

# Conference of Radiation Control Program Directors, Inc.

Office of Executive Director ◆ 205 Capital Avenue ◆ Frankfort, KY 40601 Phone: 502/227-4543 ◆ Fax: 502/227-7862 ◆ Web Site: www.crcpd.org Central E-mail: staff@crcpd.org

March 13, 2001

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Paul Lohaus Nuclear Regulatory Commission One White Flint North 11555 Rockville Pike Rockville, MD 20852

Dear Mr. Lohaus:

Please find enclosed draft copies of the latest suggested state regulations from the Conference of Radiation Control Program Directors. Part N – Regulation and Licensing of Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM), is being presented for peer review. Currently, CRCPD members and industry stakeholders are peer reviewing this Part. We request that NRC likewise review the enclosed Parts relative to eventual Federal Concurrence.

The CRCPD requests that correspondence relative to Parts A, D and J from your agency be submitted prior to April 24, 2001.

Thank you for your attention to this important matter.

Sincerely,

√Patricia Gorman

Deputy Director, CRCPD

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cc:

Charles Hardin, Executive Director, CRCPD

Paul S. Schmidt, Chairperson, CRCPD

A Partnership Dedicated to Radiation Protection

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# **CRCPD's Suggested State Regulations-Group 5**

# Conference of Radiation Control Program Directors, Inc. (CRCPD) A Partnership Dedicated to Radiation Protection

Peer Review of Part N and its Rationale

#### Dear Peer Reviewer:

Thank you for your willingness to review and comment on the revisions of the Conference of Radiation Control Program Directors, Inc. (CRCPD or Conference) Suggested Regulations for Control of Radiation, Part N and the Rationale document. These documents are enclosed and are posted on the CRCPD's web page at <a href="http://bruce.crcpd.org/N\_Draft\_2001.pdf">http://bruce.crcpd.org/N\_Draft\_2001.pdf</a>. The comments on these two documents are needed by Steve Collins, Chairman of the SR-5 Working Group, who is responsible for coordinating the review of your comments and making necessary changes to the documents. The SR-5 Working Group will be meeting April 26-28, 2001 to review your comments and take them into consideration in making revisions, as necessary. In order for your comments to be considered they need to arrive by April 24, 2001 at the address shown at the end of this letter. You may send your comments by e-mail to collins@idns.state.il.us, but we would also like to have a hard copy with a signed transmittal.

The SR-5 reviewed comments received by the NORM Commission regarding the draft of Part N that was approved by the CRCPD's Board of Directors and dated April 1999. Particular attention was given to the U.S. Environmental Protection Agency's (EPA's) concerns expressed in letters dated in 1997 and reiterated in a letter to Charles Hardin dated April 19, 1999, that clearly expressed the Agency's lack of concurrence with Part N. In the April 19, 1999 letter the EPA identified three principal concerns:

- 1. Failure to recommend a standard that is protective of human health and the environment;
- 2. Failure to include a separate standard or requirement for ground water protection; and
- 3. A lack of a preference for permanent remedies and treatment.

It should be noted that EPA was the only federal agency to express its non-concurrence with Part N. For this reason, we consider it important to review EPA's objections to previous versions of Part N in this letter and CRCPD's actions to overcome those objections. It is hoped that this particular focus will contribute to the

# Office of the Committee Chairperson Steven C. Collins

thoughtful review by the Peer Reviewers. Of course, we emphasize that Peer Review input is not meant to be limited to EPA's issues alone.

EPA asserts that Part N is not protective of human health and environment because CRCPD has not adopted verbatim the radiation protection measures sought by EPA in guidance for site cleanups implemented under the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA" or "Superfund."). Instead, CRCPD has elected to adhere to the radiation protection standards articulated in CRCPD's Part D as the substantive basis for protection afforded in Part N, in lieu of EPA's CERCLA guidance. The standards set forth in Part D were approved by all federal agencies, including EPA.

The SR-5 Committee and the CRCPD Board of Directors disagree with EPA's assertion that Part N is not protective of human health and the environment. We believe that most, if not all, of the reasons for EPA's disagreement involve a matter of policy, rather than science. Part N considers all exposure pathways in prescribing radiation protection for TENORM. This approach differs from that endorsed by EPA wherein multiple pathways – including ground water – are considered separately. In this regard, the approach taken in Part N is consistent with the recommendations of the International Commission on Radiological Protection ("ICRP"), National Council on Radiation Protection ("NCRP"), Nuclear Regulatory Commission ("NRC"), Department of Energy ("DOE"), the National Academy of Sciences ("NAS") and many other national and international experts in radiation protection, who agree that an all pathways approach achieves protection of the public with an adequate margin of safety.

During work on the 2001 revision of Part N the SR-5 Working Group considered each of the comments summarized in EPA's April 19, 1999 letter and attachments. Notwithstanding the aforementioned policy objections expressed by EPA, CRCPD has made every effort to address EPA's concerns that could reasonably be interpreted as having a technical or procedural basis, as follows:

- EPA's preference for permanent remedies is addressed by revising Part N (N.5e.) to require actions to confine TENORM be based on expected longevity related controls for 1000 years or longer.
- Possible dual regulation of TENORM or sites with TENORM is avoided by clarifying in N.4d that sites subject to CERCLA cleanup are exempt from Part N.
- The annual dose limitation of 100 mrem from a single source of TENORM is considered as a component of the 100 mrem annual limit to a member of the public from all sources and all pathways. Consequently, there should not be a problem with unacceptable risk to the public.
  - N.1 and N.2 have been modified to more accurately address the purpose and scope of Part N. It should be recognized that Part N is not limited to remedial or disposal activities.
  - N.4a. exempts 5pCi/gm or less of radium in any combination of Ra-226 and Ra-

<sup>&</sup>lt;sup>1</sup> As acknowledged by EPA in its April 19, 1999 letter, the Conference's "intention was to treat TENORM in a similar fashion to Atomic Energy Act materials and create a regulatory framework covering all aspects of these radiological materials." Consequently, the all pathways approach taken in Part N is consistent with the methodology of NRC and ALARA in establishing criteria for site decommissioning.

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- N.5a. The maximum permitted dose was clarified to indicate the dose is from all licensed sources, from all pathways, not just TENORM.
- N.7 has been rewritten to clarify the requirement for unrestricted release to not exceed Appendix A criteria. Conditional release of contaminated metal to the recycle industry is permitted only when the radiation level does not exceed 50 microroentgens/hour including background.
- N.8a. SR-5 is concerned that TENORM contamination of groundwater is a situation that is very unlikely to arise outside the uranium mining or rare metals extraction industries, which are already subject to operative controls and/or remedial programs under existing federal and state statutes. Part N is intended to bridge the regulatory gap with respect to TENORM rather than create additional regulatory burdens. If EPA can identify situations in which TENORM has caused groundwater contamination that was not amenable to regulatory intervention under existing environmental law, then this issue will receive priority attention in the Matters for Future Consideration.
- N.8a.iii. This item is in response to recent rulemaking activities of EPA rather than
  comments made by EPA in the referenced letters. This section emphasizes the
  permitting authority's broad authority to consider relevant statutes governing
  environmental media likely to be affected by the contemplated disposal action.
- N.8d. Record keeping is specified in Part D.
- N.8e. The period of compliance is specified in N.5e.
- N.10c.ii Part N was revised in response to this comment.
- N.23 The intent of EPA is met. According to the attorneys in the states contacted, when states use the regulatory language "or" it means "either or". That is why "or" is used rather than "and" which can mean that both items are necessary for the criteria to apply. Thus, total dose, both internal and external, is accounted for in assessing product safety.
- N.24 The SR-5 agrees with EPA; however, to maintain consistency of program standards for all types of radioactive material, the Table of Organ Doses has not yet been changed. This is an issue being looked at by the states and NRC for Sealed Source & Device Registry criteria. As a practical matter, the application of ALARA eliminates this from being a real radiation protection concern. This item should be added to the Matters for Future Consideration.
- N.25b.iii The wording is now as recommended by EPA.
- Appendix A. The wording is now as recommended by EPA.

