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VOLUME I

Oak Ridge Health Studies Phase I Overview

Prepared by the
Tennessee Department of Health and the
Oak Ridge Health Agreement Steering Panel

OAK RIDGE HEALTH STUDIES PHASE I REPORT

Volume I - Oak Ridge Phase I Overview

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for

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Volume I summarizes the activities of the Oak Ridge Health Agreement Steering Panel, other than the Dose Reconstruction Feasibility Study, during Phase I of the Oak Ridge Health Studies. It includes four major topics.

- **Executive Summary of the Oak Ridge Health Studies Phase I Report**
- **Health Studies Background and Overview**
- **Phase I Goals**
- **Conclusions and Recommendations for Phase I**

Volume II documents the study (referred to as the Dose Reconstruction Feasibility Study) to find out if enough data exist to estimate the historical doses of chemicals and radionuclides to the public living around the Reservation. It is comprised of four parts:

- **Part A** addresses project Tasks 1 and 2 to identify the historical operations and emissions at each of the complexes and the characterization of the availability of environmental sampling and research data.

- **Part B** addresses Tasks 3 and 4 to identify important environmental exposure pathways and contaminants released from the Reservation.

- **Part C** addresses Task 5 to identify information regarding historical locations and activities of off-site populations that could potentially be affected by releases from the Reservation.

- **Part D** addresses Task 6 to identify the hazards associated with substances used at the reservation.

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Oak Ridge Health Studies

Phase I Report

Executive Summary

EXECUTIVE SUMMARY

OAK RIDGE HEALTH STUDIES BACKGROUND

The Oak Ridge Reservation was established in 1942 as part of the federal government's World War II effort to develop and produce the first atomic bombs. Production of plutonium and enrichment of uranium for weapons components were the main objectives in the beginning. For 50 years, many different research and production activities have been performed at the three large complexes, code named X-10, Y-12, and K-25.

The three main complexes used and processed radioactive materials, including iodine, uranium, and cesium, and other chemically hazardous materials including mercury and PCBs (polychlorinated biphenyls). Some contaminants were released to the environment beyond the plant boundaries as a result of routine emissions to the air and surface water; waste disposal practices, including burial; accidental releases; and events such as the draining of White Oak Lake.

In July 1991, the State of Tennessee initiated the Health Studies Agreement with the United States Department of Energy. The purpose of the project is to carry out independent studies of possible adverse health effects in people living in the vicinity of the Oak Ridge Reservation. The health studies focus on those effects that could have resulted or could result from exposures to chemicals and radioactivity released at the Reservation since 1942. To facilitate independence, a panel of experts and local citizens, the Oak Ridge Health Agreement Steering Panel, provides direction, recommendations and oversight for the Oak Ridge Health Studies. The Tennessee Department of Health, Division of Environmental Epidemiology provides staffing support.

OVERVIEW OF PHASE I

Phase I of the project began in May 1992 and was completed in September 1993. The major focus of the first phase was to complete a Dose Reconstruction Feasibility Study. This study was designed to find out if enough data exist about chemical and radionuclide releases from the Oak Ridge Reservation to conduct a second phase. The second phase will lead to estimates of the actual amounts or the "doses" of various contaminants received by people as a result of off-site releases. Once the doses of various contaminants have been estimated, scientists and physicians will be better able to evaluate whether adverse health effects could have resulted from the releases.

The Health Studies Agreement specified five goals for Phase I. To achieve these goals, the Oak Ridge Health Agreement Steering Panel and the Department of Health completed several activities. Volume I of the *Oak Ridge Health Studies Phase I Report* gives the background and an overview of the health studies, as well as a discussion of the activities undertaken by the panel to attain the Phase I goals (Table 1). The work related to the primary goal, the Dose Reconstruction Feasibility Study, is detailed in Volume II, Parts A-D, of the report.

Table 1: Contents of the Oak Ridge Health Studies Phase I Report

Volume I discusses the activities of the Oak Ridge Health Agreement Steering Panel, other than the Dose Reconstruction Feasibility Study, during Phase I of the Oak Ridge Health Studies. It includes four major items:

- **Executive Summary of the Oak Ridge Health Studies Phase I Report** summarizes Volume I and Volume II of the *Oak Ridge Health Studies Phase I Report.*
- **Health Studies Background and Overview** provides a brief history of the operation of the Oak Ridge Reservation and an overview of the Health Studies Agreement.
- **Phase I Goals** lists the initial goals stated in the Health Studies Agreement, the approach that the panel chose for attaining each goal, and a description of the activities that were necessary to achieve the goals.
- **Conclusions and Recommendations for Phase I** contains the Consensus Statement of the panel asserting the conclusions that the panel reached at the end of Phase I and the recommendations of the panel for continuing the Health Studies into the next phase.

Volume II documents the study (referred to as the Dose Reconstruction Feasibility Study) to find out if enough data exist to estimate the historical doses of chemicals and radionuclides to the public living in the vicinity of the Reservation. It is comprised of four parts:

- **Part A** addresses project Tasks 1 and 2 to identify the historical operations and emissions at each of the complexes and the characterization of the availability of environmental sampling and research data.
- **Part B** addresses Tasks 3 and 4 to identify important environmental exposure pathways and contaminants released from the Reservation.
- **Part C** addresses Task 5 to identify information regarding historical locations and activities of off-site populations that could potentially be affected by releases from the Reservation.
- **Part D** addresses Task 6 to identify the hazards associated with substances used at the reservation.

SUMMARY OF VOLUME I REPORT: THE OAK RIDGE HEALTH STUDIES PHASE I OVERVIEW

The three facilities at Oak Ridge, K-25 (Oak Ridge Gaseous Diffusion Plant), Y-12, and the Oak Ridge National Laboratory (ORNL, previously X-10), served as sites for nuclear material processing and reprocessing. After the war, they remained active in the production of radioisotopes, reactor development, nuclear weapons components production, waste management and an array of engineering and scientific support functions worldwide.

The Health Studies Agreement provides the State with $12.4 million, from the Department of Energy, to fund independent health studies. These studies are designed to assess potential human health risks of past releases from the Oak Ridge Reservation to people living in the vicinity of the Reservation. The Agreement contains five goals for the initial studies, Phase I of the Oak Ridge Health Studies.

- **Goal I** was to assemble a panel of technical experts from across Tennessee and the United States, to design a Dose Reconstruction Feasibility Study.

- **Goal II** was to complete a Dose Reconstruction Feasibility Study to identify chemicals and radionuclides released from the Oak Ridge Reservation in the past 50 years with the greatest potential for causing adverse health effects in the people living off-site. This study was designed to determine the feasibility of estimating the doses of these contaminants, given the quality of the information located in this screening study.

- **Goal III** was to assemble a panel of experts and citizens from across Tennessee and the United States to direct and oversee all of the Health Studies Agreement activities and to assure two-way communication with the public.

- **Goal IV** is to enhance the Tennessee Cancer Registry by reviewing the quality and completeness of hospital reporting and by developing and maintaining a state birth defects registry.

- **Goal V** is to review the Department of Energy's occupational medical (worker health) program.

In order to address these five goals, the Steering Panel grouped the oversight responsibilities into four major categories.

- Dose and risk assessment
- Health effects evaluation
- Public communication
- Quality assurance

The activities related to each of these categories and the conclusions reached by the Panel are described in detail in Volume I. The Oak Ridge Health Agreement Steering Panel recommendations for continuing these activities into the next phase are as follows.

Conclusions and Recommendations for Dose Reconstruction

The primary goal of Phase I, which began in May 1992, was to carry out an initial screening study, called the Dose Reconstruction Feasibility Study. The Feasibility Study indicates that a significant amount of information is available to reconstruct the past releases and potential off-site doses. Based on this, the Oak Ridge Health Agreement Steering Panel recommends that dose reconstruction activities begin for the releases of radioactive iodine and cesium, mercury, and PCBs. The Panel also recommends that a broader-based investigation of operations and contaminants be completed to support or modify the recommended direction of future health studies. (See Volume II, Parts A-D, for the methodology and documentation that resulted in the conclusions and recommendations for dose reconstruction.)

Conclusions and Recommendations for the Evaluation of Health Effects

As the result of several meetings with the community, the Oak Ridge Health Agreement Steering Panel concludes that there is interest in health studies that not only calculate health risks, but also look for the occurrence of adverse health effects. The Panel proposes that researchers look for opportunities to conduct analytical epidemiologic studies to identify adverse health effects in exposed populations.

Continuation of Communication with the Public

The Oak Ridge Health Agreement Steering Panel believes that communication activities begun in Phase I should continue in Phase II. These activities include public meetings to receive input from the public and relay study results, the newsletter, the toll-free telephone service to the Environmental Epidemiology office, the one-on-one community feedback sessions, the speaking engagements, the technical workshops, and the interagency communications.

Continuation of Quality Assurance

The quality assurance process established and conducted in Phase I proved to be important in ensuring that the work being done is credible and accurate. The Panel recommends that significant resources continue to be devoted to the quality assurance program in all further work.

Other Recommendations

The Oak Ridge Health Agreement Steering Panel recommends that the State continue verifying cases for the Tennessee Cancer Registry and continue developing and maintaining the Tennessee Birth Defects Registry.

The Oak Ridge Health Agreement Steering Panel recommends that a formal plan to review the Department of Energy's Oak Ridge Reservation workers' health program be developed and carried out in Phase II.

During Phase I, some information provided by the public and external reviewers about contaminants was not completely investigated. The Oak Ridge Health Agreement Steering Panel recommends that an investigation of this information be pursued in Phase II.

SUMMARY OF VOLUME II REPORT: THE DOSE RECONSTRUCTION FEASIBILITY STUDY

The Phase I feasibility study has focused on determining the availability of information for estimating exposures of the public to chemicals and radionuclides released as a result of historical operation of the facilities at the Oak Ridge Reservation. The estimation of such past exposures is frequently called dose reconstruction. The Phase I researchers examined both the feasibility of performing dose reconstruction and a portion of the enormous volume of historical data to identify the releases from the facilities in the past having the highest potential to have caused harm to the health of the public.

The project work was composed of a number of individual tasks designed to meet the overall objectives of the Phase I studies. The study tasks are numbered 1 through 7. The initial project tasks, Tasks 1 and 2 were designed to identify and collect information that documents the history of activities at the Reservation that resulted in the release of contamination and to characterize the availability of data that could be used to estimate the magnitude of the contaminant releases and public exposures. **Task 7: Compilation and Indexing of Project Documents** was designed to support the collection of many of the documents and data identified in Tasks 1 and 2 in a library that could then be used in any future health studies. These three tasks represent the information collection portion of the project and included qualitative evaluations of the potential for activities to have produced significant contaminant releases. Further details of Task 1 and Task 2 efforts are described here.

Task 1: Identification of Historical Operations and Emissions

A history of operations that likely generated off-site releases was the product of Task 1 activities that are documented in Volume II, Part A of the *Oak Ridge Health Studies Phase I Report.* This history is based on extensive reviews of records of historical operations and interviews with present and past employees and other knowledgeable individuals. The investigative process is documented in the report. The time period covered is the 50-year span from 1942, when the federal government acquired 58,000 acres of land for what became the Oak Ridge Reservation, through 1992 when the study began. Four large, separate complexes code-named X-10, Y-12, K-25, and S-50 were operated on the Reservation. The Y-12, K-25, and S-50 complexes were dedicated to the production of enriched uranium during their early years of operation. S-50 was built near K-25 and operated for only a single year. Uranium enrichment involves the separation of the type of uranium required for nuclear weapons (uranium-235) from the uranium that is most abundant in nature (uranium-238). Y-12 later produced and dismantled nuclear weapon components and enriched lithium for use in thermonuclear weapons.

Activities at X-10, which were much more varied than those of the other plants, included:

- development of the world's first full-scale nuclear reactor,
- a chemical separation pilot plant to recover plutonium, and
- a wide range of activities related to applied research and development focused primarily on energy and the environment.

Volume II, Part A of the Health Studies Report presents information with respect to each of the major complexes, as well as a number of off-site areas of concern related to contamination from the Oak Ridge Reservation. While large volumes of information and documentation were found to be available for each of the major complexes, the nature and quality of the documentation differed considerably among the complexes. The complex that appears to have the largest amount of information relevant to dose reconstruction efforts is X-10. While considerable information is available for the K-25 and Y-12 sites, historical activities involving the use and release of hazardous materials do not appear to be as well documented at these complexes. Much of the information that is available for K-25 and Y-12 remains in classified documents, many of which were reviewed for the purposes of the study by individuals with appropriate security clearance. Priority is being given to the request for declassification of the information relating to off-site health impacts.

Task 1 investigations documented the historical activities of the major complexes, including routine operations, waste management, special projects, and accidents and incidents. Historical activities that appear to warrant the highest priority in any further investigations were identified based on their likely association with off-site emissions of hazardous materials as indicated by the documentation reviewed or information obtained in interviews.

Task 1 efforts identified the following activities as having the highest priority for future studies.

The X-10 Complex

- The production of radioactive barium/lanthanum (RaLa processing)
- Processing of short-decayed irradiated thorium by the Thorex process
- Graphite reactor operations
- Processing of graphite reactor fuel for plutonium recovery
- Waterborne and airborne waste disposal activities

The K-25 Complex (including S-50)

- Gaseous diffusion processing, the primary source of uranium and technetium emissions
- Feed facility and product and tails withdrawal, likely the primary sources of releases of uranium hexafluoride
- Abnormal or accidental releases of uranium hexafluoride
- Liquid waste disposal of a complex waste stream
- Further investigation of the short-lived (1 year) S-50 plant

The Y-12 Complex

- Electromagnetic separation and enrichment of uranium
- Lithium separation and enrichment operations, the primary source of mercury releases to the environment
- Uranium weapon component manufacturing
- Beryllium operations
- Waste disposal operations
- Further evaluation of the use and release of substances which cannot be publicly discussed because their presence at Oak Ridge is classified

Information that is available to support the reconstruction of historical releases of hazardous materials and possible off-site exposures for these high priority activities is summarized in Volume II, Part A of the Health Studies Report.

Task 2: Environmental Sampling and Research Data Availability

Task 2 focused on the development of an understanding of the environmental sampling and research data that are available to support any future dose reconstruction efforts. Information on the availability of environmental data was obtained from document reviews and personal interviews. Sources of information are identified below.

- Plant libraries and archives
- DOE Oak Ridge Operations files
- The Tennessee Valley Authority
- The United States Environmental Protection Agency
- The United States Geological Survey
- The Tennessee Department of Health
- The Tennessee Division of Radiological Health
- The Tennessee Division of Water Pollution Control
- Interviews with current and former investigators

Abstracts were developed to summarize approximately 100 environmental monitoring and research projects that characterize the historical presence and behavior of contaminants in areas outside of the Oak Ridge Reservation. Environmental monitoring data availability is summarized for each of the following environmental media.

- Surface water
- Sediment
- Air or atmosphere
- Aquatic and terrestrial food items (biological monitoring)
- Soil
- Drinking water derived from off-site surface waters/groundwater wells and water from wells on the Reservation

The large volume of information reviewed in the 100 studies is summarized in tables in Volume II, Part A of the Health Studies Report. The tables indicate:

- the time period during which samples were taken,
- the approximate location of the samples,
- the contaminants that were measured,
- the Oak Ridge facility that was most likely the source of the contaminant, and
- the relative quantity of sampling data available in the study.

These table summaries, as well as the abstracts of the studies, are designed to be used to identify data that can be used to support any further studies to quantify the historical exposure of the public to specific contaminants released from the Oak Ridge facilities.

Tasks 3, 4, 5 and 6: Quantitative Evaluation of Potential Impacts

In structuring the Phase I studies, there was a desire to attempt to use the quantitative data on releases from the facilities and contamination present in the environment as another means of identifying those plant activities that should receive the highest priority in any further health studies. Project Tasks 3 - 6 support a more quantitative evaluation of the potential impacts of facility releases. This quantitative evaluation is a very rough and preliminary analysis of the large quantity of information and data identified in Tasks 1 and 2 to rank those activities and contaminants having the greatest potential to cause harm to the public's health. The evaluation follows the basic steps necessary to evaluate potential human health hazards. However, the evaluation uses data and information that have not been thoroughly established or independently verified, as would be done in any subsequent, more lengthy and detailed study. Therefore, this evaluation must be considered preliminary and subject to revision by any future health studies. The basic steps performed in a quantitative health hazard assessment are:

- **Hazard identification**—identification of the contaminants that were released and capable of causing harm to health. These contaminants were identified in Tasks 1 and 2.
- **Dose-response assessment**—characterization of the toxicity of the released contaminants by identifying the health effects that can result from exposure and the amount, or dose, of the contaminant required to produce the various health effects. This step of the process is primarily addressed by Task 6 in Volume II, Part D of the Health Studies Report. Project **Task 6: Hazards Summaries for Important Materials** was accomplished by relying on, and in large part reproducing, summary-level information available in documents produced by

various regulatory agencies, government health agencies, and other authoritative bodies that publish guidelines and information on the toxicity and behavior of contaminants in the human body.

- **Exposure/Hazard Assessment**—quantification of the exposures that the public could have received. This was accomplished by identifying complete exposure pathways using information developed in Tasks 3 and 5 and calculating the potential relative magnitude of off-site exposures and health hazards for each of the contaminants for which data were available in Task 4.

Additional details of the activities associated with the completion of project Tasks 3 and 4 (documented in Volume II, Part B) and Task 5 (documented in Volume II, Part C) follow.

Task 3: Identification of Complete Exposure Pathways was performed to identify plausible exposure pathways based on environmental conditions (e.g., location of surface water and groundwater, meteorology), potential for a contaminant to move from one medium (e.g., soil, water, or air) to another, and by the life-styles, activities, and locations of the exposed population (e.g., gardening, water recreation). **Task 5: Identification of Populations** was performed to support the analysis of complete exposure pathways by evaluating the likelihood of human contact with contaminated media and the existence of human activities leading to contaminant intake or exposure. Task 5 efforts began the process of identifying available information on local historical populations and land uses near the Oak Ridge facilities, as well as, addressing other specific concerns of dose reconstruction. Other specific dose reconstruction concerns included the potential for: consumption of locally produced crops, beef, dairy products, fish, and game; the use of surface water for drinking, irrigation, and recreation; ground water use for drinking and irrigation; and river dredging and sediment spreading.

Task 3 examined the combinations of contaminated media, transport mechanisms, and routes of contact that characterized complete exposure pathways in the past for each of the Oak Ridge complexes. The task work led to the preliminary conclusion that exposure pathways associated with the direct intake of contaminated groundwater are not believed to have been complete in the past. However, various complete pathways were identified for contaminants released to the air, surface waters, and soils or sediments.

While Task 3 identified all the potentially complete exposure pathways, not all complete pathways make a significant contribution to the total potential health hazard. **Task 4: Evaluation of Complete Exposure Pathways** activities were designed to identify the most important pathways of exposure and, where possible, past activities that appear to be associated with the greatest health hazards.

The most important exposure pathways were identified by calculating the health hazards that would result from the presence of fixed concentrations (unit concentrations) of each of the contaminants in each environmental medium, for each of the complete exposure pathways (i.e., comparisons *within* environmental media). These analyses identified those pathways that will receive emphasis in any further studies of a particular contaminant release.

The second, and much more difficult analysis was the estimation of the magnitude of the health hazards that exposure to contaminants in each of the media may have posed to the public in the past (i.e., comparisons *between* environmental media). This type of comparison required the estimation of actual contaminant concentrations in environmental media. In some cases, making these estimates was very difficult or impossible as part of this first phase of the health studies. When contaminant concentrations or releases could be identified, the year or period of highest emission, or the highest environmental concentrations were used in the analyses. These analyses between media identified what we currently believe to be the activities and contaminant releases that should receive the highest priority for any further health studies, because they appear to have the highest potential to cause a health hazard to the public. The contaminants and activities receiving the highest priority included:

- the release of **iodine–131 & iodine–133** during the years of 1944 through 1956 from Radioactive Lanthanum (RaLa) Processing at X-10;
- the release of **cesium–137** (primarily in liquid wastes) during the period of 1943 through the 1960s as a result of various chemical separation activities at X-10;
- the release of **mercury** during the years of 1955 through 1963 from lithium separation and enrichment operations at Y-12; and
- the general release of **polychlorinated biphenyls (PCBs)** from electrical transformers and machining operations at K-25 and Y-12. (The period of time over which these releases occurred has not been established, but is likely associated with operations occurring more than ten years ago.)

It is important to note that this evaluation should not be considered as the definitive assessment of health hazards due to contaminant releases from the Oak Ridge Reservation. The findings of this feasibility study are useful for the purpose of focusing any future studies and are subject to change during future phases of the health studies.

Oak Ridge Health Studies

Phase I Report

Volume I: Phase I Overview

VOLUME SUMMARY

The State of Tennessee has undertaken independent studies to evaluate the potential adverse health effects in off-site populations resulting from past operations at the Oak Ridge Reservation. The Commissioner of the Department of Health appointed the Oak Ridge Health Agreement Steering Panel (ORHASP) to provide direction, recommendations and oversight to Phase I of this effort. Volume I of the *Oak Ridge Health Studies Phase I Report* gives the background and an overview of the Oak Ridge Health Studies, as well as a discussion of the activities undertaken by the Panel to attain the Phase I goals. The conclusions and recommendations of the oversight Panel for continuing these activities into Phase II are also in this volume. The methodology and documentation for the primary goal, completing a Dose Reconstruction Feasibility Study, are described in Volume II, Parts A-D, of the *Oak Ridge Health Studies Phase I Report.*

The five goals of the Health Studies Agreement are as follows.

- **Goal I** - Assemble a Technical Panel
- **Goal II** - Complete a Dose Reconstruction Feasibility Study
- **Goal III** - Assemble an Oversight Panel
- **Goal IV** - Enhance the Tennessee Cancer Registry and Develop a State Birth Defects Registry
- **Goal V** - Review the Department of Energy's Worker Health Program.

In order to address these goals, the Steering Panel grouped the oversight responsibilities into four major categories.

- Dose and risk assessment
- Health effects evaluation
- Public communication
- Quality assurance

Based on the Phase I activities related to the above categories, the Oak Ridge Health Agreement Steering Panel recommends that in Phase II:

- dose reconstruction activities begin for the releases of radioactive iodine and cesium, mercury, and PCBs;
- a broader-based investigation of operations and contaminants be completed to support or modify the recommended direction of future health studies;
- researchers begin looking for opportunities to conduct analytical epidemiologic studies;
- communication activities begun in Phase I should continue;
- significant resources continue to be devoted to the quality assurance program;
- the State continue verifying cases for the State Cancer Registry and continue developing the State Birth Defects Registry;
- a formal plan to review the Department of Energy's Oak Ridge Reservation workers' health program be developed; and
- investigation continue of issues raised by the public and outside reviewers that were not pursued in Phase I.

1.0 Oak Ridge Health Studies Background and Overview

The Oak Ridge Reservation was established by the United States government in 1942, as part of the World War II effort to produce an atomic bomb, better known as the Manhattan Project. The Oak Ridge Reservation served as a site of nuclear fuel production. Now, at most facilities associated with the Manhattan Project, including the Oak Ridge Reservation, studies are underway to investigate potential adverse health effects that occurred or were exacerbated by past off-site releases of toxic or radioactive contaminants.

There were four principle lines of activity that preceded the use of uranium and plutonium fueled weapons against Japan in August of 1945: uranium supply, uranium-235 production, plutonium production and bomb development.[1] Uranium-235 and pilot plutonium production were carried out at the Oak Ridge Reservation. Bomb development included the production of radioisotopes for weapons development. The three facilities at Oak Ridge, K-25 (Oak Ridge Gaseous Diffusion Plant), Y-12, and the Oak Ridge National Laboratory (ORNL, previously X-10), served not only as sites for nuclear fuel processing and reprocessing but after the war remained active in the production of radioisotopes, reactor development, nuclear weapons components production, waste management and an array of engineering and scientific support functions worldwide. A fourth complex, S-50 involved in uranium enrichment, was present only from 1944-45. Much of the information pertaining to operations on the reservation has been classified or restricted since the facilities inception. As a result, the sources and exposure pathways of environmental contaminants are relatively unknown to the general public.

Governor Ned McWherter initiated the Oak Ridge Health Studies Agreement between the State of Tennessee and the United States Department of Energy. The agreement was signed in July of 1991, between the Governor and Admiral James D. Watkins, Secretary of Energy. Through this agreement, the Department of Energy provided the State with $12.4 million to fund independent health studies. These studies were designed to assess potential human health risks of past releases from the Oak Ridge Reservation to people living in the vicinity of the Reservation. The Governor entered into this agreement to assure the citizens of the State that their health, safety and environment are being given a high priority through the State program of independent research, monitoring, and oversight.

The Oak Ridge Health Studies focus on those potential adverse health effects that could result from exposures to chemicals and radioactivity released from the Reservation since 1942. To facilitate independence, a panel of experts and local citizens, the Oak Ridge Health Agreement Steering Panel, provides direction, recommendations and oversight for the health studies. The Tennessee Department of Health, Division of Environmental Epidemiology provides administrative support.

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[1] U.S. Atomic Energy Commission, Division of Technical Information. Manhattan Project. In: The Atomic Energy Deskbook. New York: Reinhold Publishing Corporation; 1963:291-294.

2.0 Phase I Goals

Phase I of the health studies project began in May 1992 and was completed in September 1993. The primary goal was to carry out an initial screening study, the Dose Reconstruction Feasibility Study. The Health Studies Agreement contains five specific goals for Phase I of the Oak Ridge Health Studies:

- **Goal I** was to assemble a panel of technical experts from across Tennessee and the United States, to design a Dose Reconstruction Feasibility Study.

- **Goal II** was to complete a Dose Reconstruction Feasibility Study to identify chemicals and radionuclides released from the Oak Ridge Reservation in the past 50 years with the greatest potential for causing adverse health effects in the people living off-site. This study was designed to determine the feasibility of estimating the doses of these contaminants, given the quality of the information located in this screening study.

- **Goal III** was to assemble a panel of experts and citizens from across Tennessee and the United States to direct and oversee all of the Health Studies Agreement activities and to assure two-way communication with the public. The Commissioner of the Tennessee Department of Health appointed this panel, the Oak Ridge Health Agreement Steering Panel (ORHASP).

- **Goal IV** is to enhance the Tennessee Cancer Registry by reviewing the quality and completeness of hospital reporting and by developing and maintaining a state birth defects registry.

- **Goal V** is to review the Department of Energy's occupational medical (worker health) program.

3.0 Goal I - Assemble a Technical Panel

At the beginning of the health studies activities in September of 1991, Commissioner H. Russell White appointed a panel of technical experts to write the scope of services for a Dose Reconstruction Feasibility Study. The panel consisted of 7 members with expertise and experience in dose reconstruction, environmental toxicology, health physics, medicine, epidemiology, environmental transport and uncertainty analysis. (Appendix A)

This Panel worked with the Tennessee Department of Health, Division of Environmental Epidemiology staff to develop a request for proposals from contractors to carry out the Dose Reconstruction Feasibility Study. The request was advertised widely in the United States.

The Panel was again convened in February of 1992 for the purpose of reviewing each proposal submitted with members of the State evaluation committee. In March, the State evaluation committee met to rank the proposals and select the Phase I contractor.

ChemRisk, a Division of McLaren/Hart Environmental Engineering Corporation, was awarded the contract through this competitive bidding process in April of 1992. This contractor began work in May of that year. The technical panel was dissolved following the selection process.

4.0 Goal II - Complete a Dose Reconstruction Feasibility Study

The primary goal of Phase I was to complete a Dose Reconstruction Feasibility Study.

4.1 Purpose of the Dose Reconstruction Feasibility Study

The purpose of the Dose Reconstruction Feasibility Study was to have the State's contractors look for information to identify chemical and radionuclides that left the Oak Ridge Reservation in the past 50 years through air, water, soil, and other pathways. The study focuses on those contaminants that have the greatest potential for causing adverse health effects and identifies sources of information on which populations might have been exposed to the contaminants.

Identifying chemicals and radionuclides is only an initial step. Researchers cannot determine from this information alone if contaminants that were present caused adverse health effects in populations exposed to the substances. However, the estimation of a dose is useful for establishing the likelihood that a particular contaminant could have resulted in disease or other health related conditions. Reconstructing a dose requires in-depth study of the contaminant, including:

- when it was first used on the Reservation;
- how it traveled through the environment (air, water, soil, etc.);
- where, when and for how long a person came into contact with the contaminant; and
- what potential the contaminant had for causing adverse health effects.

Researchers need high quality information to estimate the actual amounts, or doses, of contaminants. Thus, the purpose of the Dose Reconstruction Feasibility Study was twofold:

- to identify contaminants that were released off-site and had the potential to adversely affect health and

- to determine the availability of information for use in future dose reconstruction studies that can be used to establish the likelihood that a contaminant caused adverse health effects in exposed populations.

4.2 Process Followed to Complete the Dose Reconstruction Feasibility Study

The State contractor, ChemRisk, began their work on the Dose Reconstruction Feasibility Study in May of 1992. Direction, recommendations and oversight were provided by the Oak Ridge Health Agreement Steering Panel.

ChemRisk first searched document centers, archives, libraries and files at the Oak Ridge Reservation to describe historical operations and emissions from the Reservation complexes that have historically been code named X-10, Y-12, K-25, and S-50. The researchers also interviewed past and present employees and located pertinent environmental monitoring and research data.

Next, researchers described the possible hazards associated with the contaminant emissions. They located sources of information that identified populations in the region surrounding the Reservation which could have been affected by contaminant releases. Also described were the potential pathways that hazardous chemical and radionuclide releases could have traveled, from the source to human populations.

