

The Nature of Risk Assessment and Its Application to Deployed U.S. Forces

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ABSTRACT

An analytical framework applicable to the assessment of the wide range of risks to health and safety potentially encountered by U.S. forces deployed to unfamiliar environments is presented as a guide to experts involved in the evaluation of diverse information on specific hazards. Adherence to the guidance should ensure that risk assessment results are clearly and consistently presented, and that they are suitable for practical, risk management decision-making. The analytical framework presented is that first described by the National Research Council in 1983 and long in use for assessing risks of hazardous conditions, substances, and agents (referred to collectively as “stressors”). This paper attempts to describe how the analytical framework can be applied in diverse situations, and to many types of stressors (pathogens, toxic chemicals, physical hazards, etc.). The framework for risk assessment, as originally conceived by the NRC, is a guide to the organization and evaluation of information and its attendant uncertainties, and does not require specific methodologic approaches; the methodologies used should be those appropriate to the relevant scientific disciplines (e.g., toxicology, microbiology, etc.). The framework offered in the paper includes a means for reduction of complex information to usable formats. It recognizes that the purpose of the risk assessment process is not to set standards that can be used for “yes-no” decision-making. Rather, in the current context its purpose is to allow DOD decision-makers sufficient information to examine a range of risks that might arise in rapidly changing deployment conditions, and to balance competing risks so that overall risks to deployed forces can be minimized.

INTRODUCTION

The National Research Council (NRC) is undertaking a project with the objective of providing advice to the Department of Defense (DOD) regarding strategies to protect the health of military

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personnel when they are deployed to unfamiliar environments. Such deployments might result in the exposure of U.S. forces to chemical and biological agents of war, and to other substances released by enemy forces with the intention of causing harm. Moreover, U.S. forces might also become exposed to a variety of infectious agents, environmental contaminants, and conditions of stress not necessarily arising from battle but nonetheless associated with the environments to which they are deployed.

Protection of deployed forces requires an understanding of the risks of disease and injury they face and the development and implementation of strategies to mitigate those risks. The necessary understanding of health risks arises out of the process of risk assessment. Development and implementation of strategies to mitigate risks falls within the domain of risk management. This paper offers a description of the conceptual and scientific basis for risk assessment, the types of knowledge and data necessary for its conduct, the accommodation of scientific uncertainties within its conduct, and the various ways in which risk-assessment results can be used in risk-management decision-making. In addition, the paper describes the specific problems encountered in the application or risk-assessment methodologies to the evaluation of risks faced by deployed forces. The overall purpose of the paper is thus to provide a broad, analytical framework for the assessment of the wide range of health risks potentially encountered by forces deployed to unfamiliar environments. The framework is expected to serve as a guide to experts involved in the organization and evaluation of diverse information on specific threats. The purpose of having such a guide is to ensure that risk-assessment results are clearly and consistently presented, and that their means of presentation are suitable for practical, risk-management decision-making. It is noted here, and discussed more fully below, that the analytical framework for risk assessment to be presented is not intended to replace the scientific evaluations and judgments of experts in the specific technical areas coming under discussion. Rather, it is only to serve as a guide for the systematic organization and evaluation of technical information and uncertainties, so that clarity, consistency, and practicality are achieved in the manner in which risk-assessment results are presented.

The paper is concerned with risk management only to the extent that it offers a discussion of how risk-assessment results might be used to achieve various degrees of health protection. Issues such as the options available for achieving risk-management objectives are outside the scope of this paper. Guidance documents for risk management have been developed by several branches of the DOD (Naval Safety Center 1996; Department of the Air Force 1998; Department of the Army 1998). The concepts and terms adopted in those various documents are broadly consistent with those used in this document.

The basic analytical framework presented in this paper is one long in use for assessing health risks of hazardous conditions, substances, and agents (NRC 1983, 1994). It will be seen, however, that under this framework, risk-assessment results might be expressed in different ways. Because risk assessment is a tool for practical decision-making, the specific means for describing results should be those most helpful to the ultimate users of the information, the risk managers. This paper proposes an approach that would seem to be suitable for decision-making in the context of troop deployments, but it would be recognized that alternative approaches, under the same analytical framework, exist. It is expected that some modifications in the approach offered here are expected as the NRC project develops, and as alternative risk-management options come under review.

GENERAL NATURE OF RISK ASSESSMENT

Basic Definitions and Concepts

Risk is the probability that adverse effects will occur under specified conditions. In the context of risks to human health, adverse effects manifest themselves as specific diseases or as injuries to the

structure or function of the human organism. The nature and magnitude of the risks associated with substances in the environment vary both with the nature of the substance and with the conditions of exposure to it. The conditions of exposure that determine risk usually include the magnitude, duration, and frequency of exposure to the substance, and often also includes the route of entry into the body. In the present context, and for ease of exposition, the term “stressor” will be used to describe any and all chemical, biological, and physical entities in the environment that might, singly or in combination, pose risks to deployed forces.

Risk assessment is the process through which an understanding of risks is acquired (NRC 1994). The term might be used in two somewhat different contexts. First, it might be used to describe an actual scientific investigation of a group of individuals exposed to a specific stressor for the purposes of determining whether the individuals are at excess risk and, if so, the magnitude and nature of their risk. Second, it might be used to describe the attempt to predict risks in individuals that are not the subject of study, but who might become exposed to stressors that, under other conditions, are known to pose risks. Predictive risk assessment, which is the subject of the present paper, necessarily involves the use of risk information collected under one set of conditions (including information collected in experimental settings), together with a number of science-based inferences, to describe risks that might exist under other conditions (e.g., under conditions expected to be experienced by deployed forces). Predictive risk assessment is necessary if the goal is to protect human health. It is the only means available to describe the conditions of exposure that should be avoided if human health is not to be put at significant risk, or to understand the nature and magnitude of the risks created when exposures become excessive. Human health protection can be achieved only if knowledge of these conditions is acquired in advance of exposure (Rodricks 1994).

Risk management is the term used to describe all activities involved in the development and implementation of risk-mitigation strategies. It involves decisions regarding risk acceptability and trade-offs in specific circumstances, risk avoidance goals, and the technical means for achieving them. Risk management relies upon the results of risk assessments, but involves consideration of other factors, including new risks that might arise when decisions are made to avoid certain risks (risk trade-offs). Risk management is a very large subject, and a complete discussion of it requires detailed understanding of the circumstances under which specific populations (in this case, deployed U.S. forces) might face risks. As such, it is largely outside the scope of this document.

These definitions and concepts were first proposed in 1983 by a committee of the National Research Council, which issued a report entitled *Risk Assessment in the Federal Government: Managing the Process* (NRC 1983); another committee of the NRC, in a report issued in 1994, *Science and Judgment in Risk Assessment*, reaffirmed these concepts. The definitions and concepts are now widely recognized in the risk-assessment community, and, as will be shown, are applicable to the problem at hand.

Framework for Systematic Organization and Evaluation of Knowledge and Data

Risk assessment, in its predictive mode, does not create new data and knowledge. Rather, it is the attempt to organize existing information and knowledge in useful and clear ways, so that inferences regarding risk can be made. It draws upon knowledge and data developed within the basic scientific and technical disciplines—epidemiology, toxicology, pathology, microbiology, medicine, and biostatistics, and also all of the disciplines involved in evaluating human exposures to environmental agents—and seeks to organize that information in systematic ways, consistent with the standards of those disciplines. Scientific evaluation of that organized information is left to experts in the relevant disciplines, although

risk assessment requires that the bases for conclusions reached regarding the available data be explicitly justified and described. Risk assessment also requires that all significant scientific uncertainties in the available information be described and accounted for.

