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Indicators for Human and Ecological Risk Assessment: A U.S. Environmental Protection Agency Perspective

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ABSTRACT

Assessment of risk to public health or environmental resources requires competent characterization of stressors and corresponding effects. Because of the complexity of most stressor-response relationships, it is impossible to completely characterize all the variables, so a select set of measurements is made to reflect the most critical components. Such measurements, or indicators, are included in monitoring programs to estimate trend, stressor source, or magnitude of effects and lead to thresholds for management action or restoration. Although a wide variety of programs and program objectives exists, there are some common challenges for indicator development, including a strong link to management actions. Indicator measurements used in U.S. Environmental Protection Agency (USEPA) risk assessment activities must stem from collaboration among managers, risk assessors, scientists and stakeholders. The primary objective of the USEPA's Fifth Symposium of the National Health and Ecological Effects Research Laboratory was to improve health and ecological risk assessment through dedicated sessions that maximized interaction and discussion among these groups. Existing measurements were challenged for appropriateness, efficiency and scientific validity. Emerging science was explored for greater understanding, better interpretation, and improved methodol-

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ogy. A secondary objective was to uncover and exploit common indicators and supporting data for human health and ecological models.

Key Words: ecological indicators, risk assessment, public health, ecosystem health.

INTRODUCTION

Over the last few decades, the focus of environmental protection has expanded from stressor-specific standards to broader objectives of ecosystem integrity and sustainability (Cairns *et al.* 1993). For example, water-quality indicators were once limited to end-of-pipe measurements of incoming contaminants. Not until later were effects measurements, such as fish population assessments, added to determine whether the valued public resources were actually being protected. More recently, society has recognized the need to protect a larger number and greater diversity of resources (*e.g.*, related to recreational fishing, swimming safety, food safety, economy/tourism, aesthetics), so additional measurements are needed that are responsive to multiple and varied stressors. The concept of protecting ecosystem integrity and sustainability is, at least in part, a natural outgrowth of protection for a diversity of valued public resources. Another contributing factor is the recognition that many human health concerns (*e.g.*, food safety) are directly linked to environmental quality.

Protection of human health and ecosystem integrity requires risk assessment through characterization of stressor-response relationships. This characterization can incorporate a variety of factors that influence the origin, type and magnitude of the stressor, its fate and transport, biological availability, uptake, accumulation and metabolism, as well as possible effects at the suborganismal through community levels of biological organization at a variety of temporal and spatial scales. Measurement of all these influencing factors for even a single environmental stressor could be daunting. Consideration of interactive and cumulative effects from multiple sources and routes of exposure is impractical, if not impossible. Instead, measurements must be concentrated on a set of factors that are pivotal to understanding or quantifying risks, *i.e.*, those elements that exert the greatest influence and have a high degree of uncertainty. These elements can be identified through the risk assessment process.

In risk assessment terminology used by the USEPA, *assessment endpoints* are the explicit expressions of valued entities at risk (USEPA 1998). They are normally derived from an extended discourse among risk assessors, environmental managers, and the stakeholders, *i.e.*, those at risk or likely to be affected by management alternatives. The assessment endpoint is intended to be operational; that is, it should be quantifiable through measures of exposure and effect using available technology. In some cases, societal values are obvious (safe drinking water) and assessment endpoints can be directly measured (*e.g.*, concentrations of waterborne pathogens). But in others, societal values may be more diffuse (*e.g.*, biological integrity of streams in a region) and assessment endpoints may require development and selection of surrogate measurements (*e.g.*, fish index of biotic integrity). Although a definition for the term 'indicator' might arguably be limited to these surrogate measurements, popular use of the term includes both surrogate and direct measurements and is the definition used here. Monitoring of exposure and effects indicators provides information that is applied in models to project future conditions. Such projections are the primary objective of risk assessment; they are used to identify consequences and evaluate progress of management action (or inaction). Because there are a multitude of valued endpoints at risk and a variety of program objectives related to those risks, there is clear need for a diverse array of indicators.

One of the major challenges to risk assessment then, is linking the best indicator to the assessment endpoint. What makes a useful and efficient indicator? The answer must emerge synchronously from risk assessors, scientists, and environmental and public health managers. Risk assessors first consult with stakeholders and managers to frame the societal values and generate relevant assessment endpoints, then they estimate risks to those endpoints using data generated by environmental scientists and engineers. Managers interpret the results and make decisions concerning regulatory or remedial actions. Scientists and managers ideally work together to monitor environmental and regulatory issues to determine efficacy of management actions. Although the need for their collaboration is obvious, organizational structures of regulatory institutions at county, state and federal levels do not generally support strong interactions among these critical players.