In the Feasibility Study, only complete pathways were considered for future study. When chemicals and radionuclides were in use on the Reservation, some amounts escaped into the air, water, soil, etc. The likelihood for the contaminant to travel within a medium, such as water, and reach people either directly or through foods was determined. When a contaminant was traced from the initial source on the Reservation to a population off-site, the pathway was said to be complete.

Next, all complete pathways with adequate information were studied, and a list was created which ranked the contaminants in terms of potential health threats to the public. For some contaminants, there was not enough information located in this Phase I search to evaluate their potential to cause adverse health effects in the off-site population.

After considering each contaminant's potential to adversely affect health and the availability of information about that contaminant, ChemRisk and the Oak Ridge Health Agreement Steering Panel reached a conclusion as to the feasibility of estimating doses to the off-site public. The complete Dose Reconstruction Feasibility Study report, detailing work plans, methodology, and documentation, comprises Volume II, Parts A-D, of the *Oak Ridge Health Studies Phase I Report.*

5.0 Goal III - Assemble a Steering Panel

The Oak Ridge Health Agreement Steering Panel was convened in May of 1992. The purpose of this Panel is to provide direction, recommendations, and oversight to the State staff and the State contractors working on the health studies. It is also this Panel's responsibility to ensure that public input is sought in relation to the health studies and that the public is informed of activities related to the studies.

5.1 Members of the Steering Panel

The Steering Panel was appointed by the Commissioner of Health, H. Russell White. (Appendix B) It has convened about every two months since that time. The Panel is comprised of twelve members including five technical experts, a Tennessee Department of Health representative, an Oak Ridge Reservation worker, a United States Department of Energy representative, as well as a member from the Environmental Quality Advisory Board to the City Council of Oak Ridge and three members from broad areas in the community.

5.2 State Administrative Support for the Steering Panel

The Division of Environmental Epidemiology provides administrative support for the Steering Panel. The Division staffs the Panel meetings, implements the activities related to the Oak Ridge Health Studies, and interfaces with the contractor, as well as state and federal agencies, involved in the health studies. (Appendix C)

5.3 Panel Oversight Responsibilities

Members of the Panel have grouped oversight responsibilities into 4 general categories.

- Dose and risk assessment
- Health effects evaluation
- Public communication
- Quality assurance

Four subcommittees were formed to discuss problems, review work and develop ideas relevant to each category. The subcommittees make recommendations to the whole committee. All decisions related to the health studies are by consensus agreement of the entire Panel.

5.4 Panel Oversight of Dose and Risk Assessment

In Phase I, oversight of the Dose Reconstruction Feasibility Study was a major responsibility of the Panel members. There were seven major tasks that were carried out by ChemRisk, the State contractor. Each task plan, and the work related to each plan, was reviewed and approved by Panel members.

5.5 Panel Activities for Evaluating Health Effects

During Phase I of the health studies, the need to study adverse health effects, as well as estimate the dose of contaminants received by off-site populations, was debated. The Panel's approach to evaluating health effects was in large part shaped by health care providers and the public in Oak Ridge.

5.5.1 Information on Health Effects in the Oak Ridge Area

At the first Oak Ridge Health Agreement Steering Panel meeting, a health care professional from Oak Ridge presented a report that he felt showed the people of Oak Ridge to be healthy. At the second meeting another health care professional presented data from which he concluded the people of Oak Ridge had more cases of certain diseases than would be expected. Given these disparate reports, the Panel thought it would be useful to locate other available health information for the vicinity around the Oak Ridge Reservation to help establish more about health in the region.

The Panel located only one epidemiologic study related to the health of off-site populations in the Oak Ridge area. This study, a joint Centers for Disease Control and Prevention and State study, compared city workers exposed to soil from the mercury-contaminated East Fork Popular Creek to a comparison group. No differences were demonstrated in measured health outcomes.

The Panel invited the director of the State's Center for Health Statistics to an oversight meeting for the purpose of discussing data available to describe the health of people living in the vicinity of the Oak Ridge Reservation. (Appendix D) In general, it was found that data available from the State health statistics databases are useful for finding trends in adverse health effects and for developing theories about the cause of adverse health effects. However, the data available cannot be used to determine the cause of disease or health-related conditions. To understand the reason for this inability to use the data to show "cause-and-effect," the panel discussed the role of epidemiologic studies in determining adverse health effects.

5.5.2 The Role of Epidemiologic Studies to Evaluate Health Effects

To help interpret the reports provided to the Panel and the usefulness of the available data for evaluating the health status of communities in the vicinity of the Reservation, the Panel discussed types of epidemiologic studies and their roles in health assessment. With respect to community health, epidemiology provides a systematic approach for determining *What*, *Who*, *Where*, *When*, and *Why/How*.[2] A case definition for an adverse health effect, a standard criteria for deciding whether a person has a particular disease or other health-related condition, determines the *What*, that is, whether a person has a particular disease.

Descriptive epidemiologic studies are used to characterize the occurrence of adverse health effects by person (*Who*), place (*Where*), and time (*When*). Another type of epidemiologic study, the analytical study, determines the *Why* and *How*. That is analytical epidemiologic studies sort out and quantify potential risk factors and causes of disease and other health-related conditions. This type of study is used to link an exposure to a particular factor, for example a toxic contaminant, smoking, or diet, to a specific adverse health effect. The Panel concluded that both types of studies can be used to assess health although analytical epidemiologic studies, the most complex and resource intensive, would be needed for linking exposures to contaminants with health outcomes.

5.5.3 Descriptive Epidemiologic Studies Performed in Phase I

In evaluating different descriptive reports that were brought before the Panel, conclusions regarding the health of the Oak Ridge community were found to vary according to: (1) the defined patient population and time interval in which it was studied (e.g., people in Oak Ridge over the last year vs. people in the region surrounding Oak Ridge over several years), (2) the population used for comparison (e.g., Oak Ridge vs. the State or Oak Ridge vs. the United States), (3) the type of statistical analysis performed, and (4) the case definition for a disease or other health-related events. Appendices E and F, respectively, contain reviews of health care reports prepared by Tennessee Medical Management, Inc. and by Dr. William Reid, both of Oak Ridge.

To look for trends in area health, the Division of Environmental Epidemiology did carry out some descriptive health studies with the information currently available from State databases. Using standard statistical methodology and death certificate data for a ten-year period, the age-adjusted total death rates in Anderson and Roane Counties were found to be significantly lower when compared to the rest of Tennessee. (The death rate, or mortality rate, is the number of people who have died in a specified period of time in a defined population divided by the total number of people in that population). The age-adjusted death rate for cancer was not

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[2] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention "Principles of Epidemiology, An Introduction to Applied Epidemiology and Biostatistics" Dec 1992.

significantly different in Anderson County compared to the rest of the state while the age-adjusted cancer death rate for Roane County was significantly lower than the state rate.

The 1988-1990 age-adjusted incidence rates for total cancer cases and for 23 specific physical sites of cancer for Anderson County were compared with the comparable rates for the state. (Incidence rates are the new cases of cancer that are reported within a specified period of time in a defined population divided by the total number of people in that population). Anderson County was found to have a significantly higher incidence rate for all cancers and for five of the specific sites when compared to the rest of the state. The rates for Anderson County were not significantly different from the rates for the rest of the state for the remaining 18 sites. Appendix G includes the tabulations of mortality and cancer incidence data.

The above rates take into account the impact of age on mortality, i.e. populations with a greater percentage of older people will probably have higher death rates than comparable areas. However, other factors that play a role in the development of adverse health effects, such as smoking for lung cancer, are not considered. Whether these results represent truly different numbers of cancers, variations in patterns of diagnosis and reporting, or both, cannot be determined with available data. Additionally, Anderson County cancer incidence rates may appear to be high because of the small number of reported site-specific cancer cases that have been used to calculate the rates. When rates are based on small numbers, fluctuations in the number of events may result in large variations in the rates.

5.5.4 Planning for Future Evaluation of Health Effects

At later Panel meetings citizens from the vicinity of the Oak Ridge Reservation came to tell the Panel of their health problems. They asked that studies be done to determine if their illnesses were a result of releases from the Oak Ridge Reservation. After listening to the public's concerns, the Panel expressed that estimating the doses to the population from off-site releases through dose reconstruction was a good way to estimate the likelihood of adverse health effects from contaminant exposures. And, descriptive studies could be used to evaluate trends at the county level. However, they felt that a plan to look for opportunities to do analytical epidemiologic studies to collect data useful in linking adverse health effects with exposures was necessary.

To explore ways to do environmental epidemiologic studies, national experts were invited to meet with the Panel. The difficulties and pitfalls in doing these types of studies were discussed, as were the advantages. The Panel concluded that opportunities to do more in-depth epidemiologic studies concurrently with dose reconstruction should be investigated.

Given the limitations of the available data and the difficulty of carrying out adequate analytical epidemiologic studies, especially those related to the environment, the Panel elected to work with epidemiologists from Vanderbilt University Medical Center in Nashville to develop a plan to look for epidemiologic study opportunities. Vanderbilt researchers were selected primarily because

of their knowledge of, and experience with, the State's health databases. The plan includes five major activities:

- develop guidelines for determining the need for an analytical epidemiologic study;
- review the contaminants of concern selected by the Panel in the dose reconstruction feasibility study;
- select the possible health outcomes and review relevant epidemiologic literature for these contaminants;
- review the data needs, sources of data and availability of data necessary to carry out epidemiologic studies on these contaminants; and
- prepare a report on the feasibility of performing epidemiologic studies related to the contaminants of concern.

The charge and priorities written to guide the health effects subcommittee are summarized in Appendix H. This subcommittee also provided oversight in achieving other Phase I goals discussed below, the State's birth defects and cancer registries and the review of the Department of Energy workers' health program.

5.6 Overview of the Panel's Activities to Keep the Public Informed

An important responsibility of the Oak Ridge Health Agreement Steering Panel during Phase I was to communicate with the public on health studies issues. Directed efforts were made to not only inform the public of activities and findings, but to get their feedback and input on work being done. Several methods were used to establish two-way communication between the Steering Panel and the public including:

- a fact sheet distributed to provide an overview of Phase I (Appendix I);
- the Panel business meetings that were open to the public;
- public meetings held in the counties where the Oak Ridge Reservation is located, Anderson County and Roane County;
- public questions and concerns regularly recorded, and evaluation of Panel response to these becoming part of the quality assurance plan;

- a quarterly newsletter published that (1) addressed issues raised by the public, (2) reported on Panel meetings, and (3) provided articles related to the health studies. Specific articles included in the newsletters provided overviews of the health studies, methods for carrying out the Feasibility Study, contaminants of concern, definitions of complete pathways, epidemiologic studies, establishing causation through epidemiologic studies, dose reconstruction, and estimating risk through dose reconstruction (Appendix J);

- community feedback sessions held in Anderson and Roane Counties to afford citizens one-on-one opportunities to meet with the Panel and the State staff;

- briefing books for Panel business meetings and Phase I draft reports placed in libraries and members of the public asked to make comments;

- a toll free number established to the Environmental Epidemiology Office;

- announcements of activities placed on the Oak Ridge Reservation workers' computer notification system;

- press releases sent to the media for activities related to the health studies; and

- advertisements for activities purchased on local radio, in newspapers, and on television.

A mailing list for distribution of activity notification cards and the newsletter was developed. Initially this list included regional physicians, civic organizations, churches, and opinion leaders. Participants from meetings and callers making inquiries by phone are continuously added to the mailing list. Appendix K contains a summary of all public outreach activities from Phase I.

To enhance the public communication component of the health studies, the Panel began two projects in Phase I. The first is a Knowledge, Attitudes, and Beliefs Survey to be done by the University of Tennessee's Department of Sociology. This group was selected because of their knowledge of, and experience in, working with state demographics and surveys. The information will be used to focus communication efforts once the public's perceptions of how the Oak Ridge Reservation has affected their health are better understood. The scope of services for the survey can be found in Appendix L.

A second project is to establish a program in risk communication and public education which will establish environmental hazard updates for local physicians, develop communication and education tools regarding health issues targeted by the Knowledge, Attitudes, and Beliefs Survey, and develop simplified and interesting communication methods for schools and the public.

5.7 Panel Oversight of Quality Assurance

From the beginning, the Panel faced audiences skeptical of its ability to direct and oversee health studies that were independent of the Department of Energy and State control or influence. The Panel members realized that trust in what they were doing could only be earned in time. One way to earn this trust was through public disclosure of all work, including draft reports and open meetings. The second way was by following an organized plan of checks and balances.

A quality assurance subcommittee was formed which was composed of Panel members from the Oak Ridge area that represent citizens, workers, and local government. The plan, which calls for both Panel and external review, outlines:

- technical reviews of work for accuracy and compliance with work plans;
- editorial reviews of work for readability and visual aids;
- methods to assure that public concerns and questions have been addressed by the Panel; and
- a protocol to deal with classified documents to assure that information is reviewed and evaluated in ways comparable to that of unclassified data.

A formal quality assurance plan was prepared. Appendix M contains one section of the plan in which the technical and editorial review assignments are shown for both Panel members and outside reviewers. The public concerns and questions from Phase I are listed in Appendix N along with references of where responses to these issues were made.

One of the hardest questions for the Panel in Phase I was how to assure the quality of work done on classified documents. Six panel members and State staff working on the health studies have appropriate security clearance to review classified information, as did the Phase I contractor during their research activities. At least one member of the Panel and the contractor's research team were assured access to any piece of information related to the Oak Ridge facilities by Mr. Joe La Grone, Manager of the Department of Energy Oak Ridge Operation.

Security cleared Panel members and State staff were assigned the job of reviewing classified information related to substances identified by the contractor as capable of producing adverse health effects. If, after study, the information is believed to be relevant and significant to the study, a specific series of steps will be followed to deal with this information. The methodology for handling classified material during the course of the health studies is shown in Appendix O. If the Panel believes that the information is needed to achieve the goals of the study and that the Department of Energy will not declassify the information, the Panel could elect to terminate the study.

The Panel is in agreement that information pertinent to the health studies should be declassified. Work is ongoing to establish what information should be declassified and to develop a uniform process to achieve this.

6.0 Goal IV - Review of Workers' Health Program

The Health Studies Agreement states that "DOE will provide to the State information about DOE's Occupational Medical Program in Oak Ridge." The Panel has interpreted this to mean that at a minimum the program should be reviewed and conclusions stated. During Phase I the Panel obtained the requirements of the Department of Energy's occupational medical program (Appendix P).

In addition, the Panel heard presentations and began collecting articles published related to worker health issues at Oak Ridge. "EPI-LOGS," quarterly reports of the activities of the Center for Epidemiologic Research of ORISE (Oak Ridge Institute for Science and Education) in Oak Ridge, were identified and obtained. They contain updates and listings of worker studies from this agency. Appendix Q contains a brief description of the information available in the reports. A formal plan to carry out this review and make conclusions will be developed by the Panel in the next phase.

7.0 Goal V - Enhancement of State Cancer Registry and Development of State Birth Defects Registry

The Health Studies Agreement states that the Tennessee Cancer Registry should be enhanced by reviewing the quality and completeness of hospital reporting and a birth defects registry should be developed and maintained by the State. During Phase I, the Division of Environmental Epidemiology and Office of Health Statistics, both in the Department of Health, worked together to accomplish this task. Appendix R includes an article on the development of the Tennessee Birth Defects Registry prepared for the *Journal of the Tennessee Medical Association.*

Through a competitive bidding process, a contract was awarded to establish and implement a plan to verify all cases in the birth defects registry and to verify data reported by hospitals to the cancer registry. This statewide quality control process is important for improving the uniformity and accuracy of the registries' data. This contract was awarded to the Oak Ridge Institute for Science and Education. The plan outlined for achieving this task is shown in Appendix S.

8.0 Panel Conclusions and Recommendations from Phase I

The State of Tennessee has undertaken an independent evaluation of the potential for adverse health effects in off-site populations resulting from past operations at the Oak Ridge Reservation. The Oak Ridge Health Agreement Steering Panel has been appointed by the Commissioner of the Department of Health for the purpose of making recommendations for future phases of the Oak Ridge Health Studies. The Panel wrote a Consensus Statement at the end of Phase I. The conclusions and recommendations from this document are as follows.

8.1 Conclusions and Recommendations for Dose Reconstruction

The primary objective of Phase I, which began in May 1992, was to carry out an initial screening study called the Dose Reconstruction Feasibility Study. The goal of this study was to determine if enough information existed about chemical and radionuclide releases to estimate the actual amounts, or "doses", of harmful substances received by people living in the vicinity of the Reservation.

Beginning with a large number of contaminants of concern, the Dose Reconstruction Feasibility Study evaluated a subset of contaminants released off-site that could have resulted in adverse health effects. Screening calculations were completed to create a ranking of chemicals and radionuclides in terms of potential to cause harm to health. Based on this ranking, four substances were identified as particularly important. Sufficient information exists for these off-site contaminants to justify further evaluation of the doses that the public may have received. The Panel recommends that these contaminants should be studied further to assess the possible health risks to off-site populations. To be safe, in cases where information was inadequate to complete an evaluation, contaminants were included in the list of substances with potential for causing off-site effects.

The Feasibility Study indicates that a significant amount of information is available to reconstruct the past releases and potential off-site doses. Furthermore, the doses of the following substances may have been great enough to cause harmful effects.

- **Radioactive iodine**---The largest identified releases were associated with radioactive lanthanum processing at the X-10 facility that occurred over the period of 1944 through 1956.

- **Radioactive cesium**---The largest identified releases were associated with various chemical separation activities at the X-10 facility that took place during the period of 1943 through the 1960s .

- **Mercury** ---The largest identified releases were associated with lithium separation and enrichment operations at the Y-12 facility that occurred over the period of 1955 through 1963.

- The feasibility study also indicated that the concentrations of **PCBs (polychlorinated biphenyls)** reported in fish taken from East Fork Poplar Creek (which is downstream of Y-12) and the Clinch River downstream of K-25 have also been great enough to warrant further study. However, the feasibility study did not identify any significant sources of information that could be used to reconstruct the release history of PCBs from the facilities at the Oak Ridge Reservation.

The Oak Ridge Health Agreement Steering Panel recommends that dose reconstructing activities begin for the releases of radioactive iodine and cesium, mercury, and PCBs. These dose reconstruction activities should include:

- continuing efforts to identify, collect, and evaluate all information needed to quantify and otherwise characterize the release history of these materials from the Oak Ridge facilities, focusing on the specific processes identified;

- continuing efforts to identify, collect, and evaluate environmental sampling data to be used in reconstructing doses or confirming the accuracy of transport modeling;

- characterizing the actual release history of these materials from Oak Ridge facilities, using a time scale that will satisfy the needs of dose reconstruction;

- identifying appropriate fate and transport models and collecting appropriate site-specific modeling inputs needed to predict historical off-site concentrations;

- further identifying and characterizing the populations that would have been exposed to the identified emissions and land uses affecting exposure;

- identifying an appropriate exposure model to be used in the calculations of doses to the identified exposed population.

To perform these investigations, researchers must develop dose estimates that will be produced in an iterative fashion (proceeding one step at a time with each step guiding the next step). The purpose of these iterations is to reduce the uncertainty of results and to provide the level of detail needed to support epidemiologic studies if they are found to be appropriate.

The Oak Ridge Health Agreement Steering Panel has identified a large number of contaminant releases from facilities at the Oak Ridge Reservation that appear to have a much lower potential to pose off-site adverse health effects than the releases identified in this report. Moreover, the histories of operations and contaminant releases at the large facilities on the Oak Ridge Reservation are extremely complex. Hence, a broader-based investigation of operations and contaminants should be completed to support or modify the recommended direction of future health studies. These broad-based studies will include the further review of classified documents to identify any additional release concerns, and will seek to declassify all information related to off-site exposure.

8.2 Conclusions and Recommendations for the Evaluation of Health Effects

As the result of several meetings with the community, the Panel concludes there is interest in health studies that not only calculate health risks, but also look for the occurrence of adverse health effects. Based on the conclusions from the Phase I Study, the Oak Ridge Health Agreement Steering Panel proposes that researchers look for opportunities to conduct analytical epidemiologic studies to identify adverse health effects in exposed populations. Results from the analyses of descriptive epidemiologic studies completed in Phase I and the data from the State's vital statistics and cancer registry varied depending on the methods used to analyze the data. The Panel believes that such descriptive studies cannot demonstrate "cause-and-effect" and should only be used to show trends and suggest areas for future study.

Concurrent work should begin that will:

- develop guidelines for determining the need for an analytical epidemiologic study;
- review the contaminants of concern selected by the Panel in the Dose Reconstruction Feasibility Study;
- select the possible health outcomes and review relevant epidemiologic literature for these contaminants,
- review the data needs, sources of data, and availability of data necessary to carry out epidemiologic studies on these contaminants; and
- prepare a report on the feasibility of performing epidemiologic studies related to the contaminants of concern.

Greater clarity and insight of the public's perception of their health and how the activities of the Oak Ridge Reservation may have affected it are needed in order to insure that we do not overlook important issues.

8.3 Continuation of Communication with the Public

The Oak Ridge Health Agreement Steering Panel believes that communication activities begun in Phase I should continue in Phase II. These activities include public meetings to receive input from the public and relay study results, the newsletter, the toll-free telephone service to the Division of Environmental Epidemiology office, the one-on-one community feedback sessions, the speaking engagements, the technical workshops, and the interagency communications.

The Panel advises that additional efforts should start early in Phase II which would:

- coordinate meetings between Phase I and Phase II contractors to assure a smooth transition of work;
- create further publications and presentations to educate and provide the community with information on the study;
- identify the community opinion leaders and organize focus groups to establish consistent ongoing two-way communication;
- implement an effective news media program; and
- establish a risk education program for physicians,
- establish a risk education program for local school systems.

Also, the Panel recommends continuing to carry out a Knowledge, Attitudes, and Beliefs survey. This survey would be conducted through the University of Tennessee, Department of Sociology, in conjunction with the Local Oversight Committee, to establish an understanding of regional public perception.

8.4 Continuation of Quality Assurance

The quality assurance process established and conducted in Phase I proved to be important in ensuring that the work being done is credible and accurate. The Panel recommends that significant resources continue to be devoted to the quality assurance program in all further work.

8.5 Other Recommendations

The Oak Ridge Health Agreement Steering Panel recommends that the State continue verifying cases for the Tennessee Cancer Registry and continue developing and maintaining the Tennessee Birth Defects Registry.

The Oak Ridge Health Agreement Steering Panel recommends that a formal plan to review the Department of Energy's Oak Ridge Reservation workers' health program be developed and carried out in Phase II.

During Phase I some information provided by the public and external reviewers about contaminants, was not completely investigated. The Oak Ridge Health Agreement Steering Panel recommends that an investigation of this information be pursued in Phase II.

APPENDIX A

TECHNICAL PANEL MEMBERS

PANEL OF TECHNICAL EXPERTS WHO DEVELOPED THE SCOPE OF SERVICES FOR THE FEASIBILITY STUDY

Ms. Bonnie S. Bashor
Tennessee Department of Health
Division of Environmental Epidemiology
Nashville, TN
Expertise: Toxicologist

Dr. Owen Hoffman
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN
Expertise: Environmental Transport and Uncertainty Analysis

Dr. Trent R. Lewis
Formerly of EPA & NIOSH
Cincinnati, OH
Expertise: Chemical & Environmental Toxicology

Dr. Tom Long
Environmental Toxicology Program
Division of Environmental Health
Illinois Department of Public Health
Springfield, ILL
Expertise: Risk Assessment

Dr. Norma Morin
Project Director, Rocky Flats Health Studies
Colorado Department of Health
Denver, CO
Expertise: Epidemiologist

Dr. James Ruttenber
University of Colorado School of Medicine
Denver, CO
Expertise: Ecologist, Epidemiologist, Physician

Mr. Paul Voillequé
MJP Risk Assessment, Inc
Idaho Falls, ID
Expertise: Health Physicist, Dose Reconstruction Studies

Tennessee Department of Health Staff:
Dr. Sarah Sell, Division of Environmental Epidemiology
Dr. Richard Light, Chief Medical Officer
Dr. Mary Yarbrough, Division of Environmental Epidemiology

APPENDIX B

OAK RIDGE HEALTH AGREEMENT STEERING PANEL MEMBERS

OAK RIDGE HEALTH AGREEMENT STEERING PANEL MEMBERS

Technical Members

1. Joseph Hamilton, M.S., PhD
2. Owen Hoffman, M.S., PhD
3. Norma Morin, PhD, M.P.H.
4. James Smith, M.S., PhD
5. Paul Voillequé, M.Bas.Sci., M.S.

Oak Ridge Worker Representative

6. Jacqueline Holloway

Environmental Quality Advisory Board Representative (City Council of Oak Ridge)

7. James Alexander, M.S., P.E.

At-Large Representatives

8. William Busse
9. Eugene Fowinkle, M.D., M.P.H.
10. Ralph Hutchison

Tennessee Department of Health Representative

11. Mary Yarbrough, M.D., M.P.H.

Department of Energy Representative

12. Bonnie Richter

1) **Joseph Hamilton, M.S., PhD**

Dr. Hamilton has both a Master of Science and a Doctorate from Indiana University and is a distinguished professor at Vanderbilt University, where he served as chairman of the Department of Physics and Astronomy from 1979-1985. His field of expertise is nuclear physics. He is a member of numerous committees of national and international origin primarily dealing with applied physics. He has also earned many awards including the Outstanding Educator of America in 1973, and the Jesse Beams Gold Medal for Outstanding Research, 1975. He has a high degree of familiarity with the work at Oak Ridge, having founded the Joint Institute for Heavy Ion Research and having served as the Vanderbilt counselor to Oak Ridge Associated Universities from 1974-1980. He is widely published in the field of nuclear physics and has delivered numerous papers nationally and internationally.

As a technical expert in nuclear physics, Dr. Hamilton can provide essential insight regarding assumptions of the historical use and release of radionuclides and scientific community will help promote cooperation and trust.

2) **Owen Hoffman M.S., PhD**

Dr. Hoffman is the President and Director of Senes Oak Ridge, Incorporated, Center for Risk Analysis. Prior to becoming President of Senes Oak Ridge, Dr. Hoffman was a research staff member in the Environmental Sciences Division of the Oak Ridge National Laboratory. His research interests include the validation of environmental transfer model predictions and the development of methodologies used to screen and assess the health and environmental risks of exposure to chemicals and radionuclides. Environmental transport is a special area of expertise. He has been a major consultant on numerous national and international committees, especially those involving the International Atomic Energy Agency Activities. In addition, he has served on health study oversight committees for the Hanford, Washington and Rocky Flats, Colorado, DOE facilities in the U.S.A.

Dr. Hoffman serves as a technical expert. His professional interest, reputation of being objective, and knowledge of the complexities of ORR operations make him eminently qualified for this appointment.

3) **Norma Morin, PhD, M.P.H.**

Dr. Morin is an epidemiologist with the Colorado Department of Health. She is the project director of the health related initiatives at the Rocky Flats nuclear weapons plant near Denver, Colorado. This study includes toxicologic review, dose reconstruction, toxicity assessment, risk characterization, and epidemiologic studies - elements similar the ones in the Tennessee Health Studies Agreement.

Dr. Morin will serve as a technical expert. The State will profit from the first hand knowledge of the Rocky Flats experience. Dr. Morin will be able to provide guidance in both technical matters as well as public communication.

4) **James Smith, M.S., PhD**

Dr. Smith is chief of the Radiation Studies Branch within the Division of Environmental Hazards and Health Effects at the Centers for Disease Control in Atlanta, Georgia. He has served on many national and international committees concerned with health physics, was a member of the Hanford Health Effects Review Panel in 1986, and is presently a member of the Rocky Flats Health Advisory Panel. Dr. Smith is on the editorial board of *Health Physics Journal*, an abstractor for the *Journal of Physics in Medicine and Biology*, and is widely published in the field of radiobiology. He is certified by the American Board of Health Physics.

Dr. Smith serves as a technical expert. Through his work at CDC, he is helping to develop the research agenda for DOE energy related facilities nationwide. His involvement with this project will serve as a link to both the CDC and other state projects with similar objectives.

5) **Paul Voillequé, M.Bas.Sci., M.S.**

Mr. Voillequé has a Master's Degree in Radiologic Health and is Board Certified in Health Physics. He has worked with the Fernald Dosimetry Reconstruction Project. Past projects have included development of a radiation dosimetry data base, safety analysis and environmental impact documents for nuclear waste management, and development of calculational models of radioactive deposition and resuspension for releases from light water reactors. He also contributed to the Three Mile Island recovery studies. He serves on the Thyroid/Iodine-131 Assessments Committee of the National Cancer Institute and is a member of the Radiation Advisory Committee of the Science Advisory Board to the Environmental Protection Agency. He is presently president of MJP Risk Assessment, Inc. in Idaho Falls, Idaho.

Mr. Voillequé's experience and competence in dose reconstruction will not only guide the study but will help establish scientific credibility.

6) **Jacqueline Holloway**

Ms. Holloway is employed at the Oak Ridge National Laboratory in the Biology Division. She also serves as an Atomic Trades and Labor Council Health and Safety Representative. Ms. Holloway is very active in both professional and community arenas. She has worked on numerous election campaigns and serves on several community committees, including the Tennessee Committee on Safety and Health's Board of Directors. She also serves as an Anderson County Commissioner and a permanent member of the Roane State Community College Campus Task Force.

Ms. Holloway serves as the ORR worker representative to the steering panel. She was nominated by officials of the Oil, Coal and Atomic Workers (OCAW) and the Atomic Trade Labor Council (ATLC). Together these two bodies represent the majority of union workers at the K-25, Y-12, and X-10 plants. Her professional and community service in conjunction with the cooperative efforts of union officials that resulted in her nomination make Ms. Holloway a great asset to the Health Study.

