Neptune and Company Inc.

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Appendix 12

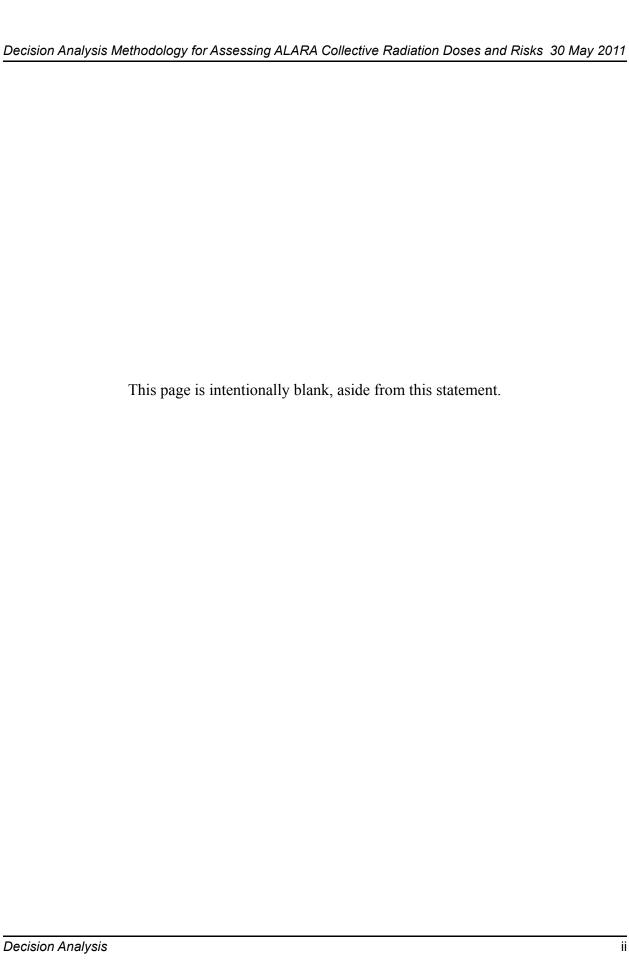
Decision Analysis (ALARA)

Decision Analysis Methodology for Assessing ALARA Collective Radiation Doses and Risks

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1 Introduction

The safe storage and disposal of depleted uranium (DU) waste is essential for mitigating releases of radioactive materials and reducing exposures to humans and the environment. Currently, a radioactive waste facility located in Clive, Utah (the "Clive facility") operated by the company Energy *Solutions* Inc. is being considered to receive and store DU waste that has been declared surplus from radiological facilities across the nation. The Clive facility has been tasked with disposing of the DU waste in a manner that protects humans from future radiological releases.

To assess whether the proposed Clive facility location and containment technologies are suitable for protection of human health, specific performance objectives for land disposal of radioactive waste set forth in Title 10 of the Code of Federal Regulations (CFR) Part 61 (10 CFR 61) Subpart C, and promulgated by the Nuclear Regulatory Commission (NRC), must be met. In order to support the required radiological performance assessment (PA), a detailed computer model will be developed to evaluate the doses to human receptors that would result from the disposal of DU and its associated radioactive compounds (collectively termed "DU waste"), and conversely to determine how much DU waste can be safely disposed at the Clive facility.

The Neptune and Company, Inc. (Neptune) white papers "Conceptual Site Model [CSM] for Disposal of Depleted Uranium at the Clive Facility" and "Exposure and Dose Documentation" detail background, issues, and methods for estimating radiation doses to future human receptors associated with DU and its decay products. The NRC specifies a clear performance goal (25 mrem/yr) that is germane to individual members of the public (MOP). This goal is the result of a complex balance of risk and feasibility, and is not specifically addressed here as it is (at present and in a practical sense) inflexible and non-negotiable.

However, the CFR (Section 61.42) also defines a second decision rule that pertains to populations as well as individuals. The regulation states "reasonable effort should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable" (or ALARA). Ionizing radiation protection limits have been utilized since the 1920s, but the concept of keeping radiation doses as low as practicable or achievable was an outgrowth of worker safety in the nuclear weapons development industry (Hendee and Edwards, 1987). The ALARA concept can be applied to either individuals or populations. In the context of the Clive DU PA, ALARA is applied to collective doses germane to the receptor populations described in the "Exposure and Dose Documentation" white paper.

