Integrated Risk Assessment/Risk Management as Applied to Decentralized Wastewater Treatment:
A High-Level Framework

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1 OBJECTIVES

This paper is part of a process intended to guide the research and development of tools and information needed to evaluate and advance the field of decentralized wastewater treatment. This paper introduces the risk assessment paradigm and broadly tailors the integrated risk assessment/risk management approach to the field of decentralized wastewater treatment. Specifically, it:

- introduces the concept and terminology of integrated risk assessment as it applies to decentralized wastewater treatment;
- provides a context within which issues can be identified, organized, and prioritized; and
- identifies several high-priority risk assessment issues for decentralized wastewater treatment, based primarily on input from three regional forums, as a basis for further discussion at the national conference.

This high-level framework is not intended to be an exhaustive treatise on integrated risk assessment for decentralized wastewater treatment, answer the questions raised in the regional forums, or provide example applications of the framework to specific decentralized wastewater treatment scenarios.

2 INTRODUCTION

This paper is part of a process intended to guide the research and development of tools and information needed to evaluate and advance the field of decentralized wastewater treatment.

2.1 Background

A previous part of this process was the convening of three regional forums on risk-based decision making in decentralized wastewater treatment. They were attended by representatives of regulatory agencies, industry, and academia. These regional forums were held during 1999 in:

- Tampa, Florida
- Narraganset, Rhode Island
- Seattle; Washington

The purpose of these forums was to introduce the risk assessment/risk management approach to experts in the field of decentralized wastewater treatment and to gather from them a compendium of issues important to the application of decentralized wastewater treatment. The findings of those meetings were used to focus this paper and to identify issues of high priority to decentralized wastewater treatment experts and interested parties.

2.2 Scope and Approach

This paper supports the final component of this research and development process, which is a national research needs conference. This conference is a national meeting to identify and prioritize research needs in the field of decentralized wastewater treatment. It is organized around the principles of risk assessment and risk management. Research needs will be discussed and prioritized with respect to their ability to support high priority risk management objectives.

This paper is the first of five topical papers commissioned to support the national research needs conference. It introduces the general concepts of risk assessment and risk management, which are used to address specific technical issues in the subsequent papers. Those papers address:

- process, function, and performance of wastewater soil absorption systems;
- fate and transport of pathogens;
- fate and transport of nutrients; and
- direct and indirect costs and benefits.

This paper begins with a general introduction to risk assessment, presents a high-level framework for integrated risk assessments of decentralized wastewater treatment systems, and briefly describes of how the principles of risk assessment and risk management are applied to the prioritization of research needs.

3 PRINCIPLES OF RISK ASSESSMENT

This section provides a general introduction to the terminology and concept of integrated risk assessment as it applies to decentralized wastewater treatment systems. It includes a list of risk assessment definitions, many of which are adapted from EPA(, 1998).

3.1 Definitions

Analysis is the second element of the general risk assessment process in which the technical issues associated with estimating risks are addressed. It typically consists of an analysis of exposure and an analysis of effects.

Assessment Endpoints are an explicit expression of the value that is to be protected. They consist of an entity, a property of that entity that can be measured or estimated, and, whenever possible, a level of effect on that property that constitutes an unacceptable risk.

Conceptual Model is a visual depiction, with supporting text, of the relationships between the stressors and the endpoint entities.

Integrated Risk Assessment is the process of bringing various disciplines (e.g., engineering, ecology, public health, and socioeconomics) together to derive information and insights that would not otherwise be possible.

Measures of effects are measurable changes in an attribute of an assessment endpoint or its surrogate in response to a stressor to which it was exposed.

Measures of exposure are measures of stressor existence and movement in the environment and their contact or co-occurrence with the assessment endpoint.

Measures of ecosystem and receptor characteristics are measures of environmental attributes that influence the distribution of a stressor or receptor attributes that influence exposure and response.

Problem Formulation is the first element of the general risk assessment process in which the purpose of the assessment is clearly defined, the problem is clearly stated, and a plan for analyzing and characterizing risks is developed.

Receptor is an entity that is exposed to one or more stressors. It is the assessment endpoint entity or its surrogate. It may include human and non-human organisms, as well as systems of interest (e.g., ecosystems and social systems).

Risk is the likelihood that a course of action (or lack thereof) will result in an undesired event.

Risk Assessment is the scientific (objective) process of estimating the likelihood and magnitude of adverse effects.

Risk Characterization is the third element of the general risk assessment process in which the methods and models developed in the analysis phase are combined to produce qualitative or quantitative estimates of risk.

Risk Management is the subjective process of deciding which actions to take in response to a potential risk

Stressor is any physical, chemical, or biological entity that can induce an adverse response in a receptor.

Susceptibility is a measure of the exposure and sensitivity of the receptor to a stressor.

Sensitivity is a measure of how readily the receptor responds to the stressor.

3.2 Purpose of Risk Assessment

Risk is the likelihood that a course of action (or lack thereof) will result in an undesired event. We assess risks because we must choose between alternative courses of action, each of which has some degree of uncertainty associated with it. We informally assess risk when we make choices in our everyday lives. Formal, technical risk analysis is used when the likelihood or magnitude of the potential risks are perceived to be very high or very uncertain.

The outcome of complex environmental actions is rarely known with high certainty. The risks include squandering limited resources, failing to reduce the most significant impacts, and creating more significant problems than those already existing.

Because resources are limited, all risks cannot be eliminated. Tradeoffs must be made when choosing which risks to reduce and how much of a reduction is enough. For example, one cannot

eliminate all risks of nutrient loading to an adjacent water body from waterfront housing without prohibiting development in the immediate vicinity. The risks can be dramatically reduced by mandating public sewer systems, but even that action entails risks. The most notable risk is the inappropriate expenditure of resources. An alternative is the use of decentralized wastewater treatment systems. The risks of nutrient loading to the water body may be higher than with a centralized system, but the risk of unnecessary expenses may be lower. The results of such decisions would have a tremendous impact on the local community and environment.

It is important for such decisions to be made from an objective frame of reference. The process of formal risk assessment provides that frame of reference.

3.3 Key Characteristics of Risk Assessment

The fundamental characteristic of risk assessment is that it provides transparency and objectivity to the decision making process. This is achieved by implementing a standard, logical structure that facilitates interactions between the technical experts and the decision makers. Key characteristics of that structure include :

- the separation of risk assessment from risk management,
- clearly defined assessment endpoints,
- rigorous technical analyses, and
- explicit characterization of uncertainty.

Each of these characteristics will be discussed below. However, separating the processes of assessment and management warrants further discussion here.

Risk assessment is the scientific process of estimating the likelihood and magnitude of adverse effects. This includes identifying the types of direct and indirect effects that may occur.

Risk management is the process of deciding which actions to take in response to a risk. It considers the results of the risk assessment along with other factors explicitly excluded from the assessment of risks (e.g., politics).

Maintaining the separation between risk assessment and risk management is critical to the integrity of the risk assessment process. That is, risk assessment is an objective process, whereas risk management is a subjective process in which value judgments are made. Injecting value judgements into the assessment process reduces the credibility of the results. That reduces the utility of the assessment in the decision making process.

This does not mean that risk assessors and risk managers must not work together. Indeed, it is equally important that the assessment address the needs of the risk managers. For that reason the process explicitly encourages interactions between the assessors and managers. However, the assessor must ensure that the estimates of risk are not improperly influenced by those interactions.

3.4 Types of Risk Assessment

There are several ways in which the principles of risk assessment can be applied to the field of decentralized wastewater treatment. These include comparative, discipline-specific, and integrated assessments.

Comparative assessments are used to choose among alternative courses of action. In the example above, one could compare the estimated risks of nutrient loading from decentralized treatment and centralized treatment.

The risk assessment process can also be applied to a very narrowly defined topic such that it only addresses issues within one technical discipline. For example, one could assess the risks of system dysfunction as part of an engineering risk assessment without estimating the risks of that dysfunction to human or ecological receptors.

Integrated risk assessments are more broadly targeted than discipline-specific assessments. They pull together disparate types of information into a cohesive and comprehensible format. This high-level framework is specifically intended to support integrated risk assessments of decentralized wastewater treatment systems. Such integrated assessments could be conducted for several alternative treatment systems, thus resulting in a comparative integrated assessment.

Integrated risk assessment is commonly thought of as a model building effort. However, integrated assessment is better defined as a process for bringing various disciplines together to derive information and insights that would not otherwise be possible. For example, engineering risks can be used to define the stressors to be evaluated in health, ecological, and socioeconomic risk assessments.

However, important feedback loops are developed to ensure that necessary decision making information is obtained. For example, the socioeconomic assessment may determine that costs and dysfunction rates of a particular pretreatment technology are critical to the assessment. This may lead to a more detailed engineering assessment for that technology.

Integrated risk assessment also integrates:

- space (e.g., across a watershed),
- time (e.g., across the life of a system),
- sources of risk (e.g., other activities in a watershed),
- results (e.g., direct effects causing indirect effects), and
- multiple endpoints (e.g. engineering costs and social impacts).

3.5 Standard Structure

There are three general elements in the standard risk assessment paradigm:

- problem formulation,
- analysis, and
- risk characterization.

These are depicted in Figure 1. The order of conduct is roughly as presented, but the overall

process is often iterative. For example, one may conduct a screening assessment and then a definitive assessment. The results of the screening assessment are used to refine the problem formulation for the definitive assessment.

Problem formulation is a process for generating and evaluating preliminary theories about what effects might occur. It is the first step in developing a sound assessment. This component requires the input of the risk manager to ensure that the final results will support the decision making process. Key steps include defining the:

- characteristics of the stressors,
- spatial and temporal scope of the assessment, and
- functional relationships of the stressors and receptors.

Products of this step include clearly defined endpoints, a conceptual model of the interactions between the stressors and the receptors, and a plan for conducting the assessment. The details of these products should be agreed to by the decision makers.

Analysis typically includes analysis of exposure and analysis of effects. These analyses occur concurrently but separately. Analysis of exposure is the technically rigorous evaluation of spatial and temporal characteristics of the stressors. Analysis of effects is the technically rigorous evaluation of the responses of receptors to the specified stressors.

These analyses are interdependent. That is, the types of stressors determine which effects should be evaluated and the time and space over which the effects occur determine the kinds of estimates of exposure that are needed.

Risk characterization is the process of combining the estimates of exposure with the estimates of effects. This process also is technically rigorous and should result in estimates of the probability and magnitude of specific effects.

