2024

RATIONALE FOR REVISIONS

Part N

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

Executive Summary

The revised SSR-N is a departure from the traditional SSR format in order to overcome identified barriers to adoption and to accommodate the various regulatory approaches many states have already taken. In short, SSR-N establishes the methodology to consistently evaluate TENORM residues or associated industrial processes and determine the appropriate level of regulatory oversight. In partnership with domestic and international regulatory bodies, the aim is to supplement SSR-N with additional technical guidance documents which provide the industry and residue-specific considerations that must be evaluated to model environmental impact, evaluate the appropriateness of any authorized exemptions or exceptions, and assess the effectiveness of engineered or institutional controls.

The revised SSR-N provides screening criteria, above which a state would annually assess industries in possession of TENORM residues, and if necessary, require an environmental monitoring plan and worker awareness-level training program. Due to the various jurisdictional authorities TENORM may fall under in the states (environmental, public health, radiation safety, natural resources, etc.); this level of regulatory oversight may need to be incorporated into an existing environmental monitoring program, conducted under a permit or a general license. Notably, SSR-N does not identify any exempted industries, exempted residue management practices or specify concentration limits on disposal. Rather, SSR-N provides the process through which a state may issue a general exemption to an entire industry or practice (like land application or landfilling wastes) – or a specific exemption to a single entity (i.e., an industrial decommissioning company) based on a consistent dose. Largely at the request of stakeholders, numerical 'screening' values are still provided to demarcate the levels of regulatory oversight.

Should industry wish not to use screening values to determine the amount of regulatory oversight necessary (which would not account for any engineered or administrative controls), a dose assessment must be performed. Stakeholders, then, must have detailed knowledge of the specific industry processes, waste forms, methods of disposition and volumes. While the supplemental guidance documents will detail the specific factors requiring consideration, the model inputs will vary by state and may not always result in the same concentration limits or permissible means of handling residuals. Attempting to capture these variations, along with permissible concentrations or waste handling practices led to some of the largest barriers in SSR-N adoption. Therefore, rather than setting prescriptive limits; SSR-N aims to prescribe the methodology and consistent dose criteria by which a state may elect to determine the necessary amount of regulatory oversight.

Finally, at a higher threshold, SSR-N then specifies the criteria at which an industry should be evaluated for the need for a specific license. A specific license should also be evaluated if the environmental monitoring program discussed above is absent, ineffective, or the entity is unable to meet public dose constraints. If warranted, the specific license is issued under SSR Part C.

Technical Basis for SSR-N Revisions

Identifying barriers and technical areas needing address

The SSR-N working group was reconvened in 2012 to review and identify needed revisions to the regulations for the licensing of technologically enhanced naturally occurring radioactive material (TENORM). The initial focus was on identifying barriers to state adoption, review existing exemption levels for radium-226, establish appropriate exemption levels for other naturally occurring radionuclides and evaluate the potential for TENORM exposures from emerging industries. The committee identified at least (38) policy and technical issues for address as well as (53) relevant publications on TENORM from consensus standard bodies requiring review. These include the American National Standard (ANSI/HPS) N13.53-2009, International Commission on Radiological Protection (ICRP) and International Atomic Energy Agency (IAEA) publications, National Counsel on Radiation Protection and Measurement (NCRP) commentaries and reports, as well as numerous studies on TENORM disposal and residue (waste or commodity) management. Among the more formidable hurdles, was identifying how to harmonize TENORM regulations among states that ranged from the absence of TENORM regulations, to those regulating only portions such as waste management, to those requiring radioactive materials licenses. Even the definition and the resulting scope varied from state to state (i.e., NORM vs. TENORM).

