DEVELOPING CLEANUP CRITERIA TO ADDRESS MULTI-AGENCY REQUIREMENTS

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ABSTRACT

This paper addresses some of the similarities and differences between radiation dose assessment and chemical risk assessment and identifies methodologies for meeting multiple regulatory frameworks relative to risk and dose assessment. The paper also presents strategies that may be used to ensure that NRC, USEPA, and other applicable state cleanup requirements are addressed in a single, cost-effective process. These strategies include integration of NRC dose-based frameworks and USEPA risk-based frameworks into development of common data quality objectives and development of cleanup goals.

INTRODUCTION

Increasingly, the United States Environmental Protection Agency (EPA) and state's environmental regulatory agencies are holding a stake in facility decommissioning and cleanup requirements at sites seeking to close or terminate their NRC license. For example, in October 2002 the Nuclear Regulatory Commission (NRC) and USEPA entered into a Memorandum of Understanding (MOU) regarding conditions under which USEPA can act under its Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) authority at NRC-licensed sites that are in the process of, or have completed, decommissioning in support of license termination. The MOU identifies specific conditions under which USEPA can require additional evaluation and potential clean-up of radioactive residues that would otherwise be satisfactorily addressed under NRC regulation and authority. In addition, USEPA or state environmental agencies often require that a facility demonstrate that post-decommissioning conditions associated with chemicals regulated under federal or state agencies, and radionuclides regulated under the NRC, do not pose unacceptable risks to public health.

The benchmark that is used by EPA and most state environmental agencies for establishing acceptable exposure levels and developing cleanup goals is through assessment of cancer risk rather than radiation dose. The method and timing of the application of risk-based assessments within the regulatory frameworks used by EPA and most state environmental agencies also differs. In order to complete site characterization and remediation for facilities that are required to comply with both NRC decommissioning regulations and state or federal environmental regulations, an understanding of the similarities and differences of the NRC and EPA regulatory frameworks is essential to designing a timely and cost-effective closure plan that addresses the requirements of all regulatory entities.

COMPARISON OF NRC AND EPA SITE RELEASE PROCESSES

Regulatory Framework

There are fundamental differences between the processes used by NRC and EPA to evaluate, remediate, and remove a site from regulatory oversight. The conceptual processes for site release under NRC, EPA and typical state's regulatory frameworks are shown in Figure 1.

The process used by the NRC involves first establishing a concentration-based cleanup criterion (derived concentration guideline level [DCGL]) considering the available historical information concerning radionuclide uses and releases at the Site, currently available characterization data, and informed consideration of the potential future site uses. Additional site characterization data may then be collected

(as necessary to make remedial action decisions) and compared to the cleanup criterion. Remedial decisions are subsequently made based upon the comparison of site characterization data to the cleanup criterion. When the responsible party (licensee) concludes that the residual concentration remaining is below the established cleanup criterion, a final status survey is performed and submitted to the NRC to demonstrate compliance. The NRC framework is sometimes referred to as "top down" because it is initiated with identification of a cleanup goal and is completed with site characterization and remediation.

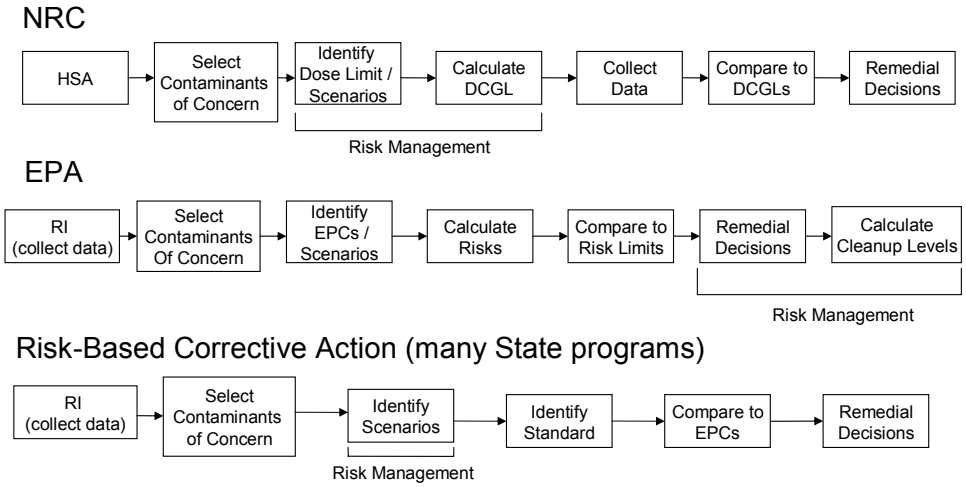

Fig. 1. Comparison of NRC and EPA Regulatory Processes for Site Evaluation and Remediation

In contrast, the process used by the EPA involves first collecting site characterization data based on a prescribed list of regulated substances. The characterization data are then used with information concerning the future site uses to calculate pre-remedial health risks. Remedial decisions are subsequently made based upon a comparison of pre-remedial health risks to regulatory health risk limits. Finally, cleanup goals are established for contaminants and areas of the site that require remedial action. The EPA framework is sometimes referred to as "bottom up" because it is initiated with site characterization and is completed with identification of cleanup goals and remediation.