The 5th National Health and Environmental Effects Research Laboratory Symposium is one effort by the U.S. Environmental Protection Agency Office of Research and Development to correct this situation. In particular, the Symposium was designed to examine the scientific underpinnings and application of indicators currently used in the risk assessment process and formulate research to strengthen or replace them. In the process, it was anticipated that assessment endpoints would be characterized and revisited to ensure that they are relevant to protecting our critical public resources. A second objective was to initiate integration of human health and ecological risk assessments by examining complementarity between indicators and scientific understanding.

Although there is a variety of management programs and program objectives, there are several common challenges to application of indicators in risk assessment. Among these are (1) developing relevant assessment endpoints, (2) identifying indicators that are responsive to the assessment question, scientifically sound, and applicable in a monitoring program, and (3) formulating an indicator program that satisfies the stakeholders, even when there are conflicting values. Meeting these and similar challenges defines the art and science of *indicator development.*

IDENTIFYING CRITICAL FACTORS THROUGH THE RISK ASSESSMENT PROCESS

Risk assessment provides the scientific basis for decision making in the USEPA and is the organizing principle for research performed by the USEPA's Office of Research and Development. Increasingly, risk assessment is becoming the basis for decision making within and outside the U.S. Simply stated, risk assessment is a process that provides technical support for making decisions when the consequences of those decisions are uncertain. Its use implies that there are valued public resources at risk, goals formulated to protect those resources and, ultimately, decisions to be made that are intended to modify outcomes toward those goals (risk management). Risk assessments should be comparative because risk management alternatives commonly have both desirable and undesirable outcomes. Such a comparison requires estimation of the nature and magnitude of effects, and incorporation of variance and uncertainty.

The process of risk assessment allows assessors to identify the critical uncertainties through analysis of exposure and effects (NRC 1983; USEPA 1998). Does a potential stressor have the ability to create adverse effects? Does it co-occur with receptors (organisms, populations, communities) long enough and with sufficient intensity to create an adverse effect? Using this approach, the USEPA's Environmental Monitoring and Assessment Program (EMAP) was organized around three basic *assessment questions* (Messer *et al.* 1991; USEPA 1991; 1994a): What is the current status of the resource, what are trends in status over time, and what is the association between the status and the occurrence of selected stressors? Examination of these questions, coupled with an understanding of the stakeholder values, should ultimately lead to *assessment endpoints* (Suter 1990; USEPA 1994a,b). These are the entities that are both at risk and are sufficiently important to stakeholders to warrant protection.

Although assessment endpoints are intended to be operational (directly measurable), they may in fact include descriptions such as 'biological integrity' or 'sustainability' that are broadly interpretable and require input from scientists and managers alike. In such cases, even simple differences in the wording of an assessment endpoint could change the selection of indicators and interpretation of results. If assessment endpoints are not posed in a manner that properly reflects the most critical uncertainties of the assessment, then even the best indicator will provide information that is useless for management.

TOWARD A MORE INTEGRATED RISK ASSESSMENT

Selection of assessment endpoints can be controversial because of competing interests or resources. Different sectors of society have different priorities. And, even when the values are the same, management alternatives can be disputed because of affiliated consequences. Because of competing management alternatives sometimes presented by ecological and human-health risk assessments, there is recent interest by risk assessors to integrate the process so that both are considered simultaneously, rather than separately. The primary focus of human health risk assessment is on individuals whereas ecological risk assessment is concerned with community integrity and populations of multiple species. Nevertheless, both often suffer similar stressors and effects, similar scientific information gaps, and could share similar indicators, models and other data.

There are several ongoing efforts to combine, or 'integrate' health and ecological risk assessments (Harvey *et al.* 1995; Suter *et al.* 2000). This integration would bring several advantages to protection of health and environmental resources: (1) Results will be more coherent because they stem from a common spatial and temporal scale, using common assumptions and expressions of uncertainty; this ultimately leads to a consistent message to the stakeholders. (2) The interdependence of human health and environmental condition will become a more legitimate issue during the assessment. (3) Sentinel organisms (*e.g.*, fish sensitive to PAH, birds sensitive to dioxins and mercury) will be better incorporated as predictors of human health issues. (4) Scientific quality will be improved because the best methods are made available from both arenas. (5) Sharing of data will improve efficiency by avoiding duplication and strengthening common concepts. (6) Finally, integration will bring a more appropriate consideration of the environment into risk assessment; currently human health concerns dominate decision making despite legal mandates and obvious ecological effects.

WHAT MAKES A MEASUREMENT AN INDICATOR?

