Dakota Century Code chapters 23-20, 23-20.1, 23-20.2, or 23-20.5, or of the license, or of any rule or order of the department.

History: Effective January 1, 2016.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-23. Record keeping requirements for site reclamation.

Each licensee shall keep records of information important to the safe and effective reclamation of a facility in an identified location until the license is terminated by the department. If records of relevant information are maintained for other purposes, reference to these records and their locations may be used. The records must include the following information:

1. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such

as concrete. These records shall include any known information on identification of involved radionuclides, quantities, forms and concentrations.

2. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination, such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.
3. If required by section 33-10-23-25, records of this reclaiming cost estimate prepared for the amount approved by the department for reclaiming.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-24. Reciprocal recognition of specific licenses.

1. Any person who holds a specific license from another agreement state or licensing state, issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within North Dakota for a period not in excess of one hundred eighty days in any 12 month period, provided that:
 - a. A current copy of the licensing document or equivalent authorization is on file with the department and the authorized activities are not limited to specified installations or locations;
 - b. The out-of-state licensee notifies the department at least three days before engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within North Dakota. Upon receipt from the out-of-state licensee of a written request containing a schedule of activities to be conducted within North Dakota, the department may waive the requirement for additional notifications during the twelve-month period following the receipt of the initial notification;
 - c. The out-of-state licensee complies with all applicable rules of the department including sections 33-10-23-11 and 33-10-23-12 and with all the terms and conditions of the licensing document or equivalent authorization, except any such terms and conditions which may be inconsistent with article 33-10;
 - d. The out-of-state licensee supplies any other information necessary to show compliance with article 33-10; and

- e. The out-of-state licensee shall not transfer or dispose of TENORM possessed or used under the general license, except by transfer to a person:
 - (1) Specifically licensed by the department or by another licensing state to receive such TENORM; or
 - (2) Exempt from the requirements for a license for such TENORM under section 33-10-23-04.

2. The department may withdraw, limit or qualify its acceptance of any specific license or equivalent authorization issued by a licensing state, or any product distributed pursuant to such license or equivalent authorization, if the department determines that, had the out-of-state licensee been licensed by North Dakota, the licensee's license would have been subject to action under section 33-10-23-22.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-25. Financial assurance arrangements.

Each licensee or applicant for a specific license shall post with the department financial assurance, or security, to ensure the protection of the public health and safety and the environment in the event of abandonment, default, or other inability or unwillingness of the licensee to meet the requirements of article 33-10 and North Dakota Century Code chapter 23-20.1. Financial assurance arrangements shall:

- 1. Consist of surety bonds, government securities, irrevocable letters of credit, corporate guarantees, insurance, state funds, or any combination of these;
- 2. Be in an amount sufficient to meet the applicant's or licensee's obligations under article 33-10 and North Dakota Century Code chapter 23-20.1 and shall be based upon department approved cost estimates;
- 3. Be established prior to issuance of the license or the commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility;
- 4. Be continuous for the duration of the license and for a period coincident with the applicant or licensee's responsibility under article 33-10 and North Dakota Century Code chapter 23-20.1;
- 5. Be available in North Dakota subject to judicial process and execution in the event required for the purposes set forth; and

6. Be established within ninety days of the initial effective date of this chapter for licenses in effect on that date.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-26. Acceptable surface contamination levels for TENORM.

1. Where surface contamination by both alpha and beta-gamma emitting nuclides exists, the limits established for alpha and beta-gamma emitting nuclides shall apply independently.
2. As used in this section, "disintegrations per minute" means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
3. Average contamination level.
 - a. For surface contamination by alpha emitting nuclides, the average contamination level shall not exceed five thousand disintegrations per minute per one hundred square centimeters of surface area.
 - b. For surface contamination by beta-gamma emitting nuclides, the average contamination level shall not exceed five thousand disintegrations per minute per one hundred square centimeters of surface area.
 - c. Measurements of average contamination level shall not be averaged over more than one square meter. For objects of less surface area, the average shall be derived for each object.
 - d. The average radiation levels associated with surface contamination resulting from beta-gamma emitters shall not exceed two microgray per hour [two tenths millirad per hour] at one centimeter and ten microgray per hour [one millirad per hour] at one centimeter, respectively, measured through not more than seven milligrams per square centimeter of total absorber.
4. Maximum contamination level.
 - a. For surface contamination by alpha emitting nuclides, the maximum contamination level shall not exceed fifteen thousand disintegrations per minute per one hundred square centimeters of surface area.