Risk assessment does not require any specific methodological approach to data evaluation, but it does require explicit justification of data choices, methodologies, and of the treatment of scientific uncertainties (NRC 1994). Most of the remaining sections of this paper are devoted to a discussion of how these goals can be achieved, drawing upon precedents established in other areas in which risk assessment has been used in decision-making, but with due consideration of the special needs of the present context.

General Content of Risk Assessment

As described by the NRC (1983, 1994), all risk assessments, irrespective of the stressors and situations to which they are to be applied, contain the same types of information and analysis. The NRC also proposed that, for the sake of clarity, the information should be organized in a specific way. Thus, all risk assessments involve, as a first step, a careful description of the specific stressors of concern, and the specific groups of individuals that might become exposed to those stressors. Once the stressors and population groups that are the subject of the risk assessment are specified, information is collected regarding the following questions (see Figure 1):

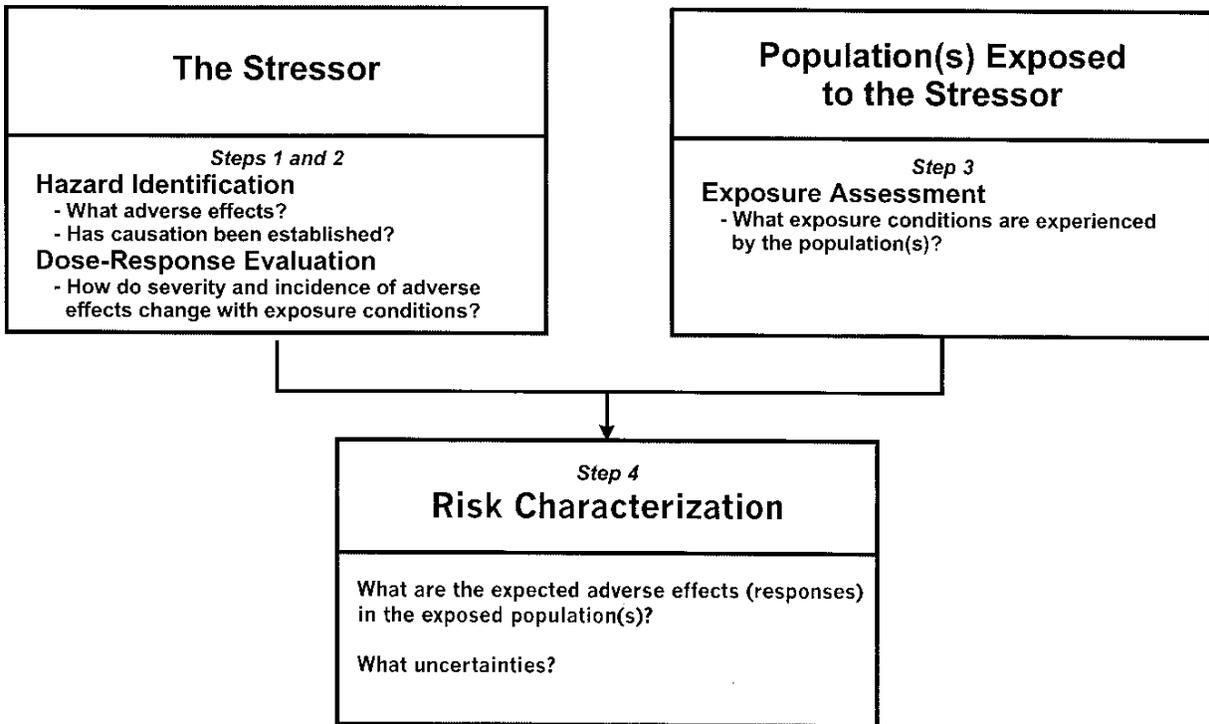


FIGURE 1 Risk assessment involves systematic organization and evaluation of data.

Step 1: Hazard Identification. What types of adverse effects have been shown to be associated with exposure to the stressor? For each effect, how well has a causal association been established? If hazards have been identified in experimental (animal) models, are the findings likely to be relevant to humans?

Step 2: Dose-Response Evaluation. For each type of adverse effect (hazard) associated with exposure to the stressor, how do the severity and incidence of those effects (responses) change as the conditions of exposure (dose)² to the agent change?

Information regarding these first two steps is specific to the stressor, and is typically to be found in the scientific and medical literature. The results of the hazard identification and dose-response evaluations are then integrated with the results of:

Step 3: Human Exposure Assessment. Under what conditions are the individuals of concern exposed or potentially exposed to the stressor? “Conditions” includes consideration of those factors (dose size, duration, frequency, route of entry) that, based on Step 2, are known to relate to response.

The result of the integration of results from Step 3 with those from Steps 1 and 2 is a description of the risks of adverse effects in the exposed population—the nature, severity, and incidence (probability) of adverse effects expected in the population under its actual or expected conditions of exposure. The NRC chose to label this fourth step in the assessment process as a risk characterization, because this term best reflects the fact that accurate and precise quantitative estimates of risk, though desired, are rarely achievable because of limitations in knowledge and data (NRC 1983). The NRC envisioned that risks would be described quantitatively, when possible, but always accompanied by qualitative descriptions of factors not readily quantifiable. Indeed, in some cases only qualitative characterizations of risk will be possible.

Although all assessments contain these four steps, they need not proceed in the order shown in Figure 1. This matter will be further discussed in connection with the discussion of the uses of risk-assessment results.

Need to Deal with Scientific Uncertainties

Although the logic in the organization of information for risk-assessment purposes is apparent, the difficulties encountered in attempts to complete a risk assessment are often formidable. Indeed, many of the questions that need to be considered to complete an assessment cannot be completely answered with available knowledge and information. Typical questions include the following:

1. How do hazard and dose-response data collected in one population group apply to population groups having a different range of susceptibilities to the agent?
2. How do hazard and dose-response data collected in experimental systems apply (if at all) to human populations?
3. How do hazard and dose-response data collected over a given period of exposure, or a given route of exposure, apply to populations exposed over different time periods or exposure routes?
4. Is it possible to predict response (risks) at doses that are lower than the minimum dose at which risks can be measured? (All risk measurement systems have limited detection power, and cannot detect many small-to-moderate-sized risks.)

²The NRC, and now common usage, refers to this step as a dose-response evaluation, but it is clear that the term “dose” is intended to be applied broadly, to include all measure of exposure relevant to the response. A more descriptive term might be “exposure-risk evaluation.”

5. What measures of dose (what conditions of exposure) provide the most accurate prediction of response (risk)?

6. How can population exposures be described based on data limited to discrete segments of the population, or limited to specific points in time?

It is often the case that well-documented answers to questions such as these are not available. Because it is not possible to complete risk assessments without providing answers to such questions, it must be recognized that risk-assessment results are necessarily uncertain, and specific assessments are uncertain in rough proportion to the number of unanswered questions that arise in the course of their conduct (Bogen 1990; Finkel 1990).

The NRC (1983) has emphasized that any attempt to provide answers to questions for which there is limited empirical support must be recognized as at least partially based on what was called a “science policy” choice. The NRC committee promoted the use of science policy choices, as long as the specific choices to be used were explicitly described, and used consistently in all risk assessments; such choices thus become “default options,” to be used when knowledge or information is highly limited.

Regulatory agencies such as the U.S. Environmental Protection Agency (EPA) have prepared guidelines for risk assessment that describe the defaults to be used. Some critical regulatory defaults are presented in Text Box 1 (Barnes and Dourson 1988; EPA 1996). Many of the defaults presented in Text Box 1 are used by agencies such as EPA and the Food and Drug Administration (FDA), when their concern is the general population. For occupational groups, additional considerations enter the picture and often lead to somewhat different choices (discussed later).