In closing, the CRCPD is confident that the model Part N, as a template for rulemaking by the states, would establish a scientifically defensible regulatory framework for the logical, systematic, and practical assurance that human exposures to ionizing radiation from TENORM are not a public health concern. Moreover, a state regulatory

program based on the Part N model would provide far more comprehensive protection than is currently afforded under existing federal rules.

If you have questions regarding these items, you may call Steve Collins at 217-785-6982. Thank you for your efforts to improve Part N.

Sincerely, Stare C. Collias

Steven C. Collins

Enclosures

Revised Part N Rationale for revisions

#### PART N

# REGULATION AND LICENSING OF TECHNOLOGICALLY ENHANCED NATURALLY OCCURRING RADIOACTIVE MATERIALS (TENORM)

Sec. N.1 - Purpose. This Part establishes radiation protection standards for the possession, use, transfer, disposal and of Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM). This includes the possession, use, processing, distribution, transfer, disposal and manufacture of products of TENORM. This Part also establishes requirements for issuance of specific and general licenses to possess and use TENORM.

#### Sec. N.2 - Scope.

- a. These regulations apply Except as otherwise excluded in this Part, Part N applies to any person who receives, owns, possesses, uses, processes, transfers, distributes, or disposes of TENORM.
- b. The manufacture and distribution of products containing TENORM; in which the TENORM's and/or its emitted radiation is considered to be a beneficial attribute to the products, are licensed under the provisions of Part C of these regulations.
- c. The regulations in this Part <u>also</u> address the introduction of TENORM into products in which neither the TENORM, nor the radiation emitted from the TENORM, is considered to be beneficial to the products.
- d. This Part does not apply to radionuclides for which NRC retains exclusive jurisdiction source material and byproduct material as both are defined in the Atomic Energy Act of 1954, as amended (42 USC §2011 et seq.) as implemented by the US Nuclear Regulatory Commission.
- e. The transportation and storage incident to transportation are governed by Parts T and D respectively of these regulations.

Sec. N.3 - Definitions. As used in this Part, the following definitions apply:

"Beneficial attribute" means the radioactivity of the product necessary to the use of the product.

"Beneficial to the product" see "Beneficial attribute". means that the radioactivity of the TENORM is necessary to the use of the product.

"Conditional release" means release by a licensee for a specified use, not release for unrestricted use.

Conditional release requires written documentation by the licensee for release to a specified facility. Written documentation shall include the date, recipient name and location, description and quantity of the material.

"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.

"General environment" means the total terrestrial, atmospheric, and aquatic environments outside the site boundary within which any activity, operation, or process authorized by a general or specific license issued under this Part, is performed.

"Institutional controls" means: (1) Permanent markers placed at a disposal site, (2) public records and archives, (3) government ownership and regulations regarding land or resource use, and (4) other methods of preserving knowledge about the location, design, and contents of a disposal system.

"Product" means something produced, made, manufactured, refined, or benefited beneficiated.

"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.

"Technologically Enhanced Naturally Occurring Radioactive Material (TENORM)" means naturally occurring radionuclides 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 as defined and byproduct material as both are defined in the Atomic Energy Act of 1954, as amended (42 USC §2011 et seq.) as implemented by the Nuclear Regulatory Commission. TENORM does not include uranium or thorium in "source material" as defined in the AEA and US NRC regulations.

["Transfer" means the physical relocation of <u>TENORM</u> containing materials not directly associated with commercial distribution within a business' operation or between general or specific licensees. This term does not include a change in legal title to <u>TENORM</u> containing materials that does not involve physical movement of those materials.]

"Total effective dose equivalent" or "TEDE" means [applicable state definition for consistency with other regulations.]

# Sec. N.4 - Exemptions. \*\*

a. Persons who receive, own, possess, use, process, transfer, distribute, or dispose of TENORM

<sup>\*</sup> States may establish alternative exemption criteria using site and industry specific data, provided that the criteria are consistent with Section N.5b through N.5d.

are exempt from the requirements of Part N with respect to any combination of <sup>226</sup>Ra and <sup>228</sup>Ra if the materials contain, or are contaminated at, concentrations less than [185 becquerel per kilogram (5 pCi/gm)] excluding natural background. This exemption does not apply to consumer or retail products which that are discussed inregulated pursuant to N.22c. and N.23. Using purposeful dilution to render TENORM waste exempt shall not be allowed without prior agency approval.

- b. Persons who receive products or materials containing TENORM distributed in accordance with a specific license issued by the Agency pursuant to N.20a., or to an equivalent license issued by another Licensing State, are exempt from these regulations this Part with regard to those products or materials.
- c. The distribution, including custom blending, possession, and use <u>and disposal</u> of fertilizers <u>and zircon, zirconia and zircon products</u> containing TENORM, is exempt from the requirements of this Part.
- d. TENORM waste regulated by the Comprehensive Environmental Response, Compensation Liability Act (CERCLA 42 USC §9601 et seq. as amended) or RCRA by the (Resources Conservation and Recovery Act) (RCRA 42 USC §6901 et seq. as amended) [or equivalent state authority] are exempt from this Part.
- e. The transportation and storage incident to transportation are governed by Parts D and T of these regulations.
- e. Other TENORM shall be exempt when the Agency makes a determination, upon its own initiative or upon request for such determination, that the reasonably maximally exposed individual will not receive a TEDE of more than 1 mSv (0.1 rem) in one year from all exposure pathways of the TENORM. The dose specified in this subsection does not include occupational dose, dose received from background radiation, or dose received as a result of administration of radioactive material to a patient.

# Sec. N.5 - Standards for Radiation Protection for TENORM Members of the Public.

- a. No person licensed under N.10 or N.20 shall conduct operations, use, <u>process</u>, <u>distribute</u> or transfer TENORM in a manner such that a member of the public will receive an annual <u>TEDE Total Effective Dose</u> in excess of 1 millisievert per year (100 mrem/yr-) from all licensed sources including TENORM.
- b. Persons subject to a license under this Part shall comply with <u>the radiation protection</u> standards for radiation protection set out in Part D of these regulations.\*
- c. Doses from indoor radon and its progeny shall not be included in Total Effective Dose Equivalent calculations of the TEDE, unless specifically directed otherwise by the Agency. The Agency will provide its basis if it directs the inclusion of radon in such calculations.