Risk management is the final component of risk-based decision making. Although functionally separated from the assessment process, it provides a critical point for feedback and refinement of the assessment process for future iterations. This is the stage at which other factors are weighed, including the various types and magnitudes of risks, the costs and benefits of potential actions, and the ethical and political considerations of each action.

3.6 Current Use of Risk Assessment

Risk is implicitly included in current permitting regulations for decentralized wastewater treatment systems. Permitting regulations typically include minimum separation distances between the drain field and the water table and minimum setbacks from property boundaries and potable water supplies. Such regulations vary among state and local jurisdictions and have been established through experience with standard decentralized systems in typical soil conditions. These regulations are implicitly based on risks.

However, the estimation of explicitly defined risks associated with these rules has not been accomplished. A major impediment to assessing the risks of standard systems is the lack of a

comprehensive and consistent approach to defining the potential risks. Alternative treatment systems are typically used when the prescriptive permitting guidelines for standard septic systems are violated. Given that baseline risks have not been estimated, it is very difficult to establish permitting rules for alterative treatment technologies.

Performance-based permits are generally issued when prescriptive guidelines do not apply. Such permits require potentially expensive monitoring and maintenance and are viewed as a risk by both home-owners and regulators.

- Home-owners fear the potential costs if their system fails the tests.
- Regulators fear the impacts to the public and environment if the system fails.

The likelihood and magnitude of risks of these two types of dysfunctions are generally not well known. As a result, both parties will tend to minimize their perceived risks, potentially by avoiding alternative treatment systems altogether.

Standardized methods for explicit risk estimation under a variety of conditions is needed to enhance and improve performance-based permitting for alternative treatment systems. With such methods one could develop and test a set of permitting guidelines that account for the site-specific variables that drive risks (e.g., depth to groundwater, soil type, temperature) to a suite of receptors (e.g. various members of the public and ecological receptors). These may ultimately take the form of new prescriptive regulations that can be applied to a wider variety of systems and sites.

Efforts are underway within the field of decentralized wastewater treatment to develop risk-based approaches to decision making. These include modeling efforts and community demonstration projects in which stakeholders identify the issues of concern and help guide the decision-making process. These efforts are an excellent step towards explicit risk-based decision making.

A significant limitation of these approaches is the lack of a standardized method for integrating disparate risks into a comprehensive approach to risk-based decision making that can be applied at various sites and geographical scales. Additional limitations generally include a lack of explicit, risk-based endpoints (i.e., a specified level of effect on an important property of the entity to be protected) and a failure to address all major types of risks (i.e., engineering, ecological, public health, and socieoconomic).

4 HIGH-LEVEL FRAMEWORK

This high-level framework provides a blueprint for integrating different discipline-specific assessments into a single cohesive risk assessment framework for decentralized wastewater treatment systems. Four disciplines are addressed:

- engineering,
- ecological,
- public health, and
- socioeconomic.

The general framework for decentralized wastewater treatment systems is presented in Figure 2.

It consists of a general problem formulation, a component framework for each discipline, a general risk characterization, and a brief discussion of risk management issues. The explanation of each of these components will be aided by including high-priority issues as examples.

4.1 General Problem Formulation

The general problem formulation defines the scope and objectives of the general framework. This entails:

- identifying the spatial and temporal bounds within which the framework will be applied;
- identifying the potential stressors and receptors;
- selecting assessment endpoints and ensuring that they can be addressed within the appropriate component assessments;
- developing a generalized conceptual model of the systems to be evaluated; and
- selecting appropriate measures of effects and exposure.

These steps occur in approximately the order they are presented, though the problem formulation process is often iterative. For example, additional indirect stressors may be identified as the conceptual model is developed. Receptors and assessment endpoints would then be selected for those indirect effects. Each of these five steps is discussed below.

4.1.1 Spatial and temporal bounds

Identifying the spatial and temporal bounds within which risks will be considered is important because those bounds will determine what types of stressors and receptors are appropriate. This, in turn, determines which assessment endpoints and which discipline-specific assessments should be included.

For purposes of discussion, we will consider two spatial scales, the micro-scale and the macro-scale. The micro-scale refers to an individual residential plot with an on-site drinking water well and a decentralized wastewater treatment system. The macro-scale refers to a watershed which contains many individual decentralized systems, as well as other point and non-point sources of pollution.

4.1.2 Stressors and receptors

Identifying the potential stressors and receptors entails listing all of the credible ways in which the treatment of wastewater can adversely affect people (individuals and communities) and the environment. Stressors include any physical, chemical, or biological entity that can induce an adverse response in a receptor. Receptors include human and non-human organisms and systems (e.g., ecosystems, communities, social systems).

Micro-scale
People are the primary receptors of concern at the micro-scale, because most non-human organisms and ecosystems are best addressed at larger spatial scales (the macro-scale). The

stressors of greatest concern for humans are pathogens and nitrogen in drinking water, based on feedback from the regional forums and the existence of prescriptive permitting requirements addressing those stressors.

The prominent pathway for exposure at the micro-scale is through the consumption of contaminated drinking water from a down-gradient well. The well in question may be on the same site as the treatment system or on an adjacent site.

Surface break-though of raw sewage is another potential pathway for human exposure. Pathogens are the primary stressor. Noxious odors may help limit incidental contact with raw sewage. Therefore, one might identify noxious odors as a secondary stressor and the property owners as the receptors.

The most obvious ecological receptor at the micro-scale is aquatic vegetation along waterfront property. Nutrient loading in the form of nitrogen and phosphorous is the primary stressor of concern.

Macro-scale
Pathogens and nutrients are also the focus of concern at the macro-scale (e.g., watersheds), but the receptors and pathways are more varied. The notable pathways for exposure to pathogens include contamination of municipal water supplies and coastal shellfish beds, in addition to the contamination of private wells. Adverse effects and receptors at the macro-level include illness in the general population. Hence, there are also socioeconomic risks in the form of inconvenience and reduced quality of life.

Nutrient-loading is a significant problem for many watersheds, as reflected in the establishment of Total Maximum Daily Load (TMDL) limits for key nutrients. Adverse ecological effects include the loss of pollution-intolerant species of aquatic animals.

4.1.3 Assessment endpoints

Selecting assessment endpoints and ensuring that they can be addressed within the appropriate component assessments is arguably the most critical and commonly mishandled step of problem formulation. Assessment endpoints are an explicit expression of the value that is to be protected. They consist of:

- an entity,
- a property of that entity that can be measured or estimated, and
- a level of effect on that property that constitutes an unacceptable risk.

Therefore, in addition to stating “protection of public health” as an objective, one would specify an assessment endpoint against which success or failure can be measured. For example, a public health assessment endpoint at the micro-scale might be defined as a rate of exceedance of drinking water standards due to contamination of a private well by a decentralized wastewater treatment system.

At the macro-level, an example assessment endpoint for the protection of public health might be

defined as a rate of exceedance of health standards in a shellfish bed contaminated by decentralized wastewater treatment systems. An alternative endpoint might be a closure rate for shellfish beds (e.g., days per year) due to contamination by decentralized wastewater treatment systems. Note that this endpoint might also be appropriate for the assessment of economic impacts.

Criteria for selecting assessment endpoints include:

- relevance to the value to be protected,
- susceptibility to the stressors of concern, and
- relevance to public policy and management goals.

Relevance depends on the value to be protected. If it is an ecological value (e.g., a "healthy" stream system in a macro-level assessment), then the endpoint must be ecologically relevant. In this example, one might select the fish community as an endpoint entity because fish are an important part of energy transfer within aquatic systems. Similarly, exceedance of drinking water standards is directly relevant to the health of the public at-large and loss of productive shellfish beds is directly relevant to the economic value provided by shell fishing.

Susceptibility to the stressors of concern is a function of exposure and sensitivity. An assessment endpoint entity must be exposed, or potentially exposed, to the stressor of concern. Exposure is typically defined as co-occurrence or contact of the receptor with the stressor. Therefore, one must consider the likely sources, transport, and fate of the stressors when selecting an assessment entity.

For example, residents with private drinking water wells (the assessment entity) are potentially exposed to pathogens (the stressor) from up-gradient decentralized wastewater treatment systems. The frequency and magnitude of exposure must also be considered. In this example, one might further define the assessment endpoint entity as permanent residents, because they are expected to be more frequently exposed to the stressor than seasonal residents. If overloading of the system by an influx of seasonal residents is a concern, then one might establish two complementary assessment endpoints, one for permanent residents and one for seasonal residents.

Sensitivity refers to how readily the endpoint entity responds to the stressor. Sensitivity is a function of the mode of action of the stressor and the characteristics of the receptor. Mode of action typically refers to the way in which physiological mechanisms are affected by the stressor.
Characteristics of the receptor that may influence sensitivity include behavior and life-stage. For example, people with some diseases and conditions are known to consume above average quantities of water. This behavior may increase their exposure to pathogens, nitrogen, or other contaminants in private drinking water wells.

An example of life-stage influencing sensitivity can be seen in the susceptibility of babies to infantile methemoglobinemia (blue-baby syndrom) from exposure to nitrates in drinking water. Their potential sensitivity is the driver for current limits on allowable levels of nitrates in drinking water. This makes them likely candidates as assessment endpoints.

Relevance to public policy and management goals is a measure of the degree to which the assessment endpoint addresses the issues of concern to decision makers and stakeholders. The

relevance (and importance) of the assessment to the decision making process depends on the relevance of the assessment endpoints. Failure to produce a relevant assessment will result in misuse or dismissal of the assessment. Selection of endpoints that are relevant to the public policy and management goals increases the probability that:

- decision makers will use the assessment and
- that the assessment will increase the quality of the decisions.

For example, if the management goal is to keep a shellfish bed open to harvesting for human consumption, then the assessment should include endpoints consistent with the local regulations for shellfish beds (e.g., specific coliform levels, etc.). If the only endpoints are those related to productivity of shellfish, then the assessment is likely to be ignored.

Ensuring that the assessment endpoints can be addressed within the appropriate component assessments (e.g., the public health risk assessment) entails 1) developing a conceptual model of the systems to be evaluated and 2) selecting measures of effects and exposure the are appropriate for the assessment endpoints and type of assessment. Those issues are addressed below.

Ensuring consistency between the component assessments and the general problem formulation phase entails iterative definition of the assessment endpoints at both levels of organization. That is, as the component assessment is developed and more is learned about the modes of exposure and effects, it may become necessary to refine the assessment endpoints in the general problem formulation. This is particularly likely for novel assessments.

It is also likely that the measures of effects and exposure will need refinement during the course of the assessment. This is why it is critical to maintain communication between the risk assessor and risk manager throughout the assessment process.