A contributing factor to this inconsistent regulatory approach lies in the fact the authority to regulate TENORM (in part or in whole), if undertaken by a state, often lies within an environmental, public health, waste management, or other agency that may lack radioactive material licensing authority. Thus, only portions of the TENORM lifecycle may be regulated, and that oversight may not necessarily occur under a radioactive materials license. Moreover, stakeholders expressed concern that TENORM regulation was often residue-specific, industry-specific or radionuclide-specific. As a result, a consistent and comprehensive regulatory framework was lacking to address all segments of existing and emerging TENORM industry. Initial efforts to expand exemptions and encompass other industries proved untenable and likely to result in a revised rule that would not keep pace with technology.

Further complicating this approach, several states advised a prescriptive rule that would address specific industries or practices may further prevent adoption. Not all states can or want to regulate all the various TENORM industries – either due to jurisdictional boundaries, political or socioeconomic factors – or simply the dose consequence to the public doesn't warrant a regulatory presence.

Stakeholder input and common ground

However, two foundations of the national materials program found consensus among stakeholders when applied to the regulation of TENORM. First, the radiation exposures to individual members of the public from TENORM operations should be no higher than those from licensed operations (1 mSv per year, 10 CFR 20.1301(a)(1)). Second, residual radioactivity in the environment resulting from TENORM operations should not be permitted to exceed the maximum radiological criteria for unrestricted use from licensed operations (0.25 mSv TEDE per year above background, 10 CFR 20.1402). Consensus aside, determining compliance on the basis of dose creates a modeling mandate that many stakeholders (regulators and industry alike) could not accommodate.

Ultimately, consensus was elusive on use of the term "NORM" or "TENORM". While the international community utilizes the term "NORM", "TENORM" was crafted domestically to demarcate regulated residues and industries from those consistent with natural background. The definition of "TENORM" is utilized by the U.S. EPA, while many states have already promulgated regulations for "NORM". Still others are prohibited by their enabling statutes from regulating "NORM" and opt for the term "TENORM". SSR-N attempts to address this issue by making the definition of "TENORM" less relevant to the scope of the rule (i.e., identifying regulated industries and residues). As discussed in the next section, the scope is instead set by a consistent dose constraint. Therefore, SSR-N uses brackets around the term "NORM/TENORM" – allowing states to select the necessary term.

<u>Exemption, Clearance or Screening Criteria?</u>

The use of concentration-based exemption criteria (e.g., 5 pCi/g of Ra-226) serves many purposes. First, notwithstanding any exemption, they effectively establish the scope of SSR-N. They also navigate around a dose modeling mandate by providing a field-measurable value around which industry can fashion a sampling and compliance program. That said, the 5 pCi/g radium-226 exemption limit was targeted for review as it was a forty-six year old performance-based limit adapted from the Uranium Mill Tailings Radiation Control Act. Over the years, it was also utilized as waste acceptance criteria, at times diverting low-concentration TENORM residues into low-level radioactive waste storage facilities. Recent U.S. Department of Energy and State modeling assessments had demonstrated TENORM-contaminated wastes could safely be deposited in RCRA landfills without adverse dose consequence to the public. Conversely, consensus standard documents such as ANSI/HPS N13.53-2009 recommended administrative release levels be lowered to 3 pCi/g for radium and thorium decay chains, with higher limits for uranium and potassium. Notably, ANSI recommended a corresponding volumetric limit of a "few metric tons". From a practical standpoint, in addition to the concentration, an assessment of the TENORM residue *volume* is essential to determining dose consequence. A few gallons of 30 pCi/g radium-226 tank sediment may not present significant radiation exposure concerns. Tens of metric tons of bulk water treatment sludge at 3 pCi/g over background can increase natural background, potentially impact groundwater, or contribute to increases in indoor radon. Building upon the efforts in ANSI/HPS N13.53-2009 and borrowing from 49 CFR 173.436; the concept of using both concentration and quantity to evaluate the appropriateness of regulatory oversight was pursued.