A number of states' environmental cleanup programs have developed a hybrid methodology that combines the "bottom up" and "top down" approaches into a single framework. This approach, called "risk-based corrective action (RBCA)" involves first collecting site characterization data and then comparing the site characterization data to a published (default) or derived (site-specific) cleanup value. Site characterization data may be collected based on historical site information or a prescribed list of regulated substances, depending on specific state regulations. Remedial decisions are subsequently made based upon the comparison of site characterization data to the cleanup criterion.

Measure of Health Detriment and Basis for Regulatory Action

A fundamental similarity between the NRC and EPA site release processes is that both regulatory frameworks use a measure of detriment to public health to determine whether remediation of a site is required. The methodology for evaluating the potential health detriment posed by exposure to contaminant residues present at a site is through prospective exposure modeling. Prospective exposure modeling places a quantitative value on human exposures to contaminants using information concerning the human behavioral patterns that are associated with specific land uses, natural environmental processes, and contaminant fate-and-transport. The quantitative exposure estimates are then combined with parameters that describe the dose-response relationship of a substance, to derive a quantitative

estimate of health detriment. As described below, the measure of health detriment used by the NRC is annual radiation dose (total effective dose equivalent [TEDE]), and the measure of health detriment used by the USEPA is cumulative excess lifetime cancer risk (ELCR) plus total non-cancer risk. Differences between the NRC and EPA methodologies that are used to evaluate detriment to public health and to establish a basis for remediation are summarized in Table I and are discussed below.

Table I Substantial differences between EPA risk-based framework and NRC dose-based framework

EPA Risk-Based Framework	NRC Dose-Based Framework
Radionuclides and chemicals (cumulative risk) - Site characterization prior to risk assessment/cleanup goal derivation - Contaminants based on prescribed list of regulated substances - Often includes substances that are present solely due to naturally-occurring background conditions	Radionuclides only - Site characterization after dose assessment/cleanup goal derivation - Contaminants based on historical uses and releases - Normally excludes substances that are present solely due to naturally-occurring background conditions
Human and ecological receptors	Human receptors only
Future land use: - 30 years - Normally use realistic future use scenario (seldom consider food-chain exposures)	Future land use: - 1,000 years - Often use subsistence farming scenario (often consider food-chain exposures)
Measure of health detriment: - Excess lifetime cancer risk, cumulative over number of years exposed at site - Non-cancer risk (chemical toxicity)	Measure of health detriment: - Radiation dose, highest dose in single year of exposure (i.e., peak annual dose)
Risk management criteria: - Excess lifetime cancer risk range (10^{-6} – 10^{-4}) - Non-cancer threshold (hazard index of unity) - Risks attributable to background conditions often included in total risk estimates, then separated from site risks as part of risk management process - Decisions typically made using deterministic assessment	Risk management criteria: - Finite dose limit (e.g., 25 mrem/year) - No evaluation of chemical toxicity - Dose associated with background conditions excluded from derivation of cleanup value - Decisions often consider probabilistic assessment

NRC Dose Assessment Methodology

The regulatory criteria for license termination and release of real property with residual radioactive material under NRC jurisdiction are contained in the U.S. Code of Federal Regulations (CFR), Title 10, "Energy," Parts 20, 30, 40, 50, 51, 70, and 72, *Radiological Criteria for License Termination*. The applicable NRC regulation is a performance-based standard that requires demonstration that a member of the public potentially exposed to residual radioactivity at the site is not likely to receive an annual TEDE in excess of 25 millirem (mrem) in any one year, having considered all credible sources and pathways for exposure.

The measure of health detriment used by the NRC is, therefore, an annualized radiation dose. Radiation dose is a function of annual radionuclide intake (picocuries [pCi]/year) and the dose conversion factor (DCF; mrem/pCi) (Eq. 1). Intake is a quantification of exposure that results from defined human receptor exposure patterns. Intake is typically quantified as a media exposure concentration (e.g., pCi radionuclide per gram soil), and receptor exposure rate to the medium. Exposure rate (e.g., grams soil ingested per year) is a function of receptor exposure frequency and time (e.g., number of days per year and time per

day that a receptor is exposed to radionuclides in each medium), and exposure rate for each route of exposure (e.g., amount of soil or water that is ingested each day exposed). A dose conversion factor relates an intake to a radiation dose. Dose conversion factors are taken from the published recommendations of the ICRP (a recognized international scientific body) and are derived from bio-kinetic models describing the behavior of radionuclides in the human body. Dose is calculated separately for each pathway that a receptor may be exposed (e.g., ingestion of soil, ingestion of water, inhalation of dust, indirect exposure to ionizing radiation). For comparison to a regulatory compliance limit, the dose associated with each route of exposure is added together to obtain a total annual dose estimate.

Dose (mrem/yr) = Media Exposure Concentration (pCi/g) X Exposure Rate (g/yr) X DCF (mrem/pCi) (Eq. 1)

When used in the "top down" approach, a media-specific concentration that is protective of the 25 mrem/year decommissioning dose limit for an established set of exposure conditions is derived by rearranging Equation 1 (Eq. 2) This concentration is termed the DCGL. Cleanup decisions are made based on comparison of the DCGL to media concentrations derived from site characterization and remedial control survey data. Achievement of the approved cleanup criteria is certified by the NRC based upon a documented final status radiological survey performed by the licensee.

