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RISK BASED GUIDELINE VALUES AND THE DEVELOPMENT OF PRELIMINARY REMEDIATION GOALS

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ABSTRACT

Risk managers at federal facilities often need a risk-based tool to rapidly assess the possible human health risks of large numbers of sites before completing a baseline risk assessment. Risk-based concentrations, based on Preliminary Remediation Goal (PRG) development methodology, can be used as screening guideline values. We have developed a set of guideline values (GVs) for the Mound Facility at Miamisburg, Ohio, that are risk based, decision-making tools. The GVs are used (with regulatory approval) to rapidly assess the possibility that sites may be considered for "no action" decisions. The GVs are neither PRGs nor final remedial action levels. Development of the GVs on a facilitywide basis incorporated known contaminants of potential concern, physical and chemical characteristics of contaminated media, current and potential future land uses, and exposure pathway assumptions. Because no one site was used in the development process, the GVs can be applied (after consideration of the land use and exposure potential) to any site on the facility. The facilitywide approach will streamline the PRG development process by minimizing the efforts to develop site-specific PRGs for each operable unit at a considerable saving of time and effort.

INTRODUCTION

The Mound Plant, a Department of Energy Facility in Miamisburg, Ohio, is not unlike many other federal facilities that have diverse environmental restoration needs. Limited resources and the need for rapid decision-making processes make vital the development of risk-based, decision-making tools for site prioritization and decision-making. The United States Environmental Protection Agency (EPA) established the Preliminary Remediation Goals (PRGs) as a risk-based decision-making tool for use in the scoping phase of the Remedial Investigation/Feasibility Study (RI/FS) (1). As each site enters the RI/FS process, as shown in Figure 1, the development of PRGs begins anew for each site. The RI/FS process, often conducted by various subcontractors for the facility, results in an costly and time-consuming redundant process of determining PRGs.

Determining the priority of site cleanups comes long before the RI/FS process, and a decision-making tool for risk-based prioritization is needed before the PRG process is prescribed. If the tool can meet with regulatory approval, decisions concerning sites requiring no further action can be expedited. We have developed a set of GVs to streamline the PRG process for the Mound Plant.

BODY

The *Risk Assessment Guidance for Superfund (RAGS): Volume 1- Human Health Evaluation Manual, Part B - Development of Risk-Based Preliminary Remediation Goals*, hereafter referred to as RAGS Part B, served as the framework for the development of the Mound GVs (1). The main steps in the initial development of the risk-based GVs for the Mound Plant are shown in Figure 2. A global approach to developing the GVs was taken to address the facility as a whole. Media of concern for the entire facility were taken from Mound documents. A conceptual site model for the various types of sources, receptors, media, and exposure pathways is shown in Figure 3. Media of concern for which GVs were developed were soil, sediment, groundwater, and surface water. Because of the limitations of the PRG equations, individual exposure pathways cannot be combined as they are in forward risk calculations. Several pathways evaluated for Mound Plant in forward risk equations such as the ingestion of fish were not included because they do not comprise major exposure pathways or have a likelihood of completion.

Step two in the process of GV development involved developing the list of contaminants of potential concern. Contaminants of potential concern were derived from Mound documents. The final list of contaminants of potential concern was verified using the Chemical Abstract Service Reference Number and standard chemical synonyms.

Step three in developing the GVs involved identifying appropriate future land uses so that the appropriate exposure pathways, parameters, and equations could be selected. The EPA documents *Risk Assessment Guidance for Superfund- Human Health Evaluation Manual, Volume 1, Part A* (2) and *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions* (3) provide guidance on identifying future land use decisions. As a rule, residential areas are assumed to remain residential. Sites that are surrounded by, or are near, operating industrial facilities are assumed to remain industrial areas. Stakeholder discussions were ongoing for the future of the Mound Plant. It was the desire of the community that economic activity continue on the Mound Plant facility even if the Mound Plant ceased operations. Some future land use options expressed in various venues included a shopping mall, business/office park, vocational school and agribusiness (4).