Regulators and industry concurred that a regulatory framework that is implementable must contain *"a number"* that is readily interpretable in the field and does not require complex modeling efforts to determine compliance with state regulations. Historically, this number has been in the form of an activity concentration, beneath which the bulk residue is largely 'exempt'. For reasons developed later in this rationale, SSR-N deviated from this approach and has now developed the radionuclide-specific numbers in Table 1 and 2 as "*screening levels*". In their development, multiple domestic and international values were evaluated, with the bounding values being from ANSI N13.53-2009 (0.111 Bq/g for radium/thorium) and 1 Bq/g (10 Bq/g for K-40) from the IAEA's General Safety Requirements Part 3. The lower value having been developed in recognition of dose impacts from environmental deposition of large volume, low-activity TENORM residues and the upper value being pragmatically derived as the upper bound of worldwide distribution of naturally occurring radionuclides. Both values were assessed against the underlying premise of SSR-N's regulatory framework: that sites utilized for the disposal or beneficial reuse of TENORM residues should not contribute more than 0.25 mSv of annual TEDE dose above background to the maximally exposed member of the public. (Additionally, as mentioned above, workers engaged in TENORM activities should not be exposed to more than 1 mSv annually.)

Therefore, SSR-N modeled the unrestricted deposition of TENORM into the environment, absent any controls on exposures pathways, to calculate the maximum permissible concentration and quantity for each radionuclide. Dose assessments were run for all common NORM nuclides with progeny in equilibrium. The resulting model outputs were plotted as a function of area covered by the source term where the 'y' axis value represents the maximum projected TEDE dose. Goal-seeking variations of the individual concentrations and quantities were performed to maximize the source term while staying beneath 0.25 mSv per year TEDE. The resulting data and additional discussion on the derivation of these 'screening values' is available in Appendix A. Generally speaking, when the upper bound of the maximum permissible concentration limits (1 Bq/g) were used, the volume (more specifically, the total activity) required to stay within a 0.25 mSv/year dose constraint became restrictively small (kilogram quantities). Additionally, the maximum permissible concentration limits for some radionuclides were reduced to limit committed dose from inhalation and ingestion, and to remain beneath 0.05% by weight for uranium. Dose assessments indicate the IAEA's 1 Bq/g exemption criteria works well with a 1 mSv/year dose constraint. However, the 0.25 mSv/year dose constraint warrants assessment of residues at much lower activity concentrations – consistent with those identified in ANSI. That said, the lower range of these concentrations are difficult to distinguish (if not consistent) with domestic background and may not be identifiable with field instrumentation. Recognizing it wouldn't be necessary to assess very small volumes of bulk residues at the low concentrations, Table 1 initially listed a cumulative activity limit as well. Bulk residues beneath both the activity concentration and cumulative activity could be administratively released. However, implementation of this approach became cumbersome. It also failed to address the environmental accumulation of multiple "administratively-released or exempted" volumes – either from multiple disposals or multiple generators. Thus, cumulative activities were removed from Table 1 and Table 2, and an annual assessment of generated residues was incorporated. The

source term concept was retained in Table 3, identifying the amount of TENORM residues an entity could conceivably use/possess on site without the need for a residue management program.

Screening levels were also needed for liquid TENORM residues. The US EPA 'Radionuclides Notice of Data Availability Technical Support Document, March 2000', allows the derivation of nuclide-specific liquid values, corresponding to 4 millirem per year. Utilizing these values as the lower bound for screening appeared appropriate, an approach which is echoed in ANSI N13.53-2009. While the US EPA's technical support document cites higher maximum contaminant limit values for alpha-emitters, it ultimately settled on a cumulative 15 pCi/L screening level for alphas. After consideration of developing separate dose-based values, screening values for liquid effluents were adopted from other applicable federal regulations (USEPA drinking water and water quality standards) so as not to create conflicting standards.