The insertion of specific factors to account for uncertainties—such as the factors of 10 used to deal with variability in responses to toxicity (Defaults 4 and 5, Text Box 1)—has become common practice in risk assessments. These uncertainty factors, and the criteria for their selection, are critical components of any risk assessment (Barnes and Dourson 1988), and they will require considerable discussion within the context of risks to deployed forces. The examples given in Text Box 1 are not all relevant to the risk questions posed in this paper, and are presented only to make clear the need to consider such factors. A final point on the issue of uncertainty in risk assessments is that the regulatory defaults listed in Text Box 1 are offered in the absence of data relevant to specific stressors. Thus, in all specific cases, actual data, when sufficient, override defaults (also discussed later).

TYPICAL USES OF RISK-ASSESSMENT RESULTS

General Nature of Decision-Making Based Upon Risk-Assessment Results

Heretofore most decision-making based on risk-assessment results has taken place in the context of the regulation of chemical and radiation risks. Both the general population and occupational populations have been the subjects of such regulations. In most cases risk-management decisions have resulted in some type of numerical standard, usually limiting the allowed concentration of an agent in a specific environmental medium. With respect to the use of risk-assessment results in such regulatory standard-setting, the process is generally the following (NRC 1983):

1. Risks under current exposure conditions are estimated.
2. A risk-reduction goal is established.
3. The exposure level that corresponds to the risk goal is estimated.
4. The level estimated in Step 3 is the maximum level of exposure allowed in the population to be protected.

TEXT BOX 1

Some Defaults Used by Regulatory Agencies for Toxicological Risk Assessments.

1. In the absence of data demonstrating their irrelevance, animal toxicity data will be used to estimate human risk.
2. In the absence of data demonstrating their irrelevance, data from the most sensitive animal model will be used.
3. Human data are preferred to animal data for purposes of human risk assessment, but only if those data are adequate (i.e., sufficient to establish causation, and sufficient to provide quantitative dose-response data).
4. In the absence of data suggesting another factor, average humans will be assumed to be ten-fold more sensitive than experimental animals (not used for carcinogens, see below).
5. In the absence of data suggesting another factor, the “most sensitive” humans will be assumed to be ten-fold more sensitive than the “average” human.
6. All forms of toxicity other than carcinogenicity will be assumed to exhibit thresholds.
7. In the absence of data to the contrary, all carcinogens will be assumed to pose risks at all nonzero exposures, and their risks will increase in direct proportion to cumulative lifetime dose.

Descriptions are those of the author. Many defaults listed here are meant to apply to the general population, not to occupational populations. (See text for references.)

5. Standards, expressed as concentrations in air or water or food or soil, or in all of these media, are calculated so that the maximum allowable exposure level is not exceeded in populations exposed via these media. (Discussions of how these goals are to be achieved, and how compliance with them is measured, are outside the scope of this paper.)

It can be seen that the first two steps—the conduct of the risk assessment and the risk-reduction goals—are the critical components of this process. In the context of regulations, it is possible to make certain generalizations about these two steps. First, risk assessments for the general population have often involved different uses of available data and different default assumptions than have risk assessments directed at occupational groups (NRC 1994). It has been assumed that, because they generally involve healthy adults and do not include the most vulnerable segments of the general population, occupational populations are likely to display less variability in response to hazardous agents than do members of the general population. Second, with respect to risk-reduction goals, regulators have sought to ensure that none of the adverse effects of the agent will occur in the populations to be protected and accordingly, have sought to reduce risks to levels thought to be negligible or insignificant (Rodricks 1992). Finally, in many cases, the selection of risk-reduction goals is influenced by considerations other than public health protection—technical feasibility, costs—that are dictated by the requirements of applicable laws.

The model for using risk-assessment results described above is not the only possible one, and is probably not the most useful one for decision-makers who are asked to protect the health of deployed forces.

Model I (NRC 1983)	Model II (Alternative)
<p style="text-align: center;">Assess risks of current exposures.</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Determine whether risk is excessive. If yes, identify risk-reduction goals.</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Estimate maximum allowable exposure levels, based on identified risk reduction goal.</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Establish standards (limiting concentrations) so that maximum allowable exposure levels are not exceeded</p>	<p>First,</p> <p style="text-align: center;">Anticipate exposure to identified stressor.</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Conduct hazard and dose-response evaluation</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Record hazard, dose-response evaluation in readily usable format.</p> <hr/> <p>Second,</p> <p style="text-align: center;">Estimate expected dose^a of stressor in population.</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Compare dose estimate to hazard, dose-Response information recorded above.</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Determine risk expected in population.</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">If relevant, compare risks of different actions.</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Determine action to be taken to minimize overall risk.</p>

^aDose is short hand for all conditions of exposure expected to determine risk.

FIGURE 2 Two models of risk-based decision-making.

Alternative Decision-Making Models Based on Risk-Assessment Results

The model for decision-making described above is applicable when populations are already exposed to a source of risk, and a determination is made that current risks are excessive and need to be reduced to insignificant levels, that is, levels that are likely to protect against any of the adverse effects of a stressor. An alternative model is designed to deal with anticipated, not current, exposures. In such circumstances (which arise in some regulatory contexts in which premarketing approvals for certain products are required), the hazard identification and dose-response evaluation steps of a risk assessment are completed for the agent of concern. These steps of the assessment yield a description of the nature of the adverse effects associated with exposure to the agent and the relationships between the severity and incidence of those effects (response) and the dose (conditions of exposure).

This information can be presented to risk-management decision-makers. These decision-makers are then presented information on the conditions of exposure experienced by the populations of concern: their exposure conditions might be estimated based on anticipated modes of contact with the agent, or based on actual data pertaining to such contact. Faced with information on conditions of exposure (either anticipated or actual), risk-management decision-makers can refer to the hazard and dose-response assessments and determine the nature and extent of risk to be incurred by the population they are charged with protecting. At this stage, decision-makers might then evaluate various options for risk

mitigation, and (in the ideal case) choose that which provides the greatest degree of health protection, given the circumstances in which the decision needs to be made.

The two models for risk-based decision-making are outlined in Figure 2. As discussed in the next section, it is the second model (Model II, Figure 2) that would appear to be the most applicable to the problem of risks to deployed forces.

RISKS TO DEPLOYED U.S. FORCES: OVERVIEW OF PROPOSED ASSESSMENT AND MANAGEMENT FRAMEWORKS

Forces deployed to unfamiliar environments might face a range of battle-related risks, including those related to chemical and biological warfare agents, and additional risks of infectious disease, exposure to chemical contaminants in air, water, food, and soil, and a variety of physical threats, including those associated with accidents and explosions, and with certain forms of ionizing radiation, and with excessive heat, cold, and noise. Even certain medical treatments designed to protect forces from certain risks might, themselves, pose other kinds of health threats (Medical NBC Battlebook, U.S. Army Center for Health Promotion and Preventive Medicine). Forces might be exposed to some of these sources of risk only infrequently but in other cases might be exposed continuously through the period of deployment. Several sources of risk might be experienced simultaneously. Actions taken to avoid certain sources of risk might result in exposure of forces to other sources. The situation is complex, and can be managed effectively only if suitable risk-based decision models are in place and their characteristics understood by decision-makers.

The risk-assessment framework described in the foregoing is, it will be suggested, suitable for organizing and evaluating all of these many types of health threats to deployed forces. It will also be suggested that Model II of risk-based decision-making, described in Figure 2, will be most useful for the protection of deployed forces.

Following is a broad overview of how the risk-assessment framework and decision-making model might be applied to each of the types of threats that might be encountered by deployed U.S. forces. Later sections will detail each of the steps outlined here. In outline form, the proposed framework is as follows:

1. Identification of all stressors of possible concern, and elaboration of their sources and pathways to deployed forces.
2. Development of hazard and dose-response information for each stressor, and presentation of information in a usable format.
3. Development of methods for estimating doses³ of stressors anticipated for or incurred by deployed forces.
4. Estimation of risks to deployed forces and application of decision-making criteria developed with the goal of maximizing health protection, consistent with the circumstances under which risks are encountered.