These land uses were used in the next step of GV development: the identification of appropriate exposure pathways. Site-specific exposure scenarios and their corresponding assumptions were developed based on the various land-use classifications. RAGS - Part A (2), RAGS - Part B (1) and the EPA guidance document, *Risk Assessment Guidance for Superfund: Volume I Human Health Evaluation Manual, Supplemental Guidance, "Standard Default Exposure Factors"* (5) provided guidance on the determination of appropriate exposure scenarios and assumptions useful in the development of the GVs. The standard default equations provided in RAGS- Part B (1) address the residential and commercial/industrial land uses. For land uses other than these, (i.e., recreational or subsistence farmer), exposure pathways, parameters, and equations were developed specifically for the Mound Plant. In the absence of site-specific information, default information was used. The exposure scenarios selected are shown in Table 1.

The GVs were calculated using EPA health criteria [i.e., reference doses (RfD) and cancer slope factors (SF)] and default of site-specific exposure assumptions. An RfD is EPA's preferred toxicity value for evaluating noncarcinogenic effects resulting from exposure to environmental contaminants. The two types of RfD toxicity values used by EPA for evaluating noncarcinogenic health effects are subchronic and chronic. A subchronic RfD is an estimate if a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without appreciable risk of deleterious effects during a portion of a lifetime (2 weeks to 7 years). A chronic RfD is an estimate of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects and is specifically developed to be protective for long-term exposure to a contaminant (7 years to lifetime) (2).

An SF is EPA's preferred toxicity value for evaluating the carcinogenic effects resulting from exposure to environmental contaminants. SFs are used to estimate an upper-bound lifetime probability of an individual developing cancer as a result of exposure to a known or potential carcinogen (2). Chemical-specific RfDs and SFs were taken from the EPA's on-line Integrated Risk Information System (IRIS) (6) and the EPA Health Effects Assessment Summary Tables (7).

The GVs and PRGs are calculations based on given levels of risk or noncarcinogenic hazard. The cancer risk levels established for this project were 10^{-4} to 10^{-6}. A hazard index of one was used for the noncarcinogens.

GVs are initial guidelines; they do not establish that cleanup is warranted to meet these goals. As a result, during a site-specific RI/FS, the initial list of chemical-specific PRGs may need to be revised or modified as new RI/FS data become available. Ultimately, GVs are modified to be used as PRGs based on the results of a final baseline risk assessment, which established the threshold criteria for protection of human health and compliance with ARARs (Figure 4). Design of remedial alternatives should remain flexible until the GVs are modified and final PRGs are available.

SUMMARY

The GV methodology is designed to streamline the EPA approach for developing site-specific PRGs at the Mound Plant by eliminating duplication of effort required to calculate risk-based PRGs for each waste site. Because the EPA PRG methodology was followed on a facilitywide scale, contaminants and media of concern, current and future land use assumptions, and likely exposure scenarios used in the development of the GVs will be applicable to the development of site-specific PRGs. This approach reduces the PRG development steps in the RI/FS scoping to a simple comparison of GVs to ARARs (Figure 4).

The GVs can be used as a risk-based screening tool to rapidly identify potential contaminants of concern, determine the need for further evaluation (baseline risk assessment), or to confirm that a site is a likely candidate for "no action" (Figure 5). The GVs can be used to screen existing data before conducting an RI or during various phases of site characterization to identify the potential for regulatorily unacceptable human health risks.

Generally, the GVs are compared to media-specific maximum contaminant concentration. Concentrations exceeding the GVs verify that a site is a potential human health threat and require the completion of an RI/FS and baseline risk assessment. Sites exceeding the upper limit of acceptable risks may be easily prioritized for rapid remediation. With regulator approval, sites that have not contaminant concentrations exceeding the GVs may be considered for no action, and RI/FS activities can be limited appropriately. Because the GVs can be used as a basis for proposing no action, sites considered for no action based solely on the use of the GVs should have adequate site characterization data (historical or current) and no evidence of past practices that generated significant quantities of waste. The GVs produced provide a wide range of exposure scenarios so that over-conservatism is avoided. At the same time, latitude is maintained in the selection of the final land use options.