In addition to establishing 'screening levels' to determine when some degree of regulatory assessment is appropriate; SSR-N Table 4 establishes the upper bound of TENORM activity limits which if present should be assessed for the need for a radioactive materials license. These correspond to activity concentrations which, absent any other engineered or institutional controls, present the potential for workers to receive a committed dose in excess of 1 mSv per year,. (NOTE: Since reference man intake is limiting, volumes are less relevant in this table).

Several consensus standard bodies have completed or are in the process of providing guidance on the conduct of TENORM dose assessments. Developments in this area are anticipated to lead to petitions to deviate from the assumptions made in Attachment A and the resulting screening levels. SSR-N continues to allow for industry (and regulators) to use site-specific or other empirical data to deviate from the table data. Indeed, the screening levels are only provided to initiate notification between industry and regulators and prompt an evaluation of how residues and potential exposures are managed. It is important to note that these screening levels are not waste acceptance criteria. As described in the next section, the screening values provide a consistent dose-based criteria which may be used in the support of regulatory decision making – in the absence of more refined dose assessments.

<u>CRCPD and IAEA Collaborative Agreement</u>

Beginning in 2016, the CRCPD established a practical arrangement with the IAEA which included a focus on the control of worker and public radiation exposures from NORM (TENORM). Several SSR-N committee members and contributors were able to benefit from this collaboration and bring the shared insights into SSR-N revisions. Additionally, SSR-N members participated in regional meetings, technical consultancies, working groups for SR-34, "*Radiation Protection and the Waste Management of Radioactive Waste in the Oil and Gas Industry*", SSG-60, "*Management of Residues Containing Naturally Occurring Radioactive Material from Uranium Production and Other Activities*" and others which further harmonized the regulatory approaches developed abroad with those under development within the CRCPD. Interestingly, many of the technical and policy hurdles faced domestically were actively being worked upon by other member states. It's worth noting IAEA TECDOC Report number 2071, "*Holistic*

Approach to Management of Naturally Occurring Radioactive Material (NORM)", which eloquently summarized the issue at hand,

> *"It is also to be [recognized] that the Radiation Protection framework was originally developed to activities (energy generation and research), medical exposures and practices involving sealed sources. Applying this framework to situations involving exposure to natural sources has proven to be quite challenging."*

While publications and input from the international community continued to shape and provide insight on SSR-N until the final drafts; not all provisions could be readily incorporated. As previously mentioned, the 1 Bq/g exemption levels utilized by the IAEA simply fail to meet domestic site release criteria when bulk TENORM residues are involved. SSR-N concurred that protection of the public from indoor radon should be addressed outside of SSR-N; but fell short of adopting the use of IAEA's reference bands and resulting permissible exposures. SSR-N does attempt to harmonize with the international community by adopting the concepts of planned, existing and emergency scenarios. Emergency scenarios are largely dismissed as being relevant to TENORM exposures and SSR-N's scope was narrowed to 'planned' scenarios. Sites that were previously remediated under an older standard (5 pCi/g of radium) or NORM found to exceed the exemption values would not be subject to SSR-N unless public exposure exceeded 1 mSv per year. This essentially 'grandfathers' legacy sites and avoids regulation of NORM anomalies unless the public exposure warrants intervention.

<u>Regulatory Framework</u>

In order to facilitate adoption and promote consistency, SSR-N was revised to be less prescriptive in terms of the concentrations and practices afforded – and more focused on allowing regulators to assess the impacts of such activities. SSR-N does not attempt to name every industry, waste form or practice. To the contrary, mention of any industry or practice (e.g., landfilling, land application, deep well injection, long term storage, etc.) was removed. Instead, SSR-N seeks to establish a single, consistent dose-based methodology for states to review these industries and practices and determine the appropriate amount of regulatory oversight.