7) **James Alexander, M.S., P.E.**

Mr. Alexander holds a Master of Science in Civil Engineering and a Bachelor of Science in Environmental Engineering. Currently, he is employed by Roy F. Weston, Inc., in Oak Ridge, Tennessee as a Senior Environmental Engineer and Health Physics Specialist. He was employed by the U.S. Department of Energy, Oak Ridge Operations from 1975 to 1988. Mr. Alexander has experience in the compliance and permitting functions for most of the major federal environmental statutes, particularly the Clean Water Act and the National Environmental Policy Act. He also served as project manager for nine projects in DOE's Formerly Utilized Sites Remedial Action Program (FUSRAP) and the Surplus Facilities Management Program (SFMP). He has participated in several functional appraisals of radiological safety and environmental protection programs at DOE facilities.

Mr. Alexander serves as the representative for the Environmental Quality Advisory Board to the City of Oak Ridge. His experience in environmental engineering, knowledge of the Oak Ridge Reservation (ORR), and involvement with community issues will be important assets to this oversight committee.

8) **William Busse**

Mr. Busse was the executive director of the American Lung Association of Tennessee from 1966 to 1992. He holds a Bachelor of Arts in Political Science and has taken several graduate courses in management. He is a member and consultant to the Kaiser Family Foundation Planning Committee for Tennessee Community Based Health Promotion Program. Mr. Busse is a member of the American Public Health Association, the Tennessee Public Health Association, and several other associations and committees concerned with public health.

Mr. Busse was appointed as an at-large representative to the steering panel. For over 25 years he has demonstrated a dedication to both health issues and the people of Tennessee. His proven skills in management and communication of health issues will be invaluable. It is felt he will represent fairly the interest of all the State's citizens.

9) **Eugene Fowinkle, M.D., M.P.H.**

Dr. Fowinkle has been the Associate Vice-Chancellor for Health Affairs at Vanderbilt University since 1983. From 1969 to 1983, he served as the Commissioner of Public Health for the State of Tennessee. He has also authored and co-authored numerous articles relating to public health issues. He has had many special appointments including the Public Health and Epidemiology Task Force of the President's Commission on Three Mile Island. He has a great deal of expertise on both medical issues and public health policies.

Dr. Fowinkle is one of Tennessee's most respected physicians in the public and private sectors. He served the State and its people for over 15 years. His training and background will provide strong leadership and guidance to this project. He has been appointed as an at-large representative to the steering panel, representing both the medical community and the public.

10) Ralph Hutchison

Mr. Hutchison is chairman of the Oak Ridge Environmental Peace Alliance (OREPA) and serves as pastor of the Bethel Presbyterian Church in Dandridge, Tennessee. OREPA is a grassroots organization composed of people living in and around Oak Ridge. In 1989 the group published the "Citizen's Guide to Oak Ridge" which gave their perspective on waste and contamination issues in the area. He serves in several other community groups dedicated to environmental concerns and publishes a newsletter for OREPA.

Mr. Hutchison has demonstrated strong interest in the ORR operations, the relationship of the operations to the health of off-site populations, and the State's plan for studying this relationship. He has been appointed to an at-large position on the steering panel. His insights into the public's perception of the ORR and the Health Studies Agreement will be extremely important. His contacts with local, state, and national environmentally conscious organizations will promote input needed to maintain credibility and balance.

11) Mary Yarbrough, M.D., M.P.H.

Dr. Yarbrough is the director of the Division of Environmental Epidemiology, Tennessee Department of Health (TDH). She has a Bachelor of Science in Biomedical Engineering, completed residencies in internal medicine and preventive medicine, and received a Master of Public Health with emphasis in international health. Prior to working for TDH, Dr. Yarbrough was involved in international health studies as a Henry Luce Scholar in Southeast Asia, a consultant for the International YMCA in Zambia, and a consultant with the World Health Organization in Geneva, Switzerland.

As project director of the Tennessee Health Studies Agreement, Dr. Yarbrough will serve as the TDH representative to the steering panel.

12) Bonnie Richter, M.D., M.P.H.

Dr. Richter is with the Office of Epidemiology and Health Surveillance, United States Department of Energy (U.S. DOE), Washington, D.C. She serves as the Project Officer for DOE on the Oak Ridge Health Studies Agreement grant. Dr. Richter serves as the Department of Energy's representative on the steering panel. She is a physician and epidemiologist and worked with the Agency for Toxic Substances and Disease Registry prior to joining the U.S. DOE. She supports the philosophy of openness and independence in the health studies, a primary objective of the project.

APPENDIX C

STATE STAFFING FOR THE OAK RIDGE HEALTH STUDIES

TENNESSEE DEPARTMENT OF HEALTH, DIVISION OF ENVIRONMENTAL EPIDEMIOLOGY STAFFING FOR THE OAK RIDGE HEALTH STUDIES

Dr. Mary Yarbrough
Project Director
Dr. Yarbrough is a physician and the Director of the Tennessee Department of Health, Division of Environmental Epidemiology. Dr. Yarbrough is a member of the Oak Ridge Health Agreement Steering Panel. She directs all of the staff work completed to support the Panel and is the primary liaison between the State and the U.S. Department of Energy for the Health Studies Agreement.

Mr. Patrick Turri
Project Manager
Mr. Turri oversees the project budget and the contract with ChemRisk. He provides staff support to the Quality Assurance Subcommittee of the Oak Ridge Health Agreement Steering Panel. Mr. Turri is responsible for maintaining the Panel's Quality Assurance Plan and for insuring that all QA activities in the plan occur.

Ms. Mary Layne Van Cleave
Epidemiologist
Ms. Van Cleave is responsible for reviewing and analyzing health data that are relevant to the Oak Ridge Health Studies. She provides staff support to the Health Effects Subcommittee and is responsible for coordinating and overseeing the Epidemiology Feasibility Study which will be completed through a grant by Vanderbilt University.

Mr. Jeff Daniel
Public Relations and Administrative Support
Mr. Daniel is responsible for developing the Panel's quarterly newsletter. He provides staff support to the Communications subcommittee and was responsible for tracking the development of the contract to enhance the Panel's public communication and education activities around Oak Ridge.

Ms. Bonnie Bashor
Epidemiologist
Ms. Bashor provides staff support to the Dose and Risk Assessment Subcommittee. She has also provided technical support for reviewing risk assessments related to the Oak Ridge area and technical work completed by ChemRisk. Ms Bashor coordinated the external review of the draft Dose Reconstruction Feasibility Study reports and has participated in the QA activities related to that study.

APPENDIX D

HEALTH DATA AVAILABLE FROM THE TENNESSEE DEPARTMENT OF HEALTH

HEALTH STATISTICS DATA AVAILABLE FROM THE TENNESSEE OFFICE OF HEALTH STATISTICS AND OTHER TENNESSEE DEPARTMENT OF HEALTH AGENCIES

This report includes a brief overview of the data sets that are available within Tennessee state government that will be useful in examining the distribution of particular types of health outcomes in Anderson and the surrounding counties as well as in the rest of the State. Assessment of the health of residents of a particular area requires both, investigating the distribution of particular disease incidence and other health outcomes as well as studying the potential determinants of those outcomes.

For each of the data sets the source of the data, the period of time for which the data are available, the types of data elements that are available to characterize the population experiencing the particular events, and the usefulness of the distribution data for assessments of health status are described. After describing the actual data sets, some of the measures that are typically used to present the data are presented.

Mortality Data

Mortality data are the data derived from the registration of deaths in the Vital Records system. Deaths have been registered in Tennessee since 1914; however, data tapes that include the mortality data are available from 1949 through the present.

Approximately every 10 years, the forms that are used to register vital events are modified to meet more current information needs. Many of the basic data elements have been included on the records since the first data files were created, but significant improvements have been made on the quality of the reported data through the addition of more sophisticated editing and querying processes and the implementation of field programs which involve personnel providing on-site training to individuals completing certificates and personnel actually tracking events and insuring that certificates are filed for all events that occur.

Mortality shows considerable variation in relation to certain characteristics of the decedent and of the event of death. In view of the very close relationship between the age of the decedent and the risk of death, age may be considered the most important demographic variable in the analysis of mortality for the general population. Other characteristics of the decedent that are also of primary importance include sex of the decedent, usual place of residence, occupation and industry, educational attainment, ethnicity, and race.

Elements of primary importance in characterizing the event include cause of death, place of death and date of occurrence of the death. Causes of Death are coded according to the International Classification of Diseases in all States in the United States. The ICD is also revised approximately every ten years under the guidance of the World Health Organization to keep the classification current with the latest diagnostic practices and medical advances.

Although cause of death data may be used to draw inferences about the incidence of disease, it is important to consider the fact that an individual's place of residence at death may not be the same as the residence at the time that a disease was contracted or an exposure occurred. The cause of death as recorded on death certificates should not be accepted as totally accurate, and data included in the Tennessee automated files includes only a portion of the cause information reported on the certificates.

The accuracy of the cause information depends on the physician's understanding of what constitutes an immediate and an underlying cause, the amount of information that the physician has when the certificate is filed, for example, autopsy results may not be available, and in some instances, the attending physician will not be available to file certificates. Therefore, the certifying physician will be different from the attending physician. To further complicate the process, coders in the Vital Records office use rules developed by the National Center for Health Statistics to assign the underlying cause of death which is maintained in the State's data file. When a large number of deaths are coded to ill defined conditions in an area, it is most likely that the incidence of other diseases are being under reported.

In addition to the total mortality of an area, the one mortality indicator that has been accepted as the most sensitive indicator of overall health status of a population is the infant mortality rate. Infant mortality is the death of infants up to one year of age. Frequently infant mortality is subdivided into two groups, neonatal mortality which is death occurring in the first 28 days of life and post-neonatal mortality which is death occurring from 28 days up to one year. This division is made because the factors influencing death and consequently the causes of death for these two groups are very different. Neonatal deaths generally comprise over 60% of the total infant deaths and are most frequently related to factors associated with pregnancy and birth. During the past two years in Tennessee, neonatal deaths were primarily due to congenital anomalies followed by disorders related to short gestation and low birth weight, and post-neonatal mortality was caused by Sudden Infant Death Syndrome most often, followed by congenital anomalies.

Because of the association of infant death with pregnancy and birth, infant death records are routinely matched with birth records in the State to create a matched infant death/birth file. The matched files have been created since 1974 and include all of the data from the birth certificate and all of the data from the death certificate for infants who died. This file allows an analysis of important data available on the birth record for infants who died. Patterns of birthweight, gestational age at delivery, prenatal care, complications of pregnancy and delivery, and maternal risk factors may be compared between infants who died and infants who survive. This type of information is essential for studying infant death in relation to events that occur during pregnancy and delivery

Fetal deaths or stillbirths are classified separately from other deaths because there is no existence of life outside of the mother prior to death. Fetal deaths are an important data set for studying the incidence of anomalies and measuring mortality that might be related to unfavorable events during pregnancy or prior to conception. However, fetal deaths have the same types of problem

as deaths with determination of cause of death and a more important issue is only fetal deaths that meet certain reporting criteria are reported to the State and all data for all very early losses are not available. The current reporting criteria are 500 grams weight or in the absence of weight of 22 weeks of gestation or more.

Neonatal deaths and fetal deaths are frequently combined to create a new measure called perinatal mortality. Although Perinatal deaths may be defined using various subsets of infant and fetal deaths, the definition that is most frequently used in Tennessee is neonatal deaths plus late fetal deaths (28 weeks or more).

Natality Data

Like Mortality data, the source of natality or live birth data is birth certificates filed with the Tennessee Office of Vital Records. Birth records were first filed in the State in 1914, and the first year that an electronic data file is available is 1959. While birth registration has been incomplete in past years, some recent requirements for children to present birth records for school enrollment and the more recent requirement that children must have a social security number to be claimed as dependent on income tax returns have had an impact on registration.

The most important limitation of use of birth data is the incompleteness of recording of medical data on the record. These data are not essential for registering the fact of birth and do not have the same legal importance as the cause of death on the death records. There is a great deal of variation on the way that the medical information is prepared for the birth certificate. The actual data included on the certificate regarding the mother's medical history may come from the mother or from the mothers record that is provided by the physician who provided prenatal care. Birth certificate clerks do not always have access to the infant's medical record when the certificates are prepared in Tennessee, complying with medical reporting requirements have not always been high priorities in some major delivering hospitals although statistical staff are working to identify patterns of problems and Vital Records staff routinely address identified problems with the hospitals.

The medical data on the birth record includes Medical Risk Factors, other risk factors which includes smoking and alcohol use data, obstetric procedures performed during pregnancy and at the time of delivery, complications of labor and delivery, abnormal conditions of the newborn and congenital anomalies. This data represents a very valuable source of information on diseases of pregnancy and infancy.

Uses that will be made of birth certificate data in epidemiological investigations are provision of denominator data for the computation of rates of diseases in infancy and as the basic record for each infant included in the birth defects registry. Although some anomalies will actually be identified from the birth records, they will also serve as the record that other data sets will be matched against to insure that duplicates are not included in the registry.

Morbidity Data

Morbidity data are data on diseases occurring in a population. Some detail on the selected data sets that should be useful in characterizing the incidence of diseases that might be associated with particular environmental exposures and are available at least at the county level are included in this report. Other data sets available in the State may be useful for some particular components of studies, and those data sets are also briefly described.

Behavioral Risk Factor Survey data are collected through a statewide telephone interview sample survey of health behaviors. This survey provides data that are essential for monitoring the prevalence of major behavioral risks associated with the leading cause of preventable death in the U. S. It includes questions on smoking, alcohol use, seat belt use, hypertension, and obesity. Although these data would be useful for assessing lifestyle factors that might influence morbidity and mortality rates, the sample is only large enough to provide estimates at the state level.

The Communicable Disease Reporting system includes data on the incidence of communicable diseases including sexually transmitted diseases reported by physicians, hospitals, clinics or others aware of a case in the State. Data are reported to the local health departments and forwarded weekly to the State Health Department where a report is transmitted to CDC.

The AIDS reporting data includes cases of AIDS reported to the Department of Health by physicians, nurses, and other health professionals as required by regulations. Bi-monthly transfers of data without identifiers are sent to CDC in Atlanta. These data are only available at the regional level because the number of cases is small and the potential to identify individuals from the data exists if data are disaggregated to a lower geographic level.

Beginning in January of 1992, HIV became reportable in Tennessee. Confirmed cases of HIV are reported by laboratories, physician's offices and medical facilities to the Department of Health. This data will be available at the county level.

Morbidity data sets that should prove useful in efforts to analyze disease patterns in Anderson and other counties include the following:

Cancer Reporting Data System
Cost Containment Information System
Newborn Screening System
Children's Special Services Data\Patient Tracking Billing Management Information System
Medicaid Management Information System

It is important to note that many of the morbidity data sets only cover segments of the population. Cancer and newborn screening are the only two with complete population coverage

Tennessee Cancer Reporting Data System

Cancer became a reportable disease in Tennessee following the passage of the "Tennessee Cancer Reporting System Act of 1983." According to that Act, reports from Tennessee hospitals and laboratories that diagnose and/or treat cancer are to be submitted to the Department of Health. The purpose of this reporting is "to insure an accurate and continuous source of data concerning cancer and certain precancerous and tumorous diseases, and to provide appropriate data to members of the medical, scientific, and academic research communities for purposes of authorized institutional research." By law, all cases diagnosed after January 1, 1986, are required to be reported.

When the State began collecting data in 1986, the data set included all treatment procedures and lifetime follow-up. However, due to problems most hospitals were having in collecting treatment and follow-up, the State revised the reporting requirements to include the items related to patient information and diagnosis, or incidence only.

The American College of Surgeons (ACoS) has established a minimum set of items that must be collected and maintained on every cancer case seen in a hospital with an approved cancer program. At the present time, Tennessee has 23 hospitals (out of 142) which either have or are working toward an approved cancer program. Of these 23 hospitals, 9 are in East Tennessee while Middle Tennessee and West Tennessee each have 7. The Tennessee Cancer Reporting System (TCRS) was designed to follow the ACoS minimum data requirements. There are several items on the TCRS abstract that are not part of the (ACoS) minimum data set: occupation, industry, family history of cancer, and tobacco usage. These items were added to the abstract by the Tennessee Cancer Reporting Advisory Committee.

Between 1986 and 1990, there were seven (7) laboratories reporting data to TCRS. Laboratories were not always capable of reporting patient identifiers or of accurately reporting the primary site of cancer when the specimen(s) they received were from metastatic sites. Without patient identifying information required to match records, it could not be determined if laboratory-reported cases were duplicates of cases reported by hospitals which would result in the over-reporting of cancer incidence. By excluding laboratory reports, there is a risk of under-reporting cancer incidence. However, laboratory reporting was discontinued in 1991.

Hospitals are required to report information regarding each patient seen for cancer diagnosis and/or cancer-directed treatment to the Department of Health. Clinical diagnoses such as those made by X-rays and CT scans are reportable, as well as diagnoses that are microscopically confirmed (those made through cytology and histology). Cancer-directed treatment usually modifies, controls, removes, or destroys proliferating cancer tissue. Treatment may be directed toward either the primary or metastatic sites. Cancer-directed treatment normally includes surgical removal of the cancerous tissue, radiation therapy, chemotherapy, or any of several "other therapies" including bone marrow transplants, immunotherapy (including Biologic Response Modifiers), interferon, and hyperthermia. Treatment provided to a cancer patient that is only intended to relieve symptoms or provide supportive care is not considered cancer-directed treatment.

There are 2 methods currently acceptable for reporting data: abstract or magnetic tape using a specified format and specified codes. The abstract includes items that are required which are printed in red and items that are optional, printed in blue. Currently, 22 hospitals report by tape while the remaining 120 report by completing the hard-copy abstract. The 22 hospitals tend to be the larger cancer treatment facilities that see the majority of cancer patients. Data are required to be reported quarterly. If a hospital has no cases to report for a given reporting period, the facility must submit a transmittal form indicating such.

The quality of the data collected by the TCRS is very important and depends on the cooperation of the hospitals submitting data. Training and educational information is provided by TCRS staff to the individuals involved in cancer reporting activities. After all of the cases for a data year have been submitted, edited and updated, the file is considered final. Routine tabulations are created which include site by sex, site by resident county, site by stage, etc. Twenty-four major site groups are used to display the cancer data.

Data from the Tennessee Cancer Reporting System are currently available for 1986 through 1990. All of the hospitals that were treating and/or diagnosing cancer were not reporting data until 1988. Therefore, most analyses of cancer incidence data are currently completed using data for 1988-1990.

Cost Containment Information System

The Cost Containment Information System is currently undergoing final testing and is scheduled to be operational next month. The data in this system are reported to the State by third party payers and include information recorded on UB-82 claims for services provided by Tennessee hospitals. The first data that will actually be processed will be data for calendar year 1990. A large portion of the 1990 data is being used to test the system and have already been processed. The data that are being maintained in the system include the name of the hospital, patient demographics, patient city, county and zipcode of residence, charges for services, diagnoses, procedures, DRG'S, admission and discharge dates, and attending physician data. The only identifier in the record is a hospital patient control number. The data cover all inpatient and outpatient claims paid to Tennessee hospitals. This number is the number assigned by the hospital to the patient.

Although the reason for the development of the Cost Containment Information System was to have data to compare charges among hospitals, the data will be as useful for analyzing disease patterns across the State. In addition to the UB-82 claims data, Medicare claims have been purchased from the Health Care Financing Administration and Medicaid claims will be available. The piece of the hospital claims data that will not be included in this data system will be the claims for persons who do not have a third party payment source which would include those who are self-pay and those who are charity patients.. In an attempt to estimate the proportion of hospital admissions that would fall into this category, data for hospitals that reported admissions by source of payment on the 1990 Joint Annual Report of Hospitals were examined. These data showed that of the 163 hospitals licensed in the State, 136 hospitals reported the distribution of

admissions by payment source and approximately 7 percent of total admissions in these facilities would be missed in the combined Medicaid Cost Containment data system.

The cost containment data will be a key portion of the data used to identify children included in the birth defects registry. the contractor will be able to use the patient control, number to identify the record in the hospital and provide additional identifiers which will allow merging of these data with birth certificate data after the hospital review if it was not possible to match the record prior to the hospital review.

The Medicaid Claims data will provide data like the data for the health Care Cost information system. Like cost containment data, claims are filed on UB-82 forms with Medicaid for payment for hospital services. In addition to the hospital inpatient and outpatient claims which will be used in conjunction with the Cost Containment data, data for EPSD&T screening swill be obtained from Medicaid for use in the development of the Birth Defects Registry. For the Birth Defects Registry, Medicaid eligibility file which can be linked to the claims file to provide complete identifying information for infants with birth defects who will be included in the registry will also be accessed.

Newborn Screening Data

The State Laboratory Newborn Screening Program will provide data on infants who are screened for particular conditions as required by Tennessee law. These conditions may cause serious complications if they are not diagnosed and treated early. The conditions for which infants are screened include, PKU, hypothyroidism, hemoglobinopathy, and galactosemia. The screening was initiated in 1965 when only PKU screening was required. Hypothyroidism was added in 1980, hemoglobinopathy in 1988 and galactosemia in 1992. The data have been entered into a data base only since February of 1991. Prior to that time some hard copy records are available.

Children's Special Services

The State Children's Special Services data system includes data for children who meet specific financial and medical criteria and receive services that are paid for by the State. The program is regionally based with clinics being held in the regional health department offices. data include infant identifiers, demographic characteristics, diagnoses, place of residence and specific service information.

Genetics Data System

Any child with a birth defect in the State is eligible to receive services from the six genetic centers across the State. Data available from the Genetic centers include demographic and diagnostic data about the children who receive services. No identifiers are maintained in the data system; however, the data will be useful to assess reporting in the birth defects registry and for examining the incidence of birth defects across the State.

In addition to the Vital Statistics Data and the morbidity data that are currently available, data are also available to describe resources available to provide health care in particular areas of the

State. Although most analyses will be completed based on the patient's resident county rather than in the county where a particular disease may have been diagnosed or treated, there may be a difference in the frequency of diagnoses due to the availability of providers in a particular geographic area. Computerized data on hospitals are available in the State beginning with 1974.

These data provide insights to the specific types of hospital services that are available in a particular area and include patient origin data which shows patterns of migration for health care services. The Joint Annual Report data include information about the services that are available in a particular hospital, the utilization of the facility, financial data for the hospital and information about the medical staff. More recent reports include admission data by major diagnostic categories. The Joint Annual Report data are collected on an annual survey administered by staff in the Division of Information Resources. Completion of the report is included in the hospital regulations as a requirement of licensure in the State.

Similarly, data on licensed physicians practicing in a given area of the State are available from the Health manpower data system. This system provides information about the amount of time the physician practices, demographic characteristics of the physicians, secondary practice locations and specialty. This data is available in an automated form from 1980 until the percent. The data are collected through the annual license renewal process. Original demographic information is collected once at the time of initial licensure and the physician is asked to update data on place of practice an activity status each time the license is renewed.

The final type of data discussed is population data. In addition to providing meaningful insights into the characteristics of people residing in the State, population data are essential for the calculation of rates of death and disease incidence. The Census Bureau actually counts the population living in every State in the United States once every 10 years. The entire population provides data on general demographic characteristics. A sample of the population completes a more detailed questionnaire that provides information on social, housing and economic characteristics. The population data are essential for calculating rates and for providing insights into social and economic characteristics that may be related to the incidence of particular diseases.

Measures of Death and Disease Incidence

Statements about the frequency of events have little meaning unless they are qualified in terms of

1. the population in which they were observed and
2. when they were observed.

A rate expresses the frequency of a disease or characteristic per unit of size of the population. The three components of a rate are the numerator which is the number of persons affected by the event; the denominator which is the population at risk of experiencing the event and a specification of time. The numerator and denominator of a rate should be similarly structured. If the numerator is limited to a particular age or sex group, the denominator should be limited

to the same group. While the denominator of a rate is the population at risk of the event in the numerator, the denominator of a ratio is the number of persons who could have experienced the event and did not. Ratios express the number of affected persons in relation to the number of unaffected persons.

The incidence of diseases is the number of cases of disease that come into being during a specified time period. Frequently, the exact time of onset of illness is not known so the date of notification or of report are used. The incidence rate is the number of persons diagnosed with a disease during a specific time. The denominator is the total population at that time

Prevalence is the frequency of a disease at a designated point of time expressed for a specific population at the same point in time. The numerator of a prevalence rate includes all persons having the disease at the given moment irrespective of the amount of time that has passed since the disease was diagnosed. The denominator is the total population.

The constant used in defining rates or ratios is dependent on the type of rate being calculated. Usually the standard for crude rates is per 1,000. For example the crude death rate is per 1,000 population. The birth rate is expressed per 1,000 population. Cause-specific rates are expressed per 100,000 due to the small number of events occurring for any one given cause relative to the entire population.

Age Adjustment

It is well known that age is directly related to the occurrence of death in a population. For some comparisons sex and race may be directly related to the events being compared. Because of the relationship between age and the occurrence of death, it is important to compare the age distributions of areas when comparing mortality in those areas. If the age distributions are different, it is likely that the area with the older population will have higher mortality, not because of an adverse event but simply because of the older population. To be able to make comparisons when age distributions are different, it is important to age adjust the data for both areas. Age adjustment takes away the effect of differing age distributions and provides data that are based on comparable age distributions for both areas. It is important to note that the age adjusted data are not the true rates for the areas.

Small Numbers

One of the most common errors made in analyzing vital statistics and morbidity data is the use of rates based on small numbers. when the numbers in the numerators and denominators of rates are small, very small fluctuations in the number of events can result in large differences in rates. Frequently statisticians will combine several years of data for small areas to try and obtain a larger and more stable data base for assessing the occurrence of events. Calculating confidence intervals around the rates can also provide insight into when the variation among rates over time represents a fluctuation that is outside of the range that would be expected for the rate.

There is a wealth of data that will be useful in identifying areas that deserve to be studied further. It is important to point out the data on distribution of events is only one part of the data that is needed to determine health effects. It is most important to determine differences in exposures between the groups of people who experience events and the groups that do not experience the events if any inferences about cause are to be made. Consideration of lifestyle characteristics are also essential in determining why a particular group might experience a given health outcome.

APPENDIX E

REVIEW OF COMPLETED BY TENNESSEE MEDICAL MANAGEMENT, INC.

COMPARISON OF ANALYSES COMPLETED BY TENNESSEE MEDICAL MANAGEMENT, INC. WITH ANALYSES COMPLETED BY THE TENNESSEE DEPARTMENT OF HEALTH, DIVISION OF ENVIRONMENTAL EPIDEMIOLOGY

Methodology

Tennessee Medical Management, Inc. calculated Standard Mortality Ratios for total deaths, total cancer deaths and deaths due to specific sites of cancer and Standardized Incidence Ratios for cancer incidence data. The classification scheme for cancer sites that TMMI used for mortality data is consistent with the classification scheme that we will be using on future analyses of cancer mortality by site.

The calculation of the standard mortality ratios involved:

(1) calculating the age, race, sex-specific rates for the U.S.,

(2) applying these age, race, sex-specific rates to the corresponding age, race, sex-specific populations in the specific geographic area that they were analyzing; i. e. Tennessee, Anderson county, Roane county, etc., and

(3) summing the age, race, sex numbers of expected deaths obtained in the step above to obtain the total number of expected deaths in the specific area.

The Standard Mortality Ratio is then the ratio of the observed deaths to the expected deaths in the given area. The Standard Incidence Ratios are calculated in the same way using incidence data instead of mortality data.

The tests that TMMI has completed involve testing the hypothesis that the observed number of deaths was not significantly different from the expected number of deaths. They are testing for a difference between the observed number and the number that would be expected if the age, race, sex of the population were the same as the population of the United States. Generally, they are testing whether the area where a population resides at death has an effect on the occurrence of the death. Because of the very small numbers of events that occur in the cause-specific data, they have used a variance stabilizing adjustment before completing the test.

It is important to note that in this analysis, the assumption is made that if you remove the effect of age, race and sex of the population, then you would expect rates to be the same between two areas. Because of the numerous other factors that influence mortality in any area including socioeconomic factors, smoking and other lifestyle characteristics, no real conclusions can be drawn.

The work that has been completed by EEP involves calculating an indirect age adjusted rate for two independent areas, usually a county and the remainder of the State, and comparing the rates for the two areas. The Mantel Haensel test for significant difference between indirect age adjusted rates is used for the comparison.

The indirect age adjusted rate is calculated using the ratio of the observed deaths in a given area to the expected deaths in that area. The expected deaths are the number of deaths that would be expected to occur if the age distribution were the same as the age distribution of the combined population. This ratio (which happens to be the SMR) is then multiplied by the crude rate for the combined population to obtain the indirect age adjusted rate. The same limitations that were listed above regarding the factors that influence mortality other than age apply to this test.

Results

The results of the tests completed by TMMI are shown on the attached tables. It is important to note that with the exception of the tests on cancer incidence for 1988-1990, the time frames for the analyses completed by TMMI are not the same as the time frames used by Environmental Epidemiology. For the mortality data, the tests that have been completed by EEP used data for 1979 through 1988, and TMMI used data for 1988-1990.

The significant differences that were found in the EEP comparisons of cancer incidence data for 1988-1990 for specific counties or groups of counties (Anderson, Roane, Rhea, Knox, and Meigs) with the remainder of the State are:

Five county total cancer was significantly higher than the rest of the State

Five county lung cancer was significantly higher than the rest of the State

Anderson county total cancer was significantly higher than the rest of the State

Roane county total cancer was significantly higher than the rest of the State

Knox county total cancer was significantly higher than the rest of the State

The two specific results that might confuse people who compare the results of the EEP analyses and the TMMI analyses are the cancer incidence in Anderson and Roane counties. However, when comparing these results, it should be considered that TMMI calculated the expected number of cases in a county based on the age, race, and sex distribution of the United States, and the Division of Environmental Epidemiology determined expected cases for a county based on the age distribution of the State.