Not all measurements used in a risk assessment are indicators. Many different measurements can be used during problem formulation and exposure and effects characterization in a risk assessment. For example, toxicity test responses can provide important and defendable information for a risk assessment, but are not indicators. They may serve as one component of an indicator, however, if combined with measures of contaminant concentrations in the environment and with supporting measures (such as water hardness) in models that estimate risks. As applied here, an indicator is a (direct or surrogate) measurement, index or model that addresses a critical element related to risk when (components are) monitored over time or space.

WHAT MAKES A GOOD INDICATOR?

Several sources have recognized the need to have a consistent set of criteria to evaluate indicators (*e.g.*, NOAA 1990; OECD 1993; Cairns *et al.* 1993; USEPA 1994a; NRC 1999). Because the measurable characteristics of any system are essentially limitless, so are the number of possible indicators. And although many different indicators can be proposed for a variety of purposes, not all will meet the program objectives. Recently, a comprehensive set of guidelines for evaluating indicators was documented for EMAP. The *Evaluation Guidelines for Ecological Indicators* (USEPA 2000) draws upon early guidance developed for EMAP (USEPA 1990; 1991; 1994a) and other programs. Fifteen guidelines are presented in a format intended to facilitate consistent and technically defensible indicator research and review. Documented standards are critical to developing a dynamic and iterative base of knowledge on the strengths and weaknesses of individual indicators; it allows comparisons among indicators and documents progress in indicator development. The *Evaluation Guidelines* emphasizes indicators for ecological monitoring and assessment, but can also apply to a variety of other indicator programs.

The *Evaluation Guidelines* utilizes a phased approach (Table 1), a concept originally suggested by the EMAP program (USEPA 1994a). The phases describe an idealized progression for indicator development that flows from fundamental concepts to methodology, then to examination of data from pilot or monitoring studies, and lastly to consideration of how well the indicator serves the program objectives. The guidelines are presented in this sequence because progression from one phase to the next often occurs in this order, and also can represent a large commitment

Table 1. Summary of the Ecological Indicator Evaluation Guidelines (USEPA 2000)

Phase 1 -	*Conceptual Relevance:* Is the indicator relevant to the assessment question (management concern) and to the ecological resource or function at risk?
	Guideline 1: Relevance to the Assessment
	Guideline 2: Relevance to Ecological Function
Phase 2 -	*Feasibility of Implementation:* Are the methods for sampling and measuring the environmental variables technically feasible, appropriate, and efficient for use in a monitoring program?
	Guideline 3: Data Collection Methods
	Guideline 4: Logistics
	Guideline 5: Information Management
	Guideline 6: Quality Assurance
	Guideline 7: Monetary Costs
Phase 3 -	*Response Variability:* Are human errors of measurement and natural variability over time and space sufficiently understood and documented?
	Guideline 8: Estimation of Measurement Error
	Guideline 9: Temporal Variability - Within the Field Season
	Guideline 10: Temporal Variability - Across Years
	Guideline 11: Spatial Variability
	Guideline 12: Discriminatory Ability
Phase 4 -	*Interpretation and Utility:* Will the indicator convey information on ecological condition that is meaningful to environmental decision-making?
	Guideline 13: Data Quality Objectives
	Guideline 14: Assessment Thresholds
	Guideline 15: Linkage to Management Action

of resources (*e.g.*, conceptual fallacies may be resolved less expensively than issues raised during method development or a large pilot study). However, in practice, application of the guidelines may be iterative and not necessarily sequential. For example, as new information is generated from a pilot study, it may be necessary to revisit conceptual or methodological issues. Or, if an established indicator is being modified for a new use, the first step in an evaluation may concern the indicator's feasibility of implementation rather than its well-established conceptual foundation. The phased approach allows interim reviews as well as comprehensive evaluations.

Guidance presented in the *Evaluation Guidelines* may be customized to suit the needs and constraints of many different applications. The evaluation process will highlight strengths or weaknesses of an indicator at its existing stage of development. Weaknesses may be overcome through further indicator research and modification. Alternatively, weaknesses might be overlooked if an indicator provides information particularly important to program objectives. Certain guidelines may be weighted more heavily or reviewed more frequently by different programs. To illustrate their utility and flexibility, the document applies the guidelines to three existing EMAP indicators.

Application of the *Evaluation Guidelines* to existing or proposed indicators will generate a common ground for interactions and discussions among risk assessors, scientists and managers. They include consideration of the assessment endpoint, scientific concepts underlying the measurement, the monitoring design, the determination of meaningful thresholds, and how indicator results can influence management actions. It is possible that discussion about the relevance of an indicator to the assessment question (Guideline 1) could lead to alteration of the assessment endpoint.