The guidance offered here pertains to the requirements of risk assessment, and does not deal with specific methodologies that properly fall within the fundamental scientific disciplines upon which risk analyses depend. The emphasis in risk assessment is on clarity and completeness of presentation, explicit consideration and accommodation of scientific uncertainties, and usable presentation of risk

³As in the earlier text, the term dose is used for ease of exposition. In the context of discussions of specific stressors, its characteristics are influenced by whatever measures of exposure are relevant to the risk being assessed.

results. The guidance is thus offered to ensure consistency, explicitness, and usability; the quality of the underlying scientific information and knowledge, and the appropriate methods for evaluating it are judgments reserved for experts in their particular, relevant disciplines. Those experts, it is hoped, will not see risk assessment as a rigid methodology requiring specific methods of scientific evaluation, but rather as a systematic framework for organizing information and for forcing a high degree of explicitness in the treatment of that information and the uncertainties in it, and for producing usable results.

STRESSORS OF CONCERN AND THEIR SOURCES AND PATHWAYS TO DEPLOYED FORCES

Definition of Stressors

For ease of exposition, stressor has been adopted to apply to all entities and environmental conditions that might threaten deployed forces. No single term is clearly appropriate to describe all such entities and conditions, but this term is arbitrarily selected for convenience. A list of the types of agents of concern as potential threats to deployed forces is presented in Table 1. The types of hazards usually associated with each stressor are also listed; further descriptions of the process of hazard identification, the first step of the proposed risk-assessment framework, is offered in the following section. Implementation of the risk-assessment strategy proposed here requires a listing of all specific stressors of concern, and not simply the broad categories listed in Table 1.

Sources of Stressors and Pathways of Human Exposure

Under the risk-assessment framework presented here, complete evaluations of how and to what extent deployed forces might become exposed to these types of stressors are conducted within the exposure assessment step, described more fully later. It is important, however, that some characterizations of the sources of these stressors, the possible pathways by which deployed forces might become exposed, and the nature of their expected exposure accompany their initial listing. It is also advisable to list stressors in approximate order of the frequency with which deployed forces are expected to encounter them, and in order of their degrees of danger. This initial listing is a useful guide to the hazard and dose-response evaluations. It can be used to set priorities for the conduct of hazard and dose-response evaluations, so that efforts at information gathering and analysis are first directed at what will likely be the highest risk stressors and exposures.

In addition, these initial characterizations of exposure will assist in identifying the types of hazard and dose-response information most relevant to the expected conditions of exposure. Thus, for example, little effort need be devoted to inhalation toxicity data for chemicals that are likely to reach deployed forces only through drinking water, and little effort need be expended researching for chronic hazard information for stressors that forces are likely to encounter only rarely and for very limited periods of time.

DOD has already assembled much information regarding stressors, their sources, and the ways in which forces might encounter them (The Medical NBC Battlebook, The U.S. Army Center for Health Promotion and Preventative Medicine). This information is no doubt the appropriate starting point for the proposed risk assessment. As steps are taken to complete the hazard identification and the dose-response evaluation, it becomes necessary to ensure that risk-assessment criteria for organizing and drawing inferences from data are met.

TABLE 1 Types of Stressors That May Pose Health and Safety Risks to Deployed U.S. Forces

Stressors ^a	Hazards to be Considered
Chemicals	Toxicity, flammability, explosivity, radiation
Pathogens	Infections, infectious diseases
Toxins ^b	Toxicity
Medicines	Side effects
Physical structures	Traumatic injuries from accidents
Moving vehicles	Traumatic injuries from accidents
Environmental conditions	Physical, psychological stresses

^aThe term “stressors” is the author’s, used for convenience (see text).

^bToxins are chemicals produced by microorganisms, plants, and animals and are typically large (and often not very stable) molecules such as peptides and proteins; it might be necessary to treat them separately from other chemicals, because of the pathways by which they might reach deployed forces.

Source: The Medical NBC Battlebook, The U.S. Army Center for Health Promotion and Preventive Medicine.

HAZARD IDENTIFICATION

Definition

Under the risk-assessment framework proposed here, the hazard identification step involves a description and critical scientific review of the available data concerning the types of adverse health effects (diseases or injuries) that have been associated with exposures to the stressor under consideration. All stressors in the environment can, under some conditions, cause harm to health (i.e., pose hazards) and most can cause different types and degrees of hazard as exposures change. Whether one or more of the hazardous properties of a stressor will be expressed in groups of deployed forces can be ascertained only after the remaining steps of a risk assessment are completed. The purpose of this first step is to describe and catalog for each stressor of interest the types of hazards that have been associated with it, under any conditions; such a thorough catalog ensures that no hazard potentially relevant to risk assessment will be overlooked.

The Problem of Causation

The ease with which a causal relationship between a stressor and a particular health hazard can be established depends upon many factors, including the nature of the stressor (whether it is a well-characterized single substance or a complex mixture), the nature of the hazard (whether it is one that appears immediately after an exposure, or only after a long delay), and the extent and nature of scientific investigation it has received (whether information derives from case reports, from epidemiological studies, or from experimental studies). A few stressors have received significant and intensive study, most have received limited study, and some have not been studied at all. All of these factors are to be considered in judgments regarding the evidence for causation.

Many scientific disciplines are involved in the study of the wide variety of stressors of potential concern to deployed forces: epidemiology, clinical medicine and toxicology, experimental toxicology, microbiology, physiology, psychology, and pharmacology, among others. Within these various disci-

plines, there are ordinarily agreed-upon criteria used to assemble relevant literature and to evaluate it, and to ascertain whether causal relationships have been adequately documented. In many cases, causal relationships might have been well established in experimental systems (e.g., in laboratory animals), and judgments will need to be made regarding the relevance to human causation (Calabrese 1983). Similarly, in the case of data from epidemiological studies, professionals usually apply certain criteria to the available evidence (e.g., The Hill Criteria, [Hill 1965]) to establish the likelihood of causation.

It is not the purpose of this paper to establish or suggest criteria for causation, but rather to ensure that each hazard identification that is undertaken conclude with a discussion of causation for each of the hazards that have been associated with the stressor. The criteria applicable to the disciplines relevant to the particular stressor under review are to be applied by experts in those disciplines. Associations that might not satisfy causation criteria should also be described.

Sources of Information

Most information pertaining to hazard identification comes from case reports, epidemiological studies, and laboratory studies. Depending upon the disciplines involved, and precedents established therein, differing weights might be given to these different sources of information. In many cases, detailed investigations of the biological mechanisms underlying the production of disease or injury might be available; information from such investigations might often aid in the establishment of causation, or of the relevance of animal data to humans (EPA 1996).

The specific sources of information relevant to stressors of concern to deployed forces include the publically available scientific and medical literature, and information developed by the DOD and other governmental agencies. The means for collecting this information is not within the scope of this paper, but it is suggested that search strategies that ensure comprehensiveness be developed and applied.

Content of Hazard Identification Narrative

The successful application of the risk-assessment framework proposed here requires that all available hazard information for each stressor be systematically assembled, and that a narrative description of that information be prepared. To be maximally useful, it is advisable that narratives for all stressors be organized in approximately the same way. The structure shown in Text Box 2 is suggested, although there are other useful ways to organize data, and discussions among future participants might lead to alternative structures. It is suggested that a relatively uniform approach be developed for all stressors.

Generally, the hazard identification narrative and the final hazard characterization section (Text Box 2) will include an extensive discussion of the specific conditions of exposure under which specific types of hazards are produced. It is critical that all such information be captured in the hazard identification step, and that it be summarized, preferably in an easily usable, tabular form. Such information will be necessary for completion of the next step in the risk assessment. In the context of risks to deployed forces, it is particularly important to note any data suggesting delayed effects. Such effects might be those coming long after exposure, or they might occur only after long-term repeated exposures.