DISCLAIMER

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Table 1. Exposure Pathways and Scenarios for Mound Plant Guideline Values.

Receptor/Scenario	Media	Pathway
Residential Child and Adult	Soil	Ingestion Inhalation External Radiation
	Groundwater	Ingestion Inhalation of Vapor Dermal Contact
Recreational Child and Adult	Soil	Ingestion Inhalation External Radiation
	Surface Water	Incidental Ingestion Dermal Contact
Subsistence Farmer Child and Adult	Soil	Ingestion Inhalation External Radiation
	Groundwater	Ingestion Inhalation of Vapor Dermal Contact
	Food	Ingestion of produce Ingestion of beef Ingestion of milk
Construction Worker Adult	Soil	Ingestion Inhalation External Radiation
	Groundwater	Ingestion Inhalation of Vapor Dermal Contact
Commercial Worker Adult	Soil	Ingestion Inhalation External Radiation
	Groundwater	Ingestion

KEY WORDS

Preliminary Remediation Goals
Streamlined Risk-based Screening

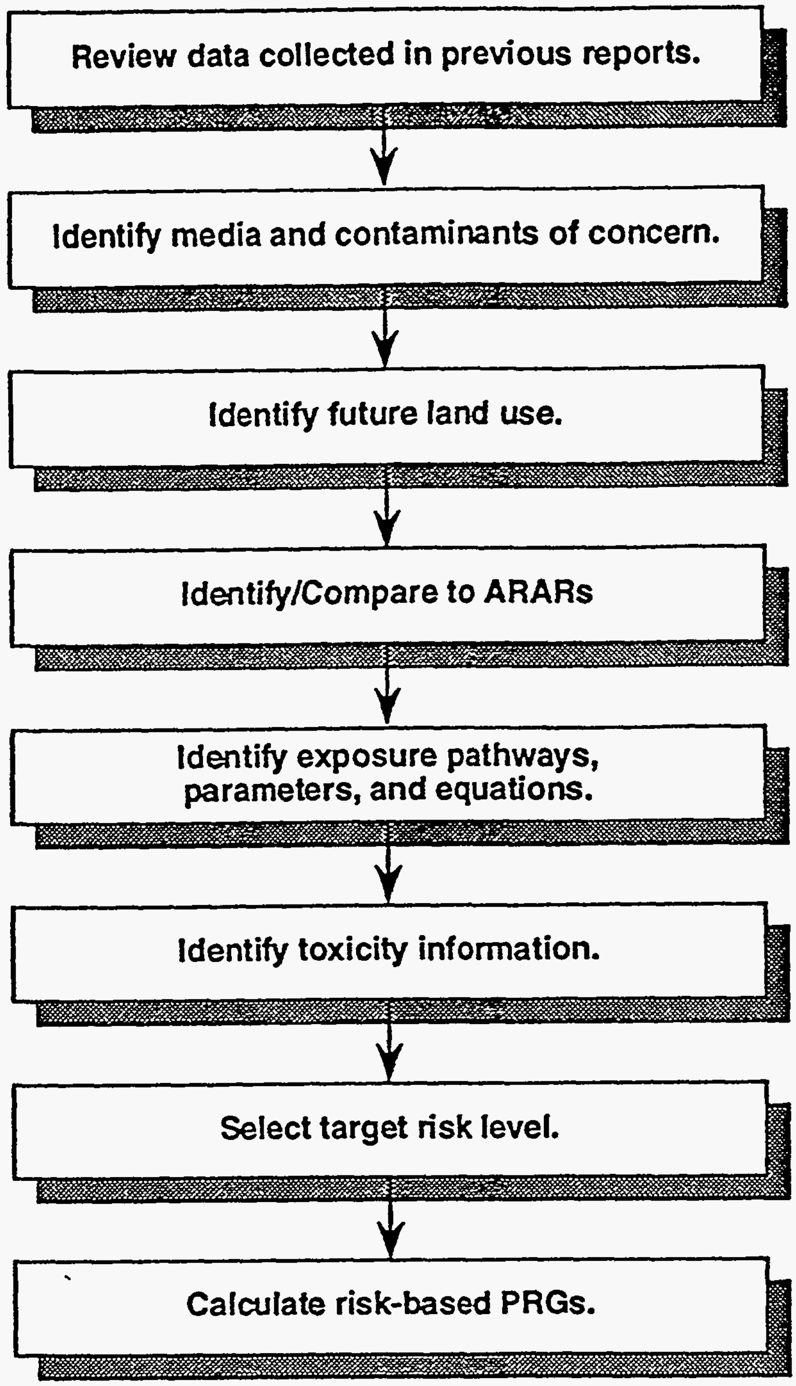

Figure 1. Development of risk-based Preliminary Remediation Goals.