The ALARA process is also described in DOE regulations and associated guidance documents such as 10 CFR Part 834 and DOE 5400.5 ALARA (10 CFR 834; DOE 1993, 1997), and in other NRC documents (NRC, 1995, 2000). The definitions in each case are very similar; indicating that exposures should be controlled so that releases of radioactive material to the environment are as low as is reasonable taking into account social, technical, economic, practical, and public policy considerations. It is also noted that ALARA is not a dose limit, but rather a process which has the objective of attaining doses as far below the applicable limit of this part as is reasonably achievable.

Unfortunately, the words "reasonably" and "achievable" in ALARA are not precise. The two words imply some degree of consideration of tradeoffs, but no clear definition is published.

Assuming that there are trade-offs, then this implies that an analysis should be performed that explicitly evaluates the trade-offs and how different disposal options, designs, or sites may differentially satisfy the objectives and resource constraints (e.g., a decision or economic analysis). Yet, at present, there is limited specific guidance on how to apply ALARA principles to the PA process.

The probabilistic Clive DU PA model is designed to estimate individual annual doses to hypothetical individuals in future populations that may be exposed to radionuclide releases from the Clive facility. The model is also able to aggregate individual doses into estimates of collective and cumulative population dose, on an annual basis as well as over the 10,000 year period of performance. Additionally, the model is able to evaluate non-radiological toxicity; e.g. associated with uranium. The remainder of this discussion will focus upon the concepts of population dose/risk and ALARA, and how these can be integrated into a Bayesian decision analysis (DA) for application to the Clive facility.

2 ALARA

The modern ALARA concept, as germane to radiation protection for both individual and population (collective) levels, was described by the ICRP in 1977 (ICRP, 1977):

"Most decisions about human activities are based on an implicit form of balancing of costs and benefits leading to the conclusion that the conduct of a chosen practice is 'worthwhile.' Less generally, it is also recognized that the conduct of the chosen practice should be adjusted to maximize the benefit to the individual or to society. In radiation protection, it is becoming possible to formalize these broad decision-making procedures."

The ICRP (1977) basically recommended a system of radiation protection that included the following principles:

- No practice shall be adopted unless its introduction produces a positive net benefit *justification of the practice*.
- All exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account *optimization of radiation protection*.
- The dose equivalent to individuals shall not exceed the limits recommended for the appropriate circumstances by the Commission *the limits of individual dose assessment*.

In other words, ICRP defined radiation protection in the context of decision analysis, at least in terms of the first two principles, considering health, economic, and social objectives; and invoked the concept of net benefit. The third principle can, instead, be interpreted as a compliance objective, so that the decision analysis can only be performed for decision options that first comply with regulatory performance objectives.

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indicating that exposures should be controlled so that releases of radioactive material to the environment are as low as is reasonable taking into account social, technical, economic, practical, and public policy considerations. 10 CFR 834 further describes the ALARA process as a "logical procedure for evaluating alternative operations, processes, and other measures, for reducing exposures to radiation and emissions of radioactive material into the environment, taking into account societal, environmental, technological, economic, practical and public policy considerations to make a judgment concerning the optimum level of public health protection". Although 10 CFR 834 is not aimed specifically at disposal of radioactive waste, the basic goals are protection of the public from DOE activities, of which radioactive waste disposal is one such activity.

NRC also provides guidance on application of the principle of ALARA. For example, although the context is different, 10 CFR Part 20 provides guidance that suggests — "Reasonably achievable" is judged by considering the state of technology and the economics of improvements in relation to all the benefits from these improvements (NRC Regulatory Guide 8.8, Revision 3, 2008). NRC also notes that "...a comprehensive consideration of risks and benefits will include risks from non-radiological hazards".

The overall implication of the various Agency regulations and guidance documents regarding ALARA is that many factors should be taken into account when considering the potential benefits of different options for disposal of radioactive waste. In order to implement ALARA in a logical system, and so that economic factors are taken into consideration, a decision analysis is implied. Decision analysis is the appropriate mechanism for evaluating and optimizing disposal, closure and long term monitoring and maintenance of a radioactive waste disposal system. Decision options for disposal at Clive might include engineering options and waste placement. More generally, if decision analysis is applied, then a much wider range of options can be factored into the decision model, such as transportation of waste, risk to workers, and effect on the environment. However, for the current Clive DU PA, the focus is on different options for waste disposal within the current proposed configuration of the Class A South embankment.