Data Limitations and Gaps

It is seen in Text Box 2 that the final section of the proposed narrative format concerns data gaps. All data characterizing hazards are expected to have limitations, and their elucidation should be contained within the critical components of the hazard narrative. Data gaps are different. The phrase as used here is intended to apply to exposure conditions for which there are no usable data concerning hazards.

TEXT BOX 2

Proposed Organizational Structure for Hazard Identification Narrative

- 1.0 Identification of stressor
- 2.0 Chemical and physical properties
- 3.0 General description of conditions under which deployed forces may come into contact with stressor
- 4.0 Routes of entry into body or modes of contact with body
- 5.0 Behavior in the body
- 6.0 Case reports relating to hazards
- 7.0 Epidemiological studies
 - 7.1 Acute exposures
 - 7.2 Repeated exposures, up to ___ days
 - 7.3 Repeated, chronic exposures
- 8.0 Experimental studies
 - 8.1 Acute exposures
 - 8.2 Repeated exposures, up to ___ days
 - 8.3 Repeated, chronic exposures
- 9.0 Data available concerning interactions among stressors
- 10.0 Mechanisms of disease or injury
- 11.0 Characterization of hazards: tabulation, critical discussion, causation
- 12.0 Gaps in available data

When such circumstances are encountered, it could mean that there is no identifiable hazard associated with a specified condition of exposure, or it might mean that no attempt has been made to identify the hazard. In any case, all such data gaps should be noted; some might be highly relevant to deployed forces, and might thus seriously hinder attempts to assess risk, whereas others might be only marginally relevant. Elucidation of data gaps is a helpful guide to research, as is elucidation of other data limitations.

Mixtures and Interactions

Data relevant to the combined effects of two or more stressors of concern to deployed forces should be included in the hazard identification narratives of each of the stressors involved. Such descriptions should include the conditions of exposure under which interactions can occur, the likelihood that such conditions could occur under the conditions experienced by deployed forces, any evidence that the adverse effects are simply additive, or that they arise out of some different type of interaction (antagonistic or synergistic) (see paper by Yang in these proceedings).

DOSE-RESPONSE EVALUATION**Definitions of Dose and Response**

The second step of the risk-assessment framework is the dose-response evaluation. This phrase arose out of the fields of epidemiology and toxicology, where its meaning is generally understood. It is, however, not a fully descriptive phrase, and might seem awkward for some of the stressors of concern

to deployed forces. For purposes of the present discussion, the phrase conditions of exposure is more apt. This phrase encompasses one or more of the following:

- the magnitude of exposure to the stressor;
- the frequency and duration of such exposure; and
- the routes of such exposure (i.e., inhalation, ingestion, dermal, other).

In some cases the physical or chemical forms of the stressor might vary (e.g., amorphous versus crystalline silica), and these variations might affect its hazardous properties; when these forms are important they are also components of the conditions of exposure. As in the use of the term stressor, the term dose will be used in the following as a convenient shorthand for conditions of exposure.

Response is the term used to describe the hazards produced at various doses. The response is thus a description of the risk. Response (risk) generally includes:

- a description of the nature of the disease or injury;
- a description of its severity;
- a discussion of whether the disease or injury is reversible, and, if so, the typical rate of reversibility;
- a description of the incidence of disease or injury; and
- a discussion of whether the hazard is immediate or delayed.

The dose-response evaluation thus entails the development of a description of the relationship between dose of stressor and response, over a range of doses.

Measures of Dose

The doses of the wide variety of stressors of concern to deployed forces are measured in many different ways. Under the criteria for sound risk assessments, it is recommended that whatever measures of dose are used, they should be those measures that are known to relate to response. It is important that the dose-response evaluation include a discussion of the reasons for the selection of specific measures of dose.

The ultimate evaluation of risk will require that the doses likely to be incurred by deployed forces be measured and expressed in ways that are directly relevant to the measures of dose that are determinants of response (risk). The means for ensuring that proper measures of dose are used will be discussed in the next section. In some cases it will be possible to express dose measures quantitatively, but in other cases it might not be possible to do so. It is expected, for example, that environmental conditions leading to excessive physiological or psychological stress will be described in largely qualitative ways; such descriptions are encompassed within the broad definition of dose within the risk-assessment framework proposed here.

The risk-assessment framework described here allows for evaluations of the risks of physical trauma and injury from accidents, explosions, fires, floods, and for evaluations of physical and psychological stress. The use of the term dose is no doubt awkward for these types of risk, and might not be well received by experts in these subjects. It is not a significant defect in the risk-assessment framework proposed here that its terms of reference are not readily adaptable to these types of risk. Experts in the relevant disciplines, using suitable descriptive terms, will nevertheless be asked to arrive at some usable description of the conditions (dose) under which deployed forces are likely to be at risk from these various stressors.

It is generally useful, and in fact convenient, to present dose-response evaluations separately for different exposure durations. It is proposed here to use three categories of exposure duration: acute,

intermediate, and chronic. The term acute is used here in its conventional sense of a one-time exposure, although it is recognized that, for different agents, the one-time exposure might extend from a few minutes to many hours. In the field of chemical toxicology, acute is often subdivided into periods of 15 minutes, 1 hour, 8 hours, and 24 hours, because the magnitudes of exposure that produce adverse effects, and the severities of those effects, can, for some agents, vary considerably with these relatively small changes in exposure duration. Acute exposures might occur more than one time in the life of an individual; exposures are to be considered acute only if they are sufficiently separated in time to ensure that any effects produced are not additive or cumulative (NRC 1986).

The terms intermediate and chronic are more ambiguous in meaning, and there appears to be no single definition involved in the evaluation of the wide range of stressors of interest here. The three categories of acute, intermediate, and chronic exposure durations will be used here with the recognition that precise and consistent definitions can be identified only after all participants in the risk assessment are able to discuss these usages and their appropriate definitions.

Response Measures and Their Relationship to Dose

Responses to various doses of hazardous stressors come in many forms. These responses will have been tabulated, discussed, and critically reviewed in the hazard identification step. Out of the information set forth there, dose-response profiles can be developed for acute, intermediate, and chronic exposure conditions.

There are many ways in which responses can be expressed. For present purposes, it is proposed that four categories of response be developed and their relationships to dose described as mortality; severe, irreversible (or slowly reversible) injuries or diseases; minor, readily reversible injuries; and no adverse effects (Table 2).

Other categories can be envisioned and, within each of the above categories, information concerning the incidence of these effects within a population might also be included. It is suggested, however, that these four categories, together with the further categorizations of doses as of acute, intermediate, and chronic duration, will provide sufficient and readily usable information for risk-management purposes. The information proposed here, together with the information to be provided about doses to be incurred by deployed forces in different circumstances, will allow risk managers to determine whether deployed forces are at risk (will incurred doses exceed the maximum no-effect dose?). Methods to be considered in the development of these types of dose-response profiles for stressors of concern to deployed forces will now be considered. It is recognized that adjustments might need to be made in the proposed approach for different categories of stressors, but it is suggested that the general goals of the evaluation, and the framework into which it fits, should not need to be significantly altered.

The Presentation of Dose-Response Information

It is proposed that, for each stressor of concern, a tabular presentation of dose-response information be developed; the suggested format is shown in Table 2. The tabular presentation should be accompanied by a narrative description of its basis, synthesized from the hazard identification narrative, and with an additional description of the reliability and representativeness of the data available relating to dose-response. Extensive discussion will follow later, on the development of the dose information.

