interrupts the progress to symptomatic disease, improves the prognosis of the disease, improves the quality of life of the individual, or is amenable to primary prevention. If the adverse health effects that are of concern in an individual or in a community are not easily detectable and not medically treatable, then medical monitoring would not be beneficial and would not be an appropriate public health activity. An easily detectable effect is one that can be found on clinical examination, or through the use of simple, diagnostic tests in an outpatient setting. Also, the test procedures must be acceptable to the patient and the community. The diagnostic tests must be nonexperimental, relatively noninvasive (such as the drawing of a tube of blood for laboratory tests), and simple to administer.

Monitoring for Evidence of Continuing Exposure

At sites with exposure in the community, the monitoring program might include biological markers of continuing exposure. For example, the Bunker Hill Superfund site has had lead screening of children for many years. Those sites would be ones in which the exposure is known to have a variety of adverse health effects, but for which no tests are available to detect those effects at a time when intervention could affect the course of the disease process. In those instances, the primary intervention is to remove the individual from the exposure. This allows the medical monitoring system to recommend referral for intervention prior to the onset of detectable adverse health effects. A monitoring system that includes biomarkers of continuing exposure is similar to medical surveillance of hazardous waste workers where changes indicative of increasing or continued exposures occur sufficiently early that the exposure can be curtailed and the risk for disease reduced (Gochfeld 1990).

Phase II

General Information

Phase II of the program is carried out by ATSDR with assistance from the community. When ATSDR has determined that exposure from a site has met the exposure and outcome criteria, a site panel will be formed based on recommendations from the community and the State and/or local health departments to review the system criteria and to assist in the development of a site-specific medical monitoring plan. The site panel will include representatives from ATSDR, the community, State or local health departments, local medical societies, and subject experts as necessary. The site panel will function in much the same manner as the Community Assistance Panels (CAPs) that are established at some sites during the public health assessment process. The site panel will follow the established procedures for those CAPs. The site panel will be responsible for assessing the available community health resources and determining the feasibility and extent of the screening program for the community. If the panel determines that a screening program is feasible in the community and ATSDR concurs with that decision, ATSDR will develop a site-specific monitoring plan. That plan will be presented to the site panel for review and concurrence. After the plan has been developed and has undergone peer review, it will be presented to the community at large for their input prior to establishing the program.

System Criteria

A. The general requirements for a medical screening program should be satisfied.

The monitoring aspect of a health surveillance program consists of the periodic medical testing to screen individuals who are at increased risk of disease. Monitoring serves to identify those individuals with an unrecognized adverse health effect. This is consistent with the definition of screening as ''the presumptive identification of unrecognized disease or defect by the application of tests, examinations, or other procedures which can be applied rapidly. Screening tests sort out apparently well persons who probably have a disease from those who probably do not. A screening test is not intended to be diagnostic. Persons with positive or suspicious findings must be referred to their physicians for diagnosis and necessary treatment.'' (Commission on Chronic Illness, 1957) In general, the ability to predict the presence or absence of disease from test results depends on the sensitivity and specificity of the test and the prevalence of the disease in the population being tested. The higher the prevalence, the more likely a positive test indicates disease (Mausner & Kramer, 1985). In order for a screening program to be of public health benefit, the population being screened should be at a significantly high risk for the undiagnosed disease (i.e., the disease should have a sufficiently high prevalence in the population).

Given that definition, there are certain requirements for screening programs that should be considered when evaluating a possible medical monitoring program for a site (adopted from Mausner & Kramer, 1985). Those requirements are:

★ The natural history of the disease process should be understood sufficiently for screening.

★ The early detection through screening should be known to have an impact on the natural history of that disease process. For example, the detection of breast cancer while it is localized has been shown to increase the ten-year survival rate. For that reason, several groups have made recommendations for the early detection of breast cancer in asymptomatic women. Those recommendations include breast self-examination, breast physical examination, and mammography (Mettlin & Dodd, 1991; Kelsey & Gammon, 1991).

★ There should be an accepted screening test that meets the requirements for validity, reliability, estimates of yield, sensitivity, specificity, and acceptable cost. The purpose of ATSDR-sponsored medical monitoring is not to develop new screening tests. The medical monitoring program will use tests that have been recommended and used for screening in other settings.

The U.S. Preventive Services Task Force has established criteria for determining the effectiveness of preventive strategies including screening tests. The criteria for effectiveness of a screening test include the efficacy of the screening test and the effectiveness of early detection. The Task Force used efficacy to mean accuracy and reliability. The accuracy is measured using four indices: sensitivity, specificity, positive predictive value, and negative predictive value (see table below for definitions). A test with poor sensitivity will result in a large proportion of persons with disease being told they are free of disease (false-negatives). A test with poor specificity will result in healthy persons being told they have the disease (false-positives). There may be serious consequences in the use of screening tests with poor sensitivity and/or specificity. Persons with false negative results may have delays in diagnosis and treatment. False positive results can result in follow-up testing that is uncomfortable, expensive and potentially harmful. The evaluation and selection of a screening test must include a determination of the likelihood of producing false positive results (the positive predictive value (PPV)). The PPV changes in accordance with the prevalence of the condition in the screened population. PPV is unlike