TMMI found that Anderson total cancer was not different than would be expected - "not significant" in terms of the hypothesis that they tested. EEP found that Anderson county cancer incidence was significantly higher than the remainder of the State based on the comparison of indirect age adjusted rates.

TMMI found that Roane County incidence was significantly lower than would be expected. EEP found that Roane county incidence was significantly higher than the incidence for the remainder of the State.

RESULTS OF COMPARISONS BETWEEN OBSERVED DEATHS AND EXPECTED DEATHS BASED ON 120 U.S. AGE, RACE AND SEX CATEGORIES FOR SELECTED CAUSES OF DEATH, 1988-1990

	Tennessee		Oak Ridge	Anderson	Roane	Clinton	Harriman	Kingston
Total Deaths	++	-	N.S.	N.S.				
All Cancer	N.S.	N.S.	N.S.	N.S.	N.S.	N.S.	--	
Site of Cancer								
Kidney	N.S.	N.S.	N.S.	N.S.				
Bladder	N.S.	N.S.	N.S.	N.S.				
Leukemia	N.S.	N.S.	N.S.	N.S.	N.S.	N.S.	N.S.	
Other Lymphatic & Hematopoietic	N.S.	N.S.	N.S.	N.S.	N.S.	N.S.	N.S.	
Digestive Organs & Peritoneum	--	N.S.	N.S.	-	N.S.	N.S.	-	
Respiratory & Intra-thoracic Organs	++	N.S.	+	+	+	N.S.	N.S.	
Breast	--	N.S.	-	N.S.	-	-	N.S.	
Uterus	N.S.	N.S.	+	-	+	N.S.	N.S.	
Other Female Genital	-	N.S.	N.S.	N.S.	N.S.	N.S.	N.S.	
Male Genital	N.S.	N.S.	N.S.	N.S.	N.S.	-	N.S.	
Lip, Oral Cavity & Pharynx	N.S.	N.S.	N.S.	-	N.S.	N.S.	N.S.	
Brain	++	N.S.	-	N.S.	N.S.	N.S.	N.S.	
Skin	+	N.S.	N.S.	N.S.	N.S.	N.S.	N.S.	
Unspecified and All Other Sites	--	N.S.	-	N.S.	N.S.	N.S.	N.S.	

A + indicates that the observed number of deaths was significantly higher ($p < .05$) than the expected number.
A ++ indicates that the observed number of deaths was significantly higher ($p < .001$) than the expected number.
A - indicates that the observed number of deaths was significantly lower ($p < .05$) than the expected number.
A -- indicates that the observed number of deaths was significantly lower ($p < .001$) than the expected number.
N. S. means the difference between the observed number and the expected number was not significant, and a blank line indicates that the particular test was not done.

RESULTS OF COMPARISONS BETWEEN OBSERVED INCIDENCE AND EXPECTED INCIDENCE OF CANCER BASED ON 72 U.S. AGE, RACE AND SEX CATEGORIES FOR ALL CANCER SITES AND FOR SELECTED SITES, 1988-1990

	Anderson County	Roane County
All Sites	N.S.	--
Kidney & Renal Pelvis	N.S.	N.S.
Bladder	N.S.	N.S.
Leukemias	-	N.S.
Non-Hodgkins Lymphomas	N.S.	-
Hodgkins Disease	N.S.	N.S.
Myelomas	N.S.	N.S.
Bone and Joints	N.S.	N.S.
Lung and Bronchus	+	+
Liver	N.S.	N.S.
Female Breast	N.S.	-
Oral Cavity & Pharynx	N.S.	N.S.
Esophagus	N.S.	-
Stomach & Small Intestine	-	N.S.
Colon & Intestinal Tract, NOS	-	N.S.
Rectum & Anal Colon	N.S.	N.S.
Pancreas	N.S.	-
Prostate	+	N.S.
Testis	N.S.	N.S.
Cervix Uteri	N.S.	N.S.
Corpus Uteri	N.S.	N.S.
Ovary	N.S.	N.S.
Brain & Nervous System	N.S.	N.S.

A + indicates that the observed number of deaths was significantly higher ($p < .05$) than the expected number.
A - indicates that the observed number of deaths was significantly lower ($p < .05$) than the expected number.
A -- indicates that the observed number of deaths was significantly lower ($p < .001$) than the expected number.
N. S. means the difference between the observed number and the expected number was not significant.

APPENDIX F

REVIEW OF HEALTH DATA PREPARED BY DR. WILLIAM REID

REVIEW OF HEALTH DATA PREPARED BY DR. WILLIAM REID BY THE TENNESSEE DEPARTMENT OF HEALTH, DIVISION OF ENVIRONMENTAL EPIDEMIOLOGY

A summary of Dr. Reid's descriptions of his patients and his conclusions about health issues that should receive additional consideration are presented in this report. The particular health effects that Dr. Reid described in his presentation to the Oak Ridge Health Agreement Steering Panel (ORHASP) in June, 1992 are:

Cancer
Immunodeficiencies
Autoimmunity
Chronic Fatigue Syndrome
Osteomalacia
Neurologic diseases including ALS
Bone marrow damage and hypercoagulable state including
early myocardial infarctions and stroke

The data that are available on the incidence of cancer by site in Oak Ridge have been compared with the rest of the State, and the incidence of cancer by site in Anderson county also has been compared with the rest of the State.

The general statements that Dr. Reid made about cancer are as follows. It is important to note that in his analysis of rates he relates his cases to the population of Oak Ridge; however, he shows his cancer patients coming from 14 different cities with the largest number residing in Clinton. It is not clear from his discussion whether or not he is only discussing cancer among residents of Oak Ridge.

Dr. Reid stated that he expects an increased rate of cancer. He feels cases are presenting early with more aggressive course.

The indirect age-adjusted cancer incidence rate for 1988-1990 for residents of Oak Ridge based on all sites combined of 435.7 per 100,000 population was significantly higher ($p < .01$) than the corresponding rate for the remainder of the State of 348.9. The data available through the cancer registry do not include residence history that would allow us to know if the cases were long-time Oak Ridge residents or consistent information on confounders like smoking. For Anderson county residents, the 1988-1990 indirect age-adjusted rate for all sites combined of 427.7 was significantly higher than the rate of 350.7 for the remainder of the State.

Dr. Reid felt he had observed an unusually high incidence of Renal cell carcinoma in Oak Ridge. He stated that the incidence of Renal cell carcinoma is 4-9 per 100,000, but in a population of 30,000 he had seen 4 cases in 6 months

The 1987-1988 average age-adjusted incidence rate for persons residing in the geographic areas covered by the SEER program, approximately 10% of the U. S. population, for kidney and renal pelvis is 8.3 per 100,000 population. There were 1,214 cases of kidney cancer reported in Tennessee during 1988-1990, and the average age-adjusted incidence rate for Kidney cancer for Tennessee for 1988-1990 is 7.4 per 100,000. For Anderson county, there were 23 cases reported in Tennessee during 1988-1990, and the rate is 9.2. These rates were adjusted to the 1970 U. S. population using the direct method of adjustment.

During the three years, 1988-1990, there were 10 cases of kidney cancer reported to the Tennessee Cancer Reporting System for residents of Oak Ridge. The indirect age-adjusted rate of kidney cancer for Oak Ridge residents of 11.5 was not significantly different from the rate for the remainder of the State. There were 23 cases of kidney cancer reported for residents of Anderson county during this same three-year period. The indirect age-adjusted rate of 10.0 for Kidney cancer reported for residents of Anderson county was not significantly different from the rate for the remainder of the State.

Dr. Reid stated that in prostate cancer, he had seen cases at unusually young age, 42 years old with very aggressive growth pattern.

There were 76 cases of prostate cancer reported for residents of Oak Ridge during 1988-1990, 143 cases for Anderson county residents, and 5,539 prostate cancer cases for residents of the total State. The 1988-1990 indirect age-adjusted rate of prostate cancer for both residents of Oak Ridge, 146.1 per 100,000, and residents of Anderson county, 122.6, were significantly ($p < .01$) higher than the comparable rates for the remainder of the State of 78.1 and 78.4, respectively. During this three year period, there was only one case of prostate cancer reported for a resident of Oak Ridge under 59 years of age, and he was in the 50-59 age group. No prostate cancer cases for residents of Oak Ridge were reported with age unknown. The stage of the disease was not included on the report. There were 3 cases of prostate cancer reported for residents of all of Anderson county for men aged 50-59. The stages reported for these three cases were, one local, one regional and one unknown.

In general, the proportion of all cancer cases reported for residents of Oak Ridge with the stage stated to be local, 47.0, is slightly higher than the proportion for the remainder of the State of 45.4. The comparable proportion for Anderson county is 43.9. The proportion of cases reported with a stage of distant for residents of Oak Ridge and residents of Anderson county was 17.2 compared with 19.7 for the remainder of the State.

Dr. Reid stated that the cancer best correlated with radiation is acute leukemia. Over 6 months is Oak Ridge, he said that he had 3 cases and the normal rate was 5 per 100,000.

The 1987-88 SEER age-adjusted rate for all Leukemia is 9.5 per 100,000 population. This includes both acute and chronic lymphocytic and myeloid as well as all other leukemias. The comparable rate for Tennessee for 1988-1990 is 6.0. There were 8 cases of all leukemias reported to the Tennessee Cancer Reporting System for residents of Oak Ridge, 15 cases for

residents of Anderson county and 961 cases for residents of the entire State during the three year period 1988-1990. The 1988-1990 indirect age-adjusted rate of leukemia for Oak Ridge of 8.1 per 100,000 was not significantly different from the comparable rate for the remainder of the State of 6.6. Similarly, the 1988-1990 age-adjusted rate for residents of Anderson county of 6.4 was not significantly different from the rate for residents of the remainder of the State of 6.6.

Dr. Reid noted that there were more cases of lung cancer and colon cancer than all of the above cancers combined. He also noted that the effect of confounders such as tobacco and diet were not considered. He did, however, state that he suspected that if smoking were controlled, the lung cancer rate would be higher for those with exposure to radioactive elements.

The indirect age-adjusted colon cancer rate for 1988-1990 for residents of Oak Ridge of 30.2 was not significantly different from the rate for the remainder of the State of 34.3. The indirect age-adjusted colon cancer rate for residents of Anderson county of 34.5 was not statistically different from the rate for the remainder of the State which was also 34.5. Data were not available to control for variations in diet that would influence the rate of colon cancer.

The indirect age-adjusted rate for 1988-1990 of lung cancer for Oak Ridge residents was 64.0. This rate was not significantly different from the rate for the rest of the State of 63.5. For Anderson County, the 1988-1990 indirect age-adjusted lung cancer rate of 78.0 was significantly higher than the rate of 63.8 for the rest of the State. Data were not available to adjust for variations in smoking history.

No other specific sites of cancer were mentioned by Dr. Reid. The indirect age-adjusted incidence rates for the 24 standard cancer sites produced from the Tennessee Cancer Reporting System for 1988-1990 for Oak Ridge residents and for Anderson county residents were compared with comparable rates for the reminder of the State. For Oak Ridge residents, in addition to total cancer and prostate cancer which have been described above, rates for female breast cancer and corpus uterine cancer were significantly greater than the rates for the rest of the State. For Anderson county, the rates of female breast cancer, corpus uterine cancer and ovarian cancer were significantly higher than the rates for the remainder of the State as were the rates for total cancer, prostate cancer and lung cancer which were previously described.

In addition to cancer, Dr. Reid sites other types of disease which are listed below that he suspects are related to living in the Oak Ridge area. There is currently no known data system that would allow one to know the total number of cases of these diseases in the population or evaluate whether or not the incidence of these diseases might be increased in Oak Ridge. He provided the following information to support his statements regarding the incidence of these diseases. No laboratory values of case definitions were provided.

Immunodeficiencies
He states that many of his patients have histories of recurring infections and evaluation often finds hypogammaglobulinemia, anergy, and low or abnormal lymphocyte panels. This cannot be evaluated without laboratory values.

Autoimmune Disease
He states that this type of disease seems markedly increased in the area. Most notably is the increase in Kingston as compared to towns in other locations. He also stated that the "data" from Oak Ridge resembles that from Kingston with a remarkably high percent increase in autoimmune diseases as well as immunodeficiencies. He does not explain what data for Oak Ridge he is discussing. This cannot be evaluated without laboratory values and case definitions.

From the information that showed the number of patients by broad type of disease and place of residence that he supplied in the graphs, Dr. Reid has seen ten patients from Oak Ridge, six patients from Kingston, two from Harriman and three from Clinton with "Immune Disorder."

Chronic Fatigue Syndrome
Dr. Reid states that this syndrome seems high in this area. According to the data provided by Dr. Reid, he had three patients from Oak Ridge and two from Kingston with Chronic Fatigue. This cannot be evaluated without case definition.

Bone Pain, Question of Osteomalacia and Secondary Hyperparathyroidism
Dr. Reid states that the number of patients with complaints of bone pain is high. His data show no patients with osteomalacia and secondary hyperparathyroidism, which he stated could be caused by metals which seek bone mimicking calcium.

Neurologic Disease, ALS
Dr. Reid states that there appears to be an increase in ALS. He states that he has one patient himself, but has discovered 4-5 more. He states the expected incidence of the disease is 2/100,000 and that in an area of 30,000 to 100,000 the rate he is seeing is 3-8 times predicted.

According to Dr. Fredia Kamel, an epidemiologist at NIEHS in North Carolina, epidemiological studies show the incidence of ALS to range from about .5 up to 2.5 per 100,000 and the accepted, expected incidence is 1 to 2 per 100,000. As far as she is aware, there is no relation between ALS and radiation exposure; however, she personally will be researching the association between metal exposure, particularly lead and mercury, and ALS.

The population base of the case that Dr. Reid has actually seen and of the 4 or 5 cases that Dr. Reid is aware of and the time frame when these cases were seen is undefined. This makes it difficult to calculate an accurate incidence rate. For example, if some of the cases were residents of Knoxville, the denominator of the rate would include the 27,300 residents of Oak Ridge plus the 165,100 residents of Knoxville. Therefore, the denominator of the rate that Dr. Reid was describing could range from 27,300 to 192,400, and the rate based on the one actual case that

Dr. Reid has diagnosed would range from 3.7 per 100,000 using only Oak Ridge in the denominator to 0.5 per 100,000 if the combined population of Oak Ridge and Knoxville is used in the denominator.

Bone Marrow Damage

Dr. Reid states that bone marrow is unusually sensitive to heavy metals and heavy metal radioisotopes. He states that this would predict an increase in low blood counts or abnormal growth patterns and he has seen low white counts, low platelet counts, and anemia with normal vitamins and mineral supplies and that there seems to be more myelodysplasia and myeloproliferative disease. No specific patient data was provided.

Recurrent Thrombosis

He states that he has a patient with recurrent venous clots in the legs. The patient had TPA deficiency and the children and spouse of the patient were also low. When the family began drinking bottled water, the assay for TPA began to return to normal. He states that this suggests that the water may have caused a deficiency of TPA. He further states that if this proves to be true, it could explain stories other patients have told him about Oak Ridge plant workers developing heart attacks or pulmonary emboli after unusually high exposures to metals or radiation. No environmental water samples were taken.

A review of the brief summary description of worker studies that have been completed by ORAU/UNC showed that none of the summaries specifically stated hypotheses related to circulatory disease and only one provided results specific to cardiovascular disease. A study of Y-12 workers from 1943 to 1979 who were involved in uranium enrichment fabrication showed reduced mortality from cardiovascular disease among the worker group. Other studies included tests of mortality from specific causes but did not list the causes. However, no statistical significance was found for the causes tested. Generally, the worker studies primarily look at mortality and most often are testing hypotheses related to cancer mortality.

The analysis that was completed using mortality data for Oak Ridge residents by Health Statistics showed that the 1979-1988 indirect age-adjusted mortality rate for Heart Disease, which includes both pulmonary embolism and myocardial infarction, for Anderson county was significantly lower than the comparable rate for the remainder of the State.

APPENDIX G

MORTALITY AND CANCER INCIDENCE RATES

TOTAL AND CAUSE-SPECIFIC INDIRECT AGE-ADJUSTED RATES+ FOR SELECTED COUNTIES AND THE REMAINDER OF THE STATE, TENNESSEE 1979-1988

	County					
	Anderson		Knox		Roane	
Cause of Death	County Rate	Remainder of the State	County Rate	Remainder of the State	County Rate	Remainder of the State
Total, All Causes	8.0*	8.9	8.8	8.9	8.3*	8.9
Cancer	183.5	189.7	187.9	189.8	175.9*	189.8
Stroke	76.8*	83.4	81.8	83.4	76.1	83.4
Chronic Obstructive Pulmonary Disease	34.2*	30.0	28.9	30.2	32.9	30.1
Heart Disease	267.4*	342.3	284.6*	345.4	324.8*	341.3
Congenital Anomalies	3.4*	5.6	5.9	5.5	4.7	5.5

+ Total Rates are per 1,000 population. Cause-specific rates are per 100,000 population.

* The rate for the county is significantly different ($p < .05$) from the rate for the remainder of the State.

Number of Cases of Cancer Reported to the Tennessee Department of Health and Indirect Age-Adjusted Rates for Anderson County Compared with the Remainder of the State, Tennessee, 1988-1990

SITE	ANDERSON No.	ANDERSON Rate	REST OF STATE No.	REST OF STATE Rate	CHI-SQUARE	SIGNIFICANCE
All Cases	998	427.7	50,148	350.7	40.627	*
Oral	22	9.3	1,415	9.9	0.006	N.S.
Esophagus	11	4.7	508	3.6	0.548	N.S.
Stomach & Small Intestine	13	5.6	944	6.6	0.253	N.S.
Colon	82	34.5	4,936	34.5	0.000	N.S.
Rectal	39	16.8	1,797	12.6	2.705	N.S.
Liver	2	0.8	223	1.6	0.351	N.S.
Pancreatic	20	8.4	1,125	7.9	0.037	N.S.
Lung	183	78.0	9,115	63.8	7.074	*
Bone	1	0.4	98	0.7	0.002	N.S.
Melanoma	18	7.8	1,072	7.5	0.032	N.S.
Female Breast	147	123.7	7,497	101.1	5.958	*
Cervical	18	16.2	976	13.2	0.499	N.S.
Corpus Uterine	34	27.8	1,399	18.9	4.956	*
Ovarian	23	19.2	903	12.2	4.431	*
Prostate	143	122.6	5,396	78.4	27.582	*
Testicular	3	3.3	255	3.7	0.001	N.S.
Bladder	41	17.1	2,130	14.9	0.763	N.S.
Kidney	23	10.0	1,188	8.3	0.525	N.S.
Nervous System	18	8.2	894	6.2	0.995	N.S.
Hodgkins	7	3.6	360	2.5	0.362	N.S.
Non-Hodgkins Lymphoma	35	14.9	1,717	12.0	1.626	N.S.
Myeloma	10	4.2	529	3.7	0.058	N.S.
Leukemia	15	6.4	946	6.6	0.011	N.S.
All Other Sites	90	39.1	4,725	33.0	2.385	N.S.

Rates are per 100,000 population.

An asterisk in the significance column indicates that the difference between the age-adjusted rate for Anderson county and the comparable rate for the rest of the State is statistically significant ($p < .05$). N.S. means that the difference is not statistically different. Significance tests were completed using the Mantel-Haenszel procedure.

APPENDIX H

CHARGE AND PRIORITIES OF THE HEALTH EFFECTS SUBCOMMITTEE

CHARGE AND PRIORITIES OF THE HEALTH EFFECTS SUBCOMMITTEE

The charge of the Health Effects Subcommittee encompasses three major priority areas. The first priority of the subcommittee is to look for opportunities to conduct meaningful, valid epidemiological studies beginning during the Phase I feasibility study. The first step that the subcommittee will take to fulfill this part of the charge is completing a review of available information. This review will include data from the cancer registry and from the birth defects registry when it becomes available. All other appropriate morbidity data, mortality data, demographic data, and other indicators of general health status such as low weight births, fetal deaths and infant mortality will be reviewed.

The second priority is to provide an explanation and interpretation of health data that have been provided to the Steering Panel by residents of the Oak Ridge area or others who have an interest in the health of the residents of the Oak Ridge area. The subcommittee will also address specific data issues raised by members of the ORHASP. The subcommittee will provide information to the ORHASP about the quality and implications of the data and will seek outside experts to provide additional information when necessary.

The third priority is to track Oak Ridge worker studies and assess the significance of those studies for the Health Studies Agreement. This priority would also include defining and fulfilling Element V of the Health Studies Agreement which requires "provision of information about DOE's occupational medical program in Oak Ridge."

Specific Issues related to each item in the charge of the Health Effects Subcommittee include the following. It is understood that in addressing these issues the subcommittee will coordinate its work with the work of the other three subcommittees. An initial decision was made that the resources do not exist within the Health Effects Subcommittee to address all of the issues. The Subcommittee will oversee the selection of a contractor to assist the subcommittee in completing the majority of the tasks required to address these issues.

Priority 1. Begin Looking for Opportunities for Epidemiological Studies

a) Develop criteria to be used to document the need for an epidemiological study.
b) Insure that the detailed information that is needed to consider an epidemiological study is made available to the subcommittee members when a significant contamination is identified.
c) Insure that qualified epidemiologist are selected to complete any indicated studies and review proposed study designs and monitor the study to insure that it is properly conducted.
d) Look in detail at the most likely materials of concern and the information about potential health effects from those materials compiled by ChemRisk for Task 6 in conjunction with available monitoring data and health status data.

Priority 1 (continued)

e) Monitor the dose reconstruction project to insure that the resulting information would be appropriate for use in an epidemiological study.
f) Determine if we have any current information that should immediately be given consideration such as mercury in the East Fork Poplar Creek, Cesium-137 in Watts Bar, or the Iodine-131 release.
g) Insure that an analysis of the mortality and cancer incidence data that are routinely available is completed.
h) Compare the demographics and the general health status indicators such as low weight birth, infant mortality, access to care, etc. between Oak Ridge and other areas of the State.
i) Review existing literature to characterize epidemiological studies that have been completed following dose reconstruction focusing on any problems that have arisen due to the design or conduct of the dose reconstruction and work with the technical subcommittee to insure that these problems are avoided in the Oak Ridge study.
j) Review the results of the cancer quality improvement study and the data from the birth defects registry as available and report significant findings to the ORHASP.

Priority 2. Review of Health Data and Analyses and Provision of Additional Information to the ORHASP

a) Review data provided by Marshall Whisnant and the later updates of this data provided by McRae Sharpe on cancer mortality and morbidity and mortality from all causes in Anderson county, Oak Ridge and surrounding counties and cities.
b) Complete an analysis of the data provided by Dr. Reid.
c) When data issues are raised at the ORHASP meetings and the panel asks for more detail, the subcommittee will search for experts in the particular field and arrange for a presentation to the full committee.
d) Prepare regular updates on the progress on the birth defects registry and the cancer quality improvement program and include these in the briefing book.
e) Consider education-adjusting the data for Oak Ridge and analyzing mortality compared with the remainder of the State.
f) Determine the most appropriate geographic area to compare with Oak Ridge and the Anderson county area to ascertain whether or not excess mortality or morbidity has occurred around the ORR.

Priority 3. Tracking Oak Ridge Worker Studies and Reviewing DOE's Occupational Medical Program at Oak Ridge

a) Review results of completed worker studies and summarize significant results.
b) Monitor current studies and report significant findings as they become available.
c) Define Element V. of the Health Studies Agreement, "Provision of information about DOE's occupational medical program in Oak Ridge," and then define the objectives for fulfilling that element. The subcommittee will also define the significance of the program in relation to the Health Studies Agreement.

APPENDIX I

HEALTH STUDIES AGREEMENT FACT SHEET

TENNESSEE DEPARTMENT OF HEALTH

Health Studies Agreement Fact Sheet

The State of Tennessee and the U. S. Department of Energy (DOE) have entered into an agreement for the State to conduct an independent assessment of human health risks that may exist as a result of past or present activities at DOE's Oak Ridge Reservation. This agreement is administered for the State by the Tennessee Department of Health. These health studies complement the other oversight activities of the State, i.e. the Federal Facilities Agreement and the Tennessee Oversight Agreement. It is important to note that this is a study of offsite populations - not a study of workers.

State Obligations

Under the Health Studies Agreement, which became effective August 15, 1991, the State will accomplish the following basic elements:

* Assessment of the feasibility of performing dose reconstruction and perhaps health studies relating to off-site populations, i.e., Phase I

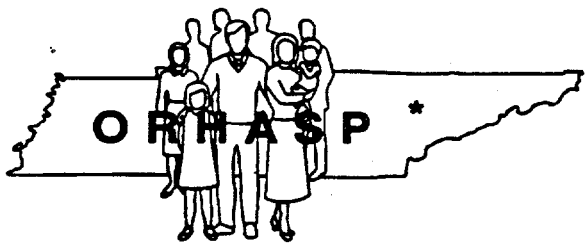
* Creation of the Oak Ridge Health Agreement Steering Panel (ORHASP) to direct and oversee a contractor's work in Phase I and to determine the need for further dose reconstruction and health studies, i.e., Phase II and III

* Enhancement of the State's cancer registry and the development of a birth defects registry

* Review of the DOE's Occupational Medical Program

Independent Panels Direct Studies

Most important, within this agreement is the assurance from the DOE to the State that the research, monitoring, and oversight of the health studies will remain completely independent. A technical panel has assisted the State in selecting the contractor for Phase I. This contractor is ChemRisk, a Division of McLaren/Hart Environmental Engineering Corporation, Alameda, California. In order to continue to assure the independence of studies and to assure the involvement and awareness of the communities in the actions of the agreement, a steering panel was appointed by the Commissioner of the Tennessee Department of Health. This panel, the Oak Ridge Health Agreement Steering Panel (ORHASP), will review and direct the work of ChemRisk. The ORHASP is made up of representatives from the Tennessee Department of Health, the Environmental Quality Advisory Board, the U.S. DOE, a representative of the workers at the DOE ORR plants, five technical experts, and three at-large representatives of the communities affected. The panel will keep the public informed through publications and public meetings. At the end of the contract period, the ORHASP will decide if further studies are indicated and, if so, initiate a request for proposal to solicit a contractor to begin Phase II, dose reconstruction.



Oak Ridge Health Agreement Steering Panel
(800) 435-9617

DOE To Provide Full Information

According to the agreement, DOE must provide the State copies of or access to all data, reports, and other information necessary to carry out the provisions of the agreement. This information will include data pertaining to the occupational medical programs at DOE. However, the objective of this study is to determine the health of populations in communities off of the DOE Oak Ridge Reservation.

Principal Contacts

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Study Process

The first step in fulfilling the agreement is the feasibility assessment (Phase I) to determine if available information is adequate for doing further studies. This assessment will include:

* A review of existing data on hazardous, toxic chemicals and radioactive substances resulting from past and present activities on the Oak Ridge Reservation;
* An analysis of human pathways of exposure to these substances;
* Characterization of the potentially affected populations.

The assessment will be conducted by ChemRisk. Work began April 18, 1992 and a final report will be made to the ORHASP in mid-1993. This would include a recommendation of the feasibility to move on to Phase II.

Disease Registries

Another important aspect of the agreement is the creation and maintenance of statewide cancer and birth defects registries. The State's Cancer Registry, which began in 1986, will be enhanced by providing resources to quality assure each reported case. The birth defects registry will be initiated under this agreement. These data bases will be necessary for quality health investigations.

Cost of the Health Studies Agreement

The full funding of the current DOE agreement is $12.4 million over a 5-year period.

For Further Information

Call toll-free (800) 435-9617.

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APPENDIX J

OAK RIDGE HEALTH STUDY BULLETINS

PHASE I : FEASIBILITY STUDY

OAK RIDGE HEALTH STUDY BULLETIN

Vol.1,No.1 A Publication of the Tennessee Department of Health September 1992

Overview of the Health Study

The Tennessee Department of Health (TDH) and the U.S. Department of Energy (DOE) entered into the Tennessee Health Studies Agreement on July 31, 1991. This agreement provides approximately $12.4 million over a five-year period for an independent state evaluation of adverse health effects which may have occurred in populations surrounding the Oak Ridge Reservation (ORR). The study will focus on populations which have been potentially exposed to releases of chemicals or radioactive substances as a result of past operations at the Oak Ridge facilities. The agreement is a complement to the Tennessee Oversight Agreement signed by the DOE and the Tennessee Department of Environment and Conservation to clean up sites identified as environmental hazards.

A panel composed of scientific and community representatives has been appointed by TDH Commissioner H. Russell White to direct and oversee the study and provide liaison with the community. This panel, the Oak Ridge Health Agreement Steering Panel (ORHASP), will meet approximately every two months. Of the twelve-member panel, five are scientific appointments and three are at-large selections. The State of Tennessee, DOE, workers at the ORR, and the Oak Ridge Environmental Quality Advisory Board are also represented with one member each. The TDH's Division of Environmental Epidemiology (EEP) will administer the project and work with the ORHASP.

A contractor was selected by the State to conduct the initial feasibility study, Phase I, in which information regarding past or present releases will be gathered and characterized (see "Focus" insert). ChemRisk, a division of McLaren Hart Environmental Engineering Corporation, will serve as the Phase I contractor. ChemRisk began work in April 1992 and is expected to complete the feasibility study in the spring of 1993.

