

Considerations and Recommendations for Implementing the Framework

AREAS OF EMPHASIS FOR IMPLEMENTING THE FRAMEWORK

Given the scope of this undertaking, which demands a risk-assessment framework covering a diverse array of sources of threats to the health and safety of deployed U.S. forces, the approach presented in this report is necessarily broad and expressed in general terms. What has been proposed is truly a framework rather than a set of procedures or methods for actually conducting the analyses; that is, it is a structured context for organizing risk-assessment activities, ensuring their completeness, and aligning them with the motivating needs and questions.

The Department of Defense (DOD) has an extensive set of organizational units implementing a variety of sophisticated programs in which data are collected, capabilities are developed, and analyses are conducted and applied to the protection of troops. However, as mentioned in Chapter 1, it is beyond the scope of this study to review all of the current activities that comprise DOD's structure and activities for protecting the health of deployed forces. Such a review of existing practices would be valuable, however, and it should focus not only on the array of capabilities, but on an assessment of how effectively these capabilities and existing activities come together to form a comprehensive program. Even before such a review, some areas can be identified that need greater DOD emphasis.

In general, there is a natural tendency to focus attention on hazardous agents already known. Although it is important to characterize known

hazards, too much emphasis on this aspect may result in overlooking other hazards that, with some attention, could have been recognized. A good part of the motivation for examining DOD's risk efforts is to establish how to avoid surprises about the toxicity of deployment exposures and to address questions that might arise even after diligent and responsible attempts have been made to ensure the protection of troops' health. Therefore, it is important that the framework include a systematic approach to discover unrecognized potential hazards and to highlight areas with inadequate information to determine whether a potential for risk exists. Among the many exposures and activities associated with deployment, it is likely that relatively few will pose previously unrecognized threats to health and safety, but it is just as important to establish the lack of a hazard for the many cases as it is to recognize the potential hazards of the few that do entail notable risks.

A similar pitfall is to attend to the known or principal toxic effects of an agent while failing to give proper attention to delayed, less-pronounced or less-frequent adverse consequences, or previously unrecognized effects—especially those that might arise from patterns of exposure other than those that called attention to the agent in the first place. For example, a great deal of attention has been focused on the acute toxicity of chemical warfare agents and the amounts and patterns of exposure that would lead to immediate battlefield casualties if troops were to be attacked with such agents. However, rather little attention seems to have been given to the potential for delayed chronic toxicity, either as a consequence of surviving such an attack or from exposures to much lower levels of the agents, as might be experienced by many troops outside the zone where concentrations are sufficient to be of immediate military concern.

Another aspect of particular concern in deployments, and one that has arisen in questions about health consequences of past deployments, is that of co-exposure to two or more agents simultaneously, including questions about exposures under conditions of physical and psychological stress. Past experience with hazardous agents, toxicity testing, and conventional risk analysis have all focused on assessing exposures one at a time, and this course of analysis might leave one unprepared to recognize the potential hazards generated when substantial exposures to several agents are experienced together.

A final special aspect of risk analysis for deployment is the large role that risk-risk comparisons must play. Given the high level of tactical risk that might be inherent in the deployment situation, some health and safety risks may be appropriate to avoid or mitigate even greater risks. Determining how to optimize the trade-offs requires simultaneous consideration of the spectrum of risks faced by deployed troops, along with the

possibility that actions taken to avoid or ameliorate some risks might exacerbate others.

All of those factors suggest that an agent-by-agent approach—focusing on determining acceptable exposure levels to each recognized hazard—might not, by itself, be sufficient for the need to assess risks to deployed forces. The framework proposed in this report has attempted to address this issue by devoting considerable attention to analyses of the activities, materials uses, and settings of deployment, and to the recognition of the situations under which potentially hazardous exposures might arise.

The agent-by-agent approach is used to organize much of the risk analysis conducted to support environmental regulation. When hazards are recognized, they are characterized and dose-response relationships are determined. Exposure levels that are deemed acceptable are then defined. These acceptable levels are expressed as standards, and activities that might lead to exposures and control measures to limit such exposures can be assessed in relation to the standards. Also, costs and effectiveness of various control strategies can be examined and the risks and benefits weighed. This mode of analysis is most appropriate when the nature and magnitude of exposures are well established and predictable, especially when exposures are ongoing.