4.1.4 Conceptual model

Developing a generalized conceptual model of the systems to be evaluated entails describing and visually depicting the relationships between the stressors and the receptors. The conceptual model includes the known and expected relationships among the

- stressors,
- exposure pathways, and
- receptors (assessment endpoints).

Only those relationships which are considered in the assessment are included in the model. The supporting text should describe the assumptions used to develop the conceptual model. Relationships that cannot or will not be addressed should be clearly identified. The supporting text should include a rationale for the exclusion of prominent relationships.

For example, one might suggest that airborne transmission of pathogens from surface break through of sewage could be excluded. The rationale might be that this has been shown to be a trivial pathway or that there is insufficient scientific understanding of the processes involved to conduct a credible assessment. This is an example only and may or may not be an acceptable

assumption. But the conceptual model provides an explicit statement of the assumptions and knowledge of the relationships between the stressors and receptors. This enhances communication with decision makers and stakeholders and highlights issues that need further research.

Two example conceptual models are presented below, one for the micro-level and one for the macro-level. Both examples address the transport of nutrients and pathogens. They are in the form of standard box-and-arrow diagrams. This is not the only way to present a conceptual model. For example, one could also use a diagram of a typical site, pictures or icons of sources and receptors, or a table with check marks indicating which pathways and stressors are associated with each receptor (endpoint). Any number of models could be developed, but the models must be clear and concise depictions of the relationships included in the assessment.

A Micro-level conceptual model for transport of nutrients and pathogens at the individual treatment system scale is presented in Figure 3. Only one ultimate source is considered in this example: a manufactured wastewater treatment system. Nutrients and pathogens may be discharged directly to the soil surface where the receptor can be exposed to the raw product. The exposure pathways for residents of the property include direct contact and inhalation of pathogens. Inhalation is conservatively included in this model (not withstanding the aforementioned rationales for excluding inhalation). Pathogens are the stressors of concern for resident receptors, but nutrients are assumed to be similarly discharged.

Discharge of the wastestream to a drainfield is the other major route for pathogens and nutrients that is considered in this example. The wastewater plume may intersect a private water supply, resulting in direct exposure to residents using the drinking-water well. Both pathogens and nutrients (nitrogen) are stressors of concern. It is recognized that the fate and transport assumptions are somewhat different for each stressor. These intricacies are addressed in the analysis of exposure, rather than in the conceptual model.

The wastewater plume may also intersect an adjacent surface water body (e.g., a lake or estuary). It is assumed that residents use this area for recreational swimming and shell fishing. Both activities are direct exposure pathways for pathogens. Nutrients (nitrogen) are not considered a stressor of concern via swimming: it is assumed that the susceptible receptors (infants) will not be swimming for significant periods of time (if any). Shellfish consumption is also assumed to be an insignificant pathway for nitrogen and infants.

Nutrients (nitrogen and phosphorous) are the stressors of concern for aquatic plants in the adjacent surfacewater body. Discharges to this area may result in accelerated growth of rooted aquatic plants and algae (eutrophication). This can have adverse effects on the people and animals that use this area.

It should be noted that more than one conceptual model can be used. This is particularly true for complex interactions. For example, one could develop a separate conceptual model for the social and ecological impacts of eutrophication. Another likely model would be one depicting the individual components of a the decentralized wastewater treatment system. It could include stressors on the system and likely points of dysfunction.

A Macro-level conceptual model for transport of nutrients and pathogens at the watershed scale is

presented in Figure 4. Four ultimate sources are considered in this example: decentralized wastewater treatment systems, agriculture, a centralized wastewater treatment system, and urban run-off. This reflects the relative complexity of watershed level assessments and the need to address cumulative impacts.

In this example, direct exposure to each of the ultimate sources is not considered to be relevant or appropriate at the watershed scale. Two proximate sources are contaminated by the ultimate sources: groundwater and surface water. These proximate sources are assumed to be interconnected. Nutrients and pathogens may pass from groundwater to surface or from surface water to groundwater. That is, decentralized wastewater treatment systems can be a significant source of nutrients to surface water, even though the model assumes there is no direct link between them.

Decentralized wastewater treatment systems are assumed to discharge to groundwater via drainfields. Agricultural sources include livestock and crop farms. These sources may contaminate groundwater and surfacewater via leeching and run-off, respectively. Urban run-off is, by definition, considered to be a direct source to surface water.

Centralized wastewater treatment systems are assumed to be direct sources to surface water via permitted discharges. Groundwater infiltration is assumed to be minimal for this sewer system. While this is likely to be an oversimplification of reality, estimating infiltration along the miles of sewer pipelines was deemed beyond scope of this (hypothetical) assessment.

Groundwater is assumed to be a potential source of contamination to private and public potable water supplies. Nutrients and pathogens are stressors of concern. At the macro-level it may be appropriate to look at impacts to the local economy from an outbreak a water-borne disease. The endpoint could be lost productivity, repair costs (treating the water, supplying bottled water, etc.), reduced property values, or any other socioeconomic endpoint of concern to the stakeholders.

Contaminated surface water may impact public health, the environment, and socioeconomic endpoints. The direct pathways are the same here as for the micro-level model. However, the increased geographic scale of the macro-level model means that additional receptors may be appropriate. In this example, fish are identified as an endpoint with habitat degradation the stressor. It is assumed that widespread eutrophication could reduce the number and types of fish in the surface water system. This could have an indirect impact on socioeconomic endpoints These could include reduced quality of life (loss of recreational fishing and swimming), lost tourism, reduced property values, or any other socioeconomic endpoint of concern to the stakeholders.

4.1.5 Measures

Measures are attributes that can be estimated or measured directly. Selecting appropriate measures is critical to establishing a link between the stressor and the assessment endpoint. EPA (1998) identifies three types of measures:

- Measures of effects are measurable changes in an attribute of an assessment endpoint or its surrogate in response to a stressor to which it was exposed,

- Measures of exposure are measures of stressor existence and movement in the environment and their contact or co-occurrence with the assessment endpoint, and

- Measures of ecosystem and receptor characteristics are measures of environmental attributes that influence the distribution of a stressor (e.g., soil temperature and depth to groundwater) or receptor attributes that influence exposure and response (e.g., age and behaviors).

These measures may be direct measurements of the assessment endpoint (e.g., occurrence of an illness in the endpoint entity). A surrogate measure may be needed when direct measurement is either impossible or impractical (e.g., fecal coliform counts in drinking water).

In the example of gastrointestinal illness in residents of an individual household due to contamination of a private well by a decentralized wastewater treatment system, which was presented above in the discussion of assessment endpoint definition, one might select the following measures of effects and exposure:

For example, one might select the following measures of effects and exposure for an assessment of contamination of a private well by a decentralized wastewater treatment system:

Effects
- Drinking water standards for the protection of human health
- occurrence of symptoms diagnostic of pathogens which are likely to be associated with water contamination by domestic wastewater sources
- results of medical tests (e.g., blood tests) that support or refute contamination by domestic wastewater sources

Exposure
- fecal coliform counts in well water samples
- hydrologic conditions consistent with treatment dysfunction
- treatment system history, including maintenance and usage patterns, which is associated with dysfunction
- exposure patterns for other potential sources of similar pathogens (e.g., contaminated food)

Characteristics
- soil temperature
- exposure of sensitive age groups (e.g., children and the elderly)

These measures provide evidence supporting or refuting the conclusion that the assessment endpoint was violated. The occurrence of symptoms likely to be attributed to pathogens from domestic sewage is circumstantial evidence. Exceedance of drinking water standards and clinical tests of the receptor are direct evidence.

Each of the measures of exposure provide circumstantial evidence of exposure. The presence of fecal coliform in the drinking water is the strongest line of evidence and may even be considered direct evidence by some. The first three lines of evidence for exposure can be used to show an increased likelihood of exposure due to treatment system dysfunctions. The fourth measure of

exposure, can provide evidence for alternative causes of the observed effects.

These measures are intended as examples only. In the course of an actual assessment of the scenario presented here, one might determine that these measures are unreliable or impractical. That would require the selection of new assessment endpoints or the pursuit of solutions to the technical problems through research and development.

4.1.6 Summary

In summary, the general problem formulation results are used to identify the discipline-specific assessments that are needed and to develop discipline-specific problem formulations. All four discipline-specific assessments may not be needed for a particular assessment, especially at the micro-level (individual decentralized treatment systems).

Engineering assessments of some form are needed for all assessments, because they provide the source terms of exposure for the other assessments. One might choose to stop at the engineering assessment if system reliability is the only issue and it has been defined as particular dysfunction types and rates (e.g., surface breakthrough of sewage) without specific consideration of the risks to potential receptors.

Most assessments will also include a public health assessment and, possibly, an ecological assessment. These address the receptors commonly protected by local and state regulations. Standard structures and methods for public health and ecological assessments have been developed for use in other applications, most notably the assessment of hazardous waste sites. These can be adapted for use in the field of decentralized wastewater treatment.

Socioeconomic risks are probably the most important risks from the public perspective. However, the socioeconomic risk assessment process is not as well defined as the engineering, public health, and ecological assessment paradigms. This often leads to incomplete or relatively informal socioeconomic assessments. Standard assessment paradigms (EPA, 1998) include socioeconomic issues in the endpoint selection process and the risk management process, without formally estimating the risks. A strength of integrated assessment is that it includes socioeconomic issues as part of the formal risk assessment <u>and</u> risk management processes.

Issues associated with development of discipline-specific problem formulations, and other discipline-specific issues, are discussed in the following sections.

4.2 Engineering Framework

The standard engineering risk assessment framework is comprised of three subcomponents: problem formulation, analysis, and risk characterization. Issues and approaches to engineering risk assessment for decentralized wastewater treatment systems are generally the same as those discussed above. Issues particular to the engineering component are addressed below

4.2.1 Objectives

The primary objectives of an engineering assessment are 1) to provide a basis for evaluating the probability of dysfunction, 2) to determine the source terms resulting from routine operations and system dysfunction for the ecological, public health, and socioeconomic components, and 3) to provide the source terms to the other components for determining the consequences, and ultimately risk, from these sources.

4.2.2 Problem formulation

The engineering problem formulation defines the scope and objectives of the engineering framework. This entails:

- identifying the spatial and temporal bounds within which the framework will be applied;
- identifying the potential modes of dysfunction and the factors that are likely to contribute to those dysfunctions;
- selecting assessment endpoints and, if they constitute source terms for other endpoints, ensuring that they are consistent with the exposure and effects models to be used in the subsequent assessments; and
- developing a generalized conceptual model of the systems to be evaluated.

Issues and approaches to problem formulation for the engineering assessment are generally the same as those for the general problem formulation. Issues particular to the engineering component are addressed below.