If sufficient information is found during Phase I to show release(s) from the ORR probably occurred, a second phase will be initiated to determine the associated quantity or "dose" of the release(s) to individuals located outside of the reservation. This process is called a dose reconstruction. An epidemiological health study will be recommended to determine the health effects resulting from chemicals or radionuclides released into the environment in sufficient amounts to impact human health.

Throughout the study, public meetings will be held to communicate the project plans and progress. All meetings of the ORHASP are open to the public, and input is always welcome.

ChemRisk - Project Status

ChemRisk began preliminary work on the Oak Ridge Health Studies in April 1992. Since then, they have conducted an introductory project meeting with representatives of DOE and Martin Marietta Energy Systems, DOE's operating contractor for the Oak Ridge facilities. ChemRisk is in the process of initial information gathering and has participated in numerous meetings with management and information services personnel from all of the facilities at the Oak Ridge Reservation.

Draft plans for the identification of complete environmental pathways, description of hazards of released contaminants, and the process that will be used to compile and track relevant documents have been prepared and presented to the ORHASP. The draft plans for the investigation of historical uses and emissions of contaminants and characterization of potentially exposed populations have also been completed.

The Oak Ridge Health Study Bulletin is published by the Tennessee Dept. of Health to provide the public information about the Oak Ridge Health Studies Project.
Project Director: Mary Yarbrough, M.D., M.P.H.
Project Manager: Patrick Turri, M.S.
Epidemiologist: Mary Lane Van Cleave, M.S.
Editor: Jeffrey Daniel
Division of Environmental Epidemiology: (615)741-5683
Tollfree line: 1-800-435-9617
Please call to be added to our mailing list.

Keeping You Informed

A major responsibility of the Oak Ridge Health Agreement Steering Panel is to keep you informed of the content and progress of this project. Effective communication between members of the general public and our panel is essential for success. We realize that much of the information is technical in nature and often not easily understood. Therefore, the panel must present information to you in a concise and understandable fashion.

In order for us to do this, we welcome any suggestions that will allow for better exchange and understanding of information. It is important for you to participate in public meetings and voice your opinions. Public meetings will be held periodically in areas around the Oak Ridge Reservation to obtain as much input from potentially affected groups as possible.

To keep the public informed, meeting notices and a quarterly newsletter will be sent to all persons who have registered at meetings or contacted the Division of Environmental Epidemiology. Notices and newsletters will also be sent to churches, civic organizations, county executives, and health professionals in Roane, Anderson, Rhea, and Meigs counties. Many Knox county health professionals will also receive the information. For media coverage, press releases will be sent to local newspapers.

ChemRisk's workplans and reports are available for public review at the Oak Ridge Community Library and the EEP office in Nashville (C1-130 Cordell Hull Bldg.). For questions, comments, or information contact: Division of Environmental Epidemiology
C1-130 Cordell Hull Building
Nashville, TN 37247-4912
(615)741-5683 or (1-800-435-9617).

PROJECT TERMS

Epidemiology- The study of the distribution and causes of diseases and injuries in human populations.
Materials of Concern- The chemicals and radioactive substances identified as having the greatest potential for producing adverse health effects to the off-site public.
Source Term- The approximate amounts of chemicals and radioactive substances released from facilities or other industrial activities.
Environmental Transport- The means by which substances are carried from their point of release through the environment.
Exposure Pathway- The route which a chemical or radioactive substance takes that leads to contact with a human being.

You Asked Us

Q: When the Health Studies Agreement states that this is a study of "off-site populations", what does this mean?

A: "Off-site populations" refers to individuals located outside the reservation. An example would be the groups of people who have been potentially exposed to releases from the Oak Ridge Reservation due to living, working, or otherwise spending time in areas downwind or downstream from the three plant facilities. Human contact with contaminants in the work place, or worker exposure, is not addressed in this study.

Q: How will the U.S. Department of Energy be involved in this study?

A: DOE provides financial support to the State which is coordinating the research, monitoring and oversight functions necessary to carry out the Health Studies Agreement. DOE contact with the State is through the DOE scientific representative serving on the Oak Ridge Health Agreement Steering Panel.

Q: How will ChemRisk deal with lost or destroyed information?

A: It is recognized at the start of the study that complete information on releases, particularly those that occurred 30 to 50 years ago, will not be available. In the absence of information that directly quantifies past releases, ChemRisk will assess whether other types and sources of information will be sufficient to estimate chemical or radionuclide releases by engineering modeling. Interviews with former employees, as well as written records, will serve as an information source on routine and non-routine historic releases.

Q: How will the public be kept informed by the State and steering panel?

A: The State along with the steering panel has established a committee to prepare a communications plan. The State has provided a toll-free telephone number (1-800-435-9617) to receive questions and concerns from the public. A mailing list will assure that all interested parties receive the newsletter and meeting announcements. Press releases regarding upcoming public meetings will also be sent to local newspapers.

FOCUS

September 1992
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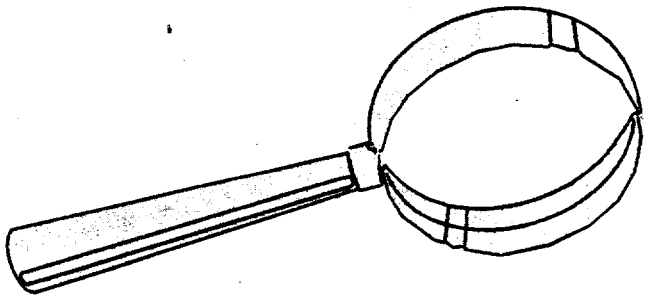

WHAT IS A FEASIBILITY STUDY (PHASE I)?

The goal of the Health Studies Agreement is to evaluate the effects of past environmental releases of chemical and radioactive substances on off-site populations. To achieve this goal, the studies will be performed in three phases: a feasibility study (Phase I), a dose reconstruction (Phase II), and a health outcome evaluation (Phase III). The feasibility study will determine the quality, quantity, and potential usefulness of the available data necessary to carry out the dose reconstruction.

ChemRisk, the environmental science consultant, is conducting the feasibility study which consists of seven tasks. The first task involves developing an understanding of the way in which toxic materials were used and released to the environment. Airborne releases from early reactor operations, liquid radioactivity releases, chemical releases to air, water, and soil, and releases resulting from waste disposal of chemicals and radioactive materials will all be given specific attention. To accomplish this task, ChemRisk will interview essential staff associated with past operations, review purchasing documents and published operational reports, and examine data that may exist in laboratory records and numerous record storage facilities.

The second task is to develop an understanding of sampling data available from environmental monitoring. This task will be completed by reviewing the laboratory records and measurements of contaminants in air, water, soil, and plant and animal life. The investigation shall also address the data being collected as part of current Oak Ridge Reservation Superfund site investigations, as well as from other ongoing studies.

In the third task, ChemRisk will identify all environmental media and pathways through which human exposure to site-related contaminants may have occurred. Direct and/or indirect exposure pathways associated with atmospheric, liquid, and solid waste releases from each of the Oak Ridge facilities will be considered. Pathway analyses will include inhalation of vapors, fumes, mists, aerosols, gases, and resuspended dust; ingestion of contaminated water, soil, and food; and dermal absorption as the result of contact with contaminated water, sediments, soil, or waste materials.

The performance of a preliminary screening and ranking of the chemicals, radionuclides, and environmental pathways will be the focus of the fourth task. The lowest priority for investigation will be given to contaminants that are clearly demonstrated to result in a minimal lifetime cancer risk or risk of other toxic effects.

Much of the information from prior tasks will be used for the completion of tasks five through seven. ChemRisk will identify the potentially affected populations likely to have received the most significant exposures in task five. This includes information on the characteristics and locations of these populations at the time of exposure. Task six will involve the compilation of information on the toxic and hazardous effects of the substances identified in task four as having the potential for the most significant human exposures. Finally, indexing the documents identified during the feasibility study will be done in task seven.

The feasibility study, Phase I, is a necessary step for comprehensively assessing potential off-site releases from the Oak Ridge Reservation. Individuals with personal knowledge which they believe would contribute to the study may call the ORHASP toll-free number (1-800-435-9617) or share their information at any of the public meetings.

"FOCUS" is an educational insert published by the Tennessee Department of Health

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Meet the ORHASP MEMBERS

Eugene Fowinkle, M.D., M.P.H., and Associate Vice-Chancellor for Health Affairs at Vanderbilt University, former Commissioner of Public Health for the State of Tennessee from 1969-1983;
Norma Morin, Ph.D., M.P.H., an epidemiologist and project manager of the health-related initiatives at the Rocky Flats nuclear weapons plant near Denver, Colorado;
Owen Hoffman, M.S., Ph.D., a nationally-recognized research scientist with the Environmental Sciences Division of Oak Ridge National Laboratory;
Jacqueline Holloway, a member of the Oak Ridge National Laboratory's Biology Division and Anderson county commissioner who will serve as the Oak Ridge Reservation worker representative;
James Smith, M.S., Ph.D., chief of the Radiation Studies Branch at the Centers for Disease Control in Atlanta, Georgia and a member of the Rocky Flats Health Advisory Panel in Colorado;
Mary Yarbrough, M.D., M.P.H., a physician and director of the Tennessee Department of Health's Division of Environmental Epidemiology;
Joseph Hamilton, M.S., Ph.D., a nationally-recognized scientist of nuclear physics and distinguished professor at Vanderbilt University;
William Busse, former executive director of the American Lung Association of Tennessee who will serve as a community representative;
Bonnie Richter, Ph.D, M.P.H., an epidemiologist from the Office of Epidemiology and Health Surveillance of the U.S. Department of Energy headquarters in Washington, D.C.;
Paul Voilleque, M.Bas.Sci., M.S., a health physicist and president of MJP Risk Assessment who has been involved with the Fernald Dosimetry Reconstruction Project in Ohio;
Ralph Hutchison, a presbyterian minister and chairman of the Oak Ridge Environmental Peace Alliance who will serve as a community representative;and
James Alexander, M.S., P.E., an environmental engineer representing the Environmental Quality Advisory Board to the City Council of Oak Ridge.

Panel Member Profiles

Eugene Fowinkle, M.D., M.P.H., a physician from Nashville, Tennessee, is chair of the Oak Ridge Health Agreement Steering Panel. Dr. Fowinkle has been the Associate Vice-Chancellor for Health Affairs at Vanderbilt University since 1983. From 1969 to 1983, he served as the Tennessee Commissioner of Public Health. Dr. Fowinkle has also authored and co-authored numerous articles relating to public health issues. He has served on the President's Commission on Three Mile Island and the Task Force on Public Health and Epidemiology along with many other special appointments.

Dr. Fowinkle is one of Tennessee's most respected physicians in public health. His training and background will provide strong leadership and guidance to this project. Dr. Fowinkle states: "This is the beginning of a complex process which must incorporate quality science and trust from the public to address the health concerns related to past releases at the Oak Ridge Reservation."

Norma Morin, Ph.D., M.P.H., is an epidemiologist with the Colorado Department of Health. She is the project manager of the health-related initiatives at the Rocky Flats nuclear weapons plant in Colorado. Dr. Morin has served as senior epidemiologist for AMC Cancer Research Center in Denver, Colorado where she designed and implemented programs for screening and control of breast and skin cancer. Dr. Morin also has training in toxicology, as well as pathway analysis, and risk assessment for environmental compliance and dose reconstruction.

Dr. Morin's personal knowledge of the Rocky Flats experience will provide guidance in both technical matters as well as public communications. "Dedication to the concept of public involvement is necessary to earn public trust. Public involvement is a two-way communication process which should be open, fair, and timely," says Dr. Morin.

Comments on Study Validity
by Dr. Mary Yarbrough, Project Director

Participants at the June 11-12 public meeting were interested in how the State's health study would provide a fair and complete assessment of historical releases at the Oak Ridge Reservation (ORR), given the secrecy and security concerns associated with the facilities. Study validity, the degree to which the final assessment will correspond to actual releases, will depend upon the ability to obtain relevant information, the quality of information identified, and the interpretation of the information once assembled.

Information for this study will be obtained from personal interviews, document reviews, environmental monitoring, and research reviews. Types of documents that will be reviewed include purchasing documents, operational reports, and laboratory records. An assurance of access to needed information is stated in the Health Studies Agreement signed by Governor Ned McWherter, the Secretary of Energy, Admiral James D. Watkins, and the manager of the DOE Oak Ridge operations, Joe LaGrone. The agreement states that "DOE will provide the State with copies of or access to all data, reports and other information necessary to carry out the provisions of the health studies."

ChemRisk, the State's contractor, will identify and review data as outlined in workplans approved by the Oak Ridge Health Agreement Steering Panel. Plans to include both classified and unclassified documents are outlined. Declassification will be sought for information deemed pertinent to the health studies. For interviews with past and present staff at the ORR, sites will be available to assure confidentiality. Accepted federal government guidelines for discussing classified information will be followed. Many state and steering panel representatives, as well as ChemRisk staff, have security clearances to insure appropriate review of the information collected.

Once information regarding past releases has been identified, ChemRisk will evaluate the quality of available data to reconstruct the releases from the reservation into the environment. The ORHASP will review the contractor's conclusions and decide if enough quality information exists to continue on with Phase II, dose reconstruction.

Careful review by a panel composed of individuals with varied backgrounds and interests will add to a system of checks and balances to insure a fair assessment of the data's quality and completeness. This panel includes physicians, engineers, a worker representative, health physicists, epidemiologists, a nuclear physicist, and community advocates. The public's participation and input throughout this five-year study will also serve to enhance the study's validity.

ORHASP Meets in October

The Oak Ridge Health Agreement Steering Panel will meet on October 5 & 6 in Nashville, Tennessee. The meeting will be held in Room 31 of the Legislative Plaza at the State Capitol complex. Study design past Phase I will be the focus of the meeting. Also, ChemRisk will present their workplans for the identification of available environmental monitoring and research data.

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PHASE I : FEASIBILITY STUDY

OAK RIDGE HEALTH STUDY BULLETIN

Vol.1, No.2 A Publication of the Tennessee Department of Health December 1992

How Potential Contaminants Will Be Investigated

A major task of the project contractor, ChemRisk, during the feasibility study will be investigating the various ways in which potentially hazardous materials were used and released to the environment at the Oak Ridge Reservation (ORR). ChemRisk will prepare a report which will document the primary missions of the ORR since its beginning, the development of facilities constructed to support these missions, and the associated processes which have involved chemicals and radioactive substances. The extent to which processes have changed over the years will be characterized, as will major material substitutions, eliminations, or additions. Significant emission sources for each material of concern will be described, including process emissions, waste disposal activities, or accidents/spills.

In areas where there is little or no information available that directly quantifies past releases, a consideration will be given to reconstructing such releases by engineering modelling of processes and materials used in past operations. Specific attention will be given to:

- airborne releases from early reactor operations, fuel processing and reprocessing research;
- liquid radioactivity releases at all sites;
- releases of contaminants (including mercury, PCBs, and uranium) to air, water, and soil at all sites;
- releases resulting from waste disposal of radionuclides, metals, and organics at all sites; and
- the potential for such information to be used to reconstruct past releases to the environment through engineering models of the historic operations conducted at the Oak Ridge facilities.

ChemRisk will examine several sources of information to prepare the report. Interviewing essential staff (both active and retired) associated with past operations will be an important information source. ChemRisk will do an extensive review of historical documentation including purchasing documents, laboratory records, and published operational reports. Large volumes of documentation are available at numerous storage facilities on the ORR and at associated information repositories. The following list contains materials which are of possible interest to ChemRisk. Other materials will be added to the list if identified in the investigative process as being associated with significant use or potential off-site emissions. Likewise, any materials listed which are not associated with significant usage or potential for off-site health effects will be given low priority for further investigation.

Materials To Be Investigated

Metals & Organics:
Asbestos
Arsenic
Beryllium
Chromium
Fluorine
Lead
Lithium
Mercury
Nickel
Plutonium
PCB's
Uranium

Solvents:
Benzene
Carbon tetrachloride
Chloroform
Methylene Chloride
Tetrachloroethylene
1,1,1-Trichloroethane
Trichloroethylene

Polycyclic Aromatic Hydrocarbons:
Acenaphthene
Acenaphthylene
Anthracene
Benzo(a)anthracene
Benzo(a)pyrene
Benzo(b)fluoranthene
Benzo(g,h,i)perylene
Benzo(k)fluoranthene
Chrysene
Dibenzo(a,h)anthracene
Fluoranthene
Fluorene
Indeno(1,2,3-cd)pyrene
Phenanthrene
Pyrene

Radionuclides:
Americium-241
Californium-252
Carbon-14
Cobalt-57
Cobalt-60
Cerium-144
Cesium-134
Cesium-137
Curium-242
Curium-243
Curium-244
Europium-152
Europium-154
Europium-155
Iodine-131
Krypton-85
Neptunium-237
Niobium-95
Phosphorus-32
Plutonium-238
Plutonium-239
Plutonium-240
Plutonium-241
Ruthenium-103
Ruthenium-106
Selenium-75
Strontium-89
Strontium-90
Technetium-99
Thorium-232
Tritium
Uranium-233
Uranium-234
Uranium-235
Uranium-238
Xenon-133
Zirconium-95

Questions For The Contractor

Q: How will the accuracy of your data be verified?

A: We employ a number of approaches to confirm the accuracy of an observation. Consistency in the data and information from as many sources as possible are used to identify potential sources of inaccurate reporting. The methods used to collect data are evaluated to determine the accuracy of the results. In addition, various current day measurements and samples are used to confirm results based on records or data from the past.

Q: How will workers be separated from the general population?

A: The feasibility study, Phase I, and dose reconstruction, Phase II, will investigate the releases of contaminants which traveled from the ORR to areas outside the reservation. Potential doses to individuals will only be calculated from the amounts of contaminants which traveled off-site. The dose an individual may have received due to job related activities on the reservation will not be addressed in this study. However, a worker who lives outside the reservation could still be potentially exposed from off-site releases of contaminants.

Q: How will this study deal with pollution from other industrial facilities?

A: The feasibility study will initially be examining the availability of data and information to quantify releases from the ORR and predict their transport in the environment. Pollution that results from other industries does not interfere with this type of predictive analysis. However, when data for contaminant sampling in the environment are used to evaluate possible doses from the ORR, analyses will be performed to determine whether other industries or background levels of the contaminant are normally present in the environment.

Types of Radiation

Most products of radioactive decay give off beta particles and gamma rays. Beta particles are high energy electrons. Gamma rays are waves of electromagnetic energy, similar to x-rays. Some radioactive materials also emit alpha particles. They are relatively densely charged particles composed of two protons and two neutrons. Alpha particles are much larger and heavier than beta particles.

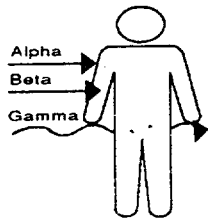
Exposure

In terms of external exposure, gamma rays and beta particles pose the greatest threat. Gamma rays can penetrate into or through the body. Thick layers of concrete or dense materials such as lead are necessary to stop gamma rays.

Beta particles only have enough energy to penetrate the skin. They can be stopped by thin layers of shielding materials, such as aluminum.

Alpha particles are too large and do not have sufficient energy to even penetrate the outer layer of skin. With the exception of eyes, alpha particles pose no significant threat from outside the body.

In terms of internal exposure, many radioactive substances can enter the body through eating, drinking, or breathing. If these substances do enter the body, living cells can be harmed or altered. The damage a particular amount of radioactive material can do depends on the kind of radiation it produces (alpha, beta, or gamma) and how quickly it decays in the body. Some materials exit the body or decay quickly, while others may remain indefinitely.



The penetrating power of radiation

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Editor: Jeffrey Daniel
Project Director: Mary Yarbrough, M.D., M.P.H.
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Please call to be added to our mailing list.

ChemRisk - Project Status

ChemRisk is continuing the process of gathering information as well as their on-site investigations of data availability for the Oak Ridge Reservation. ChemRisk is also completing a workplan for the evaluation of the relative importance of chemicals and radionuclides and their associated exposure pathways. Initial personnel interviews, focusing on retirees that have remained in the Oak Ridge area began in November.

Other ChemRisk activities include the investigation of K-25, Y-12, and ORNL plant document availability, the review of environmental data, and the setup of a database to track and index documents. A presentation for the identification of environmental monitoring and research data was given at the October 5&6 meeting of the Oak Ridge Health Agreement Steering Panel.

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Exposure Pathways

An exposure pathway is the route a contaminant follows that leads to contact with an individual. When someone is "exposed," it simply means that person has contacted some amount of a contaminant or received radiation from a radioactive substance during a given period of time. For most materials, a point of contact must exist to produce an ill health effect. However, many radioactive substances can potentially expose individuals due to indirect contact from waves of electromagnetic energy, gamma rays, or high energy electrons, beta particles.

Contaminants may be released from industrial facilities into the air, the water, or directly into the ground. As a result, individuals can be exposed to toxic and radioactive materials through contact with the air, water, soil, food, or by simply being in close proximity to a radioactive source. Several elements must exist for a complete pathway. First, there must be a way for contaminants to be released from a facility. Secondly, there must be a way for the contaminant to move through the environment such as air, water, or soil. Thirdly, a possible means for human contact must exist. Finally, there must be an exposure route at the point of contact (e.g., inhalation, ingestion, contact with the skin, etc.). All of these elements must exist for any substance to have a potential impact on the health of an individual or population.

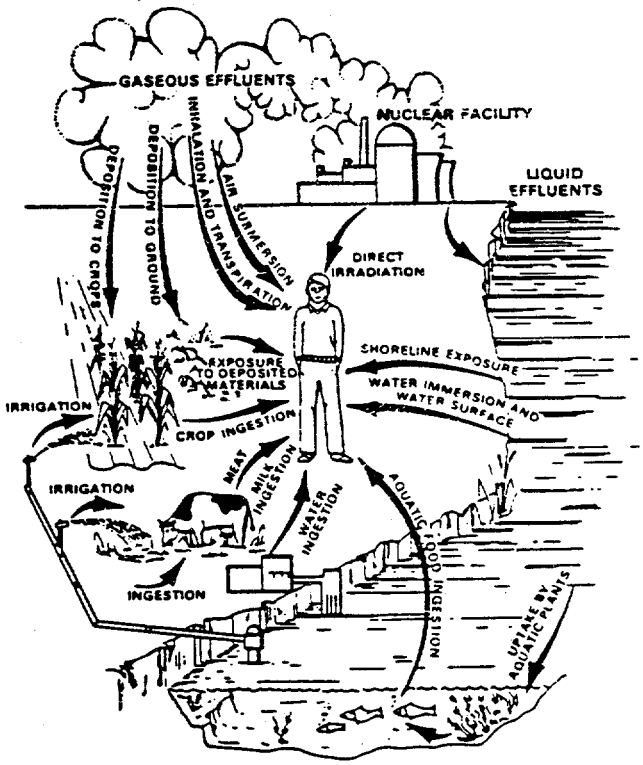
Contaminants can travel through the environment in numerous ways to come in contact with humans. Some of these are direct pathways, such as breathing toxic smoke or vapors. Other pathways can be indirect and can involve a complex series of steps for an exposure to occur. For example, radioactive material can be released from a nuclear facility into the air. This material is then deposited into the soil where it is absorbed by grass. Cows then eat the contaminated grass and the material is transported to humans when they drink the milk.

AIR

Contaminants released into the air are carried through the environment by the wind. These materials may fall or be rained out of the air resulting in the potential contamination of vegetation, land surfaces, and surface water.

Exposures from releases to the air are most likely to occur near or downwind from the point of release. When humans breathe the air, they may expose themselves by directly inhaling the contaminants. The same substances can also be inhaled by livestock or deposited on vegetation. Humans may then be exposed after eating foods from these sources.

Direct inhalation of contaminated air is more likely to affect a larger number of people since everyone in a given area breathes the same air, but not everyone eats food products raised there. In general, the larger the amount of material released, the higher the levels of the material present in the environment. The environment will dilute these substances the further they travel from the point of release.



Potential Exposure Pathways

SOIL

After being deposited onto the soil, contaminants can again provide a source of potential exposure. Toxic materials buried in the ground or dumped into settling ponds or drainage ditches may also contaminate surrounding soils or leach into groundwater. The plants grown in these soils can take up the substances and then be eaten by humans or livestock. This creates indirect exposure pathways such as the grass-cow-milk scenario. Farmers or others may also be exposed through physical contact with contaminated soils. Exposures from contaminated soils can occur as a result of:

- physical contact with soil, including breathing or swallowing contaminated dust;
- eating meat, milk, and eggs from livestock raised in areas of contaminated soil;
- eating fruits, vegetables, and grains grown in contaminated soil;
- eating meat, milk, and eggs from animals raised on plants grown in contaminated soils; and
- indirect contact of energetic beta particles or gamma rays from radioactive substances in contaminated soils.

Contaminated substances in the soil can become vaporized or attach themselves to dust particles and reenter the air where the wind will transport them to other locations. They can also be washed into bodies of water as a result of rain runoff or irrigation where they pollute the water and will be carried to areas downstream.

WATER

Water can become contaminated through three sources: the fallout of contaminants released into the air, the runoff or leaching process of contaminated soils, and direct industrial discharges into surface water systems.. In terms of direct discharges, large volumes of water flowing past the point of release will help to dilute the releases but will also carry the materials greater distances. Many substances will at least partially dissolve in water; however, others will settle to bottom sediments where they can be taken up by bottom-feeders, such as catfish and shellfish. Groundwater, the water within the earth that supplies wells and springs, may also be contaminated through the leaching process of contaminated soils and surface waters.

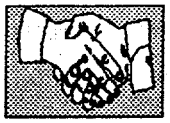
Exposure pathways from contaminated waters are:

- drinking of water;
- bathing or swimming in water;
- eating meat, milk, and eggs from livestock drinking contaminated water;
- eating fruits, vegetables, and grains irrigated with contaminated water;
- eating meat, milk, and eggs from livestock raised on vegetation grown with contaminated water; and
- eating fish obtained from contaminated waters.

Volatile materials in surface water can reenter the air through the evaporation process and be carried to other areas.

For more information about this or other topics, contact the Tennessee Department of Health at 1-800-435-9617.

Meet the ORHASP Members



Eugene Fowinkle, M.D., M.P.H., a physician and associate vice-chancellor for Health Affairs at Vanderbilt University, former commissioner of Public Health for the State of Tennessee from 1969-1983;
Norma Morin, Ph.D., M.P.H., an epidemiologist and project manager of the health-related initiatives at the Rocky Flats nuclear weapons plant near Denver, Colorado;
Owen Hoffman, M.S., Ph.D., a nationally-recognized research scientist who is president and director of Senes, Oak Ridge, Inc.;
Jacqueline Holloway, a member of the Oak Ridge National Laboratory's Biology Division and Anderson county commissioner who serves as the Oak Ridge Reservation worker representative;
James Smith, M.S., Ph.D., chief of the Radiation Studies Branch at the Centers for Disease Control in Atlanta, Georgia and a member of the Rocky Flats Health Advisory Panel in Colorado;
Mary Yarbrough, M.D., M.P.H., a physician and director of the Tennessee Department of Health's Division of Environmental Epidemiology;
Joseph Hamilton, M.S., Ph.D., a nationally-recognized scientist of nuclear physics and distinguished professor at Vanderbilt University;
William Busse, former executive director of the American Lung Association of Tennessee who serves as a community representative;
Bonnie Richter, Ph.D, M.P.H., an epidemiologist from the Office of Epidemiology and Health Surveillance of the U.S. Department of Energy headquarters in Washington, D.C.;
Paul Voilleque', M.Bas.Sci., M.S., a health physicist and president of MJP Risk Assessment from Idaho who has been involved with the Fernald Dosimetry Reconstruction Project in Ohio;
Ralph Hutchison, a Presbyterian minister and coordinator of the Oak Ridge Environmental Peace Alliance who serves as a community representative; and
James Alexander, M.S., P.E., an environmental engineer with Roy F. Weston, Inc., representing the Environmental Quality Advisory Board to the City Council of Oak Ridge.

Panel Member Profiles

Jacqueline Holloway is a member of the Oak Ridge National Laboratory's Biology Division and serves as an officer of the Atomic Trades and Labor Council and a Health and Safety representative. Ms. Holloway serves on many community committees, including the Tennessee Committee on Safety and Health's Board of Directors. In addition, she is an Anderson County Commissioner and a permanent member of the Roane State Community College Campus Task Force.

Ms. Holloway was nominated by officials of the Oil, Coal and Atomic Workers (OCAW) and the Atomic Trade Labor Council (ATLC) to serve as the Oak Ridge Reservation worker representative to the steering panel.

Paul Voilleque', M.Bas.Sci., M.S., is a health physicist and president of MJP Risk Assessment in Idaho Falls, Idaho. Mr. Voilleque has been working with the Fernald Dosimetry Reconstruction Project in Springfield, Ohio. He serves on the Thyroid/Iodine-131 Assessments Committee of the National Cancer Institute and is a member of the Radiation Advisory Committee of the Science Advisory Board to the U.S. Environmental Protection Agency.

Mr. Voilleque's past projects include the development of a radiation dosimetry database and safety analysis and environmental impact documents for nuclear waste management. He also contributed to the Three Mile Island recovery studies.

ORHASP Discusses Plans for Future Phases

The Oak Ridge Health Agreement Steering Panel met on October 5-6, 1992, in Nashville to discuss plans for study design following the Phase I, feasibility study. At the meeting, Dr. Genevieve Matanoski, from the Johns Hopkins School of Hygiene and Public Health, and Dr. James Ruttenber, from the University of Colorado Health Sciences Center, discussed epidemiological health studies and dose reconstruction. ChemRisk also presented workplans for the identification of available environmental monitoring and research data, and several guest speakers briefed the steering panel on other environmental issues which exist in Roane county.