If the generation and management of TENORM residues will result in doses to the public in excess of 0.25 mSv/year [25 mrem/year] TEDE, an environmental management program may be required (referred to herein as a residue management plan). Table 1 and 2 provide screening levels to assist regulators and industry identify TENORM residues that may give rise to such exposures. *Note that very large quantities of low-activity bulk TENORM may also require assessment based on the exposure scenarios present.* Since the regulatory authority for residue management may not necessarily reside with the radiation protection authority in all states; this need not take the form of a specific or general license. In fact, effective environmental monitoring and controls that would mitigate the potential for exposure may already be in place under other regulatory programs (NPDES, NESHAPS, deep well injection or landfill permits, etc.) Therefore, the notification and registration requirement may be met under other, existing environmental management programs. If a review of the residues generated or the management practices utilized indicates public exposures above 0.25 mSv/year are unlikely; regulatory

oversight is limited to notification and registration. In order to capture changes in TENORM residues, industrial processes or management practices; the data provided to the regulator is updated annually. Regulators should annually assess any aggregate environmental accumulation TENORM residues, as well as any contribution from other TENORM registrants. Note that the 0.25 mSv/year TEDE dose constraint, as well as the values in Table 1 and 2, are above background.

If the projected dose to a worker could exceed 1 mSv/year [100 mrem/year] TEDE or average workplace exposures to radon exceed 30 pCi/L, then occupational controls are required under Section N.7. Table 4 provides screening levels to assist regulators and industry identify TENORM residues that may give rise to such exposures. It is possible that TENORM workplace exposures can be mitigated through the use of administrative or engineered controls. These may already be in effect as a result of other regulatory programs. The registrant may elect to detail these protective measures as described in Section N.7.c or submit a dose assessment to validate worker exposures are beneath 1 mSv/year. If the dose constraint cannot be met, the operation should transition to a specific license under Part C. At all levels of regulatory oversight aside from simply notification/registration, a worker training program is required to inform workers of the hazards present in the workplace and the purpose behind any occupational and engineered controls. A template training program is provided in Appendix B of SSR-N.

Exemptions

Section N.8 details the method regulators may elect to use should they seek to categorically exclude certain TENORM industries or TENORM residue practices from the need for a residue management plan or worker protection plan. Relevant dose assessment criteria and sample data required for the assessment are listed. Exemptions are subject to public comment, the public dose constraints in Section N.4, and re-evaluation every five years.

Topics for Consideration in Future Revisions

A goal of the SSR-N committee was to review available literature and update the surface contamination limits for unrestricted release of TENORM-contaminated equipment. As discussed in Appendix A of SSR-N, the values published in ANSI N13.53-2009 remain protective and applicable. However, stakeholders expressed concern in meeting these detection limits with commonly deployed field instrumentation. An analysis of the contamination values in Reg Guide 1.86 (now superseded by Reg Guides 8.21 and 8.30), indicates they are unlikely to result in exposures to the public in excess of 0.25 mSv/ year. As technology and field detection capabilities improve, the surface contamination criteria listed in ANSI N13.53-2009 Table 2.1 should be revisited for use in future revisions. A further consideration should be the detection of alpha and beta emitters on inaccessible surfaces.

Future SSR-N revisions should also evaluate Section N.13. Stakeholders expressed concern that application of financial assurance requirements and decommissioning cost estimates to all TENORM registrants would have widespread cost implications for industry and regulators alike. SSR-N is currently structured so that TENORM industries unable to meet the 0.25 mSv per year site release criteria or the 1.0 mSv workplace exposure limits would operate under a specific

license (presumably subject to a state's existing financial assurance requirements). TENORM industries beneath this threshold have presumably demonstrated residues and workplace exposures can be managed through readily available disposal practices and administrative controls. Where disposal as low-level radioactive waste is required, Section N.13 requires a decommissioning cost estimate and referral to the State's financial assurance regulations. The presence of industries generating very large quantities of bulk TENORM residues or a high concentration of TENORM industries may result in liabilities that are not adequately covered by Section N.13 or readily recoverable under a state's enforcement process.