<u>The spatial bounds</u> of the engineering assessment for decentralized wastewater treatment systems differs from a typical engineering assessment because the environment becomes part of the system. That is, a drainfield or constructed wetland is an integral component of the treatment system, not just a part the receiving environment. This may be disputed from a regulatory perspective, but from an engineering perspective, aeration, percolation, type of soils (e.g., clay, silts, or sand), water table levels, etc., can be as important to the engineering assessment as the actual dysfunction of the manufactured components of the treatment system.

<u>Potential factors</u> that are likely to contribute to system dysfunction are conceptually similar to the stressors of concern in the general problem formulation. That is, they stress the system in ways that may lead to a violation of the endpoint (i.e., system dysfunction). Examples include, exceedance of system capacity, failure to properly maintain the system, periodically elevated groundwater levels, and decreased ambient temperatures. Such factors should be identified in the problem formulation and incorporated into the engineering analysis, to the extent practicable.

For example, if low temperatures are identified as a potential factor leading to insufficient microbial degradation prior to contact of the groundwater plume with a drinking water source, then transport models (qualitative or quantitative) that account for temperature should be sought during the analysis phase. If such models are not found, then this factor can be highlighted in the discussion of uncertainties and identified as an area needing further research.

<u>Typical assessment endpoints</u> for the engineering assessment are the expected types of dysfunction. They should include a magnitude and frequency of dysfunction (i.e., a level of effect) and a probability of dysfunction. For example, one might specify a surface breakthrough endpoint

as a five-percent probability of an occurrence of detectable discharge to the soil surface.

One might also consider non-dysfunction in a similar way. This is done to provide baseline source terms for normally operating treatment systems. That is, the system may be operating within the established norms, but the discharge may contain stressors at levels that pose a risk to public or ecological receptors. This is especially true when considering the aggregate source term from multiple treatment systems.

4.2.3 Analysis

The engineering analysis subcomponent identifies the technical issues associated with the modes of dysfunction. This entails calculating or qualitatively estimating the probability of each type of dysfunction. This also includes predicting the fate and transport of wastewater constituents in the environmental components of the treatment system (e.g., on-site soil, groundwater, and constructed wetlands).

Each item in the treatment system is considered in relation to its likely modes of dysfunction, the probability of occurrence, and the effects of the dysfunction. Each item, its function, and potential mode of dysfunction is listed, followed by other relevant information. Failure mode and failure cause include the physical or operational description of the manner in which a failure of the component occurs and an evaluation of the probable cause(s) of dysfunction. These causes include chance, over-stress, improper aeration or percolation in the soil, etc. Failure mode frequency provides a quantitative estimate of the frequency of each failure mode described. This may be limited to qualitative estimates (e.g., low, moderate, or high), because of a lack of data.

Estimating fate and transport within the environmental components of the treatment system entails using qualitative and quantitative models that account for significant environmental factors. These may include groundwater transport models, viral transport models, and biodegradation models.

4.2.4 Risk characterization

The engineering risk characterization subcomponent is where the probabilities of dysfunction for each individual element of the treatment system are combined to provide an overall estimate of the magnitude and likelihood of dysfunction.

The output from this process provides the inputs (source terms) to the ecological, public health, and socioeconomic assessments. Therefore, care must be taken to ensure that the dimensions of the engineering risks are consistent with the exposure and effects models to be used in the subsequent assessments. For example, the best available public health exposure-effects model may require estimated viral counts, rather than fecal coliform counts. Or the ecological exposure-response models may require, at a minimum, seasonal nutrient loading rates, rather than total annual nutrient loading rates.

This is also where uncertainty in the predicted failures and source terms is captured. That may be as simple as identifying and describing the sources of uncertainty or as sophisticated as quantitatively estimating the variability and uncertainty via Monte Carlo analysis. However it is done,

the purpose of this process is to ensure that uncertainties associated with the engineering assessment are not over-looked in the other discipline-specific assessments.

4.3 Ecological Framework

The standard ecological risk assessment framework is comprised of four subcomponents: problem formulation, exposure assessment, effects assessment, and risk characterization. Issues and approaches to ecological risk assessment for decentralized wastewater treatment systems are generally the same as those discussed above. Issues particular to the ecological component are addressed below

4.3.1 Objective

The primary objective of the ecological assessment is to aid environmental decision-makers faced with selecting among alternative treatment technologies to ensure that risks to ecological receptors are properly considered.

4.3.2 Problem formulation

As with the general problem formulation, ecological problem formulation includes identifying the spatial bounds of the assessment, identifying the stressors and receptors, selecting assessment endpoints, and developing a conceptual model of the ecosystem at risk.

The spatial extent of the assessment will largely determine the types of assessment endpoints that are appropriate. For very narrowly defined assessments, an ecological assessment may not be necessary. This may occur when evaluating a single system which does not discharge to susceptible environmental systems (e.g, a suburban site with no surface water resources in the immediate vicinity). An ecological assessment is more likely to be included in macro-level applications (e.g., watershed assessments).

Ecological assessment endpoints are typically limited to populations and higher levels of organization (e.g., communities, ecosystems, etc.). The relevant spatial scale for these endpoints is larger than the typical micro-level assessment (i.e., individual decentralized treatment systems). Exceptions may include impacts to natural wetlands and impacts to ecological entities that result in adverse effects to the public (e.g., excessive growth of noxious aquatic vegetation). Again, it is critical that the assessment endpoints and measures of effects and exposure be consistent with those identified in the general problem formulation.

4.3.3 Analysis

Ecological analysis is comprised of two parallel processes:

- exposure assessment identifies the technical issues associated with the pathways and mechanisms of exposure for the selected receptors;

- effects assessment identifies the technical issues associated with the exposure-response modes of the selected receptors.

Exposure and exposure-response models that address these issues are identified, evaluated for their ability to support the objectives of the ecological framework, and used to generate estimates of exposures and effects.

These assessments are performed in parallel with much effort devoted to ensuring consistency of the models and estimates. For example, the exposure model may estimate the concentrations of nutrients entering an aquatic system from one or more treatment systems and the exposure-response model may estimate the rate of growth of nuisance vegetation at various nutrient concentrations.

Each of these model types may generate uncertainty estimates (error terms) which can be used in the characterization of risks to quantify uncertainty in the predicted risks.

4.3.4 Risk characterization

The ecological risk characterization integrates the exposure models and effects models to provide an estimate of the magnitude and likelihood of adverse ecological effects (i.e., risk). This may be in the form of a qualitative estimate (e.g., low, medium, or high probability) or a quantitative estimate, depending on the data and models that are available.

Where practical, estimates of the risk should be in the form of a probability function for varying magnitudes of adverse effects. This may only be possible for stressors with extensive exposure-response data sets (i.e., chemical toxicants).

It is expected that multiple lines of evidence will be available for most assessment endpoints (e.g., measured stressor concentrations in water, measured habitat characteristics, and measured fish community characteristics). In these instances, it is generally not possible to calculate an overall estimate of risk. Instead, risks are characterized by a weight-of-evidence process, which involves determining whether or not the assessment endpoint was exceeded and what factors account for apparent discrepancies in the results, based on each of the available lines of evidence.

As for the engineering risk characterization, this is where uncertainty in the predicted ecological risks is captured. This is to ensure that the ecological uncertainties are not lost in the final assessment. That is, uncertainty characterization provides the context within which the estimates of risk are evaluated. As with the estimates of risk, uncertainty characterization may be qualitative or quantitative, depending on the available exposure and assessment data.

4.4 Public Health Framework

The public health assessment is comprised of four subcomponents: hazard identification, public exposure, health effects, and risk characterization. Many of the issues and approaches to public health assessment for decentralized wastewater treatment systems are similar to those discussed in the proceeding sections. Issues particular to the public health component are addressed below.

4.4.1 Objective

The primary objective of the public health assessment is to aid environmental and public health decision-makers, who must select among alternative treatment technologies to ensure microbial and chemical risks does not exceed public health protection standards.

4.4.2 Hazard identification

Public health hazard identification involves developing a conceptual model of potential exposure pathways associated with decentralized wastewater treatment systems.

Public health assessments are appropriate at both the micro-level (individual systems) and the macro-level (watersheds). This is because health protection is intended to extended to individual members of the public, not just to the overall population. Therefore, even micro-level assessments are relevant to the spatial requirements of the assessment endpoint entities (e.g., residents using private wells).

Assessment endpoints may also be defined as segments of the population that are highly exposed or highly sensitive to the stressors of concern. As in the examples presented in the general problem formulation, these may include persons with particular physiological conditions or those in a particularly sensitive stage of life (e.g., infants exposed to nitrates). Pathogens are likely stressors of concern, in addition to chemicals and nutrients, which are also stressors of potential ecological concern.

4.4.3 Analysis

The analysis phase of the public health assessment consists of a public exposure assessment and a health effects assessment. This process is conceptually similar to the ecological exposure and effects assessments:

- the public exposure assessment identifies the technical issues associated with the pathways and mechanisms of exposure for the selected receptors;
- the health effects assessment identifies the technical issues associated with estimating the impacts of microbes (i.e., protozoa, bacteria, viruses) and chemicals (e.g., nitrates) on humans; and
- both assessments are performed in parallel to ensure consistency of the models and estimates.

4.4.4 Risk characterization

The public health risk characterization integrates the public exposure and health effects models. The results are either qualitative (e.g., low, medium, or high probability) or quantitative estimates of risk, depending on the data and models that are available.

To the extent practical, estimates of the risk should be in the form of a probability function for varying magnitudes of adverse effects. This may only be possible for stressors with extensive exposure-response data sets (i.e., chemical toxicants).

This subcomponent should also identify and evaluate approaches for comparing chemical and microbial risks, balancing the respective risks, and assessing the relative risks of drinking water in the context of other risks to public health.

The risk characterization also should present the qualitative and quantitative estimates of uncertainty, as is practical for the available data and models.

4.5 Socioeconomic Framework

Socioeconomic risk assessment is the least well formalized of the four disciplines presented here. The approaches used to evaluate social and economic impacts are quite varied because of the wide variety of impacts that are evaluated. However, one can still organize the general process into problem formulation, analysis, and risk characterization components.

4.5.1 Objective

The primary objective of the socioeconomic assessment is to ensure that social and economic issues are properly considered when selecting among alternative wastewater treatment technologies.

4.5.2 Problem formulation

This discipline arguably addresses the widest range of issues associated with wastewater treatment. They are often the most important to the stakeholders (i.e., homeowners and local community). Potentially contentious issues include:

- costs of treatment systems,
- fairness of financial burdens,
- property rights,
- economic impacts to communities, and
- land-use planning.