UTILITY OF INDICATORS TO MANAGERS AND STAKEHOLDERS

The last phase of the *Evaluation Guidelines* concerns whether the indicator conveys information that is meaningful to decision making. This is, of course, the bottom line for risk assessment and indicator development. Sound science is not the only criterion for a meaningful indicator; it must also be understood and accepted by managers and stakeholders. They must be able to follow the conceptual logic and agree to the designated thresholds. It is often the role of the public health and environmental resource manager to educate the stakeholders, and the responsibility of scientists to provide the most compelling logic and framework. Alternatively, some programs involve stakeholders as drivers of the process. Stakeholder acceptance is assured if they are developing the endpoints and selecting the indicators. This, of course, requires that they are brought into discussions with risk assessors, scientists and managers so that all are educated simultaneously.

There are many programs that employ some form of risk assessment and indicator development as tools in decision making. One of the largest and most successful programs has been generated from the Great Lakes Water Quality Agreement between the U.S. and Canada (United States and Canada 1987). This agreement required that both nations, in conjunction with the affiliated states and provinces, develop Lake-wide management plans and remedial action plans for designated areas of concern to protect the human health and ecological resources of the Great Lakes. This program embodies a huge number and diversity of stakeholders that must come to agreement on the levels of protection afforded their resources. Much of the success of the program may be attributed to the fact that stakeholders were brought into the process early and often.

The *State of the Lakes Ecosystem Conference* (SOLEC) is a biennial venue for the governments of U.S. and Canada to publically report on the state of Great Lakes ecosystem components and on progress toward meeting the goals of the Great Lakes Water Quality Agreement. First held in 1994, SOLEC provides a continuing forum to examine the state of the Great Lakes ecosystem and public health, to inform local decision makers of changing environmental issues, and to strengthen decision making and management (United States and Canada 1999). One of the earliest

SOLEC sessions focused on the development and acceptability of indicators. This focus initiated a 'nuts-and-bolts' dialogue about information needs for environmental and public health protection under multiple Great Lakes programs. These discussions led to establishment of core groups and panels of experts in specific areas: open and nearshore waters, coastal wetlands, nearshore, terrestrial, human health, land use, and societal (socio-economics). The core stakeholder groups defined the valued resources to be protected and initiated the development, application and evaluation of indicators relevant to their needs (Bertram and Stadler-Salt 2000).

The primary goal of the early SOLEC meeting was to define a set of indicators that would provide an estimate of conditions in the Great Lakes. This led to a more efficient allocation of resources (for data collection, evaluation and reporting) and provided a consistent set of measurements for tracking progress of management actions. Each group agreed upon major organizing principles; to build upon the work of others, focus on broad spatial scales, recognize various subdivisions of the basin ecosystem, recognize different types of indicators, and identify criteria for indicator selection. For criteria, indicators first had to be necessary, sufficient and feasible. Second, they were analyzed for validity, understandability, interpretability, information richness, data availability, timeliness, and cost considerations. The groups recognized that an indicator needed not only to reflect existing condition, but also to allow the description of some goal (endpoint) that would indicate the desired state of the system. In short, these core groups were immersed in the entire process of risk assessment and indicator development; and they considered human health and environmental issues simultaneously. It is also worth noting that program managers expect the number and types of indicators to change. It is within their working perspective that they will continually meet to evaluate, revise, combine and create indicators to meet the changing social attitudes as well as public health and environmental condition. The emphasis on continual review and revision has cultivated consensus, collaboration and cooperation among the stakeholders.

OBJECTIVES OF THE SYMPOSIUM

The Fifth NHEERL Symposium was intended to explore indicators used in health and ecological risk assessment for selected topics, topics chosen partly because there is clear evidence of both human and ecological risks. The Symposium organizers recognized that the value of an indicator is in the information it brings to public health and resource management decisions. Accordingly, the sessions were designed to maximize interaction between risk assessors, managers and research scientists. From risk assessors, each session included presentations on the valued resources at risk and public perceptions of the risk, goals and objectives of a risk assessment, development of assessment endpoints and descriptions of currently used indicators and measurements that influence their decision making. From scientists, each session included presentations on the current state of knowledge regarding exposure and effects characterization from both human health and ecological perspectives, descriptions of significant gaps in scientific understanding and a technical examination of current indicators and their scientific underpinnings. Synthesis of this information, provided in this publication, is intended to redirect our efforts toward better assessment endpoints and indicators, as well as identification of data, models and indicators that are useful for both human health and ecosystem assessment.

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