The primary focus of the meeting was to have individuals on the forefront of science, such as Dr. Ruttenber and Dr. Matanoski, assess the strengths and weaknesses of dose reconstruction and epidemiological studies as public health tools in the evaluation of potential health effects to off-site populations in the Oak Ridge area.

Both types of studies can be used to complement each other. A dose reconstruction is used to determine the potential dose of a toxic or radioactive substance an individual may have received and its associated risk. If it appears the substance poses sufficient risk to health, an epidemiological study for the specific health outcome can then be pursued.

An epidemiological study determines significant health outcomes which may exist in a population. Dose reconstruction strengthens the causal relationship between a health outcome and a specific contaminant by providing estimates of the doses associated with these outcomes. By using both dose reconstruction and epidemiological studies, it is possible to assess the dose to a population and also determine if there were corresponding ill-health effects. The panel resolved that due to public interest beyond risk, both types of tools will be considered.

The briefing of other environmental issues in Roane County covered the Horsehead Resource Development in Rockwood, the Kingston steam plant, and the role of the Local Oversight Committee in Oak Ridge. An overview of the Clinch River Environmental Restoration was given by Dr. Bob Cook from the Oak Ridge National Laboratory.

The panel also formed four subcommittees: technical (dose reconstruction), quality assurance, health effects, and communications. The subcommittees will facilitate the review of material and more effectively address issues which come before the panel.

ORHASP-Community Meeting in December

The Oak Ridge Health Agreement Steering Panel will meet December 8&9, 1992, at the Holiday Inn in Harriman, Tennessee. The role of subcommittees and ChemRisk's workplans for the evaluation of the relative importance of chemicals and radionuclides and their associated exposure pathways will be discussed. A community meeting will also be held the evening of December 8 from 7-9 p.m. at the Kingston Community Center in Kingston, Tennessee.

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PHASE I : FEASIBILITY STUDY

OAK RIDGE HEALTH STUDY BULLETIN

Vol.2, No.1 A Publication of the Tennessee Department of Health March 1993

WHAT IS AN EPIDEMIOLOGICAL STUDY?

by Dr. Mary Yarbrough, Project Director

The health studies agreement at Oak Ridge is funded for five years. Why would the Oak Ridge Health Agreement Steering Panel (ORHASP) and the State of Tennessee require so much time to answer the simple question, "Do the people living in and around Oak Ridge have health problems caused by the release of contaminants from the Oak Ridge Reservation (ORR)?" Why not just do a study of some kind and answer this simple question without spending so much time and money? Two scientific methods can be used to look for health problems in communities surrounding the Oak Ridge Reservation: dose reconstruction and epidemiological studies.

Dose reconstruction judges the likelihood people will develop an illness by calculating the amount of contaminants released and where they traveled in the environment. It will not determine that illness has actually occurred. The next newsletter will feature an article on dose reconstruction.

Epidemiological studies are health studies that look for actual illness in groups of people. That is, these studies look for the types and numbers of illnesses in specific groups of people.

Ideally, the study will find the exact cause of an illness. In truth, the study will piece together information in a way that will help scientists determine what is, or is not, reasonable to assume caused an illness in a specific group of people. Epidemiological studies often take years to complete.

Epidemiological (health) studies can be of many types. One of the most common is the "case-control" study. In this type of study, two groups, cases and controls, are identified. The cases are people who were living within an area during the time a contaminant was released and later became sick. The controls also lived in the area but did not become sick.

To begin, one finds how many of the sick people (cases) actually came into contact with the contaminant being studied and how many did not. Next, one finds how many who were not sick (controls) came into contact with the contaminant and how many did not. From this information, the likelihood, or the odds, that the contaminant resulted in the disease can be determined. The higher the odds, the more one suspects the contaminant caused the illness.

But, why do we say the contaminant is "suspected" to be the cause of illness in the cases? Can't we be absolutely sure? In every epidemiological study, there are four reasons that a contaminant may appear to have caused the illness being studied.(1) The first is because of chance. Most scientists feel that study results are "significant", or believable, only when there is a less than 1 in 20 chance that the study findings would be in error if the study were repeated many times. This decision can be made with the use of a special math called "statistics."

The second reason the contaminant may appear to make people sick is because of "bias" in the way the study was done. Bias is present in every study. It is a flaw in the study design that will cause the results to differ from the true answer. For example, suppose we did a study of everyone in Oak Ridge who had a certain disease; and, to find this we went to everyone's homes and asked if they had the disease. Some would say yes. But, we would miss those who did not know they had the disease, those who had moved out of town, those not at home, and those not willing to share this information with us. Some who said they had the disease may have mistaken it for another or may have just wanted to be "overly helpful" by answering "yes." Care must be taken to minimize bias in studies.

The third reason that the contaminant may appear to cause the disease is "confounding." Confounding is a factor that confuses the final results. Suppose people working at a particular factory were found to have more lung cancer than people who did not work there. It may have been concluded that contaminants in the workplace caused the illness. But, if a large number of workers at the factory smoked cigarettes, while those they were compared to did not, tobacco use may have caused the increased lung cancer, not the job. If identified, confounding can be compensated for in the final study analysis.

The fourth reason the contaminant may be linked to the illness is because the contaminant under study did cause the illness. Another article in this newsletter, "Establishing Causation Through Epidemiological Studies," explains what should be considered before reaching this conclusion.

The Oak Ridge Reservation has operated 50 years, has carried out thousands of operations, and has dealt with many chemicals and radioactive materials. Health studies of high quality take time, study, and patience. But, in the end, we will have added several pieces to the puzzle and will begin to see the big picture where health is concerned.

1. Based on a presentation, "Untangling Causation Issues", by Dr. Phillip Cole, M.D., D.Sc., University of Alabama Birmingham, 1/6/93.

Calculating Doses of Contaminants

Doses of specific contaminants are calculated using mathematical models. These models consist of various formulas that represent the ways contaminants move in the environment and how they reach people. Models can vary in complexity and in the types of situations to which they are applied. For example, some models are used to give health officials quick answers in order to determine what actions need to be taken in the event of an accidental release. Other models, attempting to reconstruct historical doses, are much more detailed since the most accurate dose estimate possible is needed.

When designing a model, some of the questions scientists consider are:
- How does the contaminant react with air, water, and soil?
- In what form is the contaminant (solid, liquid, or gas)?
- How dense is the contaminant?
- Do people live or work close to the point where the contaminant was released?
- How soon after release are humans likely to contact the contaminant?
- To what extent will air, water, and food be contaminated?
- Where does the contaminant go after it is inside the body?

After a dose estimate has been calculated, there are still other things to consider. Some of these are:
- Was the dose to a specific organ or to the whole body? All contaminants have different properties and consequently react differently in the body. For example, iodine will concentrate in the thyroid while strontium, similar to calcium in composition, will settle in bones and teeth.
- Was the dose calculated for an internal or external exposure? You would want to know your external exposure if you swam or bathed in contaminated water and your internal exposure if your drinking water were contaminated.
- Was an average or maximum dose calculated? If the calculation of dose was based on individuals who drank an average of five glasses of contaminated water a day, it did not give an accurate estimate of those who drank ten. Therefore, the danger to individuals drinking the maximum amounts might have been underrepresented in the final estimate.

*This article is based on "Pick a Number, Any Number: How Radiation Exposures are Calculated" by Jim Thomas of the Hanford Education Action League

Community Questions

Q: How can an individual report information regarding past releases at the reservation?

A: Individuals with information regarding the release of contaminants from the Oak Ridge Reservation can contact the Division of Environmental Epidemiology by calling 1-800-435-9617 or (615)741-5683. Staff will then pass along the information to ChemRisk for further investigation. ChemRisk is also available at public meetings to accept any information relevant to the health studies.

Q: How does ChemRisk ensure that data generated by DOE is accurate?

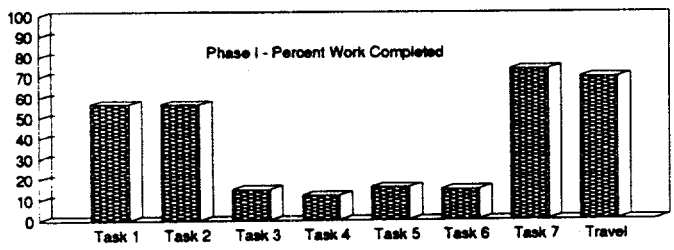
A: One of the primary purposes of the study is to critically evaluate the information and data produced by DOE related to contaminants released to the environment. The study will seek to cross-check data and verify its consistency through interviews with present and former employees and reviews of sampling data from various sources. In cases where DOE generated data must be solely used in an analysis, a description of the data quality will be given and potential problems will be documented.

Q: What is a "contaminant"?

A: A contaminant is a foreign material, such as a chemical or radioactive substance, which is released to the environment and is carried to areas where it would not normally be found.

ChemRisk - Project Status

ChemRisk is continuing to interview active employees and review historical records at the K-25, X-10, and Y-12 Plants. The researchers are also completing field investigations to determine the availability of environmental and research data. At the December ORHASP meeting in Harriman, Tennessee, ChemRisk presented its workplans for Task 4, the evaluation of the relative importance of chemicals and radionuclides and their associated pathways. ChemRisk's progress toward completing the Phase I tasks, as of January 1, 1993, is indicated below.



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FOCUS

February, 1993
Vol.2, No.1

Epidemiological Studies

Establishing Causation Through Epidemiological Studies

The Oak Ridge Health Study Project is designed to address various questions regarding health effects to the off-site public which may have resulted from releases of contaminants at the Oak Ridge Reservation.

Epidemiological studies can help scientists identify the cause(s) of health effects which may have resulted from the off-site releases (see "What Is An Epidemiological Study" on pg.1). If enough quality information about past releases is found during the feasibility study, both epidemiological studies and a dose reconstruction will be considered.

Epidemiological studies can be done to look at the types and numbers of illnesses in specific groups at any point in the project. They can also be used as a complement to dose reconstruction. Once dose reconstruction has determined the potential dose of a contaminant an individual may have received and its associated health risk, an epidemiological study for a specific health outcome can then be pursued. By using both dose reconstruction and epidemiological health studies, it is possible to assess the dose to a population and determine if there were corresponding ill-health effects.

When reviewing an epidemiological health study that concludes a particular contaminant caused a disease, nine questions should be asked. These questions are known as Hill's postulates since they were proposed by the scientist Austin Bradford Hill in 1965.

Very few epidemiological studies are able to sufficiently answer all nine questions to establish a clear cause and effect relationship. However, it is not necessary to positively answer all of the questions for a study to be valid. Several researchers attempting to find a cause for the same disease may all differ in which of Hill's questions they answer. However, if their findings are all similar, there is greater certainty that a cause and effect relationship exists. These questions provide a guideline to help determine what is reasonable to assume may or may not have caused an illness.

The following are the nine questions proposed by Hill to use when reviewing epidemiological health studies:

1. Does the study show that those with the disease actually came into contact with the contaminant more often than those without the disease? The greater the difference in the disease rate between the two groups, the more believable the results.

2. Are there other studies showing the same contaminant resulting in the same disease? If so, the studies should be in different populations, places, and times. For example, if a study finds a relationship exists between a high fat diet and heart disease, it would be more credible than one which claims there is a relationship between a high fat diet and lung cancer. Previous studies of varying design have agreed that there is a relationship between diet and heart disease but not lung cancer.

3. Did exposure to the contaminant happen before the disease developed? This criterion is often a very difficult one to address. Due to the latency period of many cancers, it is possible for 30 years to elapse before the cancer caused from a particular exposure would be recognized. However, for leukemia it may only take 5 years following the exposure for the disease to develop.

4. Could the exposures to substances other than the contaminant have caused the disease? For example, inhalation of asbestos is known to cause lung cancer, but so does smoking cigarettes.

5. Does this conclusion agree with current medical knowledge of what takes place within the body to produce this type of disease? For example, it has been medically proven that radiation can cause birth defects. Radiation is able to alter the genetic codes that determine the development of living systems.

6. Is there evidence that the higher the dose of the contaminant, the more likely the disease is to develop? This is called a dose-response relationship. The presence of a dose-response relationship is especially important when attempting to establish a causal relationship.

7. Have other studies that showed a link between the contaminant and the disease found that the doses, or other factors required to cause the disease, were similar to the ones in this study? Finding the same characteristics would strengthen the results since two or more studies that agree with one another in some respects will probably agree in others.

8. Among studies that link the contaminant and the disease, did the disease appear in the same way each time? For example, the disease may appear five months or ten years after exposure, in the same part of the body, etc..

9. Have past experimental studies, such as those in mice, shown that the contaminant can cause the disease under similar conditions? This type of experimental evidence would strengthen similar findings of a human health study.

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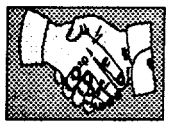
Meet the ORHASP Members



Eugene Fowinkle, M.D., M.P.H., a physician and associate vice-chancellor for Health Affairs at Vanderbilt University, former Commissioner of Public Health for the State of Tennessee from 1969-1983;

Norma Morin, Ph.D., M.P.H., an epidemiologist and project manager of the health-related initiatives at the Rocky Flats nuclear weapons plant near Denver, Colorado;

Owen Hoffman, M.S., Ph.D., a nationally-recognized research scientist who is president and director of Senes, Oak Ridge, Inc.;

Jacqueline Holloway, a member of the Oak Ridge National Laboratory's Biology Division and Anderson county commissioner who serves as the Oak Ridge Reservation worker representative;

James Smith, M.S., Ph.D., chief of the Radiation Studies Branch at the Centers for Disease Control in Atlanta, Georgia and a member of the Rocky Flats Health Advisory Panel in Colorado;

Mary Yarbrough, M.D., M.P.H., a physician and director of the Tennessee Department of Health's Division of Environmental Epidemiology;

Joseph Hamilton, M.S., Ph.D., a nationally-recognized scientist of nuclear physics and distinguished professor at Vanderbilt University;

William Busse, former executive director of the American Lung Association of Tennessee who serves as a community representative;

Bonnie Richter, Ph.D, M.P.H., an epidemiologist from the Office of Epidemiology and Health Surveillance of the U.S. Department of Energy headquarters in Washington, D.C.;

Paul Voilleque', M.Bas.Sci., M.S., a health physicist and president of MJP Risk Assessment from Idaho who has been involved with the Fernald Dosimetry Reconstruction Project in Ohio;

Ralph Hutchison, a Presbyterian minister and coordinator of the Oak Ridge Environmental Peace Alliance who serves as a community representative; and

James Alexander, M.S., P.E., an environmental engineer with Roy F. Weston, Inc., representing the Environmental Quality Advisory Board to the City Council of Oak Ridge.

Panel Member Profiles

Dr. Joseph Hamilton serves as a Landon C. Garland Distinguished Professor of Physics at Vanderbilt University, where he was chairman of the Department of Physics and Astronomy from 1979-1985. Dr. Hamilton's field of expertise is nuclear physics. He is a member of numerous national and international committees primarily dealing with basic physics. In 1975, Dr. Hamilton received the Jesse Beams Gold Medal for Outstanding Research, in 1979 an Alexander von Humbolt Prize, and in 1991 was selected Professor of the Year for Tennessee by the Council for the Advancement and Support for Education.

Dr. Hamilton has a high degree of familiarity with Oak Ridge, having founded UNISOR, University Isotope Separator at Oak Ridge, and the Joint Institute for Heavy Ion Research. In addition, he served as Vanderbilt's counselor to Oak Ridge Associated Universities from 1974-1980.

Mr. Ralph Hutchison is a community representative who serves as the coordinator for the Oak Ridge Environmental Peace Alliance (OREPA) and as a pastor for the Bethel Baptist Church in Dandridge, Tennessee. OREPA is a grassroots organization, formed in 1988, specifically to address community concerns surrounding nuclear weapons production at the Oak Ridge Reservation. In 1989, the group published the first "Citizen's Guide to Oak Ridge" which gave its perspective on waste and contamination issues in the area.

Mr. Hutchison's insights into the public's perceptions and contacts with national environmentally conscious organizations are very valuable to this study.

Dr. Mary Yarbrough is the director of the Tennessee Department of Health's (TDH) Division of Environmental Epidemiology. Dr. Yarbrough has completed residencies in internal medicine and preventive medicine and received a Masters of Public Health with an emphasis in international health. Prior to working for TDH, Dr. Yarbrough was involved in international health studies as a Henry Luce Scholar in Southeast Asia, a consultant for the International YMCA in Zambia, and a consultant with the World Health Organization in Geneva, Switzerland.

Dr. Yarbrough serves as the Oak Ridge Health Study project director and as the TDH representative to the Oak Ridge Health Agreement Steering Panel.

ORHASP Subcommittees Discuss Issues

The Oak Ridge Health Agreement Steering Panel met December 8-9, 1992, in Harriman, Tennessee. The emphasis of the meeting was for the subcommittees, created at the October meeting, to define their missions and the main issues which needed to be brought before the entire steering panel for consideration. The four subcommittees (Dose/Risk Assessment, Quality Assurance, Health Effects, and Communications) were created to facilitate the review of material and more effectively address issues which come before the steering panel.

During the December meeting, ChemRisk also presented its workplans for the completion of Task 4, the evaluation of the relative importance of chemicals and radioactive substances and their associated exposure pathways. In addition to the business meetings, the ORHASP held a community meeting on the evening of December 8, at the Kingston Community Center in Kingston, Tennessee.

The Quality Assurance (QA) Subcommittee established the objective to prepare a quality assurance plan for the health study project. A draft outline was prepared which included sections describing standard procedures for quality assurance, quality assurance for technical aspects of project reports, and quality assurance for the editorial aspects of project reports.

The QA Subcommittee also recommended a policy that the ORHASP and state would seek to have DOE release all classified or otherwise restricted information characterized as being significant to the public's health. When ChemRisk finds a document that has not been declassified and believes it to be significant to the public's health, a review of the document will be performed by a "classified information review committee." This committee will be composed of two ChemRisk staff, two state staff, and three panel members with appropriate clearances. If the decision is made that the information is significant, the State and steering panel would then seek to have it declassified.

The Dose/Risk Assessment Subcommittee discussed the format for the final report of the feasibility study, Phase I. It was suggested that the final report be broken down into four separate reports, one for each of the three major sites and one for significant off-site releases. All incidents and accidents identified by ChemRisk or passed on to ChemRisk through the Division of Environmental Epidemiology will be listed in the report, regardless of the ability to complete investigations. This will ensure written documentation of the reports and may encourage others reading the report to supply any missing information. Also, in cases where information is missing, it will be recommended that future phases continue to search for supporting documentation.

The Dose/Risk Assessment Subcommittee will also compose a position paper on the known health risks of chemicals and radionuclides, as well as review initial screening calculations. Other topics discussed by the group were the contribution of power plants to off-site radiation releases and the availability of environmental sampling data.

The Health Effects Subcommittee discussed the need to begin immediately looking for opportunities to complete meaningful, valid epidemiological health studies. The initial step to address this first priority would be completing a review of the state's available demographic and health outcome data. The subcommittee agreed the second priority should be reviewing health data and information related to the population living in Anderson and neighboring counties that are provided to the steering panel. The third priority is tracking worker studies and assessing their significance for the Health Studies Agreement. It was also felt that there should be a Q-cleared member who would be responsible for coordinating with the Technical Subcommittee to insure that the needs of an epidemiological study are considered throughout the dose reconstruction process.

The Communications Subcommittee discussed various ways to keep the public better informed of the health study project. The group felt it would be necessary to explore hiring a contractor for community outreach and education. This contractor would be responsible for providing liaison with the general public and assisting with informing elected officials, health professionals, community groups, and educators of the study. It was also suggested that a survey of the knowledge, attitudes, and beliefs of the Oak Ridge area could provide beneficial information for designing a community education plan. A discussion followed with representatives from the University of Tennessee Department of Sociology in order to determine how to effectively carry out such a survey. The subcommittee agreed that it would bring these ideas before the steering panel for consideration.

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PHASE I : FEASIBILITY STUDY

OAK RIDGE HEALTH STUDY BULLETIN

Vol.2, No.2 — A Publication of the Tennessee Department of Health — June 1993

RECONSTRUCTING DOSES THAT OFF-SITE POPULATIONS RECEIVED

by: Paul Voillequé

"Dose Reconstruction" is the process of estimating doses that individuals and groups residing near nuclear facilities like those on the Oak Ridge Reservation received years ago. The "dose" to be estimated may be due to releases from the facility of radionuclides, like cesium-137, or chemicals, such as mercury, to the environment.

Estimation of doses that were received is an important step in several activities: determining what risks are faced by the exposed populations, determining whether it is feasible to perform epidemiologic studies of exposed groups, and determining whether health outcomes are related to radionuclide or chemical exposures. (See the FOCUS section of this newsletter and the *Oak Ridge Health Study Bulletin*, Vol.2, No.1 "What is an Epidemiological Study?" for more information concerning these activities).

Dose reconstruction is like a puzzle, which may have missing or damaged pieces. To perform a dose reconstruction, one must:

* Estimate the releases of radionuclides and chemicals (these releases are called the "source term" for the study),
* Predict the movement and spread of the released materials in the air, water, soil, plants, animals and fish,
* Know locations and habits of persons potentially exposed to the pollutants,
* Combine these data, all of which are uncertain, using mathematical models (i.e. equations) to determine the set of desired dose estimates for individuals and groups, and
* Estimate the uncertainties associated with the doses that have been computed, reflecting the uncertainties in all the data used in the calculations.

The mathematical models used in the calculations will rely upon information about the wind, rain, stream flows and other data characteristic of the Oak Ridge environment during the period of interest. An essential part of the dose reconstruction process is to check the models to assure that they predict, with reasonable accuracy, concentrations of pollutants in the air, water, soil, or in human foods.

Data used for estimating releases of chemicals and radioactive substances are uncertain because historic records of operations are incomplete, monitoring equipment was not as sophisticated or sensitive in years past as it is today, measurements of releases were not comprehensive, and other reasons. Historic environmental monitoring data also suffer from similar lack of sensitivity and completeness.

In spite of all these difficulties, the pieces of the puzzle must fit together - not perfectly - but in a way that is reasonable when one considers the uncertainties involved. Checking whether the various measurements and estimates agree with one another is an essential part of completing the puzzle. Areas of inconsistency will be identified and resolved, perhaps by changing the model being used. When many approaches and types of estimates have been compared with measured values and reasonable agreement has been achieved, we can have confidence in the models and our ability to make satisfactory dose estimates.

SCHEDULE OF DRAFT REPORTS
DOSE RECONSTRUCTION FEASIBILITY STUDY

The purpose of the Dose Reconstruction Feasibility Study being performed by ChemRisk, the state contractor, is to locate historical information that identifies the chemicals and radionuclides used at the Oak Ridge Reservation and released off-site. If enough high quality information is identified, dose reconstruction and risk assessment will be considered for specific chemicals and radionuclides.

ChemRisk is scheduled to release the first draft reports for Tasks 1-6 from March through June:

TASK 1: Describe Historical Operations and Emissions

Activities that have been associated with significant off-site emissions will be described. The focus will be on historical uses and emissions of important chemicals.

K-25 & ORNL 4-12-93, comments deadline 5-29-93
Y-12 & Off-site 5-4-93, comments deadline 6-30-93

TASK 2: Identify Environmental Monitoring/Research Data

Sources of environmental monitoring and research data will be identified and described. The data that are available will be evaluated for potential usefulness in conducting a dose reconstruction.

K-25 & ORNL 4-12-93, comments deadline 5-29-93
Y-12 & Off-site 5-4-93, comments deadline 6-30-93

TASK 3: Identify Environmental Exposure Pathways

Plausible routes of historical contaminant exposure of off-site populations will be identified based on the characteristics of each material and the environmental setting at the Oak Ridge Reservation.

release date 5-31-93, comments deadline 7-9-93

TASK 4: Evaluate Environmental Exposure Pathways

Various screening methods will be used to identify complete exposure pathways that may have been most significant. This task will begin the process of focusing any future dose reconstruction efforts.

release date 5-31-93, comments deadline 7-9-93

TASK 5: Characterize Potentially Exposed Populations

Historical locations and activities of the populations likely to have been most affected by historical releases will be described. General land uses that could have influenced exposures will also be documented.

release date 4-12-93, comments deadline 5-29-93

TASK 6: Describe the Important Contaminant Hazards

Summaries of the current knowledge of the toxic and hazardous properties for each substance identified as warranting further study will be prepared.

release date 4-12-93, comments deadline 5-29-93

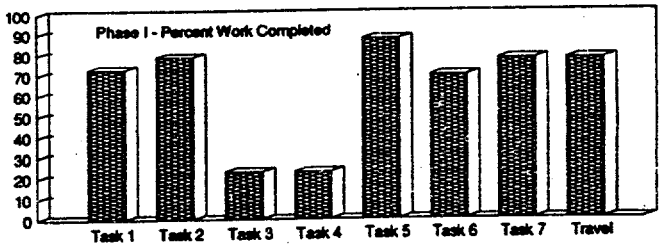
TASK 7: Compile and Index Project Documents

Selected documents relevant to the feasibility study will be collected, categorized, summarized, and indexed for future reference.

(Documents to be delivered after contract completed.)

ChemRisk - Project Status

ChemRisk has continued interviewing a number of current employees and reviewing historical records at the K-25, ORNL, and Y-12 plants. The draft report summarizing the toxic and hazardous properties of the chemicals and radioactive substances which were investigated during the feasibility study was presented at the February ORHASP meeting. The draft report identifying sources of environmental monitoring and research data for the X-10 and K-25 plants was presented at the May ORHASP meeting. All other draft reports were scheduled for release in June. ChemRisk's progress toward completing the Dose Reconstruction Feasibility Study, as of April 1, 1993, is indicated below.



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FOCUS

JUNE, 1993
Vol.2, No.2

RISK ESTIMATION

THE ROLE OF RISK ESTIMATION IN DOSE RECONSTRUCTION

by: F. Owen Hoffman, M.S., Ph.D.

The goal of dose reconstruction is to estimate the amount, or "dose," of a chemical or radioactive substance received by people who have lived in the vicinity of industrial or governmental facilities. To make this dose estimate, it is necessary to determine specifically what population group was exposed to the substance, the length of time of the exposure, and the amount of a substance to which they were exposed. Once this dose is determined, the possibility of adverse health effects can be estimated using mathematical calculations. These calculations form the basis of what is known as a quantitative "health risk" assessment.

The values used in calculations of health risk come from either past epidemiological studies in which humans have been exposed to hazardous substances or from laboratory studies where animals have been exposed. Using these calculations, scientists can estimate what chance people have of developing a certain disease when exposed to a specific dose of a hazardous substance. This process of health risk estimation is often employed to support investigations of community health in which exposure to specific hazardous substances are either known or suspected.

Some people ask, "Why do a dose reconstruction and health risk assessment at all? Why not simply analyze local health statistics?" Local and state health records and disease registries do not contain enough detailed information to link disease in a community with the presence of hazardous substances in a community. However, using dose reconstruction and risk estimation, the need for additional investigations, such as detailed epidemiological studies at specific locations, can be determined. In combination with such studies, risk estimation can be used to strengthen the evidence that observed diseases may have resulted from a given toxic exposure.

There are two basic methods for calculating health risk: one for carcinogens (cancer-causing substances) and one for noncarcinogens (toxic substances not known to cause cancer). For carcinogens, the cancer risk is calculated by multiplying the estimated dose of a substance times a number that represents the chance of getting cancer as the result of a given dose of that substance. These numbers are often referred to as cancer "risk conversion factors."

For radioactive substances, cancer risk conversion factors can be obtained from the National Academy of Sciences, the International Commission on Radiological Protection, the U. S. Environmental Protection Agency (EPA) and the United Nations Scientific Committee on the Effects of Atomic Radiation. The evidence in support of the cancer risk conversion factors for radionuclides is primarily from studies of human populations, especially those that have survived the atomic bombings of Japan. The cancer risk conversion factors obtained from these studies are assumed to be "best estimates." The largest uncertainty occurs when risk calculations are made for low levels of radiation dose. At these low dose levels, no epidemiological studies are available that confirm with certainty any relationship between the risk of cancer and exposure to radiation.

Risk conversion factors for carcinogenic chemicals (that are not radioactive) have been developed by the EPA and the Agency for Toxic Substances and Disease Registry (ATSDR). These factors are based mostly on data obtained from animal experiments conducted at very high doses. The use of this information in estimating the occurrence of cancer in humans is highly uncertain. In general, the risk conversion factors for chemical carcinogens that have been proposed by EPA and ATSDR are thought to overestimate the true risk of cancer in humans in order to err on the side of safety.

For both radionuclides and chemical carcinogens, it is assumed that as the amount of exposure, or "dose," increases, so does the probability of getting cancer. It is also assumed that for any level of exposure, no matter how small, there is always some risk of developing cancer.

(over)

Thus, at relatively low levels of dose, doubling the exposure to a specific carcinogenic chemical is said to double the risk of causing cancer, and tripling the exposure will triple the risk. The health risk from exposure to a carcinogen is usually given as the excess chance per thousand (or million) of developing cancer during one's lifetime compared to the normal incidence of cancer (which is approximately one in three).

Noncarcinogenic chemicals are not known to cause cancer but may cause various other effects such as nerve damage or kidney disease. For noncarcinogens, it is usually assumed that there is a lower level of exposure or dose below which there is virtually no risk of adverse health effects. Estimates of these "safe" levels of human exposure are referred to as "Reference Doses" by EPA and "Minimum Risk Levels" by ATSDR. Most of these estimated "safe" levels have been derived from animal studies because data from human exposures are either limited or not available.