Applying principles of risk assessment may be particularly helpful in assessing socioeconomic risks. Risk principles can be used to bring these issues forward so that they can be properly addressed in the assessment and management processes. That is, one should:

- clearly define the endpoints (i.e., include an entity, attribute, and level of effect);
- develop a conceptual model;
- select measures that link the stressor to the endpoints;
- ensure that these endpoints and measures are consistent with the management objectives;

- use models and estimates of effects that are consistent with the selected endpoints; and
- capture the uncertainties associated with the risk estimates.

These general principles are discussed in the Principles of Risk Assessment and High-Level Framework sections. Issues particular to socioeconomic risk assessments are discussed below.

Assessment endpoints for social and economic risks are conceptually similar to more traditional endpoints. They include an entity, attribute, and level of effect (when appropriate). The entity is often implied in socioeconomic evaluations. That is, the attribute may be specified but not the entity.

For example, one might evaluate the cost of treatment systems. Cost is an attribute. The entity is the group or individual that pays the costs. While this is obvious, specifying which group is paying can help clarify the goals and obstacles to the assessment. In this example, one might specify two endpoints:

- the costs to all property-owners in a watershed
- the costs to owners of newly developed property in a watershed.

Together these endpoints address the underlying issue of fairness of the financial burden. That is, are owners who are seeking new building permits forced to use more expensive systems because the existing systems in the drainage area are ineffective? This amounts to a subsidy of less effective and less expensive systems by the new property-owners.

Socioeconomic attributes are not limited to monetary costs. They also include non-monetary costs, such as convenience, aesthetics, and intrusiveness (e.g., maintenance personnel inspecting private treatment systems). Monetary and non-monetary costs are discussed in detail in the associated issue paper on socioeconomic issues.

One issue raised in the regional forums was the difference between risks and benefits. It was argued that risks could include the loss of benefits. This is implicit in many statements of risk (e.g., decreased aesthetics due to algal blooms).

However, this may be awkward for some benefits. For example, one potential benefit of decentralized systems is the ability to reuse grey water (non-septic waste water), especially in arid regions were water costs are high. Rephrasing this as “the risk of not decreasing the costs of water usage” is awkward and unclear. It is preferable to retain the positive (benefit) wording. This means one must specify in the problem formulation that both risks and benefits are considered in the assessment. However, complicated explanations as to the distinctions between risks and benefits are not especially helpful.

Measures in traditional assessments include measures of exposure and measures of effects. This terminology may be confusing for socioeconomic assessments. It seems more appropriate to think in terms of costs (risks) and benefits. As noted above, costs may be monetary or non-monetary in nature and benefits may be the reduction of risks. These terms are not conceptually parallel to exposure and effects. However, it is the costs and benefits that should be estimated or measured in a socioeconomic assessment.

4.5.3 Analysis

The socioeconomic analysis subcomponent identifies the technical issues associated with these risks and benefits. This entails calculating or qualitatively estimating each type of cost (risk) or benefit. The socioeconomic analysis draws heavily upon the engineering assessment. System costs are directly related to the types of treatment systems, types of failures, and the required amount of monitoring and maintenance.

Monetary costs (risks) are often the easiest to explain and quantify. Money is a scale to which all members of the public can relate. This is one reason economic issues are often the most important and contentious issues risk managers must confront.

Direct monetary costs are conceptually straight forward. They include items like the costs of installing and operating a treatment system. These costs can be estimated using project planning and evaluation programs (e.g., COSMO (ref)). Such programs allow one to specify the assumptions used to estimate costs in detail. For example, the assumed labor and material costs can be based on local and up-to-date estimates.

These programs make it relatively easy to generate estimates for alternative treatment systems. This can make the assessment process more transparent: all assumptions for each alternative can be presented and compared. However, transparency should not be confused with clarity. How clear these analysis are depends on how they are presented to the decision -makers.

Indirect monetary costs may be more difficult to quantify than direct monetary costs. These include costs (risks) such as the loss of economic growth due to restricted land use and loss of tourism dollars due to social and environmental changes.

For example, unrestricted development may diminish the appeal of a resort community. If tourism decreases, so do the economic benefits of tourism. However, there are also costs of tourism and benefits of general economic development. Estimating the likely changes in these areas can be very complicated. Transparency is the primary advantage of using risk assessment principles when evaluating these costs. All of the assumptions used to estimate the costs should be explicitly presented as part of the analysis of risks.

Non-monetary costs (risks) and benefits may be converted to a monetary scale. For example, one could establish the dollar value of a weed-free lake to lake-front residents. This could be the amount people are willing to pay to keep it weed-free or the amount they are willing to be compensated for not controlling weed growth. The amount is often determined by conducting surveys. These surveys may be of a specific community or a representative cross section of a larger community.

However, there are significant ethical and technical problems associated with any such valuation method (see Socioeconomic Issue Paper). These issues must be identified and discussed in the analysis phase. Any associated uncertainties should be carried forward into the characterization of risks.

Non-monetary risks and benefits can also be addressed directly, without converting them to a monetary scale. For example, one could rank the relative importance of each potential risk (cost)

and benefit. Such relative rankings are not quantitative. That is, the issue ranked number one is not necessarily twice as important as the issue ranked number two. Other non-monetary approaches are presented in the Socioeconomic Issue Paper.

4.5.4 Risk characterization

Risk characterization entails combining the monetary and non-monetary costs (and benefits) estimated in the risk analysis section. This includes ensuring the compatibility of those estimates and presenting the major sources of uncertainty in those estimates.

Integrating monetary and non-monetary costs into a decision making framework can pose significant technical challenges. One must ensure that the estimated risks and benefits are comparable. That is, the risks and benefits must be for the same:

- endpoint entities
- spatial scales, and
- temporal scales.

For example, the costs of individual treatment systems may be borne by a relatively small group of homeowners. The benefits may be realized by a much larger group of stakeholders. In this case, all members of the community might benefit from preserving the aesthetic appeal of a small community. How this disparity is handled can significantly affect the decision-making process.

How uncertainties are addressed can also significantly affect the decision-making process. It is important that all major sources of uncertainty are clearly and concisely presented. This is particularly important for socioeconomic assessments, because this discipline:

- is the least well-developed of the four risk assessment disciplines presented here and
- addresses issues very familiar to most decision-makers.

The assumptions inherent to the assessment may be based on relatively little technical information (data). That leaves them open for discussion and many interested stakeholders will have strong opinions about those assumptions. The best way to support the decision -making process is to explicitly identify the assumptions used and any information that supports or refutes those assumptions.

4.6 General Risk Characterization

4.6.1 Objective

The primary objective of the general risk characterization is to integrate the results of each component assessment into a cohesive evaluation of the risks to all of the selected assessment endpoints.

4.6.2 Approach

Two general approaches are appropriate for integrating the risks from multiple component assessments:

- mathematically propagating risks across disciplines and
- logically weighing the evidence of risks from each discipline.

Mathematical propagation is possible when quantitative estimates of risk are calculated within each component assessment. For example, it is standard practice to calculate the probability of human health effects as a rate of incidence. It is also standard practice to calculate engineering failure rates. It is theoretically possible to combine these calculations to get the probability that system dysfunction will lead to a particular health effect. This mathematical approach will probably not apply to most endpoints for decentralized wastewater treatment systems.

The integration of risks for most endpoints will be based on a variation of the weight-of-evidence process. The standard weight-of-evidence process entails logically evaluating several independent lines of evidence for a given endpoint (EPA, 1998; Suter, Efroymson et al., 2000).

A line of evidence is any model, test, or observation that can be used to estimate the magnitude or likelihood of risks. Examples include models yielding system failure probabilities, tests indicating the response of aquatic plants to increased nutrient loading, and observations indicating changes in aquatic communities. These lines of evidence may be used to characterize the risks of decentralized wastewater treatment systems damaging aquatic ecosystems.

However, one could not simply multiply the probabilities for each line of evidence to get the overall probability of impacts. Instead, one must logically evaluate each line of evidence to see how it supports or refutes the theory that decentralized wastewater treatment systems pose a risk to aquatic ecosystems. This entails weighing each line of evidence based on one or more of the following criteria, which are adapted from Suter et al. (2000):

- Relevance -Is the available information (models, data, observations, etc.) relevant to the types of treatment systems, environmental settings, and receptors being evaluated?

- Exposure/Response - Does an increase in the stressor of concern lead to an increase in the response of the endpoint (e.g., increasing installation costs results in increased aversion to alternative systems by home-owners)?

- Temporal scope - Does the information address important variations with time (e.g., depth to water table during wet season, seasonal use of vacation homes)?

- Spatial scope - Does the information adequately address the area(s) to be evaluated (e.g., includes sensitive water resources, macro-level models not used for micro-level evaluations)?

- Quality - Was the information generated using appropriate quality assurance and control procedures (e.g., appropriate analytical procedures were used, personnel installing the system were properly trained)?

- Quantity - How much information is available for a given system or circumstance (e.g., number of treatment systems tested)?

- Uncertainty - How reliable is the information in terms of estimating risks (e.g., estimated viral densities varying by several orders of magnitude, estimated costs within twenty percent of actual)?

After each line of evidence is evaluated, they are compared to each other and explanations are sought for any apparent inconsistencies. For example, public reaction to a proposed plan for using decentralized wastewater treatment systems might be more negative than was expected, based on the estimated costs. One possible explanation is that important costs (monetary or non–monetary) were not included.

Risk characterization is also the stage at which the effects of multiple stressors are evaluated. This can be done to varying degrees, depending on the types of stressors, effects, and data. One of the strengths of the weight-of-evidence process is that comparing the results for multiple lines of evidence can help elucidate the relative importance of multiple stressors. However, distinguishing the effects attributable to individual stressors, or the combined effects of multiple stressors, is complicated and difficult. This issue continues to be a focus of research in the environmental sciences.

The degree of quantification that is possible in the general risk characterization will be limited by the degrees of quantification for each discipline-specific risk characterization for a particular assessment endpoint. For example, the public health component might estimate a risk of 1 x 10-4 for a particular exposure, but the engineering component may only be able to estimate the probability of dysfunction as high.

The degree of quantification of risks in each component framework will also determine how uncertainty can be addressed in the general characterization of risks. For example, if the component assessments provide qualitative risk estimates (e.g., low, medium, or high), then the uncertainties should be identified and discussed in the form of an uncertainty narrative. Quantitative methods of risk estimation will yield quantitative estimates of uncertainty.