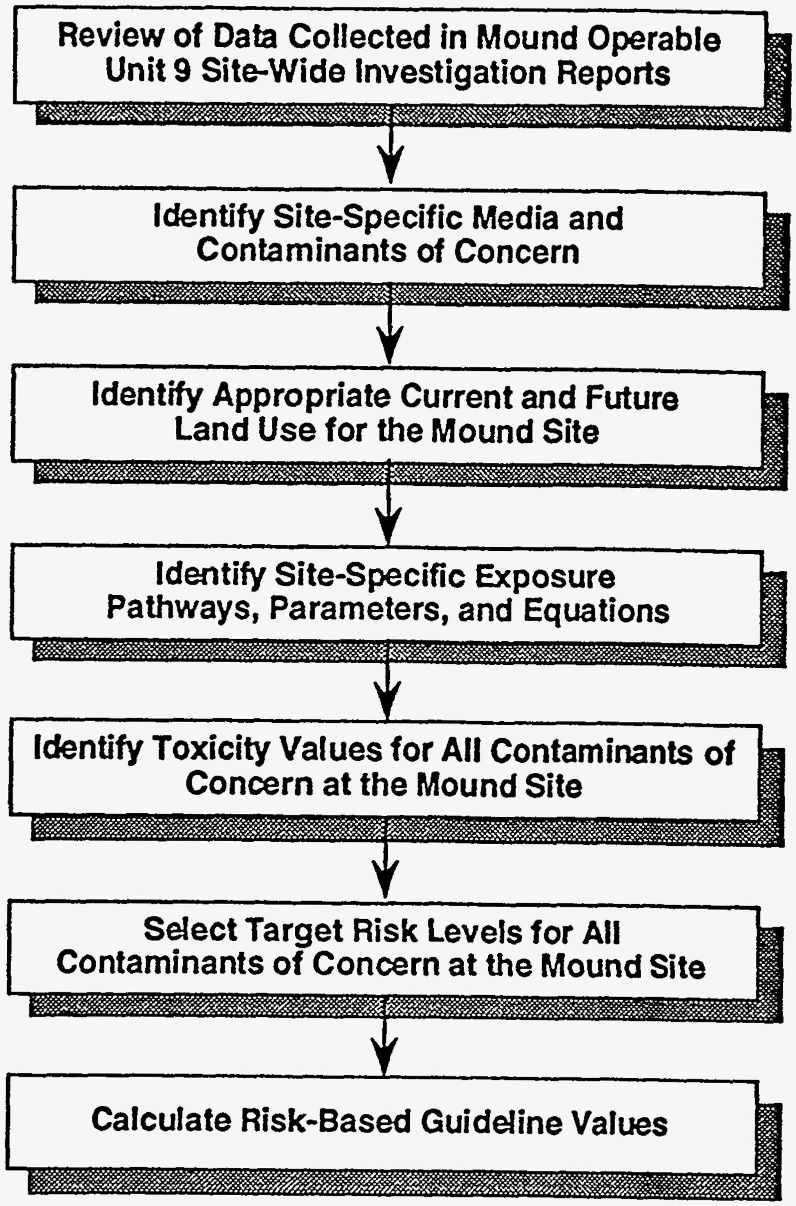

Figure 2. Development of Mound Plant risk-based Guideline Values.