An alternative approach, which is the focus of the proposed framework, is to organize efforts not around the hazards per se but rather around the probable activities of deployed troops. Such an approach is most appropriate when the activities can entail a number of different hazards, especially those that might arise from the unknown course of future events. The activities are examined to understand situations when hazards might manifest themselves and the likelihoods that those situations will arise. This is because the exposures themselves are quite uncertain, and the risks of adverse outcomes are as much a product of the likelihood of events leading to exposure as of the likelihood of adverse responses given that such exposures occur.

A typical example of this approach is the fault-tree analysis of potential failures of a nuclear power plant. A fault-tree analysis includes alternative modes and amounts of releases that might occur depending on different failure events, and the different fates of released material in the environment depending on weather conditions at the unknown time of release. In such an analysis, the risk question is more about the probabilities of exposures of different numbers of people than about the health risk to a person given a certain exposure. Moreover, the whole spectrum of kinds of plant failure needs to be considered together, because adverse outcomes can arise in a number of ways.

Many of the hazards faced in deployment are best represented by this latter approach, with the assessment of risks depending as much on the

analysis of uncertain events. Moreover, a key objective is to undertake a systematic evaluation of the sources of potential adverse effects, not simply a scanning of activities and scenarios for potential incidents of unacceptably high exposure to known hazards. The chief challenge in this task is imagining the circumstances, activities, and agents—perhaps in combination—that might lead to health and safety concerns, and thus require further investigation and analysis.

These considerations suggest that a framework organized largely around analyses of activities and settings might be appropriate for the present purposes. A good deal of emphasis is placed on recognition of potentially risk-generating situations and on constructing sets of scenarios under which adverse effects could manifest themselves. Nonetheless, analysis of these scenarios requires that they be decomposed into elements that are amenable to investigation by established exposure assessment and health risk analysis tools. The four-step NRC (1983) paradigm remains at the heart of the framework, albeit expanded somewhat to consider the role of uncertainties and contingencies in the events leading to exposures.

A large armamentarium of analytical techniques appropriate to the various constituent tasks of risk analysis has been developed through extensive practice and ongoing debate among practitioners and the larger affected community over the last decades. Although the application and interpretation of these techniques for the military's purposes—and in particular for the assessment of threats to deployed forces—need to be carefully considered, this examination is best done in the context of the larger framework. The aims of the framework are to try to ensure that the methods and analyses follow from DOD's ultimate objectives and to clarify how the results obtained bear on achieving those objectives.

MEETING THE STATED OBJECTIVES FOR THE FRAMEWORK

A set of objectives for a risk-assessment framework for deployed U.S. forces was proposed in Chapter 2. The following items discuss the benefits that could be realized by implementing the framework to meet those objectives.

- By focusing on the analysis of the hazards associated with particular deployment activities, the framework aims at enhancing the efficiency with which potential threats can be identified and characterized. Moreover, it acts to tie the analysis of threats directly to the activities and settings where they may operate, and organizing the analysis to facilitate integrated study of the spectrum of hazards that need to be considered in developing improved practices and equipment. This enables and encourages the development of

plans and designs that minimize overall impact, rather than ad hoc adjustments to existing processes to ensure that this or that exposure standard is not violated. This structure encourages true optimization and efforts at continuous improvement.