In order to establish a "safe" level for exposure to humans, "safe" levels obtained for animals are divided by additional "safety factors" ranging from 100 to 1000 or more. This is especially true when estimating "safe" levels for individuals in the population who are likely to be more sensitive than the average, e.g. children. Because these safety factors are designed to err on the side of health protection, exposures that exceed "safe" levels for humans will not necessarily produce adverse health effects. For this reason, when exposures to noncarcinogens exceed "safe levels" by small amounts (two to three times), it is very difficult to make an accurate estimate of the likely health risk.

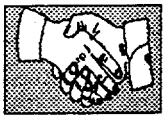
Estimates of health risk are uncertain and inexact. This is *due to* calculations to determine dose to those exposed, the use of the cancer risk conversion factors for carcinogens and the use of "safe" levels of dose for noncarcinogens. The information needed to calculate the dose and to determine the health risk is incomplete. Therefore, these calculated values must be treated as estimates, and not as proven facts.

Analysis of the uncertainties associated with the calculation of health risk estimates can be used to show where information is needed to improve the estimates and to identify the specific chemicals and radionuclides and the specific routes of exposure that should be studied in more detail. Risk estimation helps focus the need for additional human health studies and decreases the chance that limited resources will be spent on issues of minor importance.

F. Owen Hoffman, president of SENES Oak Ridge, Inc., Center for Risk Analysis, received his B.S. degree in biological conservation in 1967 from San Jose State in California, an M.S. in fisheries limnology and ecology from Oregon State University in 1969, and a Ph.D. in ecology from the University of Tennessee in 1981. Early in his career he was employed with the U.S. National Park Service and later worked as a staff ecologist for the Institute for Reactor Safety in Cologne, Germany. During his time in Germany, he was a member of the Federal Advisory Council on Radiation Ecology. From 1976 to 1992, he worked at Oak Ridge National Laboratory on research related to the evaluation of mathematical models used to predict the transport and risk of radioactive substances in the environment.

Dr. Hoffman currently serves as a Chief Scientist to the International Atomic Energy Agency in Vienna. He is a member of the U.S. National Council of Radiation Protection and Measurements (NCRP), a member of the Radiation Advisory Committee of the Science Advisory Board of the U.S. Environmental Protection Agency, and a member of the Oak Ridge Health Effects Steering Panel.

Meet the ORHASP Members



Eugene Fowinkle, M.D., M.P.H., a physician and associate vice-chancellor for Health Affairs at Vanderbilt University, former Commissioner of Public Health for the State of Tennessee from 1969-1983;

Norma Morin, Ph.D., M.P.H., a Colorado Department of Health epidemiologist and project manager of the health-related initiatives at the Rocky Flats nuclear weapons plant near Denver, Colorado;

Owen Hoffman, M.S., Ph.D., a nationally-recognized research scientist who is president and director of Senes, Oak Ridge, Inc.;

Jacqueline Holloway, a member of the Oak Ridge National Laboratory's Biology Division and Anderson county commissioner who serves as the Oak Ridge Reservation worker representative;

James Smith, M.S., Ph.D., chief of the Radiation Studies Branch at the Centers for Disease Control in Atlanta, Georgia and a member of the Rocky Flats Health Advisory Panel in Colorado;

Mary Yarbrough, M.D., M.P.H., a physician and director of the Tennessee Department of Health's Division of Environmental Epidemiology;

Joseph Hamilton, M.S., Ph.D., a nationally-recognized scientist of nuclear research and distinguished professor at Vanderbilt University;

William Busse, former executive director of the American Lung Association of Tennessee who serves as a community representative;

Bonnie Richter, Ph.D, M.P.H., an epidemiologist from the Office of Epidemiology and Health Surveillance of the U.S. Department of Energy headquarters in Washington, D.C.;

Paul Voillequé, M.Bas.Sci., M.S., a health physicist and president of MJP Risk Assessment from Idaho who has been involved with the Fernald Dosimetry Reconstruction Project in Ohio;

Ralph Hutchison, a Presbyterian minister and coordinator of the Oak Ridge Environmental Peace Alliance who serves as a community representative; and

James Alexander, M.S., P.E., an environmental engineer with Roy F. Weston, Inc., representing the Environmental Quality Advisory Board to the City Council of Oak Ridge.

Panel Member Profiles

Dr. James Smith serves as chief of the Radiation Studies Branch within the Division of Environmental Hazards and Health Effects at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. He has served on many national committees concerned with radiation issues. He was a member of the Hanford Health Effects Review Panel in 1986 and is presently a member of the Rocky Flats Health Advisory Panel. Dr. Smith is on the editorial board of *Health Physics Journal* and is widely published in the fields of radiation, biology, and physics.

Through Dr. Smith's work at CDC, he is helping to develop the research agenda for DOE energy related facilities nationwide. His involvement with this project will serve as a link to both CDC and other state projects with similar objectives.

Mr. James Alexander is the operations manager for the Oak Ridge branch office of Roy Weston Environmental Engineering, Inc. He was formerly employed by PAI Corporation in Oak Ridge as a senior environmental engineer and safety and health specialist. Mr. Alexander has experience in the compliance and permitting functions for the major federal environmental statutes, particularly the Clean Water Act and the National Environmental Policy Act. He has served as project manager for nine projects in DOE's Formerly Utilized Sites Remedial Action Program (FUSRAP) and the Surplus Facilities Management Program (SFMP).

Mr. Alexander will serve as the representative for the Environmental Quality Advisory Board to the City Council of Oak Ridge. His experience in environmental engineering, knowledge of the Oak Ridge Reservation, and involvement with community issues will be important assets to the ORHASP.

Mr. William Busse is the former executive director of the American Lung Association of Tennessee where he served from 1966 to 1991. He is a member and consultant to the Kaiser Family Foundation Planning Committee for Tennessee Community Based Health Promotion Program. Mr. Busse is a member of the American Public Health Association, the Tennessee Public Health Association, and other associations and committees concerned with public health.

Mr. Busse has demonstrated a dedication to both health issues and the people of Tennessee for over 25 years. His proven skills in management and communication of health issues should prove very valuable for the study.

ORHASP PLANS THE RELEASE OF CHEMRISK'S DRAFT REPORTS FOR THE DOSE RECONSTRUCTION FEASIBILITY STUDY

The Oak Ridge Health Agreement Steering Panel (ORHASP) met on February 17-18, 1993 in Nashville to discuss a timetable for the conclusion of the Dose Reconstruction Feasibility Study. They decided to make the first draft reports for the study available to the public as soon as the ORHASP receives them. They want to encourage public participation and reaffirm the panel's objective to keep the health study open to everyone at all times.

The timetable planned from March to August coordinates the ORHASP and public meetings with the release of ChemRisk's first draft reports for the feasibility study. In addition, ORHASP members and the state staff plan to be available at community feedback sessions in both Oak Ridge and Kingston to receive input from the public regarding the draft reports. A technical workshop is planned to review the screening calculations used to determine the need to further study specific chemicals and radionuclides. (See insert on this page.)

ORHASP Meeting and Technical Workshop Scheduled on June 22-23

The Oak Ridge Health Agreement Steering Panel will hold a business meeting on June 22-23 from 8:30 a.m. to 4:30 p.m. at the Comfort Inn in Oak Ridge, Tennessee. In addition to the business meeting, a technical workshop will be held from 6-8 p.m. at the DOE Oversight Office, 761 Emory Valley Road, in Oak Ridge. Members of the ORHASP and ChemRisk will be available at the workshop to answer questions of a technical nature regarding ChemRisk's draft reports. A community feedback session will also be held from 1-4 p.m. and 6-8 p.m. on June 24 at both the DOE Oversight Office in Oak Ridge and the Kingston Community Center in Kingston. At this time, members of the ORHASP and staff from the Tennessee Dept. of Health will be available to receive comments from the public on the draft reports.

Following evaluation by the ORHASP, outside reviewers, and the public, the draft reports will be rewritten and a final report released after the August ORHASP meeting. This final report will provide information that, with public input, will allow the ORHASP to decide which chemicals and radionuclides will require further study in terms of their potential to cause health problems in groups of people living outside the reservation.

Members of the public are urged to join in the review process. Copies and comment forms are available in the reference sections of the Oak Ridge Library and in the main libraries of the county seats in Anderson, Knox, Meigs, Rhea and Roane counties. Six weeks have been allowed for comments on each draft report. The draft reports and the release dates for each are reviewed in this newsletter, "Schedule of Draft Reports". Media announcements and notification to those on the health studies mailing list have preceded and shall continue to precede each report release and function.

Department of Health Authorization No.343197, No. of copies: 1,000
This public document was promulgated at a cost of $.34 per copy.6-92

Tennessee Department of Health
Div. of Environmental Epidemiology
C1-130 Cordell Hull Bldg.
Nashville, Tn 37247-4913

APPENDIX K

PUBLIC OUTREACH ACTIVITIES

PUBLIC OUTREACH ACTIVITIES

of the Tennessee Department of Health
and the Oak Ridge Health Agreement Steering Panel

OAK RIDGE HEALTH AGREEMENT STEERING PANEL (ORHASP) MEETINGS:

3/20-21/92	First ORHASP meeting held in Nashville, TN; panel members gave presentations on the Oak Ridge Reservation (ORR), the history of atomic energy, the Health Studies Agreement, and the mission of community involvement; members of the public were allowed to raise issues and concerns.
6/11-12/92	ORHASP met in Oak Ridge, TN; guest speakers presented information regarding past health studies conducted in the area; Dr. William Reid expressed concerns that releases from the ORR may be resulting in ill-health effects and further investigation was needed.
7/28-29/92	ORHASP met in Knoxville, TN; presentations were given on the development of Tennessee's cancer and birth defects registries as well as past and present environmental sampling around the ORR by other state agencies; ATSDR also gave an overview of health assessments and the agency's future plans at the ORR.
10/5-6/92	ORHASP met in Nashville, TN; two guest speakers discussed the strengths and weaknesses of epidemiological health studies and dose reconstruction as public health tools; overviews of other environmental issues in Roane County including the Clinch River Environmental Restoration Project were also given.
12/8-9/92	ORHASP met in Harriman, TN; the emphasis of the meeting was for the subcommittees to define their roles and issues of concern to be brought before the entire Steering Panel. Individuals from the Citizens for Better Health were also allowed to express personal concerns and problems.
2/17-18/93	ORHASP met in Nashville, TN; the primary topics discussed at the meeting were ChemRisk's draft report for the material hazards summary, a review of the DOE classification procedures, a decision on the need for a KAB survey in the Oak Ridge area, a presentation of the RFP for risk communication/public education, and a determination on a final timetable for the conclusion of the feasibility study.
5/3-4/93	ORHASP met in Oak Ridge, TN; ChemRisk presented their draft reports describing historical operations and emissions and identifying environmental monitoring/research data at the X-10 and K-25 facilities and the draft report characterizing potentially exposed populations. The ORHASP also discussed the quality assurance process for the final feasibility study report.
6/22-23/93	ORHASP met in Oak Ridge, TN; ChemRisk presented their draft reports describing historical operations and emissions and identifying environmental monitoring and research

data at the Y-12 facility and off-site. The reports identifying and evaluating environmental exposure pathways were also presented by ChemRisk. Subcommittees discussed issues related to the release of the final Phase I report.

8/24-25/93 — ORHASP met in Knoxville, TN; ChemRisk presented the revisions which had been made to all draft reports. The ORHASP reviewed a draft consensus statement and executive summary and discussed other closing issues of the Phase I final reports.

COMMUNITY MEETINGS:

6/11/92 — Community meeting was held at the Oak Ridge Community Center to learn more about public concerns in the area through small group discussions; over 100 participants were present.

12/8/92 — Community meeting was held at the Kingston Community Center; concerns from the citizenry were heard through small group discussions; approximately 25 participants were present.

5/3-4/93 — Community meeting was held at the Robertsville Junior High School in Oak Ridge, Tennessee; presentations were given on the draft report review process, the Cancer and Birth Defects Registries, communication and public education activities, the quality assurance process for the feasibility study, and a description of the process followed by ChemRisk in the feasibility study to determine which materials were most important.

5/19/93 — Community Feedback Sessions were held at both the Kingston Community Center in Kingston and the Tennessee Department of Environment and Conservation's DOE Oversight Office in Oak Ridge, Tennessee. At this time members of the ORHASP and staff the Tennessee Department of Health were available to receive comments from the public on ChemRisk's draft reports.

6/23/93 — Technical Workshop was held at the Tennessee Department of Environment and Conservation's DOE Oversight Office in Oak Ridge, Tennessee. ChemRisk presented an explanation of the calculations used to prioritize the radioactive and chemical materials released off-site where human exposure was possible and answered questions from the public.

6/24/93 — Community Feedback Sessions were held at both the Kingston Community Center in Kingston and the Tennessee Department of Environment and Conservation's DOE Oversight Office in Oak Ridge, Tennessee. At this time members of the ORHASP and staff the Tennessee Department of Health were available to receive comments from the public on ChemRisk's draft reports.

NEWSLETTER:

9/25/92	Mailed out the first edition of the project quarterly newsletter, the *Oak Ridge Health Study Bulletin* to interested parties, civic groups, churches, and health professionals in the study area; approximately 850 newsletters were mailed.
12/14/92	Mailed the December edition of the project newsletter to all individuals and organizations on the mailing list.
3/9/93	Mailed March edition of the project newsletter to all individuals and organizations on the project mailing list.
6/15/93	Mailed June edition of the project newsletter to all individuals and organizations on the project mailing list.

NEWS RELEASES/PUBLIC NOTICES/MEDIA CONTACTS:

12/27/91	Paul Sloca, reporter from the *Oak Ridger*, requested a copy of the RFP for the Feasibility Study.
12/30/91	Joe Hall, reporter from *Health Care News*, requested a copy of the RFP.
3/15/92	"Sunshine Notice" was submitted for April 21-21 ORHASP meeting.
3/24/92	Doug Pasternak of *U.S. News & World Reports* asked about the status of Dr. William Reid.
3/30/92	Frank Munger, reporter from the *Knoxville News Sentinel*, asked for more information about the Health Studies Agreement.
4/8/92	Press release was sent to the media announcing that the State would be awarding the Feasibility Study contract to ChemRisk.
4/10/92	Press release was sent to the media announcing the April 20-21 ORHASP meeting.
4/10/92	Paul Sloca indicated that he would be attending the April ORHASP meeting.
4/16/92	Frank Munger requested more information about the ORHASP.
4/22/92	Dick Thompson of *Time Magazine* requested information about the health studies project.
4/24/92	Frank Munger inquired about the roles of CDC and ATSDR in the project.
5/15/92	"Sunshine Notice" was submitted for the June 11-12 ORHASP meeting in Oak Ridge, TN.

5/15/92	Kimberely Arp of "CNN Special Assignment" requested more information about the health studies project.
6/1/92	Sent general information regarding the health study and invitations to attend the June ORHASP meeting to community leaders, health care professionals, civic groups, and Churches in the Oak Ridge area.
6/3/92	Press release announcing the ORHASP meeting was sent to the media.
6/15/92	"Sunshine Notice" was submitted for the July ORHASP meeting in Knoxville, TN.
7/20/92	Press release announcing the July ORHASP meeting was sent to the media.
7/27/92	Jim Fitzgerald of Tennessee Radio requested information about the July ORHASP meeting.
8/5/92	Nancy Amons of Nashville's WSMV, channel 4, interviewed the project director and gathered information for a special "I.D. 4 Series" on the ORR.
8/27/92	Chris Sulva from the *Tri-City Tribune* requested a copy of the I-131 Air Force document.
9/15/92	"Sunshine Notice" was submitted for the October ORHASP meeting in Nashville.
9/22/92	Sent ORHASP meeting notice cards to all individuals on the project mailing list.
9/28/92	Sent press release for October ORHASP meeting to media.
9/29/92	Paul Sloca requested an agenda for the October meeting.
11/15/92	"Sunshine Notice" was submitted for the December ORHASP meeting in Harriman, Tennessee.
11/24/92	Sent ORHASP meeting notice cards to all individuals on the project mailing list.
11/29/92	LaRue Cook of *The Standard* requested information about the December ORHASP meeting.
11/30/92	Sent press release for December ORHASP meeting to the media.
12/2/92	Posted flyers/handbills in grocery stores, restaurants, community centers, etc. advertising the community meeting on the evening of December 8 in Kingston, TN.
12/2/92	William Kistner of ABC NEWS requested a copy of ChemRisk's task plans and other project information.
1/15/93	"Sunshine notice" was submitted for the February 17-18 ORHASP meeting in Nashville

2/9/93	Press release sent to media announcing the February 17-18 ORHASP meeting
2/12/93	Paul Sloca requested a copy of the February meeting agenda
4/15/93	"Sunshine notice" was submitted for the May 3-4 ORHASP meeting
4/21/93	Press release sent to media announcing the availability for review of ChemRisk's first three draft reports of the feasibility study
4/22/93	Meeting notices for the May 3-4 ORHASP meeting were sent to all individuals on project mailing list
4/28/93	Press release sent to media announcing the May 3-4 ORHASP meeting in Oak Ridge
4/30-5/3/93	Advertisements ran in area newspapers and radio stations announcing the May 3-4 ORHASP meeting and the availability of ChemRisk draft reports for public review and comment
5/6/93	Meeting announcement cards were mailed to all individuals on the project mailing list for the May 19 Community Feedback Session
5/15/93	"Sunshine notice" was submitted for June 22-23 ORHASP meeting, Technical Workshop, and Community Feedback Sessions in Oak Ridge
6/8/93	Meeting announcement cards for the June 22-23 ORHASP meeting, Technical Workshop, and Community Feedback Sessions in Oak Ridge were mailed to all individuals on the project mailing list
6/18/93	Press release sent to media announcing the June 22-23 ORHASP meeting, Technical Workshop, and Community Feedback Sessions in Oak Ridge
6/19-22/93	Advertisements ran in area newspapers and radio stations announcing the June 22-23 ORHASP meeting, Community Feedback Sessions and the availability of ChemRisk draft reports for public review and comment
7/15/93	"Sunshine notice" was submitted for August 24-25 ORHASP meeting in Knoxville
8/10/93	Meeting announcement cards were mailed to all individuals on the project mailing list for the August 24-25 ORHASP meeting
8/18/93	Press release sent to media announcing the August 24-25 ORHASP meeting in Knoxville
8/13/93	"Sunshine notice" was submitted for September 22-23 ORHASP meeting in Nashville
9/10/93	Meeting announcement cards were mailed to all individuals on the project mailing list for the September 22-23 ORHASP meeting

9/16/93	Press release sent to media announcing the September 22-23 ORHASP meeting in Knoxville

APPENDIX L

SCOPE OF THE KNOWLEDGE, ATTITUDES, AND BELIEFS SURVEY

PROJECT DESCRIPTION

In this proposal we request support to design and conduct an attitudinal survey of residents in selected communities in Anderson, Campbell, Claiborne, Meigs, Morgan, Rhea, Roane, and Union Counties. The purposes of the study are to assess the population's extent of knowledge about past and present Oak Ridge operations and their perceptions of the environmental risks they confront due to Oak Ridge operations; the proportions in which the population attributes responsibility to the State and Federal governments for dealing with any environmental risks they confront; and recommendations on methods for improving public outreach programs, based on survey results.

This proposed study of residents' perceptions of environmental contamination and health risk attributable to the Oak Ridge Reservation is intended as a preliminary part of a much larger study directed by the Tennessee Department of Health as described in the Health Studies Agreement signed by representatives of the State of Tennessee and the U.S. Department of Energy.

Conceptual Framework for the Study

Both the popular media and communication studies reveal the general public's lack of knowledge about technical/environmental issues that confront modern postindustrial societies, for example, nuclear power, waste disposal, and ozone depletion. The studies also suggest that many citizens mistrust information from and protection offered by government officials regarding such matters.

A particularly important source of mistrust involves environmental threats posed to communities by corporate and government-sponsored production processes. The

environmental consequences of **corporate** production processes are regulated by the federal Environmental Protection Agency (EPA). But **government-sponsored** production processes receive much less attention. Some citizens question whether the government can be relied upon to regulate itself. In the case of the environmental hazards associated with the government's production and testing of nuclear and conventional weapons systems, many citizens who live nearby government production sites fear that production is not regulated at all.

In 1991 the federal Department of Energy (DOE) signed three agreements with the State of Tennessee pertaining to government-sponsored production processes at the Oak Ridge Reservation. The first, the Federal Facilities Agreement, outlines a cleanup plan and assigns responsibilities in the cleanup to DOE, the State of Tennessee, and EPA.

Under the second agreement, the Environmental Oversight Agreement, DOE provides funds for the State of Tennessee to employ personnel to oversee DOE's activities as they impact on the environment.

The third agreement, and the one most relevant to this proposal, is the Oak Ridge Health Agreement. It assures that DOE will provide the State of Tennessee with funds to conduct an independent assessment of the effects of Oak Ridge operations on the populations living near the nuclear reservation, downstream and downwind. The study proposed here is a preliminary part of the State's larger project under the Health Agreement.

We propose to conduct a public attitude survey of residents of communities adjacent to Oak Ridge. Open, clear communication with those populations will be necessary during all phases of the environmental remediation. Knowledge of and familiarity with the opinions, attitudes, and habits of the residents in regard to the ORR will enhance the State's ability to communicate effectively with them. The proposal reflects the concerns of the Oak Ridge Health Agreement Steering Panel (ORHASP) as expressed at a December 8, 1992 meeting between panel members and University of Tennessee Department of Sociology personnel. The proposed study will provide information on which the state can base its communication efforts with residents of the communities affected by environmental remediation at the Oak Ridge Reservation. Specifically, the major goals of the study will be:

1. to provide community profiles;
2. to assess the public's knowledge and perceptions of the Tennessee Health Studies Agreement;
3. to measure perceptions of health risk due to environmental contamination;
4. to measure perceptions of environmental contamination resulting from operations at the ORR;
5. to determine the sources of information routinely used by the public;
6. to provide, on the basis of survey results, recommendations for improving public outreach programs;
7. to assess public perceptions regarding remedial operations and future uses of the land.

Methodology

We propose a multi-method research strategy, encompassing the following stages: preparation, focus groups, and survey data collection and data analysis.

Stage One: Preparation

This stage involves reviewing books and newspaper and journal articles written about the ORR, other DOE sites, and the target communities. From these sources, a history of the ORR will be constructed. The history will be used as the questionnaire is constructed. Personnel required for Stage One are the Project Director and one Research Assistant. We have already begun the preparatory work so that we can start up immediately upon completing a contract agreement.

Stage Two: Focus Groups

This stage will involve a series of focus group sessions with local stakeholders and community residents. These sessions will be designed to elicit information from stakeholders and residents about what they see as the most important issues to be investigated with respect to environmental problems associated with ORR. Through the focus groups, we can learn from stakeholders and residents about community knowledge, perceptions, and attitudes; we can learn what they see as the most significant problems involving ORR and how they regard the proposed solutions to these problems. The focus groups are not meant to provide a respresentative view of community opinion. Rather, they will alert us to the potential range of issues, attitudes and perceptions within

the target communities. This information will be absolutely crucial in order for us to construct a valid and reliable questionnaire.

Personnel required for Stage Two are the Project Director, the Research Assistant, two sociology graduate students and a consultant with expertise in environmental sociology, who will help organize, conduct, and supervise the focus groups.

Stage Three: Survey, Data Analysis, and Report

The final stage of the project will be devoted to the design and administration of a survey of residents of the target communities, analysis of the resulting data, and completion of a written report. Personnel required for Step Three are the Project Director, the Research Assistant, the consultant, and the UT Social Science Research Institute. The Social Science Research Institute (SSRI) is an interdisciplinary research organization on campus whose function is to aid in the resolution of problems at the community, regional, and state levels. The Institute provides ready resources of expertise and equipment for survey research by UT faculty. Having SSRI administer the survey for the project efficiently reduces the time and expense required for the project. The going rate for social surveys by private companies is about $20-25 per completed questionnaire. SSRI can deliver the survey for about $14 per completed questionnaire.

For results that can be generalized with statistical reliability to specific counties, we recommend a random sample of approximately 3,200 respondents drawn from the combined population of the eight counties. A sample size of 3,200 will provide reliable estimates of public opinion for the eight-county area and permit analysis of county-level

variation in public attitudes. We will be able to determine whether any counties are "hot spots," that is marked by significant variation in citizens' attitudes and perceptions. The counties could then easily be analyzed separately. A sample size smaller than four hundred per county will not permit statistically reliable analyses of individual counties.

In addition, we recommend conducting a follow-up study several months later to evaluate the effects of communications with the communities. We will construct this survey with the option of a follow-up in mind.

Assuming we are able to start within the next month, the final report will be completed by April 1, 1994.

APPENDIX M

QUALITY ASSURANCE

THIS APPENDIX INCLUDES ONE SECTION OF THE QUALITY ASSURANCE PLAN WHICH DESCRIBES THE REVIEW OF THE DOCUMENTS PRODUCED BY CHEMRISK. THE COMPLETE QUALITY ASSURANCE PLAN ADDRESSES ALL ASPECTS OF QUALITY ASSURANCE FOR THE HEALTH STUDIES. THE COMPLETE PLAN IS AVAILABLE IN THE DIVISION OF ENVIRONMENTAL EPIDEMIOLOGY, C1-130 CORDELL HULL BUILDING, NASHVILLE TENNESSEE.

SECTION 5
ASSIGNMENT OF SPECIFIC QA REVIEW RESPONSIBILITIES

- **Technical Review Assignments**

	Review Element	Assigned Reviewer(s)
5.1	Technical review of all documents:	Dose/Risk Assessment Subcommittee: Paul Voillequé, Owen Hoffman, Joe Hamilton, Bonnie Bashor; Health Effects Subcommittee: Jim Smith, Eugene Fowinkle, Mary Layne Van Cleave
5.2	Completion of Technical Review Checklist 1: Review of the scoping calculation procedures used by ChemRisk to determine significance of releases and potential for complete pathways	Dose/Risk Assessment Subcommittee: Paul Voillequé, Owen Hoffman, Joe Hamilton, Bonnie Bashor
5.3	Completion of Technical Review Checklist 2: Verification that ChemRisk has properly evaluated all appropriate information related to potentially significant environmental release incident, and has conducted follow-up investigations where basic information may have been incomplete	Dose/Risk Assessment Subcommittee: Paul Voillequé, Owen Hoffman, Joe Hamilton, Bonnie Bashor
5.4	Completion of Technical Review Checklist 3: Completeness of ChemRisk's review of data sources for releases from the Oak Ridge facilities	Dose/Risk Assessment Subcommittee: Paul Voillequé, Owen Hoffman, Joe Hamilton, Bonnie Bashor
5.5	Completion of Technical Review Checklist 4: Verification of the completeness of ChemRisk's review	

	of potentially relevant environmental monitoring and operations control data and information	Dose/Risk Assessment Subcommittee: Paul Voillequé, Owen Hoffman, Joe Hamilton, Bonnie Bashor
	Review Element	**Assigned Reviewer(s)**
5.6	Completion of Technical Review Checklist 5: Validity of technical assumptions and analytical conclusions included in ChemRisk's deliverables, including the appropriateness of any computer codes used ChemRisk	Dose/Risk Assessment Subcommittee: Paul Voillequé, Owen Hoffman, Joe Hamilton, Bonnie Bashor
5.7	Completion of Statement of work Verification Checklist:	Pat Turri
5.8	Completion of Public Scoping Issues Verification Checklist:	Communications Subcommittee: William Busse, Normie Morin, Jeff Daniel
5.9	Calculation Spot-Check for specific tasks or sections:	Pat Turri & Bonnie Bashor
5.10	Comprehensive technical reviews of all documents by State of Tennessee personnel:	Earl Leming, Mike Mobley, Bonnie Bashor

- **Editorial Review Assignments**

Review Element		Assigned Reviewers
5.11	Technical reviews by outside experts:	
	1. Person with public health credentials familiar with DOE's general approach to health studies, but not previously involved with the Oak Ridge Study effort:	Jack Hanley, ATSDR
	2. Person with a public health background, but not generally familiar with DOE's approach to health studies or the Oak Ridge study effort:	Paul Erwin
	3. Several technically trained persons very familiar with the history of operations at the Oak Ridge plants and the community of Oak Ridge (one reviewer for each plant):	
	Y-12	Hap West
	ORNL	Rodney Piercy, Arthur Upton
	K-25	Roger Cloutier
	4. Several technically trained persons not generally familiar with past Oak Ridge operations or the Oak Ridge community:	Ed Zganjar
5.12	Page numbering reviews for all documents:	Jacqueline Holloway
5.13	Review of Figures, Maps, and Tables for all documents:	Jacqueline Holloway

5.14	Review of bibliographic information and credits for all documents:	Jake Alexander

	Review Element	**Assigned Reviewer(s)**
5.15	Review of spelling and grammar for all documents:	Pat Turri
5.16	Reviews for coherence for all reports:	Communications Subcommittee: William Busse, Normie Morin, Jeff Daniel
5.17	Review for reading level for all documents:	Pat Turri & Communications Subcommittee: William Busse, Normie Morin, Jeff Daniel
5.18	Review of technical material (to determine the need for a non-technical summary) for all documents:	Communications Subcommittee: William Busse, Normie Morin, Jeff Daniel
5.19	Review of clarity of goals and objectives for all documents:	Ralph Hutchison
5.20	Outside editorial reviews:	
	1. Person with an advanced college degree and considerable experience in journalism or technical writing:	Lucy Langworthy
	2. Persons from "possibly affected" communities with differing education levels:	
	Oak Ridge	Bonnie Dings
	Roane County	Lucille Johnson
	Scarboro community	Paul White
5.21	Review of presentation:	Ralph Hutchison

5.22	Spot-Check Audits of ChemRisk Activities:	Pat Turri

APPENDIX N

PUBLIC SCOPING ISSUES VERIFICATION CHECKLIST

Public Scoping Issues Verification Checklist

The "Public Scoping Issues Verification Checklist" is divided into five specific sections. Each section will attempt to verify that questions and concerns raised by the public have been addressed in a project document or through an ORHASP meeting discussion. After each question state where the response to the question can be found and any further action required.