<sup>\*</sup> States which have already adopted Part D or the equivalent shall substitute the appropriate reference

- d. No person shall release TENORM for unrestricted use in such a manner that the reasonably maximally exposed individual will receive an annual total effective dose equivalent <u>TEDE</u> from the released TENORM, excluding its radon and its radon progeny, in excess of [some fraction of 1 millisievert per year (100 mrem/yr.)\*\*/] excluding natural background.
- e. Actions taken to confine TENORM on site or to remediate sites shall be based on expected longevity related controls for 1000 years [or longer].
- <u>Sec. N.6 Protection of Workers During Operations.</u> Each person subject to a specific or general license under Part N shall conduct operations <u>such that dose to workers is</u> in compliance with the standards for radiation protection set out in Parts D and J of these regulations.
- Sec. N.7 Release for Unrestricted Use. Each person subject to a license under this Part shall:
- a. Not transfer or release for unrestricted use facilities or equipment contaminated with TENORM in excess of levels in Appendix A of this Part\*\*\*;
- b.Not transfer or release for unrestricted use equipment contaminated with TENORM in excess of a surface—gamma—radiation—level—of—[insert state screening—level micro—rems/hour including/excluding natural background]; and
- e. Not transfer land for unrestricted use where the concentration of <sup>226</sup>Ra or <sup>228</sup>Ra in soil averaged over any 100 square meters exceeds the background level by more than 185 becquerel per kilogram (5 pCi/gm), averaged over any 15 cm layer of soil below the surface, unless compliance with N.5 b through d can be demonstrated.
- Sec. N.7 Unrestricted Use and Conditional Release. Each person subject to a specific or general license under this Part shall:
- a. Transfer or release for unrestricted use facilities or equipment contaminated with TENORM which are not greater than the levels in Appendix A of this Part. Upon application, specific approval of alternative levels may be granted by the Agency.
- b. Transfer or release land for unrestricted use where the concentration of TENORM <sup>226</sup>Ra and <sup>228</sup>Ra, averaged over 100 square meters, is less than 185 becquerel per kilogram (5 pCi/gm) above the background concentration, averaged over any 15 cm layer of soil below the surface, or compliance with N.5b. through N.5d. is demonstrated.
- c. Transfer or release for conditional use in metal recycle, equipment contaminated with TENORM producing a maximum exposure level of (50 microroentgen per hour), including background radiation, at any accessible location. Recycling shall not include the processing

<sup>\*\*</sup> The implementing state must determine what fraction of 100 mrem/yr is allowable from TENORM in light of existing Federal Standards to protect the general public.

<sup>\*\*\*/</sup> States may establish screening levels based on gamma survey instrument results for use in releasing facilities and equipment, consistent with N.5.

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or use of materials in a manner that constitutes disposal without specific written approval of the Agency.

# Sec. N.8 - Disposal and Transfer of Waste for Disposal.

- a. Each person subject to a <u>specific or general</u> license under this <u>Rule Part</u> shall manage and dispose of wastes containing TENORM:
  - i. By transfer of the wastes for disposal to a facility licensed under requirements for uranium or thorium byproduct materials in either 40 CFR 192, or 10 CFR 40 Appendix A, or equivalent regulations of an Agreement State; or
  - ii. By transfer of the wastes for disposal to a disposal facility licensed by the US Nuclear Regulatory Commission, an <u>aAgreement sState</u>, or a Licensing State; or
  - iii. In accordance with alternate methods authorized by the A\_permitting agency\_for the disposal site upon application or upon the Agency's initiative, consistent with N.5 [and where applicable the Clean Water Act, Safe Drinking Water Act and other requirements of the US Environmental Protection Agency for disposal of such wastes].
- b. Equipment contaminated with TENORM in excess of levels specified in Appendix AN.7a. or N.7b., which is to be disposed of as waste, shall be disposed-of:
  - i. So as to In a manner that will prevent any reintroduction into commerce or unrestricted use; and
  - ii. Within disposal areas specifically designed to meet the criteria of referred to in N.8a.
- c. Transfers of waste containing TENORM for disposal shall be made only to a person specifically authorized by the <u>US</u> Nuclear Regulatory Commission, an Agreement State or a <u>Hicensing sState</u>, to receive such waste, or other agency with appropriate permitting authority.
- d. Records of disposal, including manifests, shall be maintained pursuant to the provisions of Part D of these regulations.
- e. Purposeful dilution to render TENORM waste exempt shall not be performed without prior Agency approval.
- f. A licensee may dispose of TENORM [not away from the point of generation] in an injection well approved in accordance with [cite the appropriate state regulation for underground injection control (UIC) permitting].

#### Sec. N.9 - Prohibition.

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

#### **General License**

#### Sec. N.10 - General License.

- a. Subject to the requirements of N.5 through N.8 and N.10, a general license is hereby issued to possess, own, use, transfer, distribute or dispose of TENORM without regard to quantity.
- b. This general license does not authorize the manufacturing of <u>consumer or retail</u> products containing TENORM in concentrations greater than those specified in N.4a. nor the receipt and disposal of wastes from other persons.
- c. The decontamination of equipment, facilities, and land shall be performed only by persons specifically licensed by the aAgency or another Licensing sState to conduct such work. However, employees or contractors under control and supervision of a general licensee can perform routine maintenance on equipment, facilities, and land owned or controlled by the general licensee. Maintenance that provides a a different pathway for exposure different from that than is found in daily operations and that increases the potential for additional exposure is not considered routine maintenance.
- [d.\*' Any person subject to the general license issued by this section N.10a. shall notify the Agency within 60 days of the effective date of this Part or of becoming subject to the general license. Such notification shall include:
  - i. Name and address of the licensee;
  - ii. Location and description of the facility or operation;
  - iii. Description of the TENORM including estimates of the amount and extent of TENORM.]
- e. Transfer of material, equipment or real property.
  - i. The transfer of TENORM not exempt from these regulations 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 the same purpose; or
    - (2) The transfer of control or ownership of land contaminated with TENORM

<sup>\*/</sup>This subsection may be omitted at the option of the adopting state.

includes [an annotation of the deed records] [notice to owners of surface and mineral rights]\*\*/ to indicate the presence of TENORM.

- ii. For Ttransfers not made in accordance with N.10e.i., require-prior written approval by the Agency is required. To obtain Agency approval, the transferor shall submit information that demonstrates compliance with N.7. Records of such compliance shall be maintained as specified in (cite record keeping for decommissioning). Procedural aspects need to be considered in a Reg. Guide}
- iii. For Ttransfers made under N.10e.i., do not relieve the general licensee who makes the transfer from the responsibilities of assessing shall assess the extent of TENORM contamination or material present, informing the general licensee receiving the TENORM of these assessments prior to such transfer, and maintaining records required by these regulations.
- iv. A general licensee intending to transfer material or real property for unrestricted use shall document compliance with the requirements of N.7 of this regulation. Records of such compliance shall be kept [state's option].
- f. <u>Distribution of TENORM products between general licensees</u>. The distribution of TENORM products not exempt from these regulations 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.
- g. The [name of regulating agency] may, by written notice, require any person authorized by a general licensee to apply for and obtain a specific license if the Agency determines that specific licensure is necessary to ensure that exposures do not exceed the criteria. The notice shall state the reason or reasons for requiring a specific license.