DCGL (pCi/g) = Dose Limit (mrem/yr) / Exposure Rate (g/yr) X DCF (mrem/pCi) (Eq. 2)

USEPA Risk Assessment Methodology

The regulatory criteria for establishing acceptable exposure levels to contaminants at hazardous waste sites under EPA jurisdiction are contained in CFR Title 40, Part 300. The regulation states that acceptable exposure levels for known or suspected carcinogens are concentration levels that represent an ELCR to an individual of between 10^{-4} and 10^{-6}. The regulation further states that the 10^{-6} level represents the point of departure for determining if remediation may be required. Levels associated with risks below 10^{-6} do not require remedial action, levels associated with risks between 10^{-6} and 10^{-4} may require remedial action based on site-specific circumstances, and levels associated with risks greater than 10^{-4} typically require remedial action. The regulation also states that acceptable exposure levels for chemicals that produce health effects other than cancer, termed non-cancer risks (or "chemical toxicity"), are concentration levels that people (including sensitive individuals such as children) can be exposed to without adverse effects occurring.

The measure of health detriment used by EPA is, therefore, excess lifetime cancer risk (ELCR) and non-cancer risk (which is expressed as a hazard index). Most state hazardous waste site programs also use ELCR and non-cancer risk as measures of health detriment. Risk is a function of total intake (e.g., pCi) and a cancer slope factor (CSF; e.g., risk/pCi) (Eq. 3). As with radiation dose estimates, the radionuclide intake used to estimate risks is a quantification of exposure that results from defined human receptor exposure patterns. Intake is typically quantified as a media exposure concentration (e.g., pCi radionuclide per gram soil), and receptor exposure to the medium. Exposure (e.g., grams soil ingested) is a function of receptor exposure frequency and time (e.g., number of days per year and time per day that a receptor is exposed to radionuclides in each medium), and exposure rate for each route of exposure (e.g., amount of soil or water that is ingested each day exposed). However, because the measure of determinant is based on a "lifetime" exposure as opposed to an annualized exposure, the intake estimate used in health risk calculations is a total cumulative intake over the number of years that the receptor is exposed and, therefore, also includes an exposure duration term (e.g., number of years of exposure at the site). A cancer slope factor relates the cummulative intake over the period of interest corresponding to the exposure scenario to an ELCR. Risk is calculated separately for each pathway that a receptor may be exposed (e.g., ingestion of soil, ingestion of water, inhalation of dust, indirect exposure to ionizing

radiation). For comparison to a regulatory compliance limit, the risk associated with each route of exposure is added together to obtain a total risk estimate.

Risk = Media Exposure Concentration (pCi/g) X Exposure (g) X CSF (risk per pCi) (Eq. 3)

When used in the "bottom up" approach, cancer and non-cancer risks are calculated using site characterization data and an established set of exposure conditions to derive cancer and non-cancer risks. The risks are then compared to the risk limits (10^{-4} to 10^{-6} for carcinogens and suspected carcinogens, and a hazard index of unity for chemical toxicants) to make cleanup decisions. For media with risks above the EPA risk limits, risk-based cleanup levels, termed preliminary remediation goals (PRGs), are calculated by deriving a media concentration that is associated with a specified risk level (Eq. 4). EPA guidance states that PRGs should be initially established at concentrations that correspond to a 10^{-6} cancer risk level.

PRG (pCi/g) = Risk Limit / Exposure (g) X CSF (risk per pCi) (Eq. 4)

There are three additional significant differentiators between the EPA and NRC frameworks that are used as the basis of remedial decisions.

1) EPA requires evaluation of radionuclides and chemicals (i.e., non-radioactive substances such as metals and chlorinated solvents). Remedial decisions under EPA regulations are based on the cumulative risk for potential exposures to both chemicals and radionuclides (i.e., risks for chemicals added to risks for radionuclides). In addition, substances that are ubiquitously-occurring and non-site related (whether natural or anthropogenic in origin) are often included in the site characterization and carried through the risk assessment under EPA's risk-based framework. Total site risks are characterized as the sum of risks associated with site-related and non-site related substances. The risks associated with site-related contaminants are then segregated and evaluated separately during the risk management decision-making process. In contrast, radionuclides that are ubiquitously-occurring and non-site related (whether natural or anthropogenic in origin) are considered to be components of background and are explicitly excluded under the NRC framework.

2) EPA requires evaluation of risks to the environment (i.e., ecological risk assessment) as well as risks to public health. Risks to the environment can drive remedial actions at EPA-regulated sites even if public health risks are acceptable. However, risks to the environment due to radiogenic effects are generally recognized to be insignificant relative to human health risks. Therefore, ecological risks are seldom a remedial action driver for radionuclides.

3) EPA considers a more simplistic exposure assessment that views a substantially shorter foreseeable time period of 30 years, versus the 1,000-year time period and complex exposure assessment used under the NRC regulations. As shown in Figure 2, under NRC's regulatory framework, a DCGL for soil would typically include an assessment of direct contact exposures (incidental soil ingestion, dust inhalation, indirect exposure to ground radiation), as well as a comprehensive assessment of food chain exposures associated with biotransfer of radionuclides in agricultural crops and livestock. In addition leaching of radionuclides from soil and protection of the underlying aquifer for its anticipated uses are also typically included in the DCGL derivation. These pathways are often evaluated under the context of a "subsistence farming resident" exposure scenario, although the use of such a scenario is not stipulated in regulation[i]. In contrast, EPA's risk assessment framework typically discounts subsistence scenarios in favor of scenarios such as a suburban resident scenario that may include a backyard garden, but does not include growing food for subsistence. Under the EPA framework, land use restrictions may also

be used as a means of limiting exposures. Therefore, exposure assessment under EPA guidance is typically limited to the direct contact exposures (e.g., incidental soil ingestion, dust inhalation, indirect exposure to ground radiation). Food chain exposures, if evaluated, are typically limited to non-subsistence consumption of home-grown produce. Soil as a leaching source to groundwater is typically not included in the estimation of health risks and is only considered in the development of final remedial goals. Finally, EPA typically makes remedial decisions based on deterministic (single point) estimates of exposure and risk, whereas NRC permits and encourages the use of probabilistic methods that account for the range of uncertainty in exposure estimates in the development of cleanup goals.

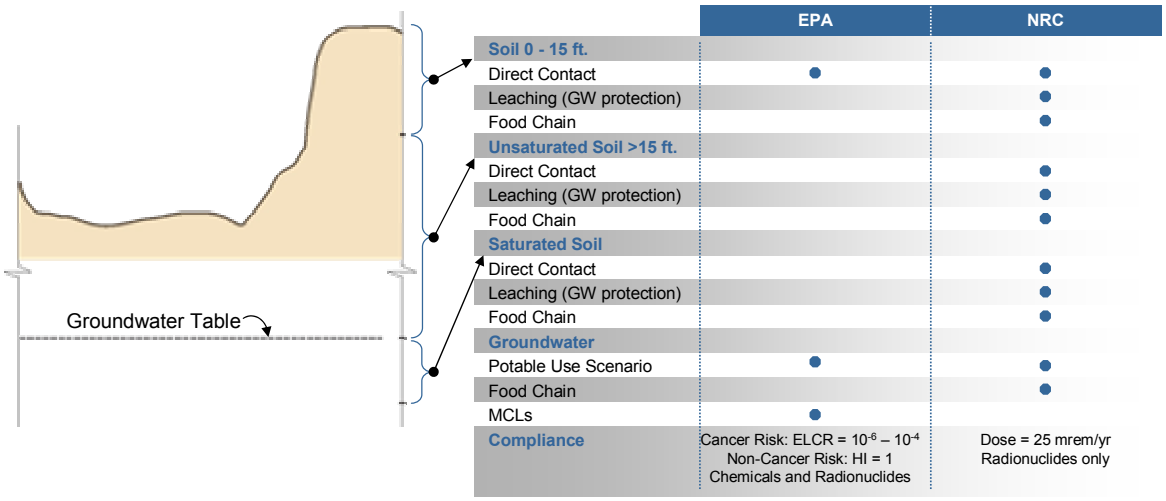

Fig. 2 Comparison of typical EPA and NRC requirements for exposure assessment

Quantitative Differences

A review of Equations 1 and 3 shows that calculation of risk and dose are conceptually similar, and in fact the same numerical values may be used to calculate intake values for the purposes of dose assessment or risk assessment. However, for the same set of numerical intake parameters, substantial differences in risk and dose estimates may be observed due to the expression of a dose estimate as an annual dose, versus the expression of risk as a cumulative lifetime risk.

Table II shows a comparison of ELCR estimates for uranium and cobalt-60 for residential receptors exposed to a defined activity of uranium and a defined activity of cobalt-60. For each radionuclide, the defined activity corresponds to a radiation dose of 19 mrem/year. However, the ELCR associated with a concentration of uranium that would produce a 19 mrem/year dose is 3×10^{-4}, whereas the concentration of cobalt-60 that would produce a 19 mrem/year dose is associated with an ELCR of only 1×10^{-4}. This example illustrates that the same radiation dose can be associated with different cancer risk estimates. In this example, the intake of cobalt-60, which has a relatively short half-life (5.3 years), is highest during year one and decreases thereafter because there is substantial decay over the time period evaluated. The DCGL is derived from the peak annual dose that occurs over the 1,000-year time frame. The peak dose would be associated with the first year of exposure and, therefore, the DCGL, based upon an annualized dose, would not account for the fact that cobalt-60 is rapidly decaying over the time period, producing ever decreasing annual dose. In contrast, since cancer risk is a cumulative risk (over 30 years of exposure in this example), the risks associated with 30 years of exposure to cobalt-60 are affected by the decay over the time period; risks become lower each successive year of exposure due to the decay (decreasing activity) of cobalt-60. For uranium, which has a very long half-life (greater than 100,000 years), the

intake remains essentially constant over the time period evaluated because there is essentially no decay or in-growth of progeny during that time frame. Therefore, the risks associated with 30-years of exposure to uranium are not affected by decay.

Table II Differences in risk and dose estimates attributable to differences in radionuclide half-life

Uranium (3% U-25 enriched) (half life - >100,000 years)	Activity (pCi/g)	Year - 1	Year - 30	Year-1000	Peak Dose (mrem/year) / Cumulative Risk (ELCR)
Dose (mrem/year)	1000	19	18	2.1	19 – Year 1
Risk (ELCR)	1000	$1x10^{-5}$	$1x10^{-5}$	NA	$3x10^{-4}$ – Cumulative over 30 years
Cobalt-60 (half life – 5.3 years)	Activity (pCi/g)	Year - 1	Year - 30	Year-1000	Peak Dose (mrem/year) / Cumulative Risk (ELCR)
Dose (mrem/year)	6	19	0.35	0.00	19 – Year 1
Risk (ELCR)	6	$1.5x10^{-5}$	$2.7x10^{-7}$	NA	$1x10^{-4}$ – Cumulative over 30 years

pCi/g – picocurrie per gram
mrem/year – millirem per year
ELCR – excess lifetime cancer risk
NA – not applicable

Table III shows a comparison of ELCR and annual dose estimates for various receptors exposed to a constant activity of uranium. The highest NRC radiation dose is associated with a construction worker scenario, yet the highest EPA cancer risk is associated with an occupational worker scenario. The explanation for the fact that highest dose and highest risk can be associated with different receptor scenarios is attributable to the fact that dose is a function of exposure over a single year, whereas risk is a function of exposure over a number of years. In this example, the construction worker scenario represents a high intensity exposure over a short period of time (one year) whereas the occupational worker scenario represents a low intensity exposure over many years (25 years). The highest annual dose is associated with the receptor scenario that has the highest intensity exposure in any one year, whereas the highest cumulative risk is associated with the receptor scenario that has the longest duration of exposure.

Table III Differences in risk and dose estimates attributable to differences in receptor scenario

Receptor Scenario	Uranium (pCi/g) (0.2% U-235)	Annual Dose (mrem/year)	Risk (ELCR)
Recreational Visitor	350	1.0	$4.7x10^{-6}$
Occupational Worker	350	1.6	$1.0x10^{-5}$
Community Gardener	350	0.66	$5.4x10^{-6}$
Construction Worker	350	6.1	$2.6x10^{-6}$

pCi/g – picocurrie per gram
mrem/year – millirem per year
ELCR – excess lifetime cancer risk

APPLICATION OF RISK-BASED ASSESSMENTS AT NRC-REGULATED SITES

Regulatory Drivers for Calculating Risk

Increasingly, facilities regulated by NRC that are undergoing license termination are being required to evaluate health risk, in addition to radiation dose. The principal reasons for these requirements include state and federal authority under RCRA regulations, state authority under state-specific property transfer and hazardous waste site regulations, and EPA CERCLA authority under the EPA/NRC MOU.

A number of facilities are regulated under state or federal RCRA regulations. Specifically, chemical (non-radiological) contaminants that are not regulated under NRC jurisdiction are often regulated under state or federal RCRA programs. Federal RCRA authority does not extend to radionuclides. However, at the time of final site closure, EPA sometimes requires a demonstration that total site risks associated with the post-remediation conditions for combined chemical and radionuclide constituent risks are not unacceptable. If post-remediation conditions are determined to be unacceptable, EPA can invoke CERCLA authority. The methodology used by EPA to determine if post-remediation site conditions are associated with acceptable exposure levels is through characterization of ELCR and non-cancer risk. Therefore, for facilities held to federal RCRA authority, it is likely that a characterization of health risks will be required to satisfy EPA, and it becomes obvious that radionuclides should be considered in this context.

Many states promulgate their own hazardous waste site regulations intended to ensure that risks to public health and the environment posed by a site are acceptable at the time of property transfer. The regulations for some states have provisions that exempt radioactive substances and defer their regulation and cleanup to NRC authority. For other states, regulations specifically require characterization of risks to public health and the environment associated with chemical and radiological contamination. Facilities within states with these regulations will likely be required to characterize health risks for radionuclides.

The NRC and EPA have entered into a MOU (signed on October 9, 2002) regarding USEPA involvement in NRC-licensed sites that are in the process of, or have completed, decommissioning and decontamination (D&D) in support of license termination. The MOU establishes conditions under which USEPA can and cannot act under its CERCLA authority. This authority applies to NRC-licensed sites that are in the process of completing, or have completed, D&D in support of license termination. Significantly, the MOU states that USEPA will defer to NRC authority and decision-making on all sites undergoing decommissioning except at sites presenting certain circumstances. Circumstances under which NRC must involve USEPA are as follows:

1. Radioactive groundwater contamination in excess of the USEPA's MCLs.

2. License termination based on restricted release (10 CFR 20.1403) or alternate criteria (10 CFR 20.1404).

3. Planned or actual residual (post-decontamination) radionuclide levels in soil exceed the "trigger" levels presented in Table 1 of the MOU.