Sensitivity analysis can be used to identify the factors and issues that have the greatest effect on the final conclusions of the assessment, provided the models and data are of sufficient quality. This process entails systematically manipulating input variables and measuring the changes in the final estimates of risks. The results may be used to refine and improve the models and data sets for the most sensitive factors. This may entail collecting more or higher quality data or conducting additional model research and development.

Sensitivity analysis is most appropriate where quantitative models are used to predict exposure or effects (e.g., fate and transport models). It is possible to apply this method to qualitative estimates of risks by changing the assumptions and re-evaluating the information. However, this can be very time consuming and may be limited to only a few iterations for a given endpoint.

4.7 Risk Management

Risk management is the process of deciding which actions to take in response to a risk. It entails considering the results of the risk assessment along with other factors explicitly excluded from the assessment of risks.

4.7.1 Objective

The primary objective of risk management is to balance the risks to all endpoints and parties of concern.

4.7.2 Approach

Risk management is the final component of risk-based decision making. This is the stage at which all potentially important issues are considered, including the:

- magnitude and uncertainty of the estimated risks (including monetary costs and social impacts),
- risks of not taking any action,
- benefits of each potential action, and
- ethical and political considerations of each action

Risk management is a subjective process: it includes the personal opinions of the decision-makers and stakeholders. Although risk assessment is often based (in part) on professional opinions, these must be justified based on the available evidence. Personal opinions require no formal justification. Thus, risk management is subject to the will of the decision-makers.

Risk management entails setting management goals and using risk management methods to make decisions that achieve those goals.

Risk management goals are specific management objectives. They typically consist of a risk (or benefit) and the desired result of managing that risk (or benefit). For example, one might set a goal of reducing the risk of eutrophication to levels that are acceptable to the public (including regulatory agencies and the affected communities). Another goal might be to balance the risks of adverse impacts (e.g., risks to public health and the environment) against the risk of intrusion onto personal property (e.g., professional maintenance and operation of treatment systems).

Two related issues raised at the National Research Needs Conference are worth noting. The first is that one general management goal should be the development of treatment systems that require "reasonable" levels of maintenance at a "reasonable" cost, rather than "cheap" systems that require "little" maintenance. The second issue is that we as a society need to consider how much risk we're willing to accept in order to have the freedom to chose a less-expensive system. These are both risk management issues that affect the selection of assessment endpoints and methods and research goals and objectives.

Management objectives and goals should be established prior to conducting the risk assessment (i.e., during the general problem formulation phase). It is these goals and objectives that the assessment is intended to support. If they are not clearly defined, then it is unlikely that the

assessment will provided the information needed by the decision-makers.

Risk management methods are the tools and techniques used to balance the perceived risks and benefits. Public decision making is still generally done ad hoc, rather than via sophisticated decision analysis tools. Examples of rigorous decision-making tools include the WARMF and MANAGE models. Such tools compel one to carefully evaluate each piece of information independently and consistently.

In the absence of formal decision support tools, care must be taken to ensure that the decision-makers are provided with a clear and concise list of issues that were critical to the conclusions of the assessment. These include an explicit list of endpoints that were and were not at risk and the degree of certainty of those conclusions.

The risk assessors should participate in the risk management process as technical advisors. They should provide assistance in interpreting the results of the assessment and developing plans to acquire new information or conduct additional assessments. This includes identifying critical data gaps and indicating how likely it is that additional research could fill those gaps.

5 EVALUATION OF RESEARCH NEEDS

The National Research Needs Conference will identify and evaluate the key issues for the field of decentralized wastewater treatment. This conference is analogous to the problem formulation phase of an effort to assess the risks and benefits of decentralized wastewater treatment systems. It entails identifying and defining the:

- problems,
- scope of the research efforts,
- objectives,
- assessment endpoints, and
- management goals.

It also includes a general plan identifying which issues will be pursued and how they will be pursued. This plan is analogous to the development of an analysis plan.

5.1 Objective

The ultimate objective of this conference is to identify the most important research and development issues so that they can be addressed by the National Capacity Development Project (NCDP) or other organizations.

5.2 Approach

The risk-based approach was selected to avoid the pitfalls of undirected research and development. The most notable pitfall is identifying projects based solely on academic interest or tractability of the problem. The undirected approach may lead to understanding of the processes and issues. However, it does not necessarily lead to better management of the field of decentralized wastewater

treatment. This includes management of research and development resources and management of the risks and benefits.

The risk-based approach to management of NCDP research and development is depicted in Figure 5. It consists of seven steps, which are discussed below. The risk-based approach will be used to guide the prioritization and review process. Each potential research topic will be evaluated regarding the degree to which it supports high-priority objectives and goals.

This approach is inherently an iterative process. As research needs are identified and met, it will be necessary to re-evaluate the research and development needs for distributed wastewater treatment. For example, the results of a particular research project may lead to a better definition of the acceptable risk associated with a given issue. This process will also help ensure that risk assessment is incorporated into the interpretation of the research results.

5.2.1 Identify objectives

The first step is the identification of objectives. Objectives are general statements, such as protection of public health from consumption of contaminated water. The identification of objectives is based the results of the regional forums and professional judgement.

5.2.2 Select endpoints and goals

The second step is selecting a set of assessment endpoints and management goals that support each general objective. Endpoints and goals are more specific than objectives.

Each objective has at least one assessment endpoint or management goal. The maximum number of endpoints and goals per objective is limited only by the feasibility of adequately addressing them. More than four or five per discipline for each objective is probably not practical.

Assessment endpoints include a specific entity and its attributes. Endpoints represent the values to be protected by an objective. The endpoints may be associated with any of the four disciplines that are part of the integrated assessment:

- engineering,
- ecology,
- public health, and
- socioeconomics.

Selection of assessment endpoints is discussed in more detail above in the high-level framework problem formulation section.

Risk management goals are similar to risk assessment endpoints: they are more specific than objectives. They typically consist of a risk (or benefit) and the desired result of managing that risk (or benefit). For example, balancing the impacts on future land use, the costs of installation and management, and the risks of water-borne illnesses.

5.2.3 Select measures and methods

The third step is selecting measures for each assessment endpoint and methods for each management goal. It is these measure and methods that are the focus of research and development efforts.

Measures are attributes of the endpoint that can be observed or estimated. This may require selecting surrogates for endpoints that can not be measured directly. Measures include: measures of exposure, measures of effects, and measures of endpoint characteristics (see the high-level framework problem formulation section).

Management methods are conceptually similar to measures for the field of risk management. They are the specific processes that would improve risk management for decentralized wastewater treatment systems (e.g., geographic information systems that improve the decision-making process).

5.2.4 Prioritize measures and methods

The fourth step entails classifying each measure and method based on three general criteria:

- importance to risk assessment or management,
- uncertainty of our current understanding of the measure or methods, and
- tractability of the associated research and development needs.

Prioritization is based on collective professional judgement. This consists largely of the considered opinions of selected experts in key fields of study. These opinions are presented in the other invited issue papers. The issues raised in those papers will be peer reviewed by the participants of the National Research Needs Conference.

Specific criteria for prioritizing the potential research topics were adapted from EPA (1996). They consist of the following questions, which are asked of each measure or method, as appropriate.

- What type of effect would be investigated?
- How severely might this effect impact the treatment of wastewater?
- How severely might this effect impact public health, ecosystems, or social systems?
- How severe are the potential economic impacts?
- Is this effect an immediate or long-term concern?
- How easily can the effect be reversed?
- What level of human, ecological, social, or economic organization would be impacted?
- How geographically extensive are the potential impacts ?

- How broadly applicable is the proposed model or method?
- To what extent will the proposed model or method facilitate or improve risk assessment or risk management?
- How large is the proposed user community for the proposed model or method?
- If risk management options currently exist, are they acceptable to stakeholders, implementable, reliable, and cost-effective?
- Could new or improved technical solutions prevent or mitigate the risks ways that are acceptable to stakeholders, implementable, reliable, and cost-effective?
- Are other research organizations currently investigating this issue or are they interested in working in partnership with the NCDP on this issue?

The final task of the prioritization step is to summarize answers to the above questions and provide a rank for each measure and method. To the extent possible, this summarization should be captured in a "quantitative" scoring system, in which each measure or method is assigned a score for each criterion (e.g., from 1 to 5) and the scores are summed across all criteria for each measure or method. This may require that answers to the 14 questions above be consolidated into a more manageable number of criteria. This concise list of criteria should include, at a minimum, the three general criteria presented above (i.e., importance, uncertainty, and tractability). Although the assigned scores are still subjective, this approach helps ensure that each criterion is applied consistently to each method or measure. The transparency of this approach will also lead to greater consistency among individuals assigning scores for each criterion.

5.2.5 Recommend for consideration

The fifth step entails recommending which measures warrant further research and development at this time. These recommendations will be based on professional judgement and may include nominations by the participants of the National Research Needs Conference. If a measure is not recommended for further research and development, then it should be identified as being of low priority.

5.2.6 Recommend for consideration by NCDP

The sixth step entails recommending which of the measures recommended for further research and development should be pursued by the NCDP. These recommendations also will be based on professional judgement and may include nominations by the participants of the National Research Needs Conference.

If a measure is not recommended for further research and development by the NCDP, then it should be identified as warranting further consideration by other organizations or institutions. For example, it was determined in the regional forums that the NCDP would not consider the appropriateness of

existing effects thresholds for viruses and other pathogens. If it is decided that this issue warrants further investigation, then it should be identified as such and passed on to appropriate agencies.

5.2.7 Define research goals

The seventh and final step entails defining the research and development goals for the measures and methods recommended for further consideration by the NCDP. This step is intended to ensure that research and development efforts are focused on goals that support the risk-based decision-making process. Doing this for all selected measures may be beyond the scope of the National Research Needs Conference. Efforts should be focused on those measures considered by the NCDP to be of the highest priority.

The development and explanation of these goals are presented in the other four issue papers. They are captured as the rationales and justifications for considering each issue to be of high-priority.

5.3 High-Priority Issues

One of the objectives of this paper is to identify several high-priority issues for decentralized wastewater treatment system. These are issues that were consistently raised in the three regional forums. The prioritization criteria mentioned above were not explicitly used in the forums. However, many of those criteria were implicitly considered in the topical discussions from which these issues were drawn. Commonly identified high-priority issues include:

- Baseline efficacy of standard and alternative treatment systems
- Baseline failure rates (standard and alternative systems)
- Impact of maintenance on performance (standard and alternative systems)
- Waste-stream characterization (constituents, loading rate, waste strength, seasonal usage)
- Impact of constituents (household chemicals, antibiotics) on treatment systems
- Disinfection by alternative systems
- Pathogen transport in soil systems (especially viruses)
- Nutrient transport in soil systems (nitrogen and phosphorous)
- Minimum depth to watertable (variation with soil type and seasonal fluctuations)
- Impact of soil temperature on treatment efficacy

- Direct costs of alternative treatment systems (installation and maintenance)
- Non-monetary costs (standard and alternative systems)
- Equity of financial burden among users
- Acceptability of performance-based permitting
- Political barriers (current system is defacto zoning)

- Cumulative impacts at the macro-level (multiple sources and stressors)
- Land use (urban sprawl, invasion of pristine environments)

6 CONCLUSIONS

Risk assessment is more formal than other approaches to evaluation and decision making. It ensures that prescribed decisive effects are estimated and that uncertainties are considered. Thus, the resulting products are more defensible and compelling. The bottom line is that the results will be more influential because they will be relevant to the concerns of decision makers and stakeholders.

If a risk-based approach to decision making is to be successful, the risk assessment process must be taken seriously. Unguided research or monitoring will not produce useful risk estimates. That is, any program intended to provide risk estimates must be guided by a risk assessment process consisting of:

- clear and acceptable endpoints,
- a logical structure,
- useful output, and
- estimates of effects and uncertainty.

Of particular note is the need for well-defined assessment endpoints. This requires all involved to clearly define the problems of interest. That is, the assessment endpoint must specify the property (e.g., entity and attribute) and a level of effect to be considered. Nebulous statements like protecting the quality of the environment or the quality of life are insufficient. Also, selected assessment endpoint properties must be measurable, either directly or by proxy (e.g., measures of exposure and effects).

Integrated risk assessment for the field of decentralized wastewater treatment can be accomplished. A prototype framework was presented. It consists of separate risk assessment and risk management sections. The risk assessment section includes subcomponents for each of for major disciplines: engineering, ecology, public health, and socioeconomics. Including a socioeconomics subcomponent means that costs (monetary and non-monetary) are explicitly included in the risk assessment section. These and other factors (politics, ethics, etc.) are also addressed in the risk management section.

A process for prioritizing research and development issues was presented. It is results in a risk-based program, rather than an unguided research and development program. It includes:

- clear and acceptable objectives,
- explicit assessment endpoints and management goals,
- explicit measures and management methods, and
- a consistent basis for prioritizing issues of concern.

The principles captured in this process were used to identify several high-priority issues. This was accomplished during the regional forums and in the issue papers commissioned for the research needs conference.

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EPA, (Environmental Protection Agency). 1998. *Guidelines for Ecological Risk Assessment*. Washington, D.C. EPA/630/R-95/002F.

Suter, G. W., II (1993). Ecological Risk Assessment. Boca Raton, FL, Lewis Publishers.

Suter, G. W., II, R. A. Efroymson, B. E. Sample and D. S. Jones (2000). Ecological Risk Assessment for Contaminated Sites. Boca Raton, FL, Lewis Publishers.