The decision analysis in this context is essentially a benefit-cost analysis, within which different options for the placement of waste are evaluated. For each option, the PA model predicts doses to the array of receptors, and the consequences of those doses are assessed as part of an overall cost model, which also includes the costs of disposal of waste for each option. The goal is to find the best option, which is the option that provides the greatest overall benefit. The consequences of risk can be measured through a simplification that is available in ALARA guidance, including NRC 1995, which provides the basis for, and history of, assigning a dollar value to person-rem as a measure of radiation dose. Prior to the NRC guidance, a single value of \$1,000 per person-rem was recommended, with the accompanying assumption that a discount rate would not be applied. The history of the selection of this value is described in NRC, 1995, and further references to prior documents. In 1995, NRC instead promoted the idea of using \$2,000 per person-rem as the relevant value, subject to present worth considerations. This appears to be an overt attempt by the NRC to allow an economic decision analysis to be performed, allowing for a discount factor to be used in the assessment of ALARA. This is made clearer in NRC, 2000, which provides examples and formulas for how to implement ALARA, which include discount factors of 7% for the first 100 years, and 3% thereafter. These are steep discounting rates that result in small costs

comparatively at 100 years into the future. DOE guidance also suggests that a range of \$1,000 to \$6,000 could be considered (DOE, 1997), but that the \$2,000 value is sufficient for most purposes. The allowable range presented by DOE, however, could be used to describe uncertainty over the appropriate value.

In assigning a value to the person-rem cost to society of radiation dose, the Agency's have short-circuited a full decision analysis. This is reasonable for a first pass at a decision analysis associated with the Clive DU PA. Hence, the value of \$2,000 will be applied, as described below. Prior to describing the specific application, a more generic discussion of decision analysis is provided.

3 Decision Analysis

A generic process for decision analysis has been described in many references, and includes the following basic steps (cf., Berry, 1995, Clemen, 1996):

- 1. State a problem
- 2. Identify objectives (and measures of those objectives i.e., attributes or criteria)
- 3. Identify decision alternatives or options
- 4. Gather relevant information, decompose and model the problem (structure, uncertainty, preferences)
- 5. Choose the 'best' alternative (the option that maximizes the overall benefit)
- 6. Conduct uncertainty analysis, sensitivity analysis and value of information analysis to determine if the decision should be made, or if more data/information should be collected to reduce uncertainty and, hence, increase confidence in the decision
- 7. Go back if more data/information are collected

This framework is iterative and flexible; e.g., sensitivity analysis can also be performed before choosing alternatives. Value-of-information analysis can be performed to help determine where further data collection will be most informative. In the case of ALARA as described in Section 2, the only disposal and design options that can be considered are those that first demonstrate compliance. If no options are identified that comply after the first pass through the decision analysis, then it might be necessary to redefine the options, or the problem. In this sense, the decision analysis process is constrained.

Generally, in a decision analysis, there are many considerations for successful applications ranging from identifying the decision makers and stakeholders, the objectives of interest for all parties involved in the decision making process, their preference structures (which attributes of the decision problem do they prefer), characterization of uncertainty in the model, and measures of the probable consequences of the different decision options. The spatial and temporal constraints on the decision are also important.

There are many technical approaches that have been used to provide some form of numerical decision support for a wide variety of decision problems (cf., Kiker et al, 2005, Linkov et al, 2009), however, only one is commonly recognized as rational and logical: Bayesian statistical decision theory, although other names have been used. The main components of Bayesian decision analysis include probability distributions that are used to capture what is known and

uncertainty about the underlying process, and specification of cost and value functions to capture the costs of each decision option that is being considered.

For an ALARA analysis of a PA, implementation of a Bayesian decision analysis requires development of a PA model for different options (e.g., different disposal options, closure options). This includes specification of probability distributions for each input parameter in the PA model so that both the best estimate and its uncertainty is accounted for, subsequent estimation of population doses from the model, and characterization of the costs of implementing each option. The cost-benefit trade-off is performed by comparing options for the risks to human health (as measured through dose), and the costs of each option considered.

In general, Bayesian decision analysis is a powerful means of facilitating decisions under uncertainty. Decision analysis models, developed properly, are transparent and easy to use, even for complex decisions. Decision analysis is also amenable to sensitivity and value-of-information analyses, which can be used to inform decision makers regarding uncertainty in the decision. That is, if the uncertainty is low enough, then confidence is high enough, and a decision can be made. However, if greater confidence is needed, then further data collection is indicated, and this is informed by the sensitivity analysis and a value of information analysis (i.e., which variables are most uncertain and have the most influence on ranking of alternatives). The idea is the reduce uncertainty cost-effectively. At some point the cost of collecting more data outweighs the benefit from the reduction in uncertainty. Then the best decision option should be selected.

4 Scope of ALARA Decision Analysis for the Clive Depleted Uranium Performance Assessment

Decision analysis in the context of ALARA is simplified for the current version of the Clive DU PA. There is one primary objective, which is to maximize human health in the context of disposal of the DU waste. The attribute of interest is dose to the receptors, which is measured in terms of millirem in a year. Note that groundwater concentrations are also of concern, but a simplification similar to the dose costs per person rem are not available for groundwater, hence, the groundwater pathway is not evaluated for this version of the Clive DU PA Model. Groundwater concentrations could be accommodated in a more complete decision analysis, however, it is also noted that groundwater at Clive is not potable, and is more saline than seawater, and, hence, has no real use. The cost consequences to human health are, consequently, negligible or non-existant.

Three decision options will be evaluated. These all assume the same basic engineered design for the Class A South embankment, but the waste is placed differently in each case. The different placement results in different dose estimates for the three types of receptors evaluated – ranchers, hunters and OHV enthusiasts. The options include 3 m of fill material under the cap prior to the first layer of DU waste, 5 m of fill and 10 m of fill. These are fully described in the *Embankment Modeling* white paper.

Assuming the cost of disposal is the same for each configuration (which might not be the case, but is a simplifying assumptions that is made for this purpose), then the differentiating factor is the cost associated with the radiation risk – i.e., the dose costs. The PA model is constructed to present both doses to hypothetical individuals and to the populations of those individuals, as described in the "Exposure and Dose Assessment" white paper. Consequently, the population

doses can be summed and presented by year. Dose costs can be associated with those population doses, with or without a discounting factor.

The is the extent of ALARA analysis that will be performed for the current Version of the Clive DU PA. Extensions that include the costs of disposal, and the varying costs for different engineered designs or waste disposal configurations can be completed for future versions.

Note also, that the evaluation that will be presented sets the stage for a relatively simple optimization of the disposal configuration for the DU waste included in the model. The engineered design includes 27 layers, each about 0.5 m in thickness, in which DU waste can be disposed. Placing the waste away from the bottom layers decreases groundwater concentrations, and placing the waste lower in the system decreases the doses. There is a middle ground in which both groundwater concentrations and doses comply with performance objectives. A reasonable goal is to place the waste optimally with respect to human health using the dose metric and ALARA principles, and groundwater concentration compliance requirements.

In terms of application of a discounting factor, it should be noted that DU has a characteristic that is different than most forms of radioactive waste; i.e., its decay dynamics result in higher radioactivity (and therefore dose) of the waste over time, as opposed to lower radioactivity associated with many other types of radionuclide decay. This perhaps has implications for whether to include a discounting factor for future benefits, risks, and costs. Population doses will be presented, and a dollar multiplier attached both with and without a discounting factor.

The overall decision scenario can be stated as in terms of the 'best' alternatives with regard to long-term disposal of DU. As a first application, the decision analysis focuses on the "best" alternatives for achieving ALARA with respect to future population doses/risks at the Clive facility. The decision analysis is presented in terms of the disposal site itself, and does not address other potentially important life-cycle issues such as interim storage, transportation, etc. However, note that the decision analysis framework could be easily expanded to address these other issues. For this decision analysis 'best' is defined in terms of overall benefit-cost in the context of the cost to reduce risk, the cost consequences of the risk, and the uncertainty associated with choosing the best option. That is, the decision problem is framed as a benefit-cost problem, but constrained by the requirement that each decision option considered must comply with the performance objectives.

Most of the inputs to the PA model are specified with uncertainty. As previously mentioned, uncertainty in the output can be evaluated to assess whether the decision can be made, or if more information might be warranted. Sensitivity analyses can determine which variables contribute most to this uncertainty, and value of information analysis can determine the 'value', in dollars, of uncertainty reduction (Morgan and Henrion, 1990, Claxton, 1999). This approach to model evaluation can be used to guide further data collection if the degree of overall uncertainty makes the decision difficult. The sensitivity analysis methods described in the "Sensitivity Analysis" white paper will be applied to the results of this simplified ALARA analysis.

5 Dose Assessment

For present purposes, as regulatory agencies have adopted and applied clear dose limits for individuals, evaluation of ALARA here will be restricted to collective doses and risks. This is appropriate in the context of design and siting of radioactive waste facilities; as it is likely, if any substantial future risks occur, that health concerns will be at a population level. Further, it is assumed that facility workers will be protected under existing health and safety regulations and guidance, and not evaluated as part of ALARA. In a complete decision analysis, however, many other factors could be considered, including health and safety of workers.

Applying formal decision analysis to the ALARA implies evaluation of the trade-off between risk reduction and the costs associated with the actions that can be taken to reduce risk and the benefits of the risk reduction. Risk in a PA is assessed through radiation dose, which is, perhaps, one of the most uncertain aspects of a PA.

Ionizing radiation protection limits have changed over time as more information regarding the negative biological effects of radiation has become available (especially after World War II). Concurrently, therapeutic and diagnostic (i.e., beneficial) uses of radiation have increased dramatically, and nuclear fission is an important source of power in most of the developed world. Thus, a tradeoff is immediately apparent; radiation can be harmful or helpful, depending upon the context.

An additional consideration are the biological endpoints of concern. Radiation in high doses kills cells (so-called 'deterministic' effects), which can be harmful or beneficial to the receptor of the doses (e.g., in the latter case, radiation is used to kill cancer cells). The effects of low doses of radiation are more uncertain. There is ample evidence that ionizing radiation can damage DNA and enhance cell proliferation in doses below those that kill cells, and thus can potentially cause cancer (so-called 'stochastic' effects).

However, it is uncertain at what low doses carcinogenicity becomes a concern (also, note that different tissues have different susceptibility). For many years, there has been a presumption in radiation protection, based upon statistical analysis of animal and human data, that ionizing radiation has a linear dose-response curve at low doses and that there essentially is no threshold of effect; i.e. any dose of radiation can result in an increased probability of cancer (this is termed the linear no-threshold, or LNT, hypothesis). This is not borne out by all experimental and clinical observation. Additionally, the fact that radiation is associated with a large number of natural sources, ranging from sunlight to radon, and the fact that multiple highly-efficient molecular and cellular defense and repair mechanisms exist, must be considered (Scott 2008). Regardless, this LNT hypothesis is the basis for most regulatory standards today. Consequently, if a PA uses the LNT approach to develop dose estimates, then the ALARA analysis essentially assumes no carcinogenic threshold of radiation carcinogenesis.

A threshold of dose effect model is, arguably, more realistic, and could be used to estimate dose and in the ensuing ALARA analysis. If ALARA is applied in the case of a threshold or "target" concentration, then the threshold would be treated as a limit on the amount of risk reduction that can be achieved by a particular management alternative. Proper evaluation of uncertainty

associated with the LNT hypothesis would be a large task in itself, but the influence of a LNT assumption could still be evaluated within the decision analysis framework.

A different sort of threshold exists with regard to natural background levels of radiation. The doses that the public receives from all environmental sources (e.g., local geology, extraterrestrial, etc.) can be quite variable. For example, people who live at a location in the US with high levels of uranium compounds in the local soil and rocks may have a much higher level of annual exposure (due to radon) than people who live at sea level with little uranium compound content of the soil and rocks (http://www.epa.gov/radon/zonemap.html). From an ALARA perspective, it might be reasonable to consider that the *incremental* population dose is of interest; i.e. the dose that is over and above background. If, instead, background is considered part of the dose assessment, then background conditions would need to be characterized. Background is not usually considered in a PA, in which case an assumption is made that the decision analysis is aimed only at risks from exposure to radioactive contaminants in the disposal facility.

Uranium and many other metals are also associated with non-radiological toxicity; e.g. kidney or liver damage. In such cases, toxicology has developed concepts such as the reference dose and benchmark dose, to account for the clear thresholds of effect that are associated with non-carcinogenic toxicity (Filipsson et al., 2003). Similar to the discussion above, in these cases the threshold can be viewed as a target, below which risks are not of substantial concern, and background risks are not considered in the PA or ALARA analysis.

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