#### **Specific Licenses**

Sec. N.20 - Specific Licenses. Unless otherwise exempt, a specific license is required to:

Licensed under the provisions of Part C of these regulations;

a.	A specific license is required under N.22c. and N.23 to Mmanufacture and distribute and material—consumer or retailer product containing TENORM unless: authorized by N.16 exempted under the provisions of N.4, or licensed under the provisions of Part C of the regulations;	€,
	i. Authorized as specified by N.10a. or N.10f.;	

iii. Exempted under the provisions of N.4; or

ii.

<sup>\*\*/</sup> This option is provided for those states in which notations to recorded deeds are prohibited.

# iv. Otherwise exempt in accordance with another Part of these regulations.

- b. Except as provided in N.10c., A specific license is required to decontaminate equipment or land not otherwise exempted under the provisions of N.4 or facilities to decontaminated with facilities contaminated with TENORM in excess of the levels set forth in N.7, except as provided in N.10c. as applicable; For purposes of this subsection, the term "decontaminate" shall not include routine maintenance which incidentally results in removal of contamination; or
- c. <u>A specific license is required to Rreceive TENORM from other persons for disposal unless otherwise exempt [or authorized in writing by the Agency.]</u>

# Sec. N.21 - Filing Application for Specific Licenses. \*/

- a. Applications for specific licenses shall be in English and filed in a manner and on a form prescribed by the Agency.
- b. The Agency may at any time after the filing of the original application, and before the expiration termination of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.
- c. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the licensee's behalf.
- d. An application for a license may include a request for a license authorizing one or more activities.
- e. Each application for a specific license shall be accompanied by the fee prescribed in [cite the appropriate regulation].
- f. In an application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency provided such references are clear and specific.\*\*/
- g. Applications and documents submitted to the Agency may be made available for public inspection [state's option: include references to applicable freedom of information statute, trade secrets, etc.].

<sup>\*/</sup> This section duplicates the requirements of SSRCR Part C; states having equivalent requirements may elect to refer to appropriate regulations.

<sup>\*\*/</sup> May be omitted by adopting state.

# Sec. N.22 - Requirements for the Issuance of Specific Licenses. \*/

- a. A license application will be approved if the Agency determines that:
  - i. The applicant is qualified by reason of training and experience to use the TENORM in question for the purpose requested in accordance with these rules in such a manner as to protect the public health and safety or property;
  - ii. The applicant's proposed equipment, facilities, and procedures are adequate to protect the public health and safety or property;
  - iii. The issuance of the license will not be inimical to the health and safety of the public;
  - iv. The applicant satisfied all applicable special requirements in this Part; and
  - v. The applicant has met the financial surety assurance requirements of N.50.
  - vi. 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 and facilities.
  - vii. 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 regulations of the Agency.
- b. An application for a specific license to decontaminate equipment, land, or facilities contaminated with TENORM in excess of the levels set forth in N.4a., N.7b., or Appendix A of this Part, as applicable, and to dispose of the resulting waste will be approved if:

- i. The applicant satisfies the general requirements specified in N.22a.; and
- ii. The applicant has adequately addressed the following items in the application:
  - (1) Procedures and equipment for monitoring and protection of 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) Method of disposing of the TENORM removed from contaminated equipment, facilities, and/or land.
- c. An application for a specific license to transfer materials or manufacture or distribute consumer or retail products containing TENORM to persons exempted from these regulations pursuant to N.4b. will be approved if:
  - i. The applicant satisfies the general requirements specified in N.22a.;
  - ii. 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
  - iii. 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 material or product to demonstrate that the material or product will meet the safety criteria set forth in N.23. The information shall include:
    - (1) A description of the material or-product and its intended use or uses;
    - (2) The type, quantity, and concentration of TENORM in each material or product;
    - (3) The chemical and physical form of the TENORM in the material or product, and changes in chemical and physical form that may occur during the useful life of the material or product;
    - (4) An analysis of the solubility in water and body fluids of the <u>radionuclides</u> TENORM\_in the <u>material or-product</u>;
    - (5) The details of manufacture and design of the material or 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 material or product;

- (6) The degree of access of human beings to the material or <u>TENORM</u> product during normal handling, use, and disposal;
- (7) The total quantity of TENORM expected to be distributed annually in the material or product;
- (8) The expected useful life of the material or product;
- (9) The proposed method of labeling or marking each unit of the material or product with identification of the manufacturer or initial transferor of the product and the radionuclides and quantity of TENORM in the material or product;
- (10) The procedures for prototype testing of the material or 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 material or 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 dose commitments committed dose equivalent relevant to the safety criteria in N.23 and the basis for such estimates;
- (13) A determination that the probabilities with respect to doses referred to in N.23 meet the safety criteria;
- (14) The quality control procedures to be followed in the <u>production processing</u> of production lots of the <u>material or product</u>, and the quality control standards the <u>material or product</u> will be required to meet; and
- (15) Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the radiation safety of the material or-product.
- [d. Notwithstanding the provisions of N.23b., the Agency may deny an application for a specific license if the end uses of the product are frivolous or cannot be reasonably foreseen.]
- <u>Sec. N.23 Safety Criteria for Products.</u> An applicant for a license under N.22c. shall demonstrate that the product is designed and will be manufactured so that:

- a. 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 TEDE 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 N.24.
- b. 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 dose commitment committed dose equivalent in excess of the dose to the appropriate organ as specified in Column II of the table in N.24 and the probability is negligible\*/ that a person would receive an external radiation dose or dose commitment committed dose equivalent in excess of the dose to the appropriate organ as specified in Column III of the table in N.24.\*\*/
- c. 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.

Sec. N.24 - Table of Organ Doses.

{PRIVATE }Part of Body	Column I*	Column II*	Column III*
	Dose	Dose	Dose
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.05 mSv	5 mSv	150 mSv
	(0.005 rem)	(0.5 rem)	(15 rem )
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.75 mSv	75 mSv	2000 mSv
	(0.075 rem)	(7.5 rem)	(200 rem )
Other organs	0.15mSv	15mSv	500mSv
	(0.015 rem)	(1.5 rem)	(50 rem)

<sup>\*/ &#</sup>x27;Exempt items' as defined in SSR Part C, even though Part C doesn't address <u>TE</u>NORM isotopes.

Low-not more than one such failure per year for each 10,000 exempt units distributed. Negligible-not more than one such failure per year for each one million exempt units distributed.

<sup>\*\*/</sup> It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such as dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The above values may be used as guidelines in estimating compliance with the criteria.

\*Dose limit is the dose above background from the product.

# Sec. N.25 - Issuance of Specific Licenses.

- a. Upon a determination that an application meets the requirements of [applicable authorizing statutes and rules of the Agency], the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.
- b. The Agency 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 Part as it deems appropriate or necessary in order to:
  - i. Protect public health and safety or property;
  - ii. 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
  - iii. Prevent loss, theft, or loss of control of TENORM subject to this Part.

# Sec. N.26 - Conditions of Specific Licenses Issued Under N.22.

### a. General Terms and Conditions

- i. Each <u>specific</u> license issued pursuant to this Part shall be subject to all the provisions of the [applicable Act], now or hereafter in effect, and to all rules, regulations, and orders of the Agency.
- ii. No specific license issued or granted under this Part and no right to possess or utilize TENORM granted by any license issued pursuant to this Part 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 Agency shall, after securing full information, find that the transfer is in accordance with the provisions of the [applicable Act], and shall give its consent in writing.
- iii. Each person <u>specifically</u> licensed by the Agency pursuant to this Part shall confine use and possession of the TENORM licensed to the locations and purposes authorized in the <u>specific</u> license.
- iv. Each person <u>specifically</u> licensed by the Agency pursuant to this Part is subject to the <u>general</u> license provisions of <u>N.5</u>, N.6, N.7, and N.8.
- v. Notification of Bankruptey.

Each licensee shall:(1) Nnotify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapters of Title II (Bankruptcy) of the United States Code (11 U.S.C.) by or against:

- (a) The licensee;
- (b) An entity [as that term is defined in 11 U.S.C. 101 (1514)] 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 in their Bankruptcy notification:
  - (a) The bankruptcy court in which the petition for bankruptcy was filed; and
  - (b) The date of the filing of the petition.
- vi. Each licensee shall notify the Agency in writing prior to commencing activities to reclaim the licensed facility.
- vii. 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 60 days, provide the following information in writing to the Agency:
  - (1) The location of the site or area;
  - (2) The plan for reclaiming or decontaminating the site or area; and
  - (3) An evaluation of any changes to the financial assurance submitted in accordance with N.50.

# viii. Temporary Jobsites\*/

- (1) When temporary jobsites are authorized on a specific license, TENORM may be used at temporary jobsites throughout the State of [name of your state] in accordance with N.40 (or C.90 of these regulations), in areas not under exclusive federal jurisdiction.
- (2) Before TENORM can be used at a temporary jobsite at any federal facility within the State of [name of your state], 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 federal agency with jurisdiction for TENORM at the temporary jobsite. [Authorization for use of TENORM at jobsites under exclusive federal jurisdiction must be obtained from the federal agency having jurisdiction of the property. Also, specific licenses issued by the Agency do not authorize activities in other states or in areas of exclusive federal jurisdiction in this state or in any other state. Before radioactive materials can be used at a temporary jobsite in another state or an area of exclusive federal jurisdiction, a license must be obtained from the appropriate state or federal agency.]

- [b. Quality Control, Labeling, and Reports of Transfer. \* Each person licensed under N.22c. shall:
  - i. 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 Agency;
  - ii. Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the material or product and the TENORM in the product can be identified; and
  - iii. Maintain records [identifying, by name and address, each person to whom TENORM is transferred for use under N.4b. or the equivalent regulations 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 Agency. Each report shall cover the year ending December 31, and shall be filed within 90 days thereafter. If no transfers of TENORM have been made pursuant to N.22c. during the reporting period, the report shall so indicate.]

# Sec. N.27 - Expiration and Termination of Specific Licenses.

- a. Except as provided in N.28b., 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. Except as provided in N.27d.vi. and N.28b., each specific license shall expire at the end of the specified day in the month and year stated therein.
- b. Each licensee shall notify the Agency <u>immediately</u>, in writing, and request termination of the license when the licensee decides to terminate all activities involving <u>TENORM</u>-radioactive

<sup>\*/</sup> State option; this section may be omitted or modified as appropriate based on state quality control standards.

<sup>\*\*/</sup> Implementing state may require reporting as appropriate for each category of licensee.

materials authorized under the license. This notification and request for termination of the license must shall include the reports and information specified indocuments required by N.27d.iv. and shall otherwise substantiate that the licensee has met all of the requirements in N.27d. The licensee is subject to the provisions of N.27d. and N.27e., as applicable.

- c. No less than 30 days before the expiration date specified in a specific license, the licensee shall either:
  - i. Submit an application for license renewal under pursuant to N.28; or
  - ii. Notify the Agency, in writing, under N.27b., if the licensee decides to not renew the license. The licensee requesting termination of a license shall comply with the requirements of N.27d; discontinue all activities involving TENORM.
- d. <u>Termination of Licenses.If a licensee does not submit an application for license renewal under N.28, the licensee shall, on or before the expiration date specified in the license:</u>
  - i. Terminate use of TENORM; If a licensee does not submit a complete application for license renewal pursuant to N.28, 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 N.7, to the extent practicable;
    - (3) Properly dispose of the TENORM specified in the license;
    - (4) Submit a completed Agency Form T "Certificate—Disposition of Radioactive Materials"; 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. 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 1 centimeter from surfaces in units, multiples, or subunits of sieverts or rem per hour or microroentgens per hour;
      - (b) Gamma radiation at 1 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 100 square centimeters of surface area or in disintegrations (transformations) per minute per 100 square centimeters of surface area;
- (d) Fixed radioactivity on surfaces in units, multiples, or subunits of becquerels or curies per 100 square centimeters of surface areas or in disintegrations (transformations) per minute per 100 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.
- ii. Remove TENORM contamination consistent with the requirements of N.7; If levels of residual radioactive contamination attributable to activities conducted under the license are less than those established in N.7, the licenses shall so certify. If the Agency determines that this certification and the information submitted pursuant to N.27d.i(5) is adequate and monitoring confirms the findings, then the Agency will notify the licensee, in writing, of the termination of the license.
- iii. Properly dispose of TENORM; and If residual radioactive contamination attributable to activities conducted under the license are not in conformance with criteria established in N.7:
  - The license continues in effect beyond the expiration date, if necessary, with respect to possession of residual TENORM material present as contamination until the Agency notifies the license in writing that the license is terminated. During this time the licensee is subject to the provisions of N.27e.
  - (2) In addition to the information submitted pursuant to N.27d.i(4) and N.27d.i(5), the licensee shall submit a plan for decontamination and disposal, if required, as regards residual TENORM contamination remaining at the time the license expires.
- iv. Submit a report of disposal of TENORM and radiation surveys to confirm the absence of TENORM or to establish the levels of residual TENORM contamination. The licensee shall, as appropriate:
  - (1) Report levels of radiation in units of microroentgens per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries or becquerel per milliliter in water, and picocuries or becquerels

per gram in contaminated solids such as soils or concrete; and

- (2) Specify the instruments used and certify that each instrument is properly calibrated and tested.
- v. If levels of residual activity are less than those established in N.7, the licensee shall so certify. If the Agency determines that this certification and the information submitted under N.27d.iv. is adequate and surveys confirm the findings, the Agency will notify the licensee in writing that the license is terminated.
- vi. If levels of residual TENORM—are not in conformance with criteria established in N.7, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual TENORM until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of N.27e. In addition to the information submitted under N.27d.iv., the licensee shall submit a plan, if appropriate, for decontaminating the location(s) and disposing of the residual TENORM.
- e. Each licensee who possesses residual—TENORM material underpursuant N.27d. viii, following the expiration date specified in the license, shall:
  - i. Be <u>IL</u> imited to actions involving TENORM <u>as specified in the license to those related</u> to decontamination and other activities related to preparation related to preparing the <u>locations</u> for release for unrestricted use; and
  - ii. Continue to control entry to restricted areas until the <u>locationsthey</u> are suitable for release for unrestricted use and the Agency notifies the licensee in writing that the license is terminated.

### Sec. N.28 - Renewal of Specific Licenses.

- a. Applications for renewal of specific licenses shall be filed in accordance with N.21.
- b. In any case in which a licensee, not less than [30 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, such existing license shall not expire until final action by the Agency.
- <u>Sec. N.29</u> <u>Amendment of Specific Licenses at Request of Licensee.</u> Applications for amendment of a license shall be filed in accordance with N.21 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.
- Sec. N.30 Agency Action on Applications to Renew and Amend Specific Licenses. In considering an application by a licensee to renew or amend the license, the Agency will apply the

<sup>\*/</sup> State option; appropriate time for review.

criteria set forth in N.22.

# Sec. N.31 - Modification and Revocation of Specific Licenses.

- a. 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 the [applicable Act], or by reason of rules, regulations, and orders issued by the Agency.
- b. In accordance with [cite appropriate rule], Aany license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the [applicable Act], or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Agency 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 the [applicable Act], or of the license, or of any rule, regulation, or order of the Agency.
- c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, the Agencyno license shall not be modifymodified, suspended or revoked a licenseunless, prior to the institution of proceedings (?), unless facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

# [Sec. N.32 - Agency Action to Remove an Authorized User or a Radiation Safety Officer.

- a. The Agency may act to remove authorized users or the appointed Radiation Safety Officer from a license for any one or more of the following causes:
  - Willfully evading the statute or regulations pertaining to the radiation safety program, or willfully aiding another person in evading such statute or regulations;
  - ii. Having been convicted of a felony under the laws of this State, another state, or the United States, unless the convicted individual demonstrates to the Agency that he has been sufficiently rehabilitated, by restoration of all civil rights, to warrant the public trust;
  - iii. Exhibiting significant or repeated incompetence in the handling of radioactive material, or in the performance of Radiation Safety Officer duties;
  - iv. Performing authorized user duties or Radiation Safety Officer duties in such a manner that requirements of the Agency are violated resulting in a threat to health and safety of an individual, other workers or the public; and
- b. If, based upon any of the above grounds, the Agency determines that action to remove an authorized user or the appointed Radiation Safety Officer from a radioactive material license is warranted, the Agency shall notify the individual and shall provide an opportunity for a hearing in accordance with [cite appropriate Agency rule]. An opportunity for a hearing shall

be provided before the Agency takes action to remove an authorized user or a Radiation Safety Officer from a license unless the Agency finds that an immediate removal is required to protect against immediate danger to health or safety, (cite Act that gives authority for this action), in which case the Agency shall remove the individual pending a hearing.

- c. If the Agency finds that removal of an authorized user or a Radiation Safety Officer is warranted, the usual action shall be a suspension of duties for up to one year. The term of suspension may be reduced by the [title of Agency authority who can reduce the suspension], upon the recommendation of the [title of hearing officer], if the [title of hearing officer] finds, based upon evidence presented during a hearing, that the conditions leading to the [name of the Order for Suspension] can be cured in less than on year. However, if the Agency finds that the causes are of a serious or continuous nature, such as past actions which posed an immediate threat to occupational or public health or safety or deficiencies that cannot be cured within one year, the Agency shall remove the individual from the radioactive material license.
- d. An individual who has been removed from a radioactive material license may seek reinstatement of duties by filing with the Agency a petition for reinstatement. Such petition may be filed one year or more after the beginning of the removal period. The individual shall be afforded a hearing in accordance with [cite Agency's hearing rules] and shall bear the burden of proof of establishing that the individual should be reinstated due to rehabilitation or other just cause.]
- Sec. N.33 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 Agency. If records of relevant information are maintained for other purposes, reference to these records and their locations may be used. For purposes of N.33, "reclaiming" \* shall mean returning property to a condition or state such that the property no longer presents a health or safety hazard or threat to the environment. Information the Agency considers important to reclaiming includes:
- a. 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 must include any known information on identification of involved radionuclides, quantities, forms and concentrations.
- b. 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

<sup>\*/</sup> For purposes of N.33, the term "reclaiming" includes but is not limited to 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 license).

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- drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.
- c. If required by N.50, records of this reclaiming cost estimate prepared for the amount approved by the Agency for reclaiming.

#### Reciprocity

# Sec. N.40 - Reciprocal Recognition of Specific Licenses.

- a. Subject to these regulations, any person who holds a specific license from an Agreement State or a Licensing State, and 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 this State for a period not in excess of 180 days in any calendar year 12 month period, provided that:
  - ai. A current copy of the licensing document or equivalent authorization is on file with the Agency and the authorized The licensing document does not limit the activity authorized by such document activities are not limited to specified installations or locations;
  - The out-of-state licensee notifies the Agency in writing at least [3] days by telephone, telefacsimile, telegraph, or letter prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the [3] day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. Upon receipt from the out-of-state licensee of a written request which contains a schedule of activities to be conducted within [name of the State] The Agency willmay waive the requirement for filing-additional written notifications during the remainder of the calendar year 12-month period following the receipt of the initial notification from a person engaging in activities under the general license provided in N.40a.;
  - eiii. The out-of-state licensee complies with all applicable regulations of the Agency 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 applicable regulations of the Agency;
  - div. The out-of-state licensee supplies such any other information necessary to show compliance with these regulations as the Agency may request; and
  - ev. The out-of-state licensee shall not transfer or dispose of TENORM possessed or used under the general license provided in N.40a. except by transfer to a person:

- i-(1) Specifically licensed by the Agency or by another Licensing State to receive such TENORM; or
- ii.(2) Exempt from the requirements for a license for such TENORM under N.4.
- b. The Agency 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 Agency determines that had the out-of-state licensee been licensed by [name of the State], the licensee's license would have been subject to action under N.31 or [cite State's rules for Administrative or Criminal Procedures as applicable].
- <u>Sec. N.50</u> <u>Financial Surety Arrangements.</u> Pursuant to [cite applicable State statute], each licensee or applicant for a license under N.22 shall post with the Agency financial surety, 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 the Act and these regulations. Financial surety arrangements shall:
- a. Consist of [surety bonds], [cash deposits], [certificates of deposit], [government securities], [irrevocable letters or lines of credit], [corporate guarantees], [insurance], [state funds],\*/ or any combination of these;
- b. Be in an amount sufficient to meet the applicant's or licensee's obligations under the Act and these regulations and shall be based upon Agency approved cost estimates;
- c. 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;
- d. Be continuous for the duration of the license and for a period coincident with the applicant or licensee's responsibility under the Act and these regulations;
- e. Be available in [name of State] subject to judicial process and execution in the event required for the purposes set forth; and
- f. Be established within 90 days of [the effective date of this regulation] for licenses in effect on that date.
- [Sec. N.51 Effective Date. The provisions and requirements of this Part shall take effect on [effective date of the regulations] and shall apply to all facilities or sites owned or controlled by a person on that date. [Products introduced into commerce and disposals approved prior to that date are not subject to the provisions of this Part.]\*\*/

<sup>\*/</sup> State option; may include corporate guarantees, insurance, state funds, as state deems appropriate.