I. ORIGIN AND SCOPE OF THE PROJECT:

A. Question: Who originated the project?
Answered: Vol. 1, No. 1 "Overview of the Health Study"
Further Action:

B. What are the goals of the study?
Answered: Vol. 1, No. 1 "Overview of the Health Study" & "Focus"
Further Action:

C. Who selected the ORHASP panel members?
Answered: Vol. 1, No. 1 "Overview of the Health Study"
Further Action:

D. Who are the panel members?
Answered: All newsletter editions "Meet the ORHASP"
Further Action:

E. How is the project funded?
Answered: Vol. 1, No. 1 "Overview of the Health Study" & pg. 2 "You Asked Us"
Further Action:

F. Who will the project study? workers? off site population?
Answered: Vol. 1, No. 1 "You Asked Us"
Further Action:

G. What is the geographic area to be covered?
Answered: ChemRisk-Task 5 Report: *A Summary of Information Concerning Historical Locations and Activities of Populations Potentially Affected by Releases from the Oak Ridge Reservation*
Further Action:

Note: Volume and Number citations refer to issues of the State and ORHASP Newsletter, the *Oak Ridge Health Studies Bulletin.*

II. PUBLIC INTERACTION/EDUCATION:

A. Will the public have input into the project? If so, how?
Answered: Vol. 2, No. 1 "Community Questions," Vol. 2, No. 2, Newspaper & Radio ads May 1-4 & June 19-22
Further Action:

B. Will the public be informed concerning the results of the project?
Answered: Vol. 1, No.1 "Keeping You Informed"
Further Action:

C. By what means will the public be kept informed?
Answered: Vol. 1, No. 1 "Keeping You Informed"
Further Action:

D. Will the public be invited to participate at hearings?
Answered: Vol. 1, No. 1 "Overview of the Health Study" & Newspaper & Radio Ads May 1-4 & June 19-22
Further Action:

E. Who of the public will be invited to participate?
Answered: Vol. 1, No. 1 "Overview of the Health Study"
Further Action:

F. Will the public be made aware of the results of the findings?
Answered: Vol. 2, No. 2 "ORHASP Plans the Release of ChemRisk's Draft Reports for the Dose Reconstruction Feasibility Study"
Further Action:

G. Will the reports and information presented be readable and understandable by the general public?
Answered: *Oak Ridge Health Studies Phase I Report - Citizen Summary*
Further Action:

Note: Volume and Number citations refer to issues of the State and ORHASP Newsletter, the *Oak Ridge Health Studies Bulletin.*

III. QUALITY ASSURANCE AND CREDIBILITY OF THE PROJECT:

A. Is the DOE information valid and will there be a cover-up of information? Will workers be too intimidated to speak out?
Answered: Vol. 1, No. 2 "Questions for the Contractor" Vol. 1, No. 1 "You Asked Us"
Further Action:

B. Who is ChemRisk and will an "outsider" be able to collect and review the necessary information and data?
Answered: Vol. 1, No. 1 "Comments on Study Validity," Vol., 1 No. 2 "How Potential Contaminants will be Investigated"
Further Action:

C. Is the TDH credibility suspect?
Answered: Vol. 1, No. 1 "Comments on Study Validity"
Further Action:

D. Will project funding by DOE jeopardize the study's independence?
Answered: Vol. 1, No. 1 "Comments on Study Validity"
Further Action:

Note: Volume and Number citations refer to issues of the State and ORHASP Newsletter, the *Oak Ridge Health Studies Bulletin.*

IV. DOSE RECONSTRUCTION AND TECHNICAL ASPECTS OF THE PROJECT:

A. What is the definition of "off-site?"
Answered: Vol. 1, No. 1 "You Asked Us"
Further Action:

B. How long will phase I take?
Answered: Vol. 1, No. 1 "Overview of the Health Study"
Further Action:

C. How will people with information be identified?
Answered: Vol. 1, No. 2 "How Potential Contaminants will be Investigated"
Further Action:

D. Will worker studies information be considered?
Answered: Vol. 1, No. 1 "You Asked Us"
Further Action:

E. Are only historical releases going to be addressed? What about ongoing releases?
Answered: ChemRisk - Tasks 1&2 Report for K-25, X-10, Y-12, & off-site: *A summary of Historical Activities on the Oak Ridge Reservation with Emphasis on Information Concerning Off-Site Emission of Hazardous Material*
Further Action:

F. What about the unique meteorological patterns in the area?
Answered: ChemRisk - Tasks 3&4 Report: *Identification of Important Environmental Pathways for Materials Released from Oak Ridge Reservation,*
Further Action: Will be evaluated in greater detail in next phase

G. Will water, soil and air pollution be considered?
Answered: *Vol. 2, No 2 "Exposure Pathways" and ChemRisk - Tasks 3&4 Report: Identification of Important Environmental Pathways for Materials Released from Oak Ridge Reservation*
Further Action:

Note: Volume and Number citations refer to issues of the State and ORHASP Newsletter, the *Oak Ridge Health Studies Bulletin.*

H. Will the potential for contaminant movement be considered?
Answered: Vol. 2, No. 2 "Exposure Pathways" and ChemRisk - Tasks 3&4 Report: *Identification of Important Environmental Pathways for Materials Released from Oak Ridge Reservation*
Further Action:_____

I. Will other exposed sites such as Witherspoon's operations and South Knoxville Contaminated sites be considered?
Answered: ChemRisk - Tasks 1&2 Report for K-25, X-10, Y-12 & off-site: *A Summary of Historical Activities on the Oak Ridge Reservation with Emphasis on Information Concerning Off-Site Emission of Hazardous Material*
Further Action:_____

J. Will natural background radiation levels be taken into account?
Answered: ChemRisk - Tasks 3&4 Report: *Identification of Important Environmental Pathways for Materials Released from Oak Ridge Reservation*
Further Action:_____

K. Will competing industrial processes in the area be considered?
Answered: Vol. 1, No. 2 "Questions for the Contractor"
Further Action:_____

L. Is dose reconstruction the best approach? Should health studies be done immediately?
Answered: Vol. 2, No. 2 "Reconstructing Doses that Off-Site Populations Received"
Vol. 2, No. 1 "What is an Epidemiological Study?"
Further Action:_____

M. Can quantification of hazardous waste releases over the last 50 years actually be done now?
Answered: Vol. 2, No.2 "Reconstructing Doses that Off-site Populations Received"
Vol. 1 No. 2 "How Potential Contaminants will be Investigated"
Further Action:_____

N. Will lost or destroyed information affect credibility of project?
Answered: Vol. 1, No. 1 "You Asked Us"
Further Action:_____

Note: Volume and Number citations refer issues of the State and ORHASP Newsletter, the *Oak Ridge Health Studies Bulletin.*

V. HEALTH EFFECTS:

A. Will any specific health effects be explored?
Answered: Vol. 1, No. 2 "ORHASP Discusses Plans for Future Phases," Vol. 1, No. 1 "Overview of the Health Study" minutes of Oct 5-6, 1992 ORHASP meeting, page 16
Further Action:

B. How will an "adverse health effect" be identified?
Answered: Vol. 2, No. 1 "Establishing Causation Through Epidemiological Studies"
Further Action:

C. Will endpoints other than death and cancer be considered?
Answered: Health Studies Agreement (Birth Defects) - ChemRisk Task 6 Report: *Hazard Summaries for Important Materials at the Oak Ridge Reservation*
Further Action: Epidemiology Feasibility Study will continue to define health effects for selected materials. The ORHASP has recomended that we continue to look for data on ALS.

D. Why not look at health outcomes and work backwards?
Answered: Vol. 2, No. 2 "The Role of Risk Estimation in Dose Reconstruction"
Further Action:

E. Will Dr. Reid's observations be considered in the study?
Answered: Minutes of Feb 17-18, 1993 ORHASP meeting, page 7, Minutes of Oct 5-6, 1992 ORHASP meeting, page 3, Minutes of Dec 8-9, 1992 ORHASP meeting, page 8
Further Action:

F. Will other health agency databases be considered?
Answered: Minutes of July 28-29, 1992 ORHASP meeting, pages 11-12, Vol. 2, No.1 "ORHASP Subcommittes Discuss Issues"
Further Action: Epi Feasibility Study will consider all available data bases

G. Will regional health problems and community differences be considered?
Answered: Minutes of June 11-12, 1992 ORHASP meeting, page 5
Further Action: Epidemiology Feasibility Study will define appropriate analyes and comparison groups

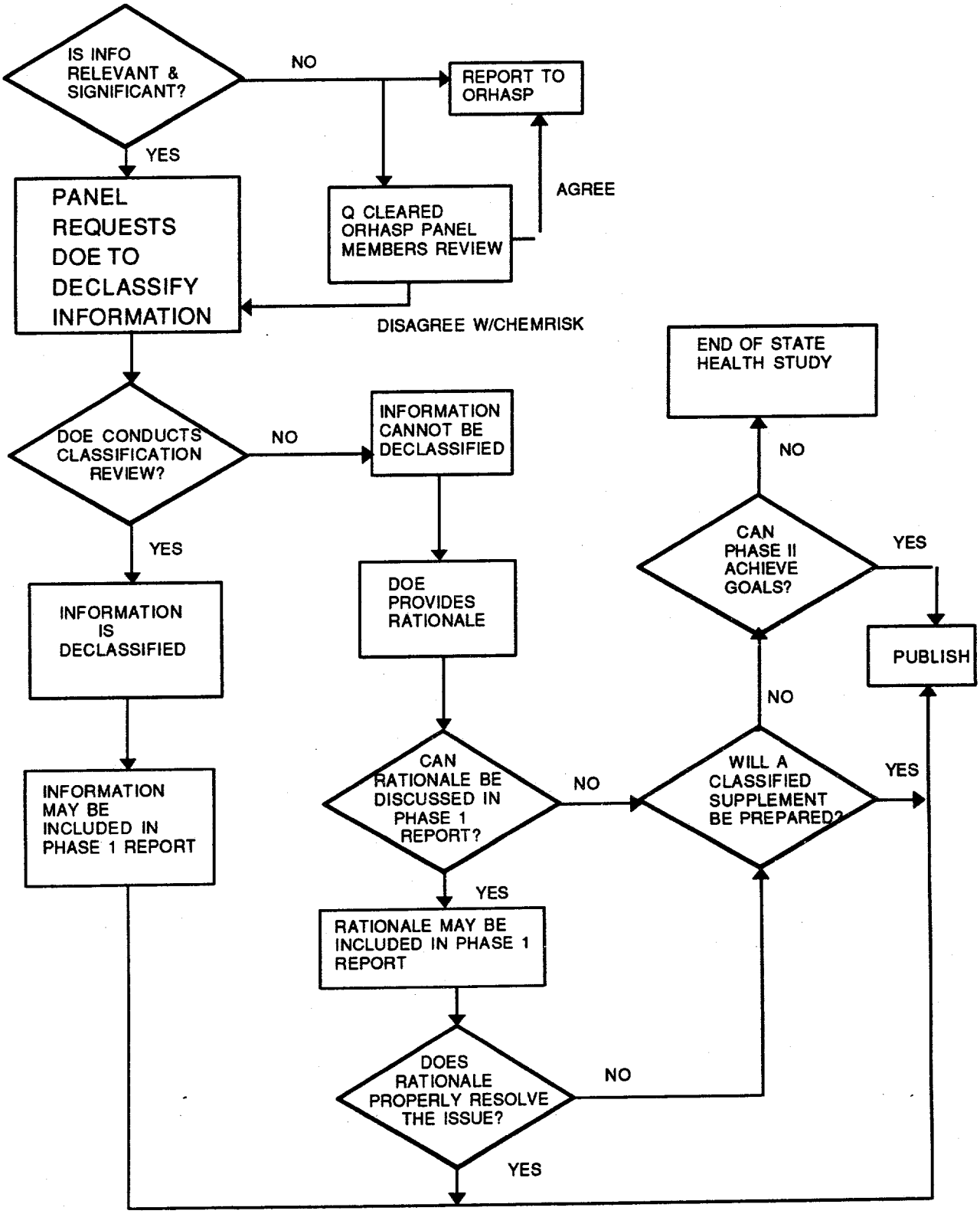
H. Will smoking and passive smoke exposure effects be considered?
Answered: Minutes of October 5-6, 1992 ORHASP meeting, page 12, Minutes of Feb 17-18, 1993 ORHASP meeting, page 6
Further Action:

I. Will social, cultural, geographic, and economic issues be considered?
Answered: Minutes of July 28-29, 1992 ORHASP meeting, page 13

APPENDIX O

METHODOLOGY FOR HANDLING CLASSIFIED INFORMATION

METHODOLOGY FOR HANDLING CLASSIFIED INFORMATION: ChemRisk encounters classified information related to the health studies.



APPENDIX P

DOE OCCUPATIONAL MEDICAL PROGRAM

U.S. Department of Energy

Washington, D.C.

ORDER

DOE 5480.8A

6-26-92
Change 1: 10-19-92

SUBJECT: CONTRACTOR OCCUPATIONAL MEDICAL PROGRAM

1. PURPOSE. To establish the occupational medical program requirements for the Department of Energy (DOE).

2. CANCELLATION. DOE 5480.8, CONTRACTOR OCCUPATIONAL MEDICAL PROGRAM, of 5-22-81.

3. SCOPE. Except as excluded at paragraph 5 below, the provisions of this Order apply to all DOE Elements.

4. APPLICATION TO CONTRACTS. Except as excluded at paragraph 5 below, the provisions of this Order are to be applied to covered contractors and they will apply to the extent implemented under a contract or other agreement. A covered contractor is a seller of supplies or services awarded a procurement contract or a subcontract which contains or should contain the clause, "Safety and Health (Government-Owned or -Leased Facility)" (DEAR 970.5204-2) as prescribed at DEAR 923.7002, 952.223-71, and 970.2303-2 or another clause whereby DOE elects to exercise its authority to enforce occupational safety and health standards.

5. EXCLUSION. The Naval Nuclear Propulsion Program is exempt from the provisions of this Order (see Paragraph 12e, Responsibilities and Authorities).

6. REFERENCES.

   a. DOE 1300.3, POLICY ON THE PROTECTION OF HUMAN SUBJECTS, of 8-23-90, which provides for the protection of human subjects through required evaluation of the risk, ethics, and the rights of participants for any proposed research involving human subjects.

   b. DOE 1324.2A, RECORDS DISPOSITION, of 9-13-88, which assigns responsibilities and authorities and prescribes policies, procedures, standards, and guidelines for the orderly disposition of records.

Vertical line denotes change.

DISTRIBUTION:

All Departmental Elements

INITIATED BY:

Assistant Secretary for Environment, Safety and Health

c. DOE 1800.1A, PRIVACY ACT, of 8-31-84, and Title 5 U.S.C., Section 552A, which protects the privacy of certain information contained in Government records.

d. DOE 5483.1A, OCCUPATIONAL SAFETY AND HEALTH PROGRAM FOR DOE CONTRACTOR EMPLOYEES AT GOVERNMENT-OWNED CONTRACTOR-OPERATED FACILITIES, of 6-22-83, which requires DOE contractors to be consistent with the safety and health standards of the Occupational Safety and Health Administration (OSHA).

e. DOE 5480.10, CONTRACTOR INDUSTRIAL HYGIENE PROGRAM, of 6-26-85, which establishes the industrial hygiene requirements for DOE.

f. DOE 5484.1, ENVIRONMENTAL PROTECTION, SAFETY, AND HEALTH PROTECTION INFORMATION REPORTING REQUIREMENTS, of 2-24-81, which establishes procedures for the reporting of information having environmental protection, safety, or health protection significance.

g. DOE 5500.1B, EMERGENCY MANAGEMENT SYSTEM, of 4-30-91, which establishes policy and requirements for an Emergency Management System that provides for the development, coordination, and direction of Departmental planning, preparedness, and readiness assurance for response to operational, energy, and continuity of Government emergencies involving or requiring Departmental assistance.

h. DOE 5610.3, PROGRAM TO PREVENT ACCIDENTAL OR UNAUTHORIZED NUCLEAR EXPLOSIVE DETONATIONS, of 12-18-80, which establishes the Personnel Assurance Program for sensitive security positions.

i. DOE 5631.6, PERSONNEL SECURITY ASSURANCE PROGRAM, of 1-19-89, which establishes a program to improve security reliability of DOE and DOE contractor employees.

j. DOE 6430.1A, GENERAL DESIGN CRITERIA, of 4-6-89, which provides general design criteria for use in the acquisition of DOE facilities and establishes responsibilities and authorities for the development and maintenance of these criteria.

k. Volume 43 FR 4377, "Radiation Protection Guidance to Federal Agencies for Diagnostic X-Rays," of 2-1-78.

l. Americans with Disabilities Act of 1990.

m. Title 29 CFR 1910, General Industry Standards, Occupational Safety and Health Administration, and 29 CFR 1926, Construction Industry Standards, Occupational Safety and Health Administration.

7. DEFINITIONS.

a. Contractor Medical Department. The occupational medical program or occupational medical department established by the contractor as required by this Order.

b. Dedicated Medical Computer System. A computer system under the control of the occupational medical department designed to receive, collect and store occupational medical information.

c. Employee Assistance Program (EAP). A program offering employees counseling, treatment, rehabilitation, and referral services for a wide range of medical, drug, alcohol, stress, and mental health problems, as well as for legal, financial, or job or career development problems.

d. Fitness for Duty. The determination that the physical and mental health of an individual is consistent with the performance of assigned duties in a safe and reliable manner.

e. Full-time Occupational Physician. A physician providing full-time occupational medical services.

f. Guidance. Information to assist in achieving the program policies and objectives.

g. Health and Safety Group. The contractor organizations which are concerned with health and safety programs.

h. Job Task Analysis. A statement outlining the physical and mental requirements and the potential exposures and hazards of a specific job.

i. Monitored Care. The monitoring of the quality of medical care of employees who have extended absences from work due to illness or injury for the purpose of facilitating their rehabilitation, recovery, and early return to work.

j. Minimum Requirements and Standards. The program content necessary to satisfy the policies and objectives of this directive.

k. Occupational Health Examiner (OHE). Physicians or nurse practitioners, physician assistants, or other appropriately licensed allied health professionals who provide health care under the direction of a licensed physician.

l. Occupational Health Nurse. A registered nurse providing occupational health nursing services under the direction of a licensed physician.

m. Occupational Medical Program. A program to assist in the maintenance and protection of optimal health through the skills of occupational medicine, psychology, and nursing; and to maintain a close interface with allied health disciplines, including industrial hygiene, health physics, and safety.

n. Occupational Medicine. Those specialty branches of the professions of medicine, nursing, and psychology which deal with the health protection and health maintenance of employees with special reference to job hazards, job stresses, and work environment hazards.

o. Part-time Occupational Physician. A physician providing occupational medical services on a less than full-time basis.

p. Site Occupational Medical Director. The physician responsible for the overall direction and operation of the site occupational medical program.

8. POLICY. It is the policy of DOE to protect and enhance the physical and mental health of all DOE contractor employees and to promote public health.

9. OBJECTIVES. The objectives of the DOE Contractor Occupational Medical Program are to:

a. Assist contractor management in protecting employees from health hazards in their work environments;

b. Assist contractor management in assuring the placement of employees in work that can be performed in a reliable and safe manner consistent with the requirements of the Americans with Disabilities Act of 1990;

c. Provide support to contractor management in the medical, mental, and substance abuse aspects of personnel reliability and fitness for duty;

d. Assure the early detection, treatment, and rehabilitation of employees who are ill, injured, or otherwise impaired;

e. Apply preventive medical measures toward the maintenance of the optimal physical and mental health of employees through health promotion and education;

f. Provide professional guidance and consultation to contractor management on all health-related issues;

g. Provide employees, as appropriate, with professional medical evaluation, guidance, counseling, and referrals to specialists in support of optimal physical and mental health;

h. Protect the privacy of employees and the confidentiality of their medical records; and

i. Provide support to DOE and contractor management and the Office of Epidemiology and Health Surveillance/Office of Health by the collection and analysis, when requested, of employee health data for the purpose of early detection and prevention of occupational and nonoccupational illnesses and injuries, thereby reducing morbidity and mortality.

10. CONTRACTOR OCCUPATIONAL MEDICAL PROGRAM REQUIREMENTS.

a. Implementation of an onsite occupational medical program shall be the responsibility of the Site Occupational Medical Director. The occupational medical director for each contractor site shall develop a written occupational medical plan detailing the methods and procedures used to implement the minimum requirements of this Order which are set out in paragraph 11.

b. A contractor can meet its obligations under this Order if it arranges to have occupational medical services provided for its employees by:

(1) an onsite medical program;

(2) a DOE contractor providing DOE-approved occupational medical services; or

(3) a private physician or medical group capable of providing occupational medical services as set forth in this Order.

11. CONTRACTOR OCCUPATIONAL MEDICAL PROGRAM IMPLEMENTATION.

a. Maintenance of a Healthful Work Environment. The interaction of employees with their environment is one of the primary concerns of the occupational physician. This requires close cooperation and coordination with industrial hygiene, health physics, and safety professionals. However, the term "environment" is a broader concept, and is not limited to the physical and chemical exposures of the individual worker. If the worker's total environment is to be productive and safe, psychological and cultural factors cannot be ignored and must be understood.

(1) Occupational physicians and selected medical staff shall make regular visits to worksites and facilities so as to become familiar with employee job tasks, worksite environments, and existing or potential health hazards. Such visits should be coordinated with industrial hygiene, health physics, and safety personnel and management, and should include a review of materials, processes, and procedures used with emphasis on physical, chemical, and biological hazards. The information obtained from these visits may form the basis for recommendations to management for corrective action or preventive measures. The frequency of worksite visits should be determined by the Site Occupational Medical Director, taking into account such factors as the size of the workforce, and number and types of operations. Other factors should include the nature and amounts of physical, chemical, or biological agents used; the accident and incident rate; and the occupational illness and disability rate. Appropriate medical staff should conduct familiarization visits at selected worksites at least monthly.

(2) Contractor management shall furnish the Site Occupational Medical Director with information on potential, physical, chemical, and biological hazards in the worksite.

(3) Prior to the performance of a periodic health examination, the contractor management shall provide to the OHE a summary of potential exposures to hazardous agents or tasks and any

worksite exposures in excess of OSHA/DOE permissible exposure limits pertaining to the employee to be examined.

(4) Contractor management should afford the Site Occupational Medical Director or designee the opportunity to participate in new materials and process review committees, safety committees, and other health-related meetings.

b. Employee Health Examinations.

(1) Rationale for Employee Examinations. Employee health examinations shall be given to provide initial and continuing assessment of the employee in order to:

(a) Determine whether the employee's physical and mental health are compatible with the safe and reliable performance of assigned job tasks in accordance with the Americans with Disabilities Act of 1990;

(b) Detect evidence of illness or injury and determine if there appears to be an occupational relationship;

(c) Contribute to employee health maintenance by providing the opportunity for early detection, treatment, and prevention of disease or injury;

(d) Provide an opportunity to assess risk factors which will cause premature morbidity or mortality (e.g., hypertension, smoking, elevated lipids); and

(e) Maintain documented records of the physical and mental health experience of employees.

(2) Comprehensive Health Examination Content. The comprehensive health examination shall be conducted by an OHE under the direction of a licensed physician, using whatever ancillary assistance is needed in accordance with current, sound, and acceptable medical practices. The minimum content is described for the preplacement or other required comprehensive examinations. Additions may be needed, as determined by the Site Medical Director, considering the purpose(s) of the examination, health hazards of current and former employment, and personal health-risk factors.

(a) Medical History. The medical history shall include information concerning the employee's current illness or health status, review of systems, past medical history, occupational history, review of a current job task analysis, family history, immunization history, smoking and other lifestyle factors, allergy history, travel history, and history of mental or emotional disorders.

(b) Physical Examination. The physical examination shall include an evaluation of head, neck, eyes, ears, nose, throat, mouth, heart, lungs, abdomen, genitourinary system, vascular and lymphatic systems, skin, musculoskeletal system, a brief neurological examination, and a measurement of height, weight, pulse and blood pressure. A digital rectal and prostate examination shall be offered to males age 40 and above. Both a pelvic and breast examination shall be offered to females. It may include mammography, a pap smear, sigmoidoscopy, and tonometry over 34 years of age to conform to good preventive medicine practices. When the resources and capability will not permit the performance of these specialized examinations, the employee is to be advised as to their value and urged to obtain them from a personal physician.

(c) Laboratory Studies. The basic laboratory work shall include:

1 Vision testing (to include near, distant, color vision, depth perception, and horizontal peripheral field of vision);

2 Complete blood count and blood chemistry profile;

3 Urinalysis and serology when indicated;

4 An audiogram as a baseline, then every 3-5 years unless exposed to noise at or above 85 decibels, then annually;

5 A pulmonary function test as a baseline, then every 3-5 years unless exposed to pulmonary irritants, a history of pulmonary disease, or when OHE deems it necessary;

6 An electrocardiogram as a baseline, then annually for over age 50, a history of heart disease, or when OHE deems it necessary; and

7 Other laboratory tests required by OSHA/DOE shall be obtained.

(d) Guidelines for Use of X-rays. The recommendations and guidance contained in 43 FR 4377, of 2-1-78, should be considered. All radiographs shall be interpreted by a qualified radiologist or as specified by OSHA/DOE.

(e) Review and Evaluation of Examination. The OHE shall discuss the results of the examination with the employee. The OHE shall provide health counseling and advice, especially as related to risk factors that may cause premature morbidity or mortality. Employees shall be encouraged to have private physicians and should be referred to private physicians for any necessary definitive care or followup treatment, and for any necessary additional diagnostic studies that are beyond the scope of the occupational health examination. The health interests of employees are best served by close communication and cooperation between private and occupational health physicians.

(3) Classes of Health Examinations/Evaluations.

(a) Preplacement Evaluations.

1 A medical evaluation of an individual shall be conducted after the job offer, but prior to the performance of job duties, and in the case of an employee, prior to a job transfer. The health status and fitness for duty of the individual shall be determined, thereby assuring that assigned duties can be performed in a safe and reliable manner and consistent with the Americans with Disabilities Act of 1990.

2 Contractor management shall provide to the Site Occupational Medical Director a job task analysis pertaining to the applicant/employee to enable the medical examiner to assess the individual as required in 11b(3)(a)1.

3 The scope of the initial preplacement evaluation shall be a comprehensive examination as outlined in paragraph 11b(2). The Site Occupational Medical Director shall determine additional examination content, considering such factors as special physical or mental requirements of the job, potential hazardous exposures, or medical surveillance requirements mandated by the Occupational Safety and Health Act, 29 CFR 1910 or 29 CFR 1926.

4 Those contractor operations requiring large numbers of preplacement evaluations may defer the comprehensive evaluation of individuals not assigned to hazardous work or potentially hazardous exposures after a review of the individual's medical history. The evaluation shall be performed within 6 months of the hire date.

5 The occupational medical department shall be informed of all job transfers. The Occupational Medical Director or designee should determine whether a medical evaluation is necessary.

(b) Medical Surveillance Examinations and Health Monitoring. Standards and requirements for special health examinations and health monitoring of employees who work in jobs involving specific physical, chemical, or biological hazards shall be in accordance with applicable OSHA/DOE standards. When employees are exposed to potential hazards not covered by regulations, appropriate special examinations may be required as determined by the Site Medical Director and approved by the DOE Director, Office of Occupational Medicine.

(c) Qualification Examinations.

1 Examinations shall be conducted to qualify employees for specific job assignments for which specific medical qualification standards exist (e.g., drivers, pilots, protective force personnel, and respirator wearers).

2 Special medical evaluations shall be performed in response to contractor management's request to determine employee fitness for duty.

Vertical line denotes change.

(d) Voluntary Periodic Examinations. Voluntary periodic examinations shall be offered; however, it should be recognized that specific work hazards or statutory requirements as outlined in 11b(3)(b) and 11c may dictate more frequent health examinations to maintain an effective occupational medical program. A fundamental purpose of these examinations is to provide employees with the periodic assessment of their health. Accordingly, relevant components of the comprehensive examination, paragraph 11b(2), may be included, as well as other preventive health measures such as health-risk appraisals or wellness counseling as authorized by the Site Medical Director.

1 Employees age 50 and over shall be offered a biennial health examination. Content shall be based upon guidelines established by the Site Medical Director, considering work assignment and individual risk factors.

2 Employees age 40-49 shall be offered a health examination every 3 years.

3 Employees under age 40 shall be offered a health examination every 5 years.

(e) Return-to-Work Health Evaluations.

1 Occupational Injury or Illness. All employees with occupationally-related injuries or illnesses shall be evaluated before returning to work. The scope and content of this evaluation shall be determined by the OHE, based upon the nature and extent of the injury or disease, and shall be sufficient to ensure that the employee may return to work without undue health risk to self or others. Written clearance from the occupational medical department shall be required before such an employee may return to work.

2 Nonoccupational Injury or Illness. Contractor management, in the following situations, shall ensure that employees will not be allowed to return to work until they receive a health evaluation and written clearance from the occupational medical department. Situations warranting evaluation and clearance include

Vertical line denotes change.

nonoccupational-related illnesses or injuries causing absence from work for 5 consecutive workdays or more, procedures or treatments that would affect negatively the employee's ