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Breaking Through Historical Biases in Performance Assessments - 18056

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ABSTRACT

Performance assessments (referred to as safety assessments internationally), which include mathematical modeling of natural and engineered systems for many hundreds and thousands of years, play an important role in decision-making for disposal of radioactive waste and cleanup of sites and facilities contaminated with radioactive material. These decisions can involve options costing hundreds of millions or even billions of dollars. Thus, it is critical to understand the underlying assumptions behind regulatory and technical aspects of these assessments to better understand and communicate the basis for decisions.

Policy and technical biases deliberately built into early assessment approaches allowed safety margin to account for uncertainties known to be present, but not quantitatively assessed. Many of these biases (e.g., regulatory standards, human habits, effectiveness of waste forms, inadvertent intrusion assumptions, etc.) continue to exist in spite of advances in technical approaches and knowledge. These built-in biases, often not effectively communicated, can lead to misleading interpretation of results and potentially influence public confidence and costly regulatory decisions regarding the safety of a disposal facility or a closure action.

INTRODUCTION

US DOE follows a “risk-informed, performance-based” approach to support decision-making for waste disposal rather than the designed-based approach used for disposal of hazardous wastes. A risk-informed, performance-based approach involves a quantitative demonstration of protectiveness for a site- and facility-specific design. This results in a need for quantitative metrics (performance objectives) and modeling to assess performance of the facility. In a design-based approach, compliance is demonstrated by constructing the facility to meet a specific design requirement and providing for long-term oversight of the facility (e.g., double liner, leachate collection system for hazardous waste).

US DOE requires that performance assessments (PAs) are conducted to assess the potential long-term impacts of closure actions (e.g., closing tanks) and disposing of radioactive waste in on-site disposal facilities. PAs are also used to support decision-making regarding the waste types, volumes, waste form and containers, and disposal facility design. Biases have been built into many layers of inputs/ assumptions that are required to implement a PA for a risk-informed, performance-based approach to decision-making (see Table I). These biases are present, for example, in the performance objectives and measures used to pass judgement on potential effects on human health and the environment, inputs/ assumptions about the site and facility design features, identification of receptors and their habits, and modeling approaches that have been applied. Over the past few decades, PA models and approaches continue to be refined, but many of the historic biases continue to have an impact on decision-making. Examples of these biases are described, followed by a discussion of the impacts of the biases and how improved PA methods may be used to support more informed decision-making.

TABLE I. Examples of Biases Built-in to Performance Assessments.

Performance Objectives and Measures	• Performance objectives are a small fraction of annual average background exposures • Performance objectives are a fraction of the limit recommended by ICRP and IAEA • Inadvertent human intrusion is assumed to occur • Assume impacts observed at high doses are extrapolated to lower doses
Protective Barriers	• Pessimistic assumptions about lifetime of engineered barriers • Pessimistic assumptions about performance of engineered barriers • Assume instantaneous failure of engineered barriers or containers • Not accounting for other barriers to exposures (records, memory, land use controls, government ownership, etc.)
Receptors and Habits	• Assume loss of controls and memory of facility • Assume exposure occurs at location and time of peak concentration • Assume residential, subsistence farmer • Inadvertent intruder ignores indications of waste
PA Methods and Models	• Probabilities of exposure and scenarios typically not considered • Often opt to not include processes rather than defend assumptions • Limited quantification of uncertainties and use for decision-making • Pressure to consider “What-If” cases that represent extremes

PERFORMANCE ASSESSMENT REQUIREMENTS

LLW disposal and tank closure at US DOE facilities are regulated under US DOE Manual 435.1-1, *Radioactive Waste Management* [1], which provides performance objectives and requirements for protection of human health and the environment. US DOE performance objectives have remained relatively consistent over time. The requirements were developed in recognition of international recommendations and standards intended to provide a reasonable expectation of protection of human health and the environment. PAs and other supporting documentation are subjected to an independent review from the Low-Level Waste Disposal Facility Federal Review Group (LFRG) and in many cases other external reviews are also involved.

US DOE uses PAs to provide quantitative input to support a demonstration of whether there is a reasonable expectation that releases from a disposal facility will not exceed performance objectives for 1,000 years following facility closure. Notably, additional calculations are provided to address potential longer-term peaks as part of risk-informed decision-making. The appropriate “time of compliance” for PAs has been a topic of much debate as discussed later in this section.

Performance Criteria

US DOE Manual 435.1-1 states that there must be a "reasonable expectation" that the following performance objectives will be met:

- "Dose to representative members of the public shall not exceed 25 mrem (0.25 mSv) in a year total effective dose equivalent from all exposure pathways, excluding the dose from radon and its progeny in air.
- Dose to representative members of the public via the air pathway shall not exceed 10 mrem (0.10 mSv) in a year total effective dose equivalent, excluding the dose from radon and its progeny.
- Release of radon shall be less than an average flux of 20 pCi/m^2/s (0.74 Bq/m^2/s) at the surface of the disposal facility. Alternatively, a limit of 0.5 pCi/1 (0.0185 Bq/l) of air may be applied at the boundary of the facility."

The term reasonable expectation is used in recognition of the uncertainties involved in long-term estimates of performance and reflects the recognition that it is not possible to provide absolute proof that the objectives will be met.

US DOE Manual 435.1-1 also includes a performance measure to address the potential impacts to an inadvertent intruder:

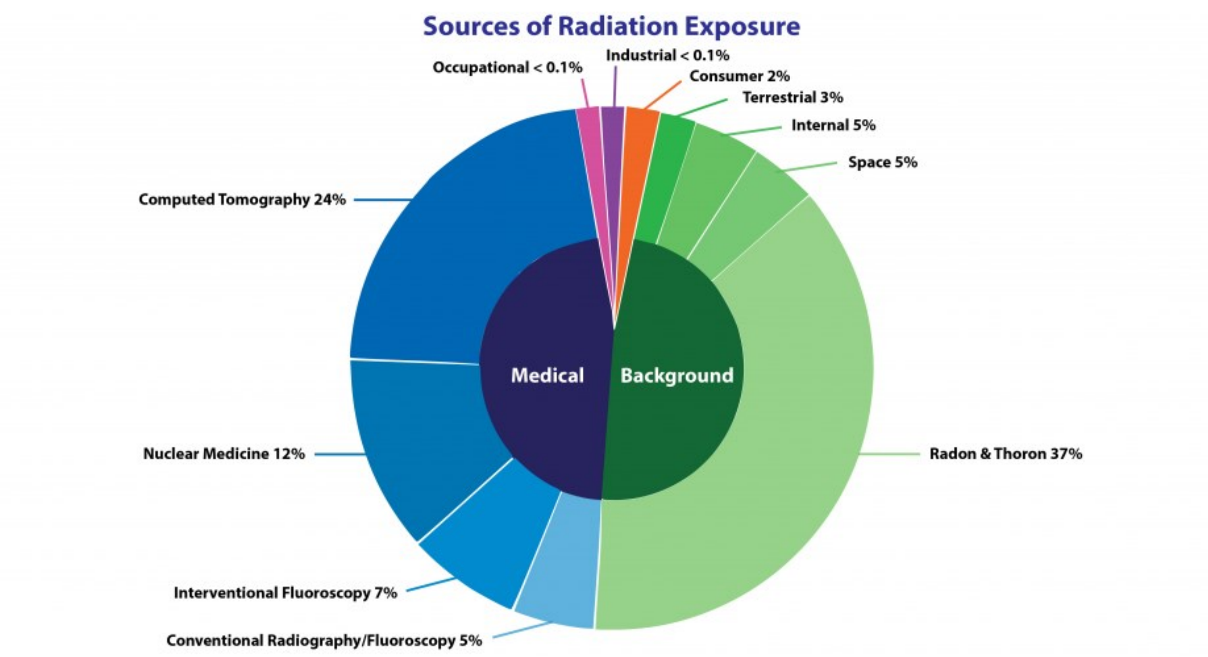
> "For purposes of establishing limits on the concentration of radionuclides that may be disposed of near-surface, the performance assessment shall include an assessment of impacts calculated for a hypothetical person assumed to inadvertently intrude for a temporary period into the low-level waste disposal facility. For intruder analyses, institutional controls shall be assumed to be effective in deterring intrusion for at least 100 years following closure. The intruder analyses shall use performance measures for chronic and acute exposure scenarios, respectively, of 100 mrem (1 mSv) in a year and 500 mrem (5 mSv) total effective dose equivalent excluding radon in air."

This requirement is stated as a performance measure to signify that it is not interpreted as a strict limit, which allows some room for optimization consistent with the nature of the scenario. It is generally implied that inadvertent intrusion is assumed to occur with a probability of one, which is believed to significantly overstate the likelihood. Although, the performance measure is greater than the objectives above, the difference does not make up for the very low likelihood of a full inadvertent intrusion scenario occurring. Thus, use of the term performance measure allowing for optimization provides some room for risk-informed decision-making rather than implying that you must assume a probability of one and you must meet an absolute limit based on that assumption.

Biases in Performance Criteria

US DOE performance objectives were developed consistent with international recommendations and other similar regulations in the United States. The International Commission on Radiological Protection (ICRP) and International Atomic Energy Agency (IAEA) issue publications and standards, respectively, that serve as guidelines for demonstrating protection of human health and the environment. ICRP and IAEA recommend a limit of 1 mSv/yr for planned exposures to radioactivity. This value was established based on an assumption that observed impacts at higher doses would linearly extrapolate to potential impacts at low doses. US DOE performance objectives were established as a fraction of this overall limit. Thus, there is a margin of bias introduced at this point due to the assumed linear extrapolation and setting objectives at a fraction of the overall limit.

Comparing the dose limits and performance objectives to background doses and the average annual dose assumed to occur in the United States provides some additional perspective on the amount of bias built in to the criteria before any modeling is conducted. The National Council on Radiation Protection and Measurements (NCRP) has estimated that the average annual exposure in the United States is about 6.2 mSv/yr, which is roughly 25 times higher than the all pathways performance objective (0.25 mSv/yr). The average annual exposure includes doses incurred due to natural background, medical, industrial, occupational and consumer applications (Fig. 1). Note that these are averages and there are examples of situations with background levels substantially higher without recognizable deleterious effects.



Average Annual Radiation Dose

Sources	Radon & Thoron	Computed Tomography	Nuclear Medicine	Interventional Fluoroscopy	Space	Conventional Radiography/ Fluoroscopy	Internal	Terrestrial	Consumer	Occupational	Industrial
Units mrem (United States) mSv (International)	228 mrem 2.28 mSv	147 mrem 1.47 mSv	77 mrem 0.77 mSv	43 mrem 0.43 mSv	33 mrem 0.33 mSv	33 mrem 0.33mSv	29 mrem 0.29 mSv	21 mrem 0.21 mSv	13 mrem 0.13 mSv	0.5 mrem 0.005 mSv	0.3 mrem 0.003 mSv

(Source: National Council on Radiation Protection & Measurements, Report No. 160)

Fig. 1. Sources of Radiation Exposure and Average Annual Dose in the United States [2].

Decision-making for waste disposal is being based on criteria applied for potential exposures that may occur to a relatively limited group of individuals that is roughly 25 times lower than average annual exposures to individuals in the United States today. There is a rationale to provide for protectiveness, but when making decisions there should be some recognition of how these built-in margins can impact decisions, especially when considering the need for added costs for barriers, additional remediation, or follow-up actions to address assumptions that could be required to demonstrate compliance with the lower performance objectives.

When a performance objective is viewed as a strict limit, even though the objective is a fraction of the ICRP limit and significantly less than average annual exposures, it can lead to bad decision-making. This is an important consideration for all scenarios, but probably most significant for inadvertent intrusion (discussed below). There is a need to make a transition from risk-based (interpreting dose criteria as an absolute limit) to risk-informed decision-making with the ability to consider biases and uncertainties to make an informed decision.

PROTECTIVE BARRIERS

Disposal facilities and closed tanks include multiple engineered barriers between the waste and a potential receptor. When releases occur from the engineered system, the natural system also serves as a barrier. Barriers can physically limit water flow, chemically limit the migration of contaminants and serve as a deterrent to inadvertent human intrusion. Depending on the waste and conditions at a given site, there may be more reliance on engineered features. For example, at a humid site, there may be more credit for engineered features and at a semi-arid site, more reliance on performance of the natural system.

Internationally, the concept of protective measures has been identified in the context of inadvertent human intrusion [3]. Measures are defined to include all features that can serve to reduce the likelihood and magnitude of impacts resulting from intrusion. This concept also applies to exposures from normal evolution scenarios not involving intrusion. Measures include engineered barriers and the natural system, but also include other factors like waste acceptance criteria and administrative controls and records that can serve to maintain knowledge of the disposal facility. These additional measures have traditionally been implemented for disposal facilities, but the role and contribution to decision-making has been relatively limited (e.g., complete loss of memory after only 100 years of institutional control). Fig. 2 illustrates layers of different types of measures or controls which contribute to defense-in-depth for waste disposal.

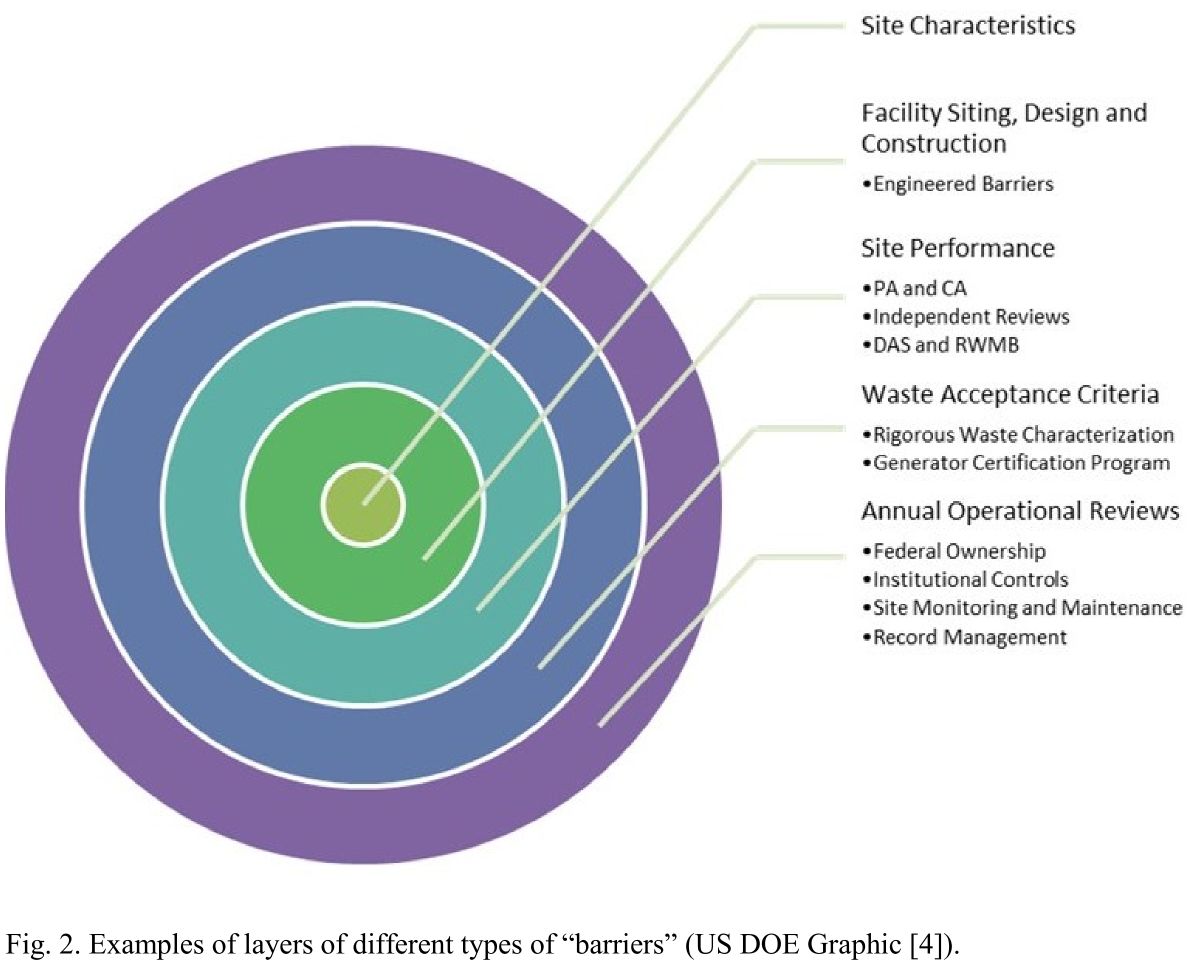


Fig. 2. Examples of layers of different types of “barriers” (US DOE Graphic [4]).

Addressing Performance of Barriers

Historically, engineered barriers have been addressed in varying levels of detail in a PA, largely depending on the need for the demonstration of compliance. This is a practical approach that emphasizes an efficient and defensible demonstration of compliance. Essentially, the analyst must make choices about which barriers to credit (e.g., covers, waste form, containers, vaults or tanks, liners, and the natural system), and thus, where to invest time and effort to defend input/assumptions. There are time and cost implications of taking credit for barriers (e.g., experiments, field studies, improved modeling approaches), thus some pragmatic considerations will always be necessary. For implementation of a PA, it becomes a balancing act between pragmatic considerations and the need to appropriately portray the expected performance.

Biases when Considering Barriers

The pragmatic approach described above leads to a general over-estimation of doses that would be expected to occur. Historically, there has been little or no indication of the margin added by ignoring a given barrier and, furthermore, only limited discussion of biases that were built-in to the calculations. Over time, as modeling approaches have improved and there has been more experience working with stakeholders, limitations of this pragmatic approach have become more apparent. For stakeholders, there can be a perception that the PA results were real doses rather than calculations deliberately intended to over-predict the consequences to provide a reasonable expectation of compliance with the performance objectives. This can lead to artificial limitations on waste acceptance criteria or over-design of waste forms, containers and barriers. Simply ignoring the benefit of a given barrier is one example of bias, some other examples of biases are described in the following paragraphs.

Another simplification that has historically been applied relates to assumptions about changes in properties of a barrier. It is understood that barriers will likely evolve over time and the physical and chemical properties will change (e.g., increased hydraulic conductivity, change in assumed K_d). In PAs, these changes are often reflected as a step change for the entire barrier or all waste forms/containers. In reality, the changes will occur over some time and will start in localized areas and spread. The implications of a step change tend to be a relatively sharp spike after the change, which then contributes to a peak that will appear in the projected dose. Similarly, if all of a given type of container are assumed to fail at the same time, that will concentrate the releases into a peak rather than distributing the releases in time. These types of assumptions are made because of the difficulty defending assumptions, for example, about the actual changes in a cover over time or establishing and defending a distribution for the failure of containers in a facility.

As formal uncertainty analyses became more common, new biases were introduced. For example, when establishing distributions for input parameters, there can be a tendency to bias the distribution towards what was considered a more pessimistic assumption rather than trying to use a distribution to capture uncertainty around the expected performance. The analyst would include the potential for more pessimistic or bounding values, but not include the potential for optimistic or expected values in the distribution. This resulted in some interesting comparisons of the results of a Monte Carlo analysis with a deterministic case, where the deterministic case appeared relatively low compared to the range of results for the Monte Carlo analysis.

RECEPTORS AND HABITS

In a performance based approach, there is a need to define the receptor in order to calculate a dose. We cannot know or quantify the uncertainty in habits of people hundreds or thousands of years in the future.

The concept of stylized scenarios has been adopted to address these unquantifiable uncertainties. Stylized exposure scenarios are developed based on current habits that are typical in the region rather than implying a need to speculate about future human behavior.

Although such stylized approaches help to focus the definition of a receptor, there are still many assumptions that need to be quantified, for example:

- When and where does the exposure take place?
- What type of scenario (residential, recreational, industrial)?
- Where is food/water obtained (subsistence farmer, fraction obtained at home, all food purchased elsewhere, well water/municipal water supply/bottled water)?
- What are consumption rates of different foods?
- How much time is spent indoors and outdoors in contaminated area?
- How old is the receptor?

Exposure Scenarios in a Performance Assessment

Over time, a variety of different terms have been used to define a stylized receptor (e.g., maximally exposed individual, average member of the critical group, representative person). There have also been different representations used to determine the dose coefficients that translate an intake to a dose (e.g., reference man, reference person, reference adult). These capture whether the receptor is male or female and adult, adolescent or a child in order to address different sensitivities. US DOE currently requires the use of the maximally exposed individual or a representative person/adult. The maximally exposed individual is used to obtain bounding results and the representative person or adult approach would be used more typically for a PA.

Once the receptor is identified, then exposure scenarios are developed in order to identify exposure pathways and intakes of radionuclides. The scenarios have generally reflected a few general classes of exposures (e.g., resident farmer, recreational user, industrial worker) that can be limited by land use controls during an institutional control period. For example, an area may be classified as industrial use only, where the only exposures are to workers in the area for a typical work schedule, or an area could be designated for no residential development, but people could be on the site occasionally for recreational activities (e.g., hunting, fishing, swimming). Typically, after any institutional controls are assumed to lose effectiveness, some form of residential scenario is considered.

When assigning specific values for intakes and exposure parameters, US DOE recommends the use of averages or central tendencies rather than extremes. This is consistent with ICRP recommendations when using regional data. Formal uncertainty analyses including variability in consumption rates and other exposure parameters are not as common, given the fact that the scenarios are stylized from the start, because the uncertainty cannot be quantified. Implying the ability to assign a distribution to consumption rates for someone in the future would give the impression of more knowledge than is reasonably possible.

Biases

There are many biases that can be and are introduced into assumptions about receptors and exposure scenarios for a PA. Some examples are provided here aligned with the list of bullets in the previous discussion. One of the more significant biases is the basic assumption that the exposure will occur at the time and location of the peak concentration outside of the facility (including a buffer zone). There is typically no credit for the remoteness of the location or the desirability in terms of availability of water, etc.

Another bias is commonly introduced by assuming there will be a resident farmer at the location and time of the peak concentrations. The farmer is often defined to obtain water from a well and to grow crops, raise cattle, etc. for a food supply. Well usage is still relatively common in rural areas, but subsistence farming is less common and leads to bias in the amount of contaminated food that is assumed to be consumed.

US DOE PAs are inconsistent in the approaches used to specify consumption rates. Some PAs use 95th percentile data whether it is based on generic information or region-specific information. This can introduce roughly a factor of 3 bias relative to the use of average consumption rate data. The assumed time in a contaminated area, indoors and outdoors, while in the area can also introduce bias. Assumptions regarding the age of the receptor are also an area of inconsistency for US DOE PAs and can be of interest for stakeholders. Age-weighted dose coefficients have been developed by the ICRP, and thus, the implied need to identify age-weighted consumption rates. Some US DOE sites are using an age-weighted representative person approach and others use the representative adult. Recent recommendations from US NRC and US DOE suggest that the use of adult data for doses occurring far in the future is appropriate given the large uncertainties about habits in the future.

IMPROVED CONSIDERATION OF BIASES DURING DECISION-MAKING

A number of historic biases continue to be introduced in PAs. These biases can have a significant impact on the projected doses in a PA and on decision-making based on the PA results. It is not realistic to expect that all biases can be removed or quantitatively addressed, but there are ways to improve how the biases are communicated and considered in decision-making. There are a number of ideas that have been implemented to help address these biases and support better decision-making, many of which have been reinforced in the recently published US DOE Technical Standard [4].

In general, the most important step is to acknowledge and document areas where biases have intentionally been introduced. Any additional insight that can be provided regarding the expected impact of the assumptions is also beneficial. This was not done as effectively in the past and has led to misinterpretation of earlier PAs. By documenting known bias, it can be considered in decision-making and bias can be removed at a later time, if necessary to improve decision-making.

The concept of safety functions has been introduced internationally. This concept provides a convenient and effective structure to identify and document biases. By identifying the functional role of each barrier in terms on reducing the peak dose, there is an opportunity to then document which safety functions are included in the PA and also document those functions that are not or pessimistically credited. The concept of protective measures has also been introduced that provides perspective on measures beyond engineered features that also contribute to safety. Although often not credited in a PA, administrative and other controls should be identified and discussed as part of decision-making.

A significant bias that is often forgotten is the bias introduced in the dose limits that are applied. The safety margin built-in to the dose limits needs to be effectively communicated. This is especially important given modern PA approaches that include multiple "what-if" analyses and distributions of results from uncertainty analyses where there may be some calculated results above 0.25 mSv/yr. There is a need to change the narrative from a perspective that any dose above 0.25 mSv/yr is not safe to acknowledge that 0.25 mSv/yr was intentionally established below the 1 mSv/yr limit and well below the annual average dose received in the United States. This should lead to more risk informed decision-making.

Biases in quantitative assumptions for PAs can be addressed by better implementation of uncertainty analyses, especially placing an emphasis on focusing uncertainty analysis on more realistic expectations rather than including bias in assumed distributions. It is common to use a combination of deterministic and probabilistic modeling, if the deterministic analysis is used as the demonstration of compliance, it may have some biases intentionally included. The uncertainty analysis can supplement the deterministic analysis by providing a more realistic perspective on the actual doses that would be expected. If the uncertainty analysis is used for the demonstration of compliance, there will be more scrutiny on the assumed distributions, which would be expected to lead to some potential biases being introduced. Although uncertainties in consumption rates can be difficult to defend for receptors in the far future, approaches to consider the likelihood of specific scenarios may also be beneficial (e.g., the amount of food consumed from on-site versus other non-contaminated sources).

CONCLUSIONS

US DOE uses a "risk-informed, performance-based" approach for decision-making for waste disposal and tank closure. Such an approach involves the need to identify quantitative criteria to evaluate protection of human health and the environment and the quantitative analyses to project doses to compare against those criteria. Many biases have been and continue to be built-in to the PA process. These biases are present, for example, in the performance objectives and measures used to pass judgement on potential effects on human health and the environment, assumptions about the site and facility design features, identification of receptors and their habits, and modeling approaches that have been applied. It is critical to first acknowledge and document known biases in order to support better informed decision-making. This paper identified many biases that are common to PAs and some recommendations for approaches to address biases resulting in better decision-making.

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