- b. For surface contamination by beta-gamma emitting nuclides, the maximum contamination level shall not exceed fifteen thousand disintegrations per minute per one hundred square centimeters of surface area.
 - c. The maximum contamination level applies to an area of not more than one hundred square centimeters.
 - d. The maximum radiation levels associated with surface contamination resulting from beta-gamma emitters shall not exceed two microgray per hour [two tenths millirad per hour] at one centimeter and ten microgray per hour [one millirad per hour] at one centimeter, respectively, measured through not more than seven milligrams per square centimeter of total absorber.
5. Limits on removable contamination.
- a. For surface contamination by alpha emitting nuclides, the removable contamination shall not exceed one thousand disintegrations per minute per one hundred square centimeters of surface area.
 - b. For surface contamination by beta-gamma emitting nuclides, the removable contamination shall not exceed one thousand disintegrations per minute per one hundred square centimeters of surface area.
 - c. Measurements of average contamination level shall not be averaged over more than one square meter. For objects of less surface area, the average shall be derived for each object.
 - d. The amount of removable radioactive material per one hundred square centimeters of surface area shall be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of surface area A (where A is less than one hundred square centimeters) is determined, the entire surface shall be wiped and the contamination level multiplied by the quantity [one hundred divided by A] to convert to a "per one hundred square centimeter" basis.
 - e. The maximum radiation levels associated with surface contamination resulting from beta-gamma emitters shall not exceed two microgray per hour [two tenths millirad per hour] at one centimeter and ten microgray per hour [one millirad per hour] at one centimeter, respectively, measured through not more than seven milligrams per square centimeter of total absorber.

History: Effective January 1, 2016.
General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-27. Specific licenses – Radiation protection program required.

1. A licensee shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.
2. A licensee shall establish, in writing, the Radiation Safety Officer's authority, duties, and responsibilities.
3. A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:
 - a. Identify radiation safety problems;
 - b. Initiate, recommend, or provide corrective actions;
 - c. Stop unsafe operations; and
 - d. Verify implementation of corrective actions.
4. A licensee shall retain a record of actions taken under subsections 1 and 2 of this section for five years.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-23-28. Radiation safety officer – Qualifications.

1. Except for licenses exclusive to the transport of TENORM waste, the specific licensee shall require an individual fulfilling the responsibilities of the Radiation safety Officer as provided in 33-10-23-27 to be an individual who has completed a department approved training program consisting of forty hours of classroom training in the following areas:
 - a. Characteristics of radiation;
 - b. Units of radiation dose and quantity of radioactivity;
 - c. Hazards of exposure to radiation;
 - d. Radiation detection and measurement;

- e. Minimizing radiation exposure (time, distance, shielding, and respiratory precautions);
 - f. Use and types of personnel-monitoring equipment;
 - g. Proper use of protective equipment; and
 - h. Transportation of licensed material.
2. For licenses exclusive to the transport of TENORM waste, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer to be an individual who has completed a department approved training program consisting of eight hours of classroom training in the following areas:
- a. Characteristics of radiation;
 - b. Units of radiation dose and quantity of radioactivity;
 - c. Hazards of exposure to radiation;
 - d. Radiation detection and measurement;
 - e. Minimizing radiation exposure (time, distance, shielding, and respiratory precautions);
 - f. Use and types of personnel-monitoring equipment;
 - g. Proper use of protective equipment; and
 - h. Transportation of licensed material.

History: Effective January 1, 2016.

General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04