FIGURES

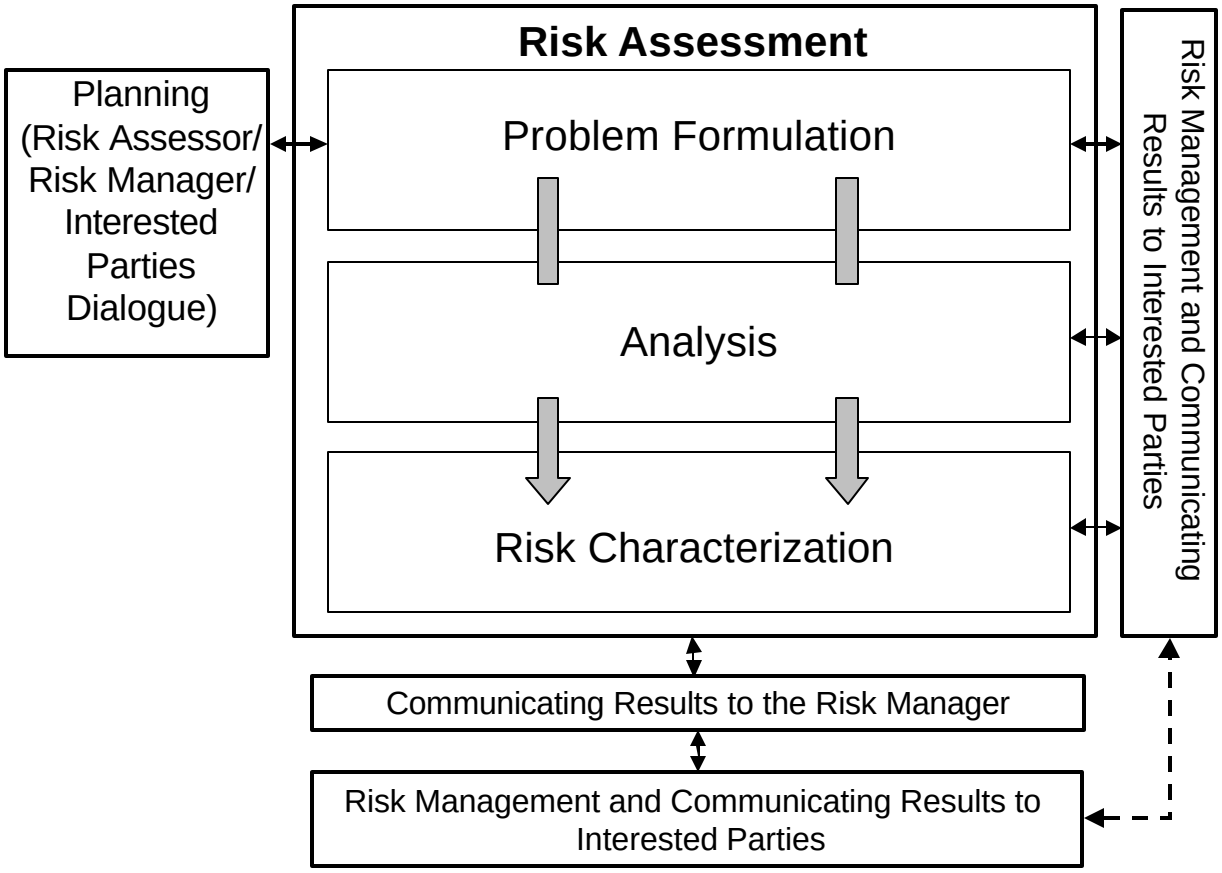

Figure 1.Standard risk assessment framework

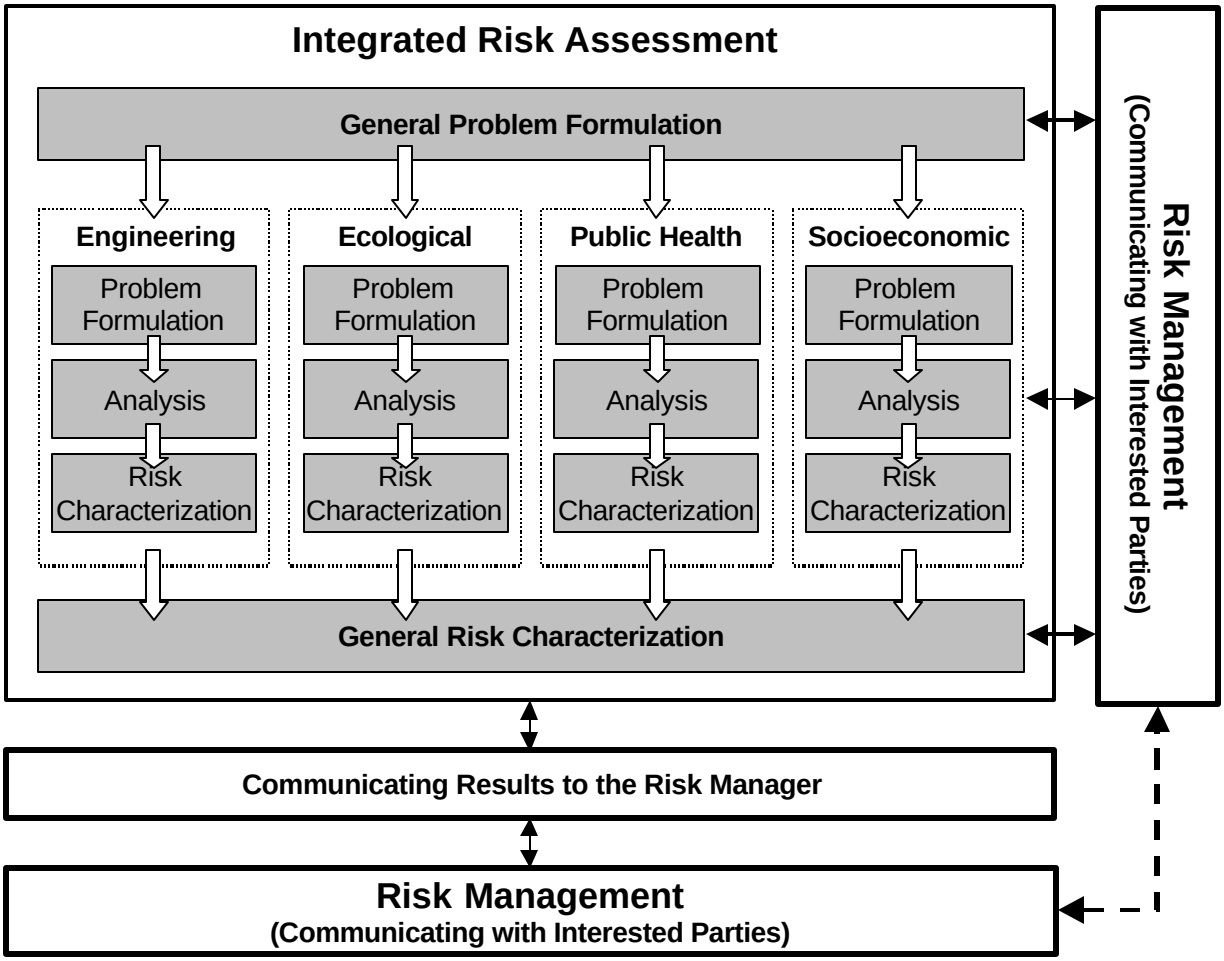

Figure 2.Integrated risk assessment framework for decentralized wastewater

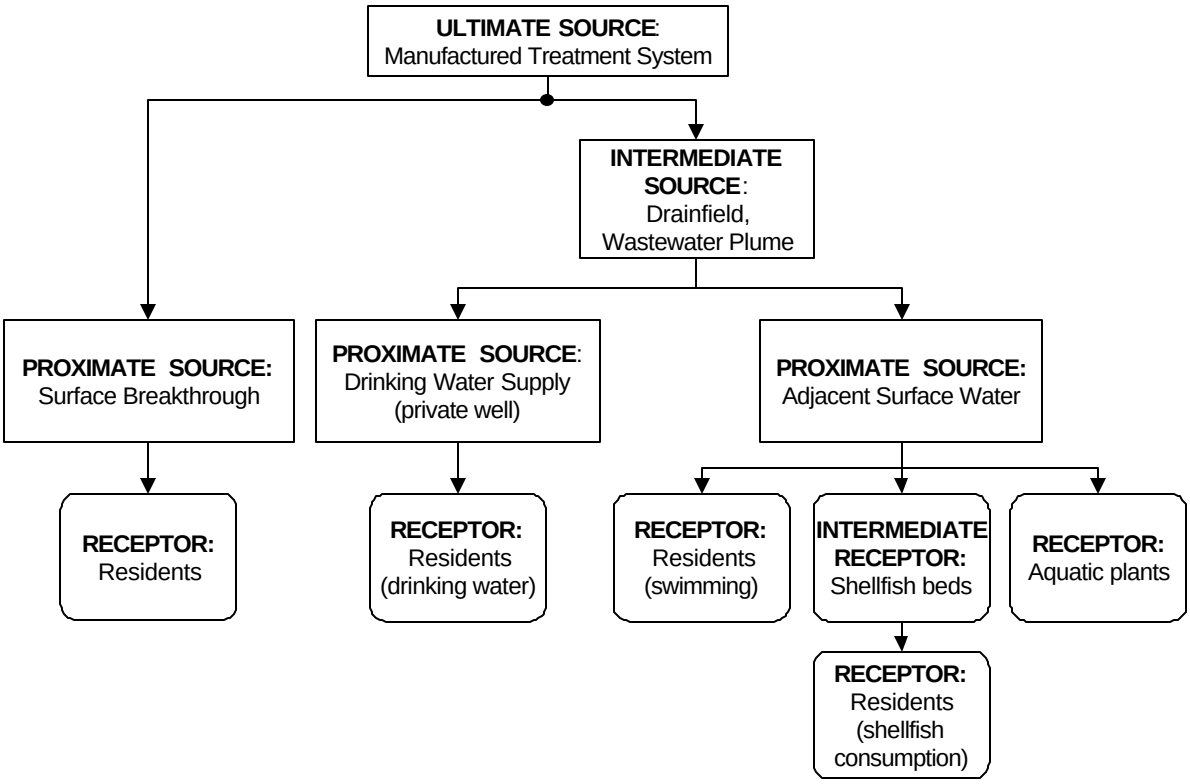

Figure 3.Example conceptual model for transport of nutrients and pathogens at the micro-level (individual treatment system).

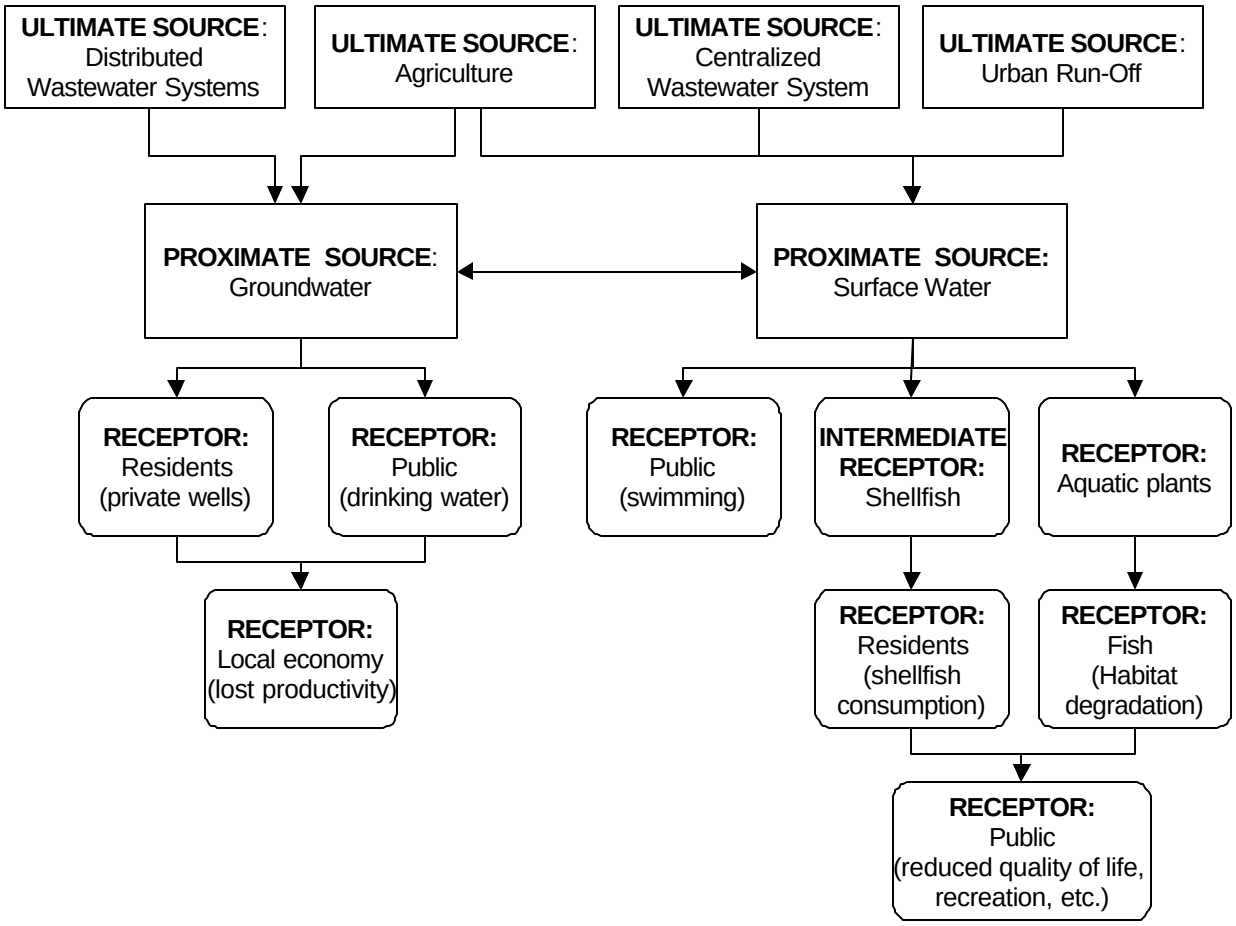

Figure 4. Example conceptual model for transport of nutrients and pathogens at the macro-level (watershed scale)

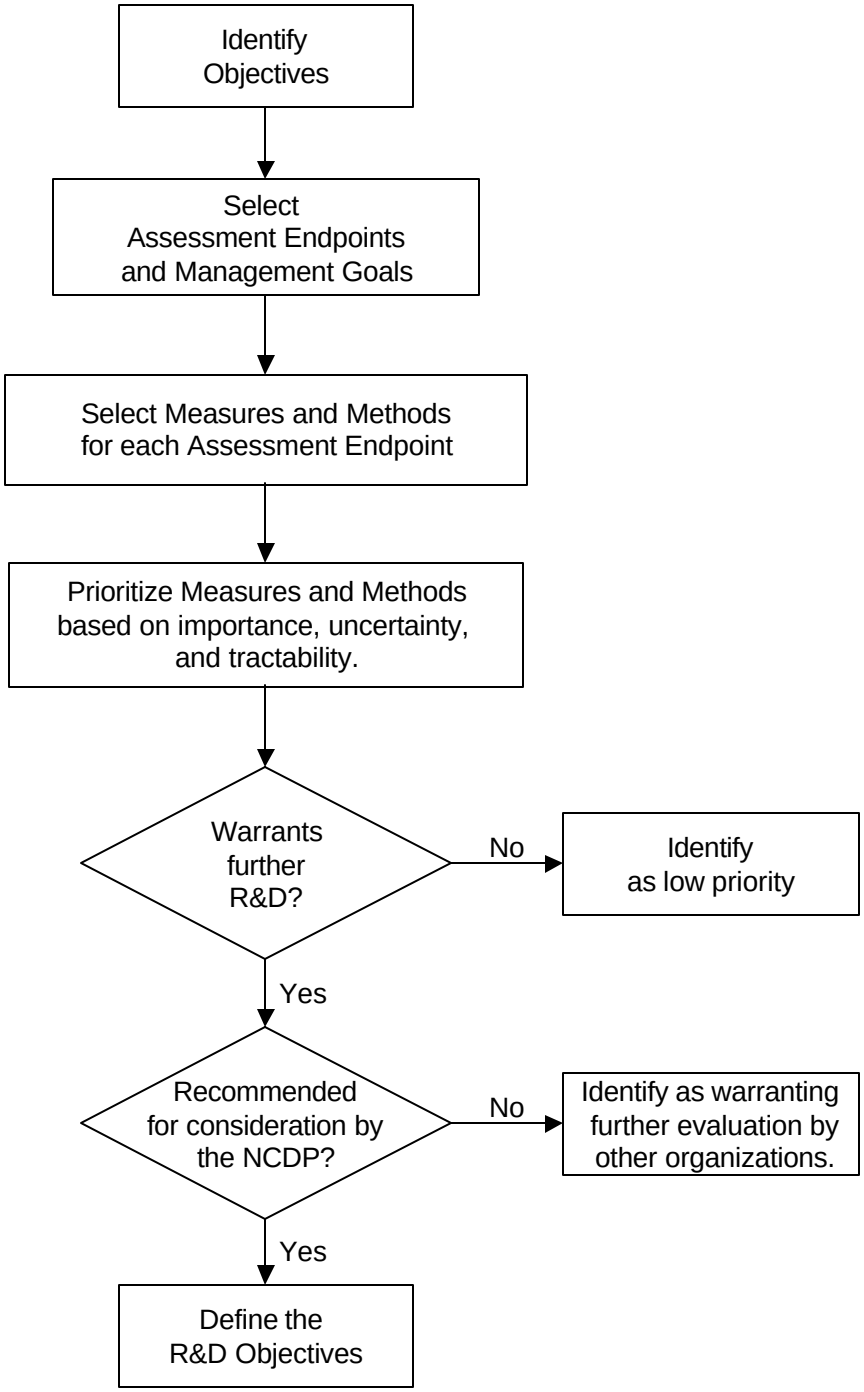

Figure 5. Risk-Based approach to management of the NCDP research and development efforts