OVERVIEW OF A FRAMEWORK FOR RISK-INFORMED DECISION-MAKING IN NMSS

Risk-informed decision-making uses risk insights, along with other important information, to assist in making decisions. Because there are many factors to consider (such as security, defense-in-depth, safety margins, and cost), using a structured process can facilitate in making transparent, comprehensive, and consistent risk-informed decisions. This attachment describes a proposed structured framework to risk-inform decisions in the materials and waste arenas.

The proposed process consists of four major steps:

Step 1. Clearly define the regulatory issue and preliminary alternative actions
Step 2. Decide whether to risk-inform
Step 3. If a risk-informed approach is to be used, perform a risk assessment as needed
Step 4. Apply risk-informed decision method

The four-step process is illustrated in Figure 1-A. Although the process is shown as a simple single-pass sequence of steps, in practice, it is an iterative process that is expected to be carried out as a coordinated team effort involving a number of disciplines and responsibilities. The staff having responsibility for the regulatory area where the issue resides should be substantially involved in Steps 1 and 2. The third and fourth steps often require assistance from risk analysts. A more detailed discussion of each of the four steps follows. The reason for this four step approach is that, unlike the reactor arena, a variability exists in the feasibility and usefulness of risk-informed regulation in material and waste programs. Hence risk-informing should be pursued in a manner adapted to each activity.

STEP 1: CLEARLY DEFINE THE REGULATORY ISSUE AND PRELIMINARY ALTERNATIVE ACTIONS.

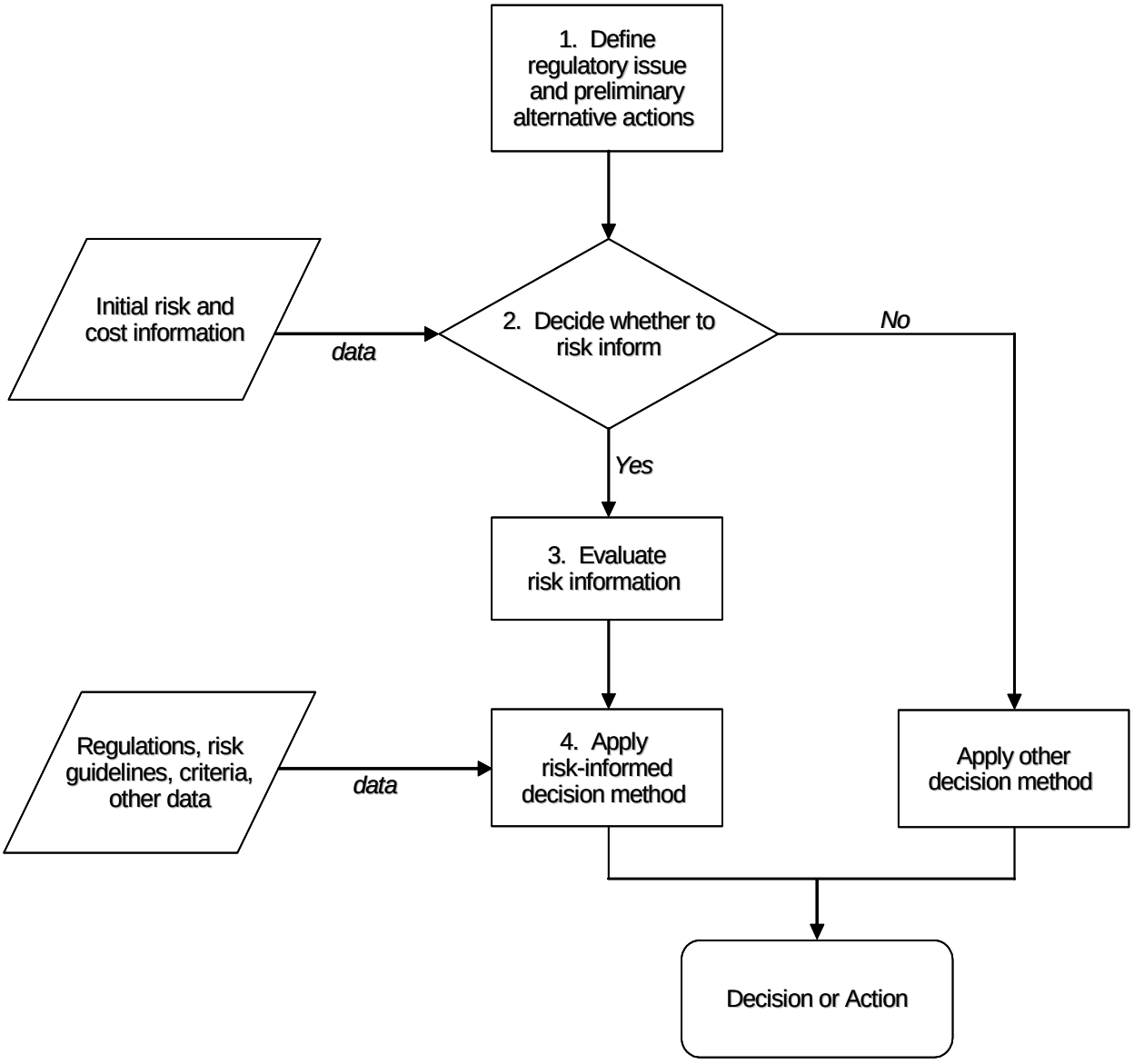
The first step in any decision-making process is to clearly define the issue or question; that is, what is the concern and how might risk information help resolve it. After defining the issue, one or more actions that might resolve the issue should be proposed. Two common alternative actions may be to impose a new safety requirement to reduce risk, or to grant an exemption or change to an existing requirement, where the concern is that risk may increase. It is typically useful to formulate a number of proposed alternative changes which can be evaluated (in Step 4 below) to determine which appears to be most effective.

STEP 2: DECIDE WHETHER TO RISK-INFORM.

After the issue has been defined and preliminary alternative actions have been identified, the next step is to review against a set of four screening considerations to determine if the choice among the alternatives should be risk-informed. Table 1-A lists these screening considerations. The first screening consideration determines whether risk information would be useful in a decision process supporting one of the Commission's strategic goals of safety, security, openness, effectiveness, and management excellence. These considerations are closely related to Step 1, that is, defining the issue and objective. If risk insights will not inform the decision process, then a risk-informed approach need not be pursued. The last three considerations ask whether developing and using the risk information is feasible, cost-effective, and not precluded by other considerations such as legal or policy constraints. The purpose of

using these screening considerations is to ensure that risk-informing is used in a cost-effective manner and is focused on the agency's strategic goals.

Figure 1-A. Overall Risk-Informed Decision-Making Process Diagram



STEP 3: PERFORM RISK ASSESSMENT AS NEEDED.

The third step is to develop or compile the necessary risk information to support a risk-informed decision. The initial task is to determine the scope of the risk assessment. The analyst needs to identify the risk metrics that need to be calculated, and the level of quality and detail needed in the risk assessment. This step does not necessarily require performing a large-scale complex probabilistic risk analysis. In some cases, risk information may already be available. In other cases, a simple risk analysis may be sufficient to yield the appropriate level of risk information. The degree of completeness, applicability, detail, and robustness in the risk assessment should be commensurate with the type of decision to be made.

It is usually important to include the uncertainty in the risk assessment results, either quantitatively or qualitatively. This information can be used in Step 4 to evaluate the robustness of the risk information in making a risk-informed decision.

Table 1-A. Screening Considerations

BENEFITS OF A RISK-INFORMED REGULATORY APPROACH

(1) Could a risk-informed regulatory approach help address one or more of the goals in the Commission's Strategic Plan? (safety, security, openness, effectiveness, management excellence)

If the answer to the above is yes, proceed to next consideration; if not, the activity is considered to be screened out.

FEASIBILITY OF IMPLEMENTING A RISK-INFORMED APPROACH

(2) Do information (data) and/or analytical models exist that are of sufficient quality or could they be reasonably developed to support risk-informing a regulatory activity?

If the answer to consideration 2 is yes, proceed to next consideration; if not, the activity is considered to be screened out.

(3) Can startup and implementation of a risk-informed approach be realized at a reasonable cost to the NRC, applicant or licensee, and/or the public, and provide a net benefit?

If the answer to consideration 3 is yes, proceed to next consideration; if not, the activity is considered to be screened out.

(4) Do other factors exist which would limit the utility of implementing a risk-informed approach?

If the answer to consideration 4 is no, a risk-informed approach may be implemented; if the answer is yes, the activity may be given additional consideration or be screened out.

STEP 4: APPLY RISK-INFORMED DECISION-METHOD.

In this step, the risk insights developed in Step 3 are used, together with other pertinent considerations, in an integrated manner to facilitate decision-making. This decision process is structured to assure that factors known to affect regulatory decisions are given proper consideration. The factors considered in this step include risk to individual workers and the public from both routine and accidental exposures, defense-in-depth, safety margins, security, cost impacts, and others as indicated in guidance on regulatory analysis. Some of these factors are considered quantitatively, such as routine and accidental exposures, while others can only be judged qualitatively.

Consideration of the risk to individuals is based on a concept of three regions of risk to individuals. This conceptual framework is shown in Figure 1-B. The framework embodies three concepts:

1) If a proposed action results in risk to individuals that is judged to be too high, this may be sufficient grounds to reject it.
2) If the resulting level of risk to individuals is in the tolerable region (and other factors are adequately addressed), then alternative actions should be preferred based on highest net cost-benefit.
3) Proposed new requirements to lower risk, when it is already in the negligible risk region should normally not be pursued.

Figure 1-B. Three-Region Risk Diagram

The three-region risk diagram is a conceptual representation of decision considerations involving individual risk. Both in theory and practice, the “lines” separating these regions are not unique and precise. In particular, in considering whether individual risk is too high (in the unacceptable region), uncertainties must be taken into account. In practice, the uncertainty is often managed by specifying a limit value that incorporates margin, by prescribing a conservative method of analyzing the risk against it, or by requiring multiple diverse preventive and mitigative measures to be in place. Thus, the practical methods chosen to implement the 3-region concept may be considerably more complex than this simple diagram.

Both routine exposure and unanticipated events should be considered in risk-informed decisions. Routine exposure is dealt with quantitatively in 10 CFR Part 20, which prescribes what is unacceptable from a regulatory standpoint, including public and worker annual dose

limits. The annual dose limits in 10 CFR Part 20 can be used as a risk-informing tool to assure that proposed regulatory actions make sense in terms of keeping individual routine dose in the tolerable region of the three-region diagram.

The principles embodied in the three-region decision framework can also be applied to managing unanticipated events. This risk involves both the frequency or probability of occurrence for each scenario, as well as the dose that would occur. Since there are typically multiple possible scenarios, risk is the sum over all scenarios of the product of frequency, dose, and probability of fatality given that dose. Thus, in the three-region framework, risk is typically expressed as frequency of fatality. Unlike the situation for routine doses under 10 CFR Part 20, unanticipated event risk limits appear only occasionally in the regulations. The Commission has not ascribed generally applicable numerical limits on this type of risk. However, limiting the risk to a tolerable level is one factor to be considered, along with others, in evaluating public safety on a case-by-case basis.

The negligible level of risk is useful as a screening tool when new regulatory requirements are to be imposed for the purpose of reducing risk. If the risk is already in the tolerable region or below, and the proposed new requirement would reduce it by an amount that is negligible, then the new regulatory requirement is unlikely to be cost-effective, and should not be pursued. Negligible risk levels are well below the limit levels of risk, and represent an insignificant addition relative to average normal risks.