The notes to Table 2 define the Ds consistently with the descriptions given previously. With Table 2, risk managers can, for example, see that for the particular stressor reviewed, acute exposures from zero up to D1A are likely to be without adverse effects; doses in the range from D1A to D2A are likely

TABLE 2 Suggested Format for Presentation of Dose-Response Information for Each “Stressor” of Concern to Deployed Forces

Responses (Adverse Effects, Immediate & Delayed)	Doses (for different exposure durations)		
	Acute (A)	Intermediate (I)	Chronic (C)
Mortality	D3A	D3I	D3C
Serious, Irreversible	D2A	D2I	D2C
Minor, Reversible	D1A	D1I	D1C
No Effect Likely	D=0	D=0	D=0

Notes

1. Ds are the doses at which adverse effects, either immediate or delayed, are expected to occur. Generally, $D3 > D2 > D1$ and $DA > DI > DC$.
2. D3 = min. dose for mortality; D2 = min. dose for serious, irreversible effect; and D1 = min. dose for the most minor effect.
3. Some Ds can be expressed only qualitatively, as a set of conditions (e.g., conditions leading to physical or psychological stress). The Ds are expressed in the terms or units that are relevant to the responses.
4. Ds are derived by considering the nature of the data upon which they are based, the nature of the population whose risk is being assessed, and sources of variability and uncertainty in the data and the population under assessment.
5. Table to be accompanied by narrative description of its scientific basis.
6. In the typical regulatory use of this framework, health protection standards fall somewhere between D=0 and D1.

to cause only minor, reversible effects (e.g., irritation of the eyes, airways, or skin); and doses above D2A might be highly hazardous; and doses above D3A are likely to be lethal. Again, the measurement of dose will vary according to the stressor.

For some stressors, to which deployed forces might be exposed by more than one route, it might be necessary to develop a separate dose-response profile for each route. The risk assessor will need to determine whether specific responses are restricted to a specific route (in which case doses incurred by that route are to be considered independent of doses incurred by other routes) or whether doses from all relevant routes are to be combined. If the latter is the case, some means will have to be found to limit the allowable Ds by each route, so that combined exposures by several routes do not exceed the total allowable D. Finally, it should be emphasized that for some stressors, the Ds can be expressed only qualitatively, or semi-quantitatively, as a set of environmental conditions. Some means will have to be found to define such Ds in usable ways—a simple, narrative statement for example—that can be included as footnotes to the table.

Considerations in the Development of Dose-Response Information for Table 2

Thresholds

For many if not most of the stressors of concern, there will be some dose (broadly defined to include all relevant conditions of exposure) that must be exceeded before even minimal adverse effects are produced. The so-called threshold dose will vary among stressors, with different effects of the same stressor, and will also vary among individuals in a population. The doses labeled D1 in Table 2 are intended to represent minimum-effect doses, and thus will lie just above the threshold dose. Just as threshold doses will vary among members of a population, according to their individual sensitivities, so will the D1s and all the other Ds in the dose-response table. One challenge for risk assessment is the

problem of estimating Ds for populations having the characteristics of deployed forces, when the data from which they are to be estimated derive from different human populations or from experimental animals (Dourson et al. 1996).

The Possibility That Some Stressors Do Not Display Thresholds

It might be the case that some stressors, particularly biological and chemical agents designed as weapons of war, have threshold doses and minimum effective doses that are so small that it is practically impossible to avoid seriously harmful exposures. For such stressors, it might be that all doses are to be considered harmful, and the critical assessment of risks comes only in the exposure assessment step, where the probability of exposure becomes the determinant of risk.

Some chemical carcinogens and forms of radiation are thought to pose risks at all nonzero exposures (NRC 1994, EPA 1996). In the regulatory context, described earlier, it was seen that carcinogenic chemicals and radiation are assumed to pose risks at all exposures greater than zero, and that their risks increase in proportion to dose. The adoption of linear, no-threshold models to describe low-dose risks for carcinogenic substances is based in part on biological evidence and in part on science policy assumptions and public health dictates that involve the precautionary principle (NRC 1994).

It should be emphasized that with respect to such carcinogenic agents, it has not been considered necessary to reduce exposures to zero (to ban products) to protect public health. Rather, the approach has been to reduce exposures to those corresponding to low levels of risk (as estimated using linear, no-threshold models). The Occupational Safety and Health Administration (OSHA) and the Nuclear Regulatory Commission have, in a relatively large number of decisions, not forced lifetime risks for occupational carcinogens to levels below about 1 in 10,000 (Rodricks 1992, 1994). Standards for carcinogens established by these agencies are, it should be noted, often accompanied by warnings to workers and other protections to ensure that excessive exposures do not occur, or occur only rarely.

It is likely that some of the stressors to be encountered by deployed forces will be carcinogenic. In many, if not most cases, these exposures will be limited in duration and will often occur only intermittently. The occupational groups of concern to the OSHA and the Nuclear Regulatory Commission are usually exposed every working day, and for a working lifetime. It is possible that exposures to carcinogens of the type expected for deployed forces will pose little or no risk because of their limited duration. Some such stressors (e.g., those that are direct-acting, genotoxic substances) might pose risks of cancer even after a few exposures (EPA 1996).

Other mechanistic considerations enter the picture. It is now widely recognized that not all carcinogens operate by the same mechanisms, and that, irrespective of the exposure duration, some of these carcinogens are likely to operate by threshold mechanisms, and so their dose-response evaluation might proceed as it does for other threshold stressors (see paper by Rozman in these proceedings).

Judgments regarding the appropriate approach of low-dose risk assessment for such stressors, in the context of the exposures to be experienced by deployed forces, will have to be left to experts in toxicology and carcinogenicity, and case-by-case decisions will have to be made. If threshold and minimum effect doses (Ds) can be identified and justified, then their estimation will proceed as with other threshold stressors. If there are some stressors that are thought to present risks at all nonzero exposures, then a decision will have to be made regarding the level of risk that is to be considered minimal. Precedents from the OSHA and the Nuclear Regulatory Commission might be useful to guide such decisions (Rodricks 1992).