<sup>\*\*/</sup> This provision may not be necessary if covered by generally applicable laws or rules of the state.

#### Part N

### APPENDIX A

# ACCEPTABLE SURFACE CONTAMINATION1 LEVELS FOR TENORM

{PRIVA TE }	AVERAGE <sup>2, 3, 6</sup>	MAXIMUM <sup>2, 4, 6</sup>	REMOVABLE <sup>2, 3, 5, 6</sup>
Alpha	5,000 dpm/100 cm <sup>2</sup>	$15,000 \text{ dpm} / 100 \text{ cm}^2$	$1,000 \text{ dpm} / 100 \text{ cm}^2$
Beta- gamma	5,000 dpm/100 cm <sup>2</sup>	15,000 dpm /100 cm <sup>2</sup>	1,000 dpm /100 cm <sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Where surface contamination by both alpha and beta-gamma emitting nuclides exists, the limits established for alpha and beta-gamma emitting nuclides should apply independently.

<sup>&</sup>lt;sup>2</sup> As used in this table, dpm (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.

<sup>&</sup>lt;sup>3</sup> Measurements of average contamination level should not be averaged over more than one square meter. For objects of less surface area, the average should be derived for each object.

<sup>&</sup>lt;sup>4</sup> The maximum contamination level applies to an area of not more than 100 cm<sup>2</sup>.

<sup>&</sup>lt;sup>5</sup> The amount of removable radioactive material per 100 cm<sup>2</sup> of surface area should 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 100 sq. cm) is determined, the entire surface should be wiped and the contamination level multiplied by 100/A to convert to a "per 100 sq cm" basis.

<sup>&</sup>lt;sup>6</sup> The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/hr (2  $\mu$ Gy/hr) at 1 cm and 1.0 mR/hr (10  $\mu$ Gy/hr) at 1 cm, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

# 2001 Rationale

# Part N Regulation and Licensing of Technically Enhanced Naturally Occurring Radioactive Material (TENORM)

The following are reasons for changes made to the April 1999 version of Part N:

Sec. N.1 – Purpose.

Changes clarify the activities for which radiation standards have been established by Part N.

Sec. N.2 – Scope.

- N.2a. The minor editorial change is for clarification that some TENORM is excluded, such as the TENORM that is exempt.
- N.2b. and N.2c. The order of these two sections was swapped. Because "beneficial attribute" and "Beneficial to the product" had the same meaning, the first term was replaced by the second in the text. The "and/or its" words were deleted from N.2b. because the item being covered is covered well in N.2c.
- N.2d. Here and elsewhere specific references to the Atomic Energy Act (AEA) definitions of source material and byproduct material were used because the NORM radionuclides for which NRC retains exclusive jurisdiction are defined by the terms used in SR-5's revised language rather than by radionuclide. Work is being done that may change the concentrations at which these materials are regulated by the NRC and Agreement States.
- N.2e. The reference to location of transportation requirements has been moved here from N.4e. because the requirements are not exemptions.

N.3 – Definitions.

The term "Beneficial attribute" has been deleted because the identically defined term "Beneficial to the product" is now used throughout to be clearer.

The term "Conditional release" has been defined because it has been use in N.7.

The term "Consumer or retail product" has been defined because it has been used in several sections including N.10, N.20, N.22. The definition is a slight modification of the definition in the Consumer Product Safety Act (15 USC Section 2052).

The terms "General environment" and "Institutional controls" are not used in the text so these terms have been deleted.

The term "Product" had a word that is not the generally accepted term of art for the affected industries so it was replaced with the generally accepted word.

The definition of "Technologically Enhanced Naturally Occurring Radioactive Material (TENORM)" has been modified to match the language used in N.2d. See the reference for N.2d. above for the reason.

## N.4 – Exemptions.

- N.4a. Minor editorial changes were made for clarification. The last sentence was moved to N8e. because it is a prohibition rather than an exemption. Disposal is not the only issue here dilution could be done to become or remain exempt. NOTE: SR-5 also introduced a section, N.9, to address the prohibition.
- N.4b. Because the reference is to TENORM distributed in accordance with N.20a. and such TENORM is only regulated by Part N, "these regulations" has been changed to "this Part" for clarity.
- N.4c. Disposal was added because it is also exempt pursuant to Part N for the listed products. Zircon, zirconia and zircon products were added to the list of exempt materials and products after evaluation of information submitted that demonstrated that the dose criteria specified in N.4e. would not be exceeded.
- N.4d. To be consistent the words have been spelled for the acronym CERCLA as was done for RCRA. The statutory references for the two federal statutes have been added as a user-friendly item for persons desiring the information.
- N.4e. The transportation provision has been moved to N.2e. because it is not an exemption. Transportation of TENORM is covered by the same regulations as all other radioactive material.

The criterion upon which exemptions from Part N are to be based has been added.

N.5 - Standards for Radiation Protection for Members of the Public.

The title has been changed for clarity because radiation protection for workers is address in N.6.

N.5a. This provision includes standards for radiation protection for TENORM that are consistent with Part D. N.5a. refers to controlling exposure to the general public from activities licensed or registered by the Agency. N.5d. pertains to standards for sites released to unrestricted use. The 100 mrem per year limit in N.5a. includes exposure from all licensed or registered sources including TENORM, whereas the 100 mrem per year limit in N.5d. addresses a specific TENORM release. The SR-5 agrees with the National Council on Radiation Protection in its assertion that exposure to more than one source at a substantial fraction of the annual limit is not likely for any particular individual. The total dose provision of N.5a. includes the contribution from sources under N.5d. States also apply the

- ALARA principle in such situations.
- N.5a. For clarity minor editorial changes were made to include words used in the referenced sections.
- N.5b. For clarity the words were changed to correspond with the title of Part D.
- N.5c. For licensed facilities that cause the release of radon from materials being processed, the dose from the released radon should be included in dose to members of the public and workers. There may be other situations were such dose should be included for licensed operations. The licensee shall be advised in writing of such requirement because past practice has been to exclude dose from radon. The radon release rate through a disposal site cover is a criteria limited by some regulations.

Section N.5b. and c. The standards for radiation protection exclude doses from indoor radon and its progeny. Radon, a radioactive gas, can accumulate to elevated levels inside buildings. Isotopes of radon are formed by the decay of radium and thorium. There are many factors such as construction methods that make it nearly impossible to accurately predict the level of radon expected from a given concentration of radium or thorium in soils or building materials. The Agency recommends that use, transfer or disposal of TENORM be done in such a manner to be consistent with EPA/HHS 1994 indoor radon guidance. This may be achieved by institutional controls or the adherence to building codes. As such, implementation of the Agency's radon program should provide adequate protection of the public from indoor radon.

