Medical monitoring should be directed toward a target community identified as being at ''significant increased risk for disease'' on the basis of its exposure. Significant increased risk will vary for particular sites depending upon such factors as the underlying risk of the selected outcome, the risk attributable to the exposure, and the presence of sensitive subpopulations. These factors will be considered when evaluating the appropriateness of medical monitoring in a community. The CERCLA legislation also provides for a mechanism for referral for treatment of those who are screened positive for the selected health outcomes; therefore, a mechanism to refer people for diagnosis, interventions, or treatment should be in place prior to the initiation of a medical monitoring program.

The primary purpose of a medical monitoring program is not considered to be a research activity that further investigates the cause-effect relationship between exposure and outcome. The purpose of a medical monitoring program is case-finding in order to refer individuals for further evaluation and, as appropriate, treatment. Within this framework, medical monitoring includes both testing for early biological effect and an assessment of exposure using biological specimens (for example, blood or urine), when appropriate. This is provided as a service to individuals in communities where there is believed to be an increased risk of disease from exposure to hazardous substances released into the environment.

Criteria for Considering Medical Monitoring

The criteria outlined below will be used to determine the appropriateness of conducting medical monitoring in a community and will be applied in a phased approach. Phase I, conducted by ATSDR, consists of an evaluation of the exposure and outcome criteria. Phase II consists of an evaluation of the system criteria. Phase II will be conducted with the input of a panel consisting of community, State and local health officials, and ATSDR. At the end of Phase II, a detailed medical monitoring plan will be written at sites where a monitoring program is established. All of the criteria must be met at a site in order for a medical monitoring program to be established at that site. In addition, resources must be available to initiate and sustain the program.

Phase I

Exposure Criteria

A. There should be evidence of contaminant levels in environmental media that would suggest the high likelihood of environmental exposure to a hazardous substance and subsequent adverse health outcomes.

The National Research Council (NRC) defines exposure as ''an event that occurs when there is contact at a boundary between a human and the environment at a specific contaminant concentration for a specified period of time; the units to express exposure are concentration multiplied by time'' (NRC, 1991). The specific contaminant concentration and period of time will vary for different chemicals and different media. The exposure must be to a hazardous substance as defined under CERCLA, and the result of a release from a CERCLA-covered facility. A release from a CERCLA-covered facility includes those events that establish an open pathway of exposure (i.e., an unfenced area with high soil contamination could be considered a ''release'') or allows contaminants to go off-site via air, surface water, ground water, or other pathway. The primary criteria for medical monitoring should be documented evidence of exposure of a population to a hazardous substance in the environment. An exposure will be considered to be at a sufficient level if there is documentation of an increased opportunity for exposure to a level that meets or exceeds some health-based comparison value (such as Minimum Risk Levels (MRLs) or Reference Doses (RfDs)) or that meets or exceeds a level reported in the peer-reviewed literature to result in some adverse health effect. Documentation is considered sufficient if it is from an exposure assessment, environmental exposure modeling, or sampling from a general area (for example, water samples from an aquifer or a town water supply). Documentation of individual levels of exposure is not required. In cases in which exposures are unknown or undocumented, environmental monitoring is a more appropriate initial activity.

B. There should be a well-defined, identifiable target population of concern in which exposure to a hazardous substance at a sufficient level has occurred.

Initially, the target population of concern will be defined geographically on the basis of exposure. In addition, all populations considered will be assessed for the presence of any sub-population at increased risk of the adverse health effects associated with the exposures. An example of a subpopulation at increased risk would be preschool children in an area with known lead exposures. The size of the target population of concern is not a factor in the decision for monitoring. In areas where biological markers of exposure have not been collected, environmental sampling can be used to estimate exposure levels. The target population of concern is the population in which there is documented exposure at a sufficient level to place the individuals in that population at significant increased risk for developing some specific adverse health effect.

Outcome Criteria

A. There should be documented human health research that demonstrates a scientific basis for a reasonable association between an exposure to a hazardous substance and a specific adverse health effect (such as an illness or change in a biological marker of effect).

Previous studies on human populations must demonstrate a reasonable association between a particular exposure and an adverse health effect. In order to make that inference, consideration should be given to the strength, specificity, and consistency of the association among the identified studies. The period of exposure (including the timing and duration of the exposure) and its relationship to the latency period for the disease or illness should also be examined if information is available. Consideration should be given to whether the association has demonstrated a dose-response relationship and whether the association is consistent with the existing body of knowledge. This information could include a variety of occupational, epidemiological, or other studies involving human populations.

B. The monitoring should be directed at detecting adverse health effects that are consistent with the existing body of knowledge and amenable to prevention or intervention measures.

The monitoring should be established for specific adverse health effects. The specific adverse health effect being monitored should be a result of the possible exposure consistent with the existing body of knowledge. An adverse health effect is consistent with the existing body of knowledge if it has been described in the literature as caused by that agent or by similar agents, taking into account structure-activity relations.

In addition, the adverse health effects (disease process, illness, or biomarkers of effect) should be such that early detection and treatment or intervention