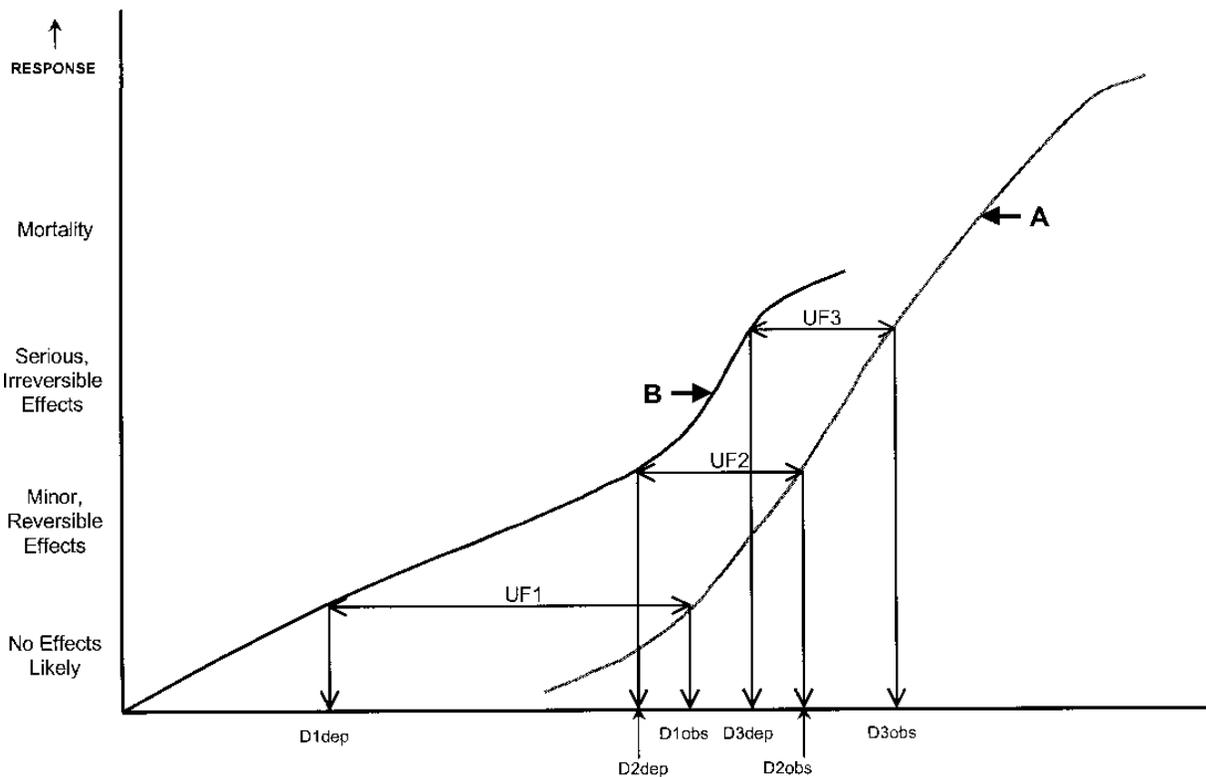


FIGURE 3 Hypothetical dose-response relationships for exposure to a hazardous stressor. Curve A is a composite relationship derived from the available data relating to *Dobs* to response. In most actual cases, information for different portions of Curve A will derive from different studies or sources. Curve B is the relationship intended to apply to deployed forces. UFs are uncertainty factors applied to deal with uncertainties in the observed data. UFs vary as a function of the nature, quality, and representativeness of the observed data. The Ds are expressed in whatever units or terms are relevant to the response for the particular agent under review. $D1_{dep}$, $D2_{dep}$, and $D3_{dep}$ are transferred to table format in Table 2.

Estimating Critical Risk Doses (Ds) for Deployed Forces

Figure 3 displays two hypothetical dose-response curves for a stressor of concern. The response axis is divided into the four categories of adverse effects already discussed. Along the dose axis are a range of increasing doses expressed in units or terms appropriate to the stressor. Curve A represents the dose-response relationship for the agent and, as discussed earlier, one curve will be developed for acute exposures, another for intermediate exposures, and a third for chronic exposures. It can be seen that the available evidence suggests that no effects are expected until the dose labeled $D1_{obs}$ is reached, and that effects become increasingly serious as the dose is increased to $D2_{obs}$ and $D3_{obs}$.

This observed dose-response relationship might not, indeed is likely not, to come from any single study. It is more likely to represent a composite of data from several studies, some involving human subjects and some involving experimental animal subjects. For some stressors, data might not be available to describe such a relationship in full; in fact, incomplete data are likely in many cases. For the present, it will be assumed that the evidence will allow estimation of a relationship approximating Curve A in Figure 3.

It must now be considered that the data supporting Curve A will in most cases be derived from studies in population groups that might or might not represent the range of sensitivities expected in the population of deployed forces. Moreover, in many cases, the observed data will have been derived from animal studies. As in all areas of risk assessment, it must be decided how well the observed dose-response data represent the population—in this case deployed forces—that is the subject of the risk assessment.

It is the general practice in risk assessment to evaluate potential differences in response between the subjects studied and those that are the subjects of the risk assessment (NRC 1994; Dourson et al. 1996). As a starting point, deployed forces represent a segment of the human population that is generally the healthiest and, therefore, the least vulnerable to the adverse effects of environmental stressors. In this respect, they are like many other occupational cohorts—children, the aged, the infirm, and individuals with debilitating health conditions are generally excluded. The importance of these observations lies in the fact that not only are deployed forces likely to be less sensitive or vulnerable to the adverse effects of stressors in the environment, but the range of variability in response is also likely to be much smaller than it is for the general population.

Deployment is, it should be emphasized, an unusual situation that most individuals never have to face. It is possible that normally healthy individuals, who should be the most resistant to the effects of environmental stressors, might, under conditions of deployment, become more vulnerable than would ordinarily be expected. This subject requires more review and analysis by participants in the risk-assessment process. It should probably not be assumed, without further investigation, that deployed forces are no more vulnerable to environmental stressors than are ordinary occupational cohorts.

Within the context of risk assessment, it is necessary that experts make some judgment regarding how well the population studied represents the population of deployed forces. Once this judgment is made, uncertainty factors (UFs) are introduced to estimate critical doses applicable to deployed forces. These are noted in Figure 3 as *D1dep*, *D2dep*, and *D3dep*, and Curve B represents an approximation of the dose-response relationship for deployed forces. No particular UF is to be inferred from Figure 3, although UFs of differing magnitude, including UFs of magnitude 1, are possible, depending upon the nature of the database used to develop the composite Curve A.

Text Box 1 presented some UFs commonly used by regulatory agencies for assessing variability in thresholds for toxic chemicals among humans and differences in response between experimental animals and humans. It should be emphasized that the specific UFs listed in Text Box 1 are intended to apply to the general population, in which more individuals of greater sensitivity will be present than in the population of deployed forces, and in which a wider range of sensitivities is expected. No similar standardized UFs have been established for occupational groups; rather, case-by-case judgments have been made. It is expected that such case-by-case judgments will also have to be made in the context of risks to deployed forces, taking into account the ways in which such populations might differ from their ordinary occupational cohorts.

It should also be pointed out that there are often uncertainties other than those related to variabilities in response between experimental animals and humans and variabilities among members of the human population. UFs have been used to compensate for other types of data limitations (e.g., for the absence of data relating to chronic exposures, or for the absence of data on the minimum effective dose [D1]). Within the field of toxicological risk assessment, it is accepted practice to introduce UFs, in the manner described above, as long as some justification is given for their use. It is not clear that such precedents exist in other areas of risk assessment, so that further discussion of this important issue will be needed before appropriate methodologies can be described.

Creating Dose-Response Tables and Narratives

The derivations of estimated critical doses for each stressor and for each of the three different exposure durations, as depicted in Figure 3, lead to the estimates necessary to create Table 2. It is proposed that Table 2 be accompanied by a narrative statement of its basis. With this table and statement, the hazard identification and dose-response steps of the risk assessment will be complete.

Relationships to Existing Standards

OSHA, EPA, the American Conference of Governmental Industrial Hygienists, and other organizations have published chemical and biological exposure guidelines for many chemical and some biological stressors. Several compilations of recommended exposure limits for short-term exposures are also available for some chemicals (USACHPPM 1999; see references therein). These various recommended exposure limits were developed in a variety of contexts, and for a number of reasons might not be directly applicable to the risk-assessment goals presented here. Some elaboration of this point is necessary.

First, it should be recognized that most existing occupational exposure guidelines are intended to be applied as lines of demarcation between safe (risk free) and unsafe (risky) exposures. They were derived to provide risk managers with a simple yes-no decision model. (Although the developers of these various limits recognize that occasional excursions above them are not necessarily harmful, they are nevertheless applied as if such excursions should be avoided.) This yes-no approach is suitable for situations in which risk managers are in a position, through careful planning, to control exposures (in a regulatory context), and to ensure that when (in the case of accidents) exposures cannot be controlled, individuals can be removed from affected areas. The yes-no model is most useful in circumstances such as these.

The circumstances in which deployed forces might become exposed are often not controllable in the same way, and in many cases some degree of harm will not be avoidable. The type of information on risk proposed here, as expressed in Table 2, provides decision-makers far more information on the likelihood, magnitude, and seriousness of the risks that might arise under different conditions.