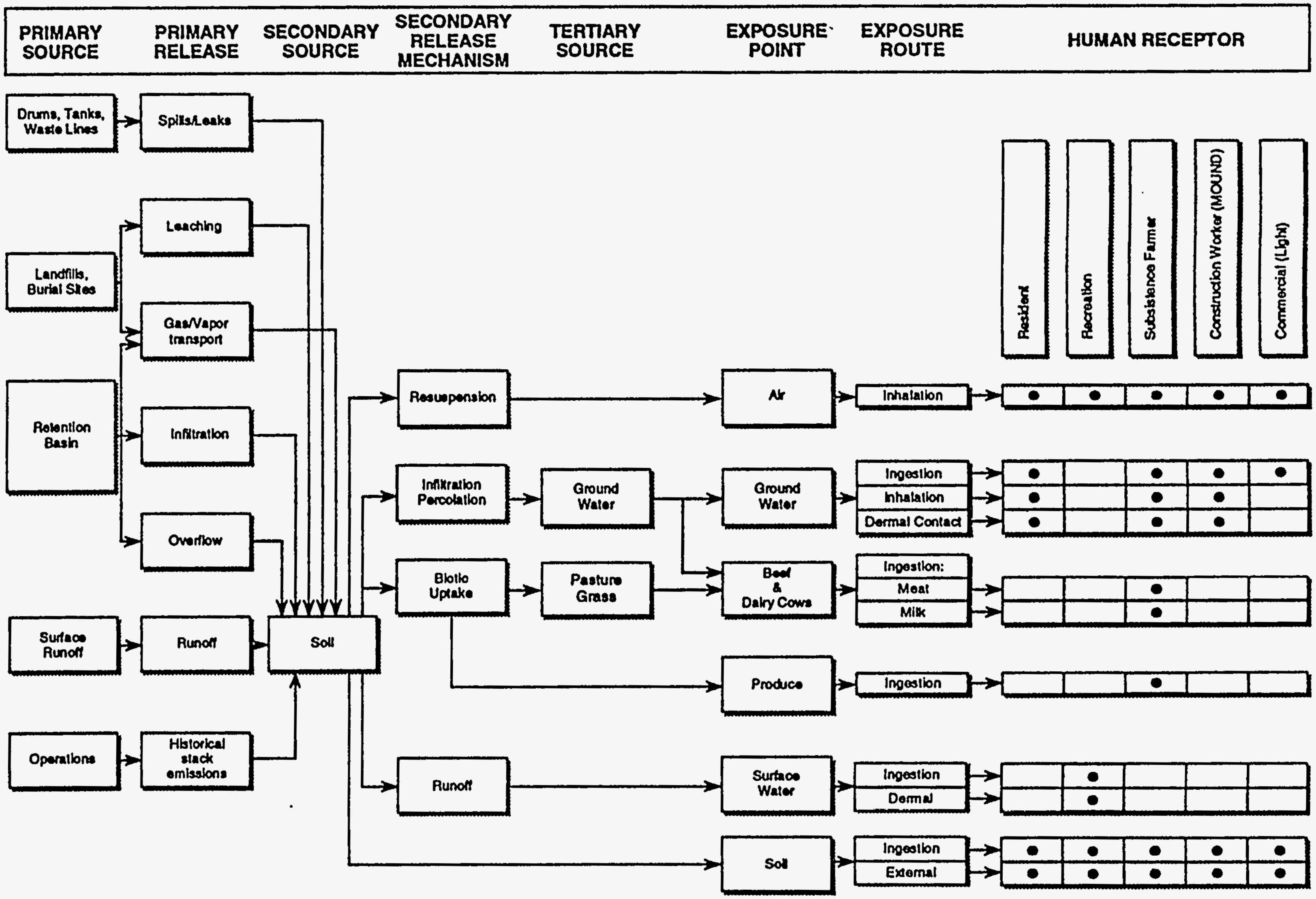

Figure 3. Conceptual site model for site-wide investigations at the Mound Plant.

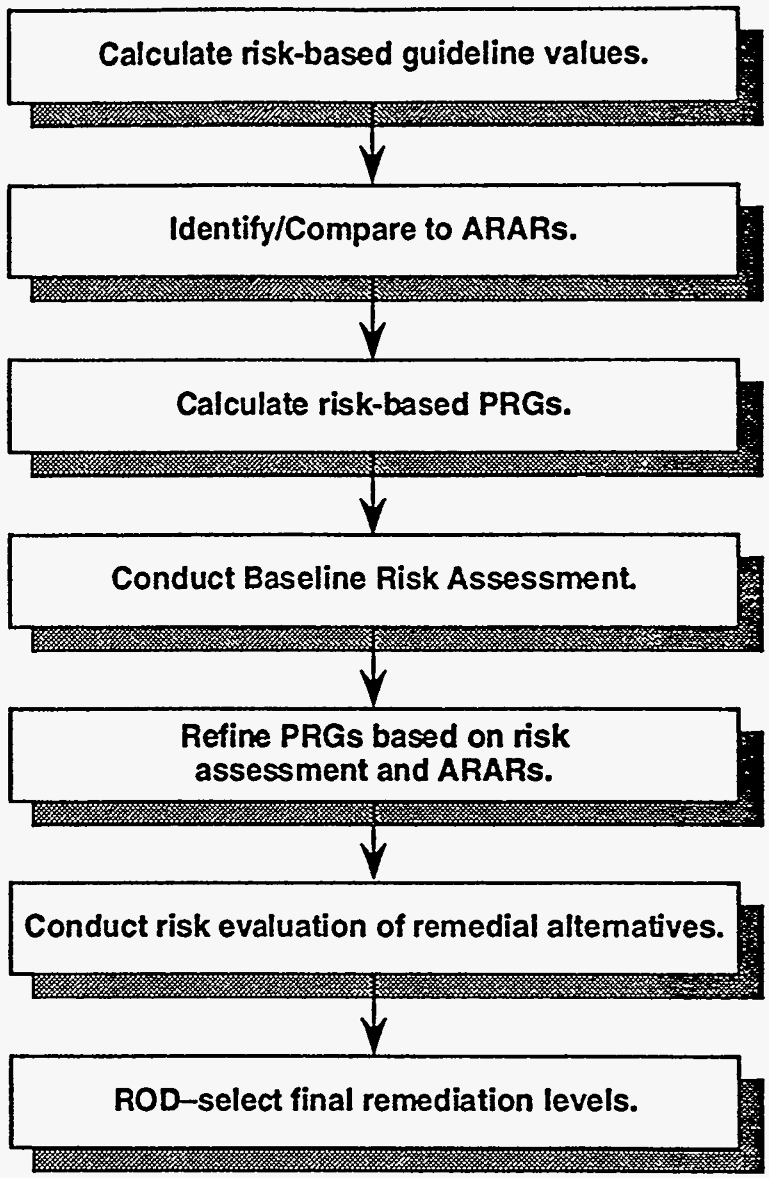

Figure 4. Use of the Guideline Values in the development of Preliminary Remediation Goals.

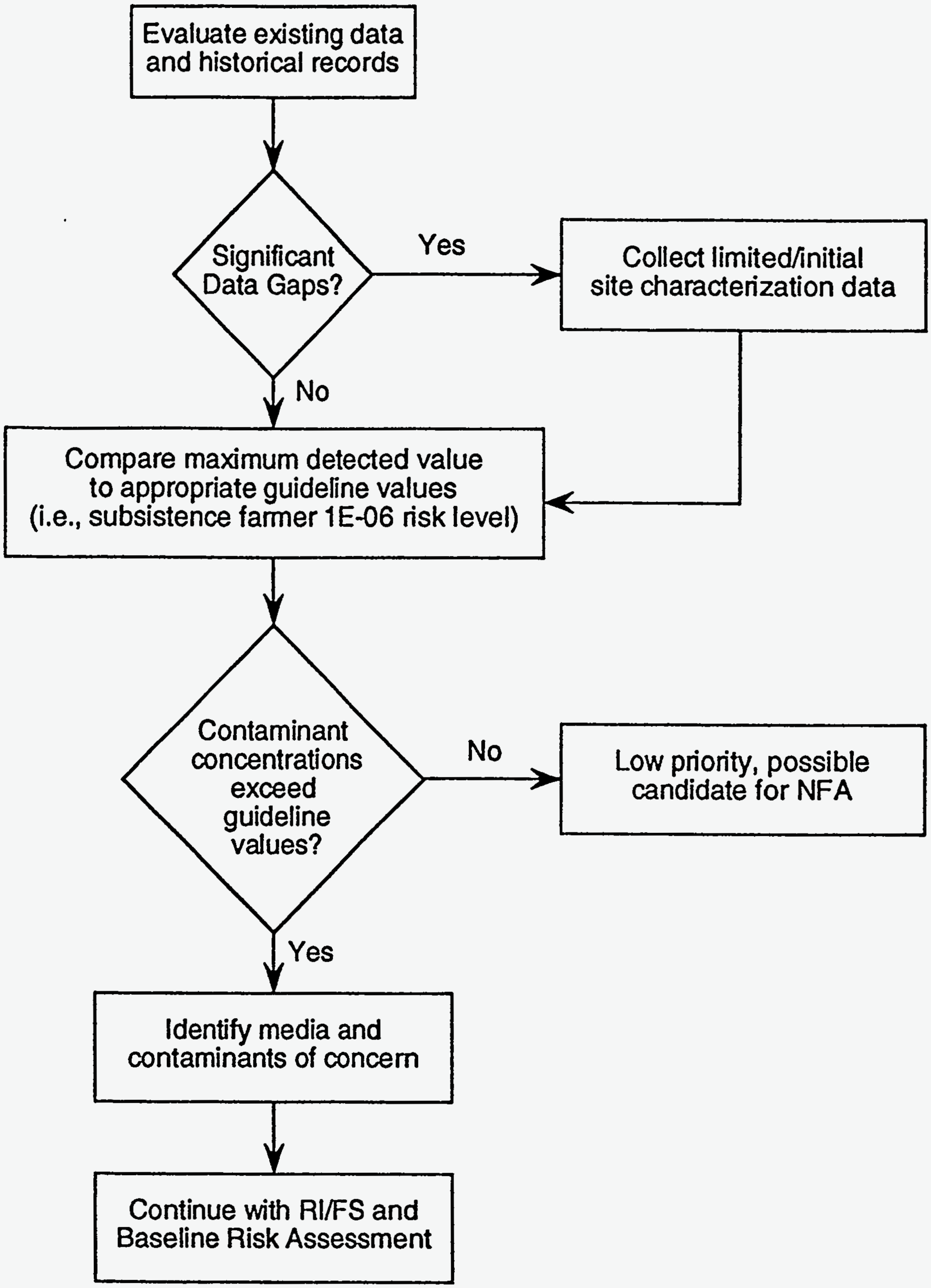

Figure 5. Use of Guideline Values in preliminary site screening.