For facilities affected by the MOU, the NRC is expected to consult with USEPA first and then take action the NRC deems appropriate based on its consultation with USEPA. The MOU states that USEPA does not generally expect to take CERCLA actions related to radioactive materials at sites decommissioned in compliance with NRC's standards. The MOU also states that USEPA reserves the right to take CERCLA actions at such sites if USEPA disagrees with NRC decisions in response to USEPA consultation. These

actions could include listing the site on the National Priorities List (NPL), thus compelling additional investigation and/or cleanup under USEPA oversight.

As discussed above, the EPA's methodology for evaluating acceptable exposure levels is through characterization of ELCRs and non-cancer risks, as opposed to radiation dose. Therefore, for facilities in which decommissioning criteria include any of the conditions listed, it is likely that a characterization of health risks associated with radionuclides will be required to satisfy EPA.

Integration of Dose-Based and Risk-Based Frameworks

For sites where both dose-assessment and risk-assessment must be performed, significant issues that must be recognized and addressed in order to achieve a technically-defensible, timely, and cost-effective characterization include:

- Collection of site characterization data prior to risk characterization/cleanup goal derivation, versus collection of characterization data after cleanup goal derivation (i.e., "bottom up" versus "top down")

- EPA's range of acceptable risks versus NRC's discrete dose limit

- Land use scenario and pathway differences between EPA risk-based assessments and NRC dose-based assessments

The NRC regulatory framework allows for establishment of cleanup goals in the absence of an understanding of the disposition of site contamination relative to the cleanup goals. This has the advantage of placing risk management at the beginning of the process where it cannot be influenced by the relationship between the cleanup goal value and extent of remediation. Collection of site characterization data after cleanup goals have been established and approved by regulatory agencies permits the sampling and analysis program to be designed to address the site-specific data quality objectives that must be met to demonstrate compliance with the cleanup criteria. This is typically performed under a statistical framework (e.g., as described in MARSSIM) that targets data collection for only those contaminant residues (radionuclides) subject to the cleanup criteria that have been developed, and for only the minimum numbers of samples that are required to understand the source term relative to the hazard or to demonstrate compliance.

In contrast, under the EPA's regulatory framework decisions concerning remediation and associated cleanup goals are determined after the disposition of the site relative to potential health risks is known. This places risk management at the end of the characterization process. Coupled with the fact that EPA uses a risk range rather than a discrete risk limit, subjectivity can enter into the remedial decision-making process. In addition, because site characterization data are collected prior to establishment of site-specific cleanup goals and are generally required to target a prescribed list of regulated substances, the sampling objectives cannot be targeted specifically at chemicals that will require remediation or permit bounding of areas requiring remediation, without incurring a substantial financial burden. Therefore, the sampling and analysis program for sites under EPA regulation often require two or more separate rounds of data collection: one round of sampling to characterize the site and for use in initial risk characterization, and at least one additional round of sampling to refine the risk characterization (e.g., provide sufficient information for the substances that pose unacceptable risks and drive remedial decisions) and provide sufficient characterization for remedial design.

Differences in land use scenarios and exposure pathways that require evaluation under EPA and NRC frameworks can lead to differences in the exposure media and substances that drive remedial concerns. A

review of Figure 2 would suggest that the NRC requirements for exposure assessment, being more encompassing than those required under EPA's framework, would lead to more stringent cleanup goals. However, because EPA uses health risk and NRC uses annual dose as the benchmarks for health detriment, and because the correlation between risk and dose is specific to receptor, pathway, and radionuclide, the regulatory driver for each exposure medium at a site where both risk and dose-based requirements apply cannot be determined unless both dose and risk are calculated.

Although the NRC's "top down" approach offers some clear advantages in terms of cost savings and timeliness compared to EPA's "bottom up" process, it is unlikely that a strictly "top down" process can be used to comply with EPA's risk-based regulatory framework. Nonetheless, for sites where both NRC and EPA regulations apply, there is a benefit to integrating the NRC and EPA regulatory processes to the extent possible so that cost savings can be recognized. The liabilities associated with not integrating NRC and EPA frameworks include:

- Incompatibility of site characterization data. Analytical sampling data that are generated strictly in consideration of EPA regulations will not likely meet the data objectives for license termination, and vice-versa, due to differences in media, contaminants, and pathways of concern, differences in analytical detection requirements, and differences in overall data quality objectives. If the requirements of both regulatory frameworks are not recognized and addressed, it is likely that two separate site characterization programs will be required.

- Incompatibility of exposure assessments. Differences in the receptor scenarios and exposure pathways evaluated under the EPA and NRC frameworks, as well as the different health effect endpoints used by EPA (i.e., risk) and NRC (i.e., dose) can lead to different conclusions regarding media and areas that require remediation. It is beneficial to overlap the exposure assessments for EPA risk and NRC dose assessments to the extent possible. This helps avoid generating conclusions regarding site risks and required remediation that are based on different land use and receptor exposure assumptions. Conclusions that do not compliment each other raise questions in the pubic arena and can cause regulatory re-visiting of the risk or dose assessments and remedial decisions.

- Risk of performing two separate remedial events. If NRC and EPA-required evaluations are performed in isolation of each other it is possible that two separate and potentially incompatible, remedial events will be required. In such circumstances, it is possible that closure under one regulatory framework will be held up while cleanup is being performed under the other regulatory framework. Finally, questions related to perceived incompatibilities can arise in the public arena regarding why one regulatory framework may require additional cleanup of an area that was previously remediated under the other regulatory framework.

The following sections describe three methods that may be used to integrate dose and risk based assessments into a single framework that address the technical issues while capitalizing on the positive aspects of the "top down" approach to the extent possible within the regulatory frameworks.

Method 1 - Derive DCGL that Accounts for Dose and Risk

A method for evaluating NRC's dose-based regulations and EPA's risk-based regulations while maintaining the NRC's "top down" approach is to derive a DCGL that accounts for both risk and dose. This approach is most likely to succeed in state cleanup programs that use RBCA techniques to evaluate risk and make cleanup decisions. The specific advantages to this approach include:

- The methodology for evaluating compliance with the cleanup value is analogous to the MARSSIM-based process;

- The target risk, like the target dose, used to develop the cleanup value is a discrete value that is known at the time the cleanup value is derived;

- With a defined cleanup value, the analytical data may be collected to satisfy both regulatory frameworks during a single site characterization program;

- Exposure assessments and basis of remedial decisions are compatible and complimentary;

- A single remedial event may be used to address both regulatory frameworks.

Technical and regulatory issues that may present challenges to this approach include:

- Agreement on the data metric that is used to evaluate compliance with the cleanup value. A central tendency estimate of the exposure point is typically used in MARSSIM-based evaluations, whereas many state regulatory programs require an upper-percentile estimate of the data set.

- Risk-based targets when multiple contaminants are present may be too low to be technically or economically-feasible to demonstrate compliance with. Similar to the NRC's dose-based regulation that requires the total dose among all radionuclides to meet a 25 mrem/year dose limit, many state promulgated risk-based regulations also require consideration of risk additivity. When several contaminants require cleanup values, the target risks used to establish cleanup goals may require setting at levels that result in very low cleanup values. This, in turn, can require the use of analytical methods that are more sensitive, and can substantially increase the number of samples required to demonstrate compliance with statistical integrity, which together can substantially increase the costs of a demonstrating compliance. One method for addressing this situation is to establish the cleanup value for each contaminant at the total risk limit (or dose limit), and then apply a sum-of-ratios technique when evaluating compliance with the cleanup value.

The process that would be followed for a site that uses this approach is:

1) Derive and obtain regulatory approval of cleanup goals that account for dose- and-risk based endpoints (the cleanup goals for each chemical/medium would be the lesser of the risk- or dose-based values);

2) Determine data metric that is used to compare site data to cleanup goal;

3) Perform site characterization sampling that is designed to obtain the appropriate amount of data necessary to compare to the cleanup goal; and

4) Perform remediation and confirmatory sampling as needed.

Method 2 – Pre-Remediation Risk Assessment

A second option for sites with regulatory requirements to address both dose under NRC license termination requirements and risk under EPA regulations is to develop a DCGL and perform a risk assessment prior to remedial activities. This approach is most likely to be accepted at sites regulated

under CERCLA, because CERCLA typically requires a risk assessment that evaluates the pre-remediation, or "baseline" conditions (termed a "baseline risk assessment" under CERCLA).

The specific advantages to this approach include:

- Preserves the MARSSIM-based process for compliance with NRC requirements and preserves the baseline risk assessment process for compliance with EPA requirements;
- The analytical data may be collected to satisfy both regulatory frameworks during a single site characterization program;
- Exposure assessments and basis of remedial decisions can be compatible and complimentary;
- A single remedial event may be used to address both regulatory frameworks.

Technical and regulatory issues that may present challenges to this approach include:

- Timeline for closure under both regulatory frameworks is likely to be longer than would be if both regulatory frameworks could be addressed in harmony (Method 1) or if only one regulatory framework applied to the site, due to increases in the numbers of stakeholders, reviewers, and review cycles in the process;
- Contaminants and media with risks that exceed EPA's risk management criteria will require risk-based PRGs to be established. It is possible that EPA will require PRGs to be initially established at a 10^{-6} risk level. The 10^{-6} risk level is almost always associated with remedial goals that are substantially lower than dose-based remedial goals, and remediating to meet a contaminant level associated with a 10^{-6} risk may be very costly. It is therefore beneficial to negotiate cleanup goals that will result in a residual (post-remediation) risk that is associated with cumulative risks that do not exceed the 10^{-4} risk level, as it is the residual risk and not the specific cleanup goal that is of significance at the time of site-closure.

The process that would be followed for a site that uses this approach is:

1) Derive and obtain regulatory approval of cleanup goals that account for dose;
2) Perform site characterization sampling that is designed to obtain the minimum amount of data necessary to compare to the cleanup goal and satisfy site characterization requirements under CERCLA;
3) Perform baseline risk assessment;
4) Develop PRGs;
5) Design remediation to account for dose-based cleanup values and final risk-based cleanup values (i.e., remediation to account for the regulatory driver for each contaminant and medium) and perform remediation and confirmatory sampling as needed.

Method 3 – Post-Remediation Risk Assessment

A third option for sites that must complete both dose and risk-based assessments is to develop a DCGL prior to remedial activities and a risk assessment after remedial activities. This approach is a potential option at sites regulated under RCRA, because RCRA does not regulate radionucides and thus cannot require a risk assessment for radionuclides as part of a baseline (pre-remediation) characterization of acceptable levels. However, at many sites regulated under RCRA there is a requirement to demonstrate that the post-remediation conditions of chemicals and radionuclides do not pose unacceptable risks. Therefore, a post-remediation risk assessment (i.e., "residual risk assessment") may be performed to satisfy the requirement.

The specific advantages to this approach include:

- Preserves the MARSSIM-based process for compliance with NRC requirements and provides a risk assessment process for compliance with EPA requirements;
- The analytical data may be collected to satisfy both regulatory frameworks during a single site characterization program;
- Exposure assessments can be compatible and complimentary;
- Provides flexibility in developing remedial solutions. The remediation can be tailored to achieve risks within the EPA risk limits by selectively reducing chemical concentrations, radionuclide concentrations, or both chemical and radionuclide concentrations, based on the most cost-effective solution;
- Addresses concerns about MOU trigger value exceedances by demonstrating post-remediation conditions are associated with acceptable risks;
- A single remedial event may be used to address both regulatory frameworks.

Technical and regulatory issues that may present challenges to this approach include:

- Requires interim evaluations and iterative risk analysis to ensure that site characterization is sufficient to address risk-based endpoints, and remediation achieves conditions that do not pose risks in excess of risk limits.
- Possible liability associated with performing remediation to meet dose and risk-based requirements, and then EPA rejecting post-remediation risk assessment due to disagreement with basis of assessment (e.g., exposure scenarios and exposure assumptions), and post-remediation risk (e.g., subjectivity associated with application of "risk range" rather than a discrete risk limit). One potential method for addressing this liability is to obtain EPA review and approval of risk assessment approach prior to performing remediation.

The process that would be followed for a site that uses this approach is:

1) Derive and obtain regulatory approval of cleanup goals that account for dose;

2) Perform site characterization sampling that is designed to obtain the minimum amount of data necessary to compare to the cleanup goal and satisfy site characterization requirements under RCRA;

3) Perform RCRA risk assessment for chemicals (required risk assessment activity under RCRA);

4) Perform internal analysis of radionuclide risks;

5) Develop PRGs that account for cumulative risk of chemicals and radionuclides;

6) Design remediation to account for dose-based cleanup values and final risk-based cleanup values (i.e., remediation to account for the regulatory driver for each contaminant and medium) and perform remediation and confirmatory sampling as needed. Verify that remediation will achieve acceptable exposure levels for chemicals and radionuclides as remediation progresses;

7) Perform cumulative risk assessment for chemicals and radionuclides based on post-remediation site conditions and submit to EPA as documentation of acceptable risks associated with site closure.

CONCLUSIONS

Although there are fundamental differences between the regulatory frameworks that NRC and EPA use to characterize, remediate, and remove a site from regulatory oversight, as well as different metrics of health detriment that are used to establish acceptable exposure levels of residual contaminants, it is possible to harmonize NRC dose-based closure requirements and EPA risk-based closure requirements into a single process. Three approaches to integrate these two regulatory frameworks have been presented. These include:

1) Developing DCGLs that account for risk and dose. This approach is most likely to be successful in state regulatory frameworks that use a RBCA-based approach that is conceptually similar to the MARSSIM-based approach.

2) Performing a pre-remediation (baseline) risk assessment and integrating the dose-based cleanup values (DCGLs) with risk-based cleanup values to complete a single remedial action. This approach is most likely to be successful in EPA regulatory frameworks that follow CERCLA where a baseline risk assessment is typically required.

3) Performing a post-remediation (residual) risk assessment to demonstrate that site closure is associated with acceptable exposure levels. This approach is most likely to be successful in EPA regulatory frameworks that follow RCRA where there is not a requirement to evaluate baseline risks for radionuclides, but where there may be a requirement to demonstrate that cumulative risks for chemicals and radionuclides are acceptable upon regulatory release of the site.

The benefits to integrating NRC dose and EPA risk-based frameworks into one site characterization and remediation process include: collecting analytical data to satisfy both regulatory frameworks during a single site characterization program; completing exposure assessments that are compatible and complimentary, resulting in remedial decisions with a common basis; using a single remedial event to address both regulatory frameworks; and addressing concerns about MOU trigger value exceedances by considering risk when establishing acceptable exposure levels.

The potential liabilities to a responsible party if NRC dose and EPA risk-based frameworks are not integrated include: the cost associated with performing two separate site characterization programs; generating conclusions regarding site risks and required remediation that are based on different land use and receptor exposure assumptions; and the cost associated with the likelihood that two separate remedial programs will be required. Together, these liabilities increase the overall timeline for obtaining regulatory release, increase the scrutiny of the site in the pubic and regulatory arenas, and increase the potential for re-visiting of the risk or dose assessments and remedial decisions.

FOOTNOTES

[i] The NRC has indicated that the presumptive use of a subsistence farming resident scenario as the "NRC preferred" scenario has lead many licensees to over commit when deriving DCGLs. The NRC does not have an official policy as to a "preferred" or "default" exposure scenario. Rather, the licensee is encouraged to propose and support realistic and plausible future use scenarios when deriving DCGLs.