Most existing occupational and general population standards are also intended to represent exposures that are not likely to pose any discernible risk. They thus fall somewhere in the no-effects-likely zones of Table 2 and Figure 3. Their relationships to the minimum-effective dose (D1) is ascertainable by reference to the data upon which those standards are based, but cannot otherwise be known. In the context of exposures incurred by deployed forces, it is not sufficient for decision-makers simply to be aware of the no-likely-risk exposure, but rather it is necessary that such decision-makers have knowledge of the exposure at which adverse effects are first expected (D1), and the levels at which serious effects are likely to occur (D2 and D3). (It is recognized that recent efforts by EPA and the NRC are directed at developing the type of dose-response information for acute exposures that is proposed here, although with the intention that they be applied to the general population.)

Other differences between available occupational standards and those to be developed for deployed forces need to be considered. For example, occupational standards are generally applicable to workers exposed 8 hours a day and 5 days a week, for a working lifetime. Deployed forces might be exposed to some stressors for 24 hours a day, and on every day, but are not likely to be exposed for a working lifetime. Some stressors for which there are inhalation occupational standards might be present as contaminants of the food or water of deployed forces. For these several reasons and more as well, great care must be taken in using available occupational standards, and certainly in using standards developed by EPA or FDA to protect the general population, without considering their relevance to the nature of the population of deployed forces and their applicability to the risk-assessment requirements depicted in

Table 2. No doubt some of the information used to develop available occupational standards can be used for assessing risks to deployed forces, but wholesale adoption of such standards without critical review will lead to a wholly different and far less useful risk-assessment model. The earlier point, that deployed forces might not be similar in sensitivity to ordinary occupational cohorts, needs also to be considered.

The U.S. Army Center for Health Promotion and Preventive Medicine (ACHPPM) has developed in an undated draft form, a set of *Short-Term Chemical Exposure Guidelines for Deployed Military Personnel*. These guidelines were developed for air and water contaminants, and are intended to cover a range of exposure durations, from 1 hour to 14 days (air), and from 5 days to 2 weeks (water). Considerable effort and thought has gone into the development of the guidelines, and ACHPPM has drawn from the work of the NRC and other expert regulatory and scientific authorities. The guidelines are, however, conceptually similar to regulatory standards, and do not present the more thorough dose-response and long-term exposure information envisioned herein. It is, however, a possibly usable model for yes-no decision-making.

ASSESSMENT OF EXPOSURES OF DEPLOYED FORCES

Using the Results of the Hazard and Dose-Response Evaluations (Table 2)

Referring to Figure 2, and the model proposed herein for decision-making (Model II), it can be seen that it is now necessary to discuss the problem of assessing the exposures to stressors expected or incurred by deployed forces. Health risks to be expected or incurred can be identified only if such an exposure assessment can be completed. In effect, the purpose of the exposure assessment step is to estimate the doses (Ds) of the stressor to be expected or incurred by forces under the circumstances of deployment. Such estimates will allow risk managers to understand the extent and severity of the expected health risk by reference to the proposed dose-response (Table 2). A discussion of some of the issues that need to be resolved to develop adequate exposure information for use in risk assessment, as well as a discussion of the various options for risk-management decision-making, follows.

Measurement or Estimation of Doses

For some stressors of concern, analytical methods are or will be available to measure directly the doses to which deployed forces might be exposed. In other cases, methods are or will be available to measure concentrations of stressors in the various environmental media to which deployed forces might be exposed; these measurements of concentrations might or might not be direct measurements of the relevant doses, and means will have to be developed to convert concentration information to dose information. The subject of the availability of reliable analytical methods for measuring stressor doses or concentrations is not discussed in this paper. It is assumed that such methods are or will become available. Without such methods, it will not be possible to understand the nature or magnitude of the risks expected or incurred by deployed forces.

This paper is concerned, instead, with the methods for evaluating exposure information for purposes of use in risk assessment. Two approaches to acquiring relevant dose estimates are available:

1. Estimation of doses expected to be incurred under various deployment scenarios, in advance of deployment; and
2. Measurement of doses during deployment (real time measurement).

Both of these approaches have value. The first can be used for planning purposes, and can guide risk management on the stressors expected to be of greatest concern during specific deployments. The second can provide direct measurement data during deployment; by quick reference to the dose-response information, immediate knowledge of potential health risks can be acquired.

As previously discussed, there are some stressors that are so extremely hazardous that there might be no practical means to ensure health protection of exposure were it to occur. For such stressors, the exposure assessment would take the form of an estimation of the probability of exposure expected under various deployment scenarios; the availability of such estimates would allow appropriate safeguard planning in advance of deployment. The use of this approach for some stressors falls within the framework for risk assessment proposed in this paper; it simply recognizes the fact that exposures to certain extremely dangerous stressors must be prevented if health is to be protected, and uses projected estimates of the probability of exposure as a guide to risk management.

The Need for Commensurate Measurement of Dose

For each stressor it is necessary that the measurement of dose expected or incurred by deployed forces be the same as that in which its risk information is presented in Table 2. Thus, the experts involved in the estimation or measurement of doses need to have knowledge of the requirements for risk assessment. In many cases there will be little difficulty meeting these requirements. Risk doses for chemical contaminants of air, for example, will ordinarily be expressed in units of air concentration times duration ($c \times t$); analytical methods for such contaminants can readily provide the same data for deployed forces. Similarly, the dose information for risks of contaminants of drinking water can be expressed as drinking-water concentrations, based on the incorporation of knowledge of the daily water consumption rates of deployed forces.

Food contamination presents a somewhat more difficult problem, because it might be difficult to predict the specific dietary component that will become contaminated with a given stressor. Rates of consumption of different components of the diet vary greatly, so that contamination of a greatly consumed component at a given concentration of a stressor will result in a larger dose than does contamination (at the same concentration) of a little-consumed item. The most conservative approach for food is one that assumes that each component of the diet constitutes the total daily diet, but such an approach might lead to large overestimates of risk in many situations. Further discussion of the question of the appropriate expressions of dose for food contamination will be necessary before the problem can be resolved.

The greatest exposure assessment difficulty arises when a given stressor might contaminate all environmental media. In those instances in which the dose-response evaluation demonstrates that risks by one route of exposure are different from and independent of risks resulting from other routes, then the problem is somewhat simplified, in that air exposures can be evaluated separately from exposures through food and water (and possibly soil), as can dermal exposures. Even in this simplified case, it will still be necessary to express risk doses as concentrations in food and water (and perhaps soil) to ensure that the total oral dose from all sources can be estimated. Thus, data or assumptions regarding relative rates of consumption of food and water will have to be incorporated into the evaluation. Clearly, if risks are additive across all exposure routes, the problem is even more difficult. The problem can be at this time only pointed out, but it cannot be resolved without discussions among the risk-assessment experts during the evaluation of specific stressors (Lioy 1997).

Risk Characterization and Decision-Making

Completion of the exposure assessment step for deployed forces provides the information necessary to assess risks. At this stage, estimated Ds incurred by deployed forces are evaluated by reference to Table 2 that is applicable to the stressor of concern. In the ideal, risk managers would have an understanding of each of the risks faced by deployed forces in a given deployment situation and would also have an understanding of the new risks that might arise should various actions be taken to alter the circumstances of deployment. The availability of all this risk information would presumably allow the best possible decisions, given the deployment circumstances and the alternatives available, to minimize overall risks to health. The risk-assessment framework proposed here, although identical to that ordinarily used in regulations, is not intended to yield results that are used only to establish standards. Rather, they are intended to give DOD decision-makers sufficient information to examine a range of risks that might arise in rapidly changing deployment conditions, and to balance competing risks. It recognizes that a simplistic yes-no decision-making model is inadequate to deal with the circumstances under which forces are deployed, and that in many cases some risks will have to be incurred. The framework offered here provides decision-makers sufficient understanding of the range of exposures over which risks of differing severity might occur (Table 2), and thus maximizes the likelihood that the most serious hazards can be avoided.

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