- N.5d. Because of the change to N.5c., clarification regarding the exclusion of radon and its progeny has been added.
- N.5e. A limit has been added for application to results from environmental pathways dose assessments to ensure the engineering design of sites, when remediation is performed, and the assumptions used in the dose assessment modeling meet the longevity requirements of 10 CFR 20 and correspond to the requirements of the EPA for radioactivity with similar characteristics.
- N.6 Protection of Workers During Operations.

Words have been added for clarification.

N.7 – Unrestricted Use and Conditional Release.

The title has been changed to reflect changes in what is now covered by this section.

The section has been replaced with a new section that has been rephrased to state what can be done rather than what can not. The order of the subsections has been changed. A provision stating that the Agency may grant alternative levels for release of facilities or equipment upon specific application has been added. To be consistent with N.4 and for clarity "<sup>226</sup> Ra or <sup>228</sup> Ra" has been changed to "<sup>226</sup> Ra and <sup>228</sup> Ra". The screening criterion, which is a conditional release, has been

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rephrased to clearly state that such release is for metal recycle only. This eliminates the apparent contradiction with the concentration criterion. Also, SR-5 is specifically stating a 50 microroentgen per hour screening level in an effort to encourage uniformity of this level nationwide. Specification in this manner eliminates arguments regarding what the true value of background was for each measurement.

- N.8 Disposal and Transfer of Waste for Disposal.
- N.8a. Several words have been changed for purposes of clarity. In N.8a.iii. changes have been made to clarify that use of a disposal site is appropriately a function of the permitting agency for that disposal site not another Agency issuing the license to use the TENORM. This change eliminates potential conflicts with existing regulatory structure in some states. It also increases the options likely to be available to TENORM licensees.

For example; WCS (Waste Control Specialists), in Texas, does not have a license for disposal of radioactive waste or TENORM, but under the Texas regulatory structure, it has permits for disposal of NORM exempt from the Texas NORM regulations (30 pCi/g of radium). Also, there are two sites in California with permits for disposal of geothermal NORM waste. The SR-5 group does not wish the Part N rules to restrict these permitted options.

- N.8b. Because N.7 was revised, N.7b. has been revised to specify criteria in Appendix A and other criteria also used. Other editorial changes have been made for clarity.
- N.8c. A change has been made to ensure no conflict with the revised language in N.8a.iii. Minor editorial changes were made for clarity and consistency with SSRCR use of the changed words.
- N.8e. This provision has been moved here from N.4a.
- N.8f. This provision has been added because it is an available option in many states that should be specifically identified.
- N.9 Prohibition.

This section has been added to clarify that dilution is not allowed to be used to avoid regulation by an Agency. This section applies to materials that are not waste, because waste is covered by a similar provision in N.8e.

- N.10 General License.
- N.10b. The words "consumer or retail" have been added to clarify that a specific license is required to manufacture such products.
- N.10c. Minor editing has been done for clarification.

- N.10d. Minor editing has been done for clarification. A time limit for the notification has been added.
- N.10e. The title was revised for clarity to include the item covered by the provisions that was not previously indicated in the title.
- N.10e.ii. This provision has been rewritten to clarify that the prior approval must be in writing to transfer property and equipment in a manner other than the same person for the same purpose or there is a ownership/possession of property change. The criteria used to grant approval has been added. A record keeping provision has been added that conforms to decommissioning record keeping requirements.
- N.10e.iii Minor editing has been to change to a clear positive requirement rather than a negative statement.
- N.10g. A phrase has been added to clarify that radiation exposure concerns are the basis for an Agency to require a general licensee to apply for a license and become a specific licensee. This should be a rare event. An example of such would be some Florida facilities that have already been specifically licensed because of concerns for personnel exposures.
- N.20 Specific Licenses.
- N.20 Editorial rephrasing has been done for clarity. We tried to eliminate some of the confusion caused by use of "unless", "except" and "not."
- N.20a. The words "consumer or retail" have been added to clarify the type of manufacturing and distribution operations that require a specific license rather than a general license.
- N.21 Filing Application for Specific License.
- N.21a. Words were added to require an application for a license to be in English.
  - N.21b. The word "expiration" was changed to "termination" to conform to regulatory practice. This change also has been made in other appropriate sections of the rule.
- N.22 Requirements for the Issuance of Specific Licenses.
- N.22a.v. The legally correct term has been used by changing "surety" to "assurance".
  - N.22a.vii. Because the land owner is or can be ultimately held liable for contamination existing on the property, this provision has been added. It may reduce potential liability for the licensing Agency.
- N.22c. The words "consumer or retail" have been added to clarify the type of manufacturing and distribution operations that require a specific license rather than a general license. Defining "consumer or retail product" also indicated the need to delete "material or" where it was used with "product" for clarity.

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N.22c.iii.(4) The word "radionuclides" replaced "TENORM" to clarify that solubility analysis will be for each form of each element.

N.22c.iii.(6) The word "material" has been replaced with "TENORM", because that is the material we are concerned with and want to keep isolated.

N.22c.iii.(12) The dose terminology was changed to match the current Part D terminology.

N.22c.iii.(14) The term "processing" seemed clearer than "production" before "production lots".

N.23 – Safety Criteria for Products.

N.23b. The dose terminology was changed to match the current Part D terminology.

### N.25 through N.40

These generic sections of licensing are found in Part C and basically applied to all kinds of licensees. An Agency may choose to reference appropriate section of Part C rather than repeat them. The Agency should carefully review the recommended changes included in Part N before deciding to reference Part C provisions. The sections have been placed in Part N so that Part N can stand alone for most of the affected licensees.

N.26a.i., ii., iii. and iv. The word "specific" or "specifically" has been added for clarity to avoid misunderstanding.

N.26a.iv. N.5 has been added to the referenced sections to provide a comprehensive list of applicable sections.

N.26a.v. Editorial changes have been made for clarification and accuracy in reference to the definition of "entity".

N.26a.vi. and vii. These are updated requirements from the License Termination Rulemaking.

N.26a.viii. The temporary jobsite provision from Part C has been modified to cover the lack of jurisdiction under the Atomic Energy Act of 1954, as amended.

# N.27 – Expiration and Termination of Specific Licenses.

This section has been rewritten to more clearly indicate the distinction between expiration and termination of a license. It also more clearly indicates the licensees continuing responsibility for licensed material when a license has expired but has not been terminated by the Agency. Radiation monitoring reporting requirements are more clearly specified. Procedural requirements are more detailed for clarity.

N.28 - N.30 No changes have been made.

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N.31 - Modification and Revocation of Specific Licenses

Minor editorial changes have been made for clarity.

N.32 - Agency Action to Remove an Authorized User or a Radiation Safety Officer.

This optional section was developed in response to problems in some states and is provided form those Agencies who think it beneficial.

N.33 - Record Keeping Requirements for Site Reclamation.

These are updated requirements from the License Termination Rulemaking.

N.40 – Reciprocal Recognition of Specific Licenses.

The section has been revised to make it more user friendly and for clarity.

N.40b. This provision has been added to advise licensees who have been licensed under a less restrictive set of conditions that conditions or limitations can be imposed by the Agency with authority to grant the reciprocal recognition.

N.50 – Financial Surety Arrangements.

No changes have been made.