- The framework proposed in this report is designed to provide a structure that ensures systematic progression through all of the tasks and requirements of the many programs and activities that DOD already has in place. It is also aimed at showing how all of the pieces fit together to contribute to the overall goals. It provides a context for evaluating the effectiveness of efforts to address the needs of the overall program.
- The framework encourages assiduous search for potential hazards and recognition of situations in which risks to health and safety might arise. There is a large emphasis on investigation, planning, and design carried out prospectively, not just in reaction to problems that might arise. By having an organized, vigorous program to identify and characterize threats, DOD can establish its interest in prevention and forthrightly address risk issues.
- The organizing principle of the framework encourages awareness of the potential risks in all activities by examining the consequences of those activities. Thus, risk considerations are not simply added on as extra requirements or constraints on design of procedures and materiel, they are an integral part of such design. The framework calls on analysts to think through all activities to identify conditions that might lead to encountering hazards, which can lead to recognition of potential but not immediately obvious risks.
- By making protection from hazards an integral part of planning and training, the readiness and capabilities produced are known to military personnel. The existence of a comprehensive program can foster confidence among the troops that their health and safety are taken seriously and that the risks they are asked to bear are minimized and justified.
- The framework provides for sample-taking and record keeping that will permit post hoc reconstruction of deployment exposures should the need arise for analysis of potential links of exposures with health outcomes. It calls for systematic procedures to gain from the experience of deployments as they occur. By emphasizing prior planning and recognizing previously uncharacterized hazards, the framework aims at minimizing the chances that consequential risk factors are overlooked, and it provides evidence that a systematic, thorough, good-faith effort is continually made to identify, characterize, and avoid sources of threats to the health and safety of deployed forces.

- The need to balance measures taken to protect against hazards with military concerns and with the other risks that these measures might engender is considered throughout the framework. By explicitly considering hazards in the context of the activities and settings in which they arise, and by considering all of the various hazardous aspects of an activity in one analysis, this framework encourages making the kind of risk-risk comparisons and optimization of design of procedures that are required to achieve protection without undue burdens. By characterizing the impacts of various levels of exposure, and not simply defining safe levels, the ability to make appropriate trade-offs is enhanced. The framework attempts to structure the risk-assessment activities to enhance the utility of the results for the risk-management process.

Implementing a framework such as that proposed in the present report is a significant challenge. It is intended that the framework provide a structure and context for organizing current DOD risk assessment activities, and is not necessarily a suggestion for developing new activities. The challenge of implementation will be to ensure that as an operating plan is developed, the conceptual organization and ties among activities that the framework attempts to foster are captured in the practical organization of the workforce, its tasks, and its missions. DeRoos et al. (1988) have provided a useful set of observations on organizing a work force for assessing environmental health risks. This includes listing the necessary skills, training, and specialization of workers, and stresses that accomplishing the larger ends is a function of the appropriate interaction of (1) the skills of personnel, (2) the definition and organization of the tasks they carry out, including appropriate interaction and teamwork among personnel, and (3) the work organization objectives. The present framework attempts to address the third aspect of developing a strategy for assessing risks in the context of the constraints and challenges of deployment. To reiterate a point made earlier in the present report, what makes the framework relevant is not the execution of each of its elements, however competently done. Only by keeping the ends and goals in mind and continually evaluating the collective effectiveness of the risk-analysis activities in meeting them will the individual component activities play their needed role in the overall program.

Risk assessment should never be a process of blindly following the results of prescribed analyses; sound analysis will always require the exercise of considerable professional and expert judgment. Risk assessment is a tool in exercising such judgment, not a replacement for it. The importance of judgment, and the need to apply it in an open and frank manner, if risk analyses are to gain wide support and public confidence,

are stressed in several recent panel reports (NRC 1994, 1996; PCCRARM 1997a,b). The recommendations below should be viewed in this light.

RECOMMENDATIONS

1. A Risk-Assessment Framework

DOD should consider the risk-assessment framework presented in this report as a basis for organizing its efforts to protect the safety and health of forces deployed in hostile environments.

The proposed framework presented in Chapter 4 constitutes the major recommendation of this report. The recommendations that follow apply to the further development and implementation of the framework.

2. Objectives for the Framework

DOD should develop an explicit list of objectives, such as illustrated in this report, for its efforts to protect the health and safety of deployed forces.

Because a risk-assessment framework for action should be designed to achieve objectives, a fully realized framework cannot be constructed until those objectives are clearly articulated. Although lofty goals are admirable and might be useful in defining a vision, simply stating a set of ideals to be striven for is not, by itself, sufficient. It is important that the objectives deal with the practical difficulties that will be encountered and set out how the conflicts among objectives will be dealt with.

The objectives should serve as part of a strategic plan for DOD to increase trust among the public and among military personnel that matters of health and safety from deployment activities are being forthrightly and competently addressed. The plan should be followed by specific, active measures.

Also, the objectives should be practical, concrete, and measurable. Measurement of progress would serve as an index to the adequacy of the framework and efforts to implement it.

3. DOD's Special Responsibilities

DOD should examine and analyze the military's special responsibilities for protection of its personnel and how these responsibilities differ from those of a typical employer, manufacturer, or regulator.

The aim here is to define what DOD's duty is regarding protection of its personnel and what it might be held accountable for in retrospect.

These matters are as much moral, social, and philosophical as they are technical, and the question should be approached accordingly. The risk-assessment framework should then be refined to reflect those special responsibilities.

Issues to be considered include the unusual degree of control the military has over the actions and exposures of its personnel; the need to call for individual troops to put life, limb, and health at risk in the interests of the military mission and the nation at large; the problems of trading off possibilities of health effects in later life with immediate risks of casualties and impacts on military mission or military capabilities; and other matters in which the equity and voluntariness of risk-bearing arise.

If the risk analysis is to effectively contribute to such decisions, it will require an articulation of a doctrine on how risk trade-offs are to be considered. In addition, DOD should attempt to articulate a set of principles on how the balance of long-term risks to the troops and risks to the military mission should be approached. This effort should also address the nature of responsibilities for the post-deployment and post-career health of personnel, and appropriate standards for treatment or compensation of personnel who are possibly affected by exposures to hazards suffered during deployment.

4. The Capacity to Recognize New Hazards

DOD's efforts to assess risks from deployment activities should include a substantial effort to recognize previously unappreciated hazards and to examine the activities and potential settings for deployment to determine where hazards might arise.

Although more fully characterizing known hazards and the circumstances under which they arise is essential to effective mitigation of risks, these efforts should not blind the program to the possibilities of novel hazards. Attention to this task is essential for providing for measures to reduce the chances that exposures come into question after the fact, as well as for meeting those cases that might nonetheless arise with evidence that appropriate diligence in evaluating safety issues was exercised. Activities and settings of potential deployment should be pursued by systematically examining the contexts in which exposures that need investigation might arise.

5. A Full Consideration of the Toxic Effects of Harmful Agents

DOD should attend to all of the effects of a hazardous agent, not only the principal ones or those that called attention to the agent as a hazard in the first place.

In particular, attention should be paid to the possibility that long-term or delayed chronic effects might result from exposures to agents that are examined mainly for their acute toxicity. Frequently, the possibility of such latent effects has been poorly examined, but the lack of data should not be confused with a presumption that no effects exist. The natural tendency to regard acutely toxic agents only as potential sources of immediate casualties should be tempered by this realization. Another important consideration is low-level exposure as a possible cause of chronic toxicity.

6. Extrapolating Information on Toxic Effects

DOD should continue to conduct research and develop methods to improve its capabilities to extrapolate information on toxic effects to address the full variety of magnitudes, durations, patterns, and co-exposures that might be encountered during deployment.

The problems of extrapolating toxic effects across different patterns of concentration and time are particularly important to the assessments the military must carry out. Exposures can range from a single event to chronic exposures over long periods. Similarly, possible effects can become apparent over different times, including rapid response and long-delayed response.

7. Psychological and Physical Stress

Risk-assessment methods need to be developed to characterize and predict effects of stress, so that this dimension can be integrated into the analysis of the spectrum of threats faced by deployed forces.

The roles of psychological and physical stress in potentiating or exacerbating the toxicity of physical, chemical, and biological agents and as hazards in their own right are not well understood, but their role in the deployment situation is potentially large. DOD has an opportunity and a need to become a leader in the study of stress and its interaction with toxicity. Moreover, stress itself as a sufficient cause of adverse health effects is relatively poorly understood despite substantial and convincing evidence that it is common among deployed troops.

8. Microbial Agents

DOD should conduct research and develop methods to assess risks from exposure to microbial agents and should strive to characterize the variety of disease organisms—and troops' vulnerabilities to them—that might be encountered around the world.

Despite recent major advances, the ability to assess quantitative risks of adverse health outcomes from exposure to microbial agents is in need of further research and development of methodology, an area in which DOD could play a large role that would also be of service to the larger risk-assessment community. This would permit the incorporation of microbial threats into risk-risk tradeoff comparisons.

9. Anticipating Potentially Harmful Exposures

Intentional or unintentional exposures that result from the procedures, equipment, and activities associated with maintaining a presence in an unusual environment should be scrutinized for potential threats to the health of deployed troops.

Many and perhaps most of the hazards encountered during deployment are ascribable to the activities, agents, and materials of deployment per se or to the risks inherent in the tasks of the military mission. DOD should continue its efforts to document hazards associated with places around the globe as a contingency for possible future deployments. This should include documentation of the use and storage of toxic industrial chemicals, identification and characterization of indigenous infectious diseases, and descriptions of local environmental pollution and contamination. It should also include assessments of hazards posed by terrain and infrastructure and the accumulation of climate, meteorological, and hydrological data for use in fate and transport modeling of potential releases.

10. Exposures to Mixtures

DOD should undertake special examination of patterns of co-exposure.

Deployment might entail simultaneous exposures to a number of hazards, and possible toxicological synergism among agents has played an important role in debates about health effects among veterans of past deployments. This is a rising issue in the arena of risk assessment generally, raised by mandates of the 1996 Food Quality Protection Act. DOD has an opportunity and a need to be a leader in developing approaches to this question, including practical means to identify important co-exposures, methods for assessing cumulative risk, and approaches to testing for health effects resulting from co-exposures. Consideration should be given to the role of prophylactic substances that might be part of the combined exposures.

11. Exposure Scenario Development

In cases of hazardous agents for which the possibility and degree of exposure to troops is uncertain due to dependence on circumstances and events that vary

widely from case-to-case, DOD should create scenarios describing the possible chain of events leading to exposure to troops.

For many hazards of interest in the assessment of risks to deployed forces, the key question for analysis is not about the health effects of a certain exposure, but about the likelihood that the events will produce that exposure. DOD should consider approaching such questions by creating scenarios describing the possible chains of events leading to exposures of troops, and then quantitatively assessing the likelihood of alternative courses of events, as further described in Chapter 4. There may be some advantage in using a standard set of scenarios for broad classes of hazards, with additional details as needed for specific hazards.

12. Biological Markers

DOD should conduct research on developing appropriate biological markers of exposure and effect for surveillance of those exposures that are of particular relevance to the deployment setting.

13. Identifying Different Degrees of Exposure and Impact

As an aid to quick decision-making when emergencies arise from particular hazardous exposures, DOD should identify a series of exposure levels and durations at which individuals are expected to begin to suffer progressively severe effects.

To be useful for assessing settings in which some levels of risk must be borne, it is necessary that quantitative risk analysis not confine itself to identification of safe or acceptable levels of exposure alone; it is also necessary to characterize the different degrees of impact that one might expect at levels of exposure that exceed levels that would normally be thought of as safe. A simple scheme such as that suggested by Rodricks (1999) should be considered, in which exposure levels are identified that begin to produce adverse effects of different levels of severity in some individuals among an exposed group. This approach captures the main features of the quantitative relationship and provides a quick guide that is useful in making time-critical judgments regarding risk trade-offs, an important ability in the deployment context. For such guides to be effective in practice, a clear layout of decision-making responsibility and authority is necessary.

14. A Risk-Management Framework

DOD should consider developing an explicit framework for risk-management decision-making.

A risk-management framework would bring the risks characterized by the risk-assessment framework proposed in this report to bear on the improvement of procedures, doctrine, and materiel to diminish unnecessary risk as far as possible; to reduce risks that cannot be avoided; and to make rational, informed decisions about how to optimize action in the face of risks and uncertainties that cannot be eliminated. The tools of operations research and decision analysis are applicable, including value of information analysis, benefit-cost analysis, cost-effectiveness analysis, and multiattribute utility theory.

15. Determining Whether DOD's Objectives Are Met

In considering the present proposed framework for assessing risks to the health and safety of deployed forces, DOD should review its existing activities in this area and determine the degree to which they fulfill its objectives.

It is important, however, to go beyond an accounting of the component activities; it is necessary to assess the way in which the various activities come together to address all aspects of protecting the health and safety of deployed forces and to determine how the objectives are being addressed. As stated at the outset, the technical procedures are merely the means to an end. The technical results must be thoughtfully and vigorously applied to the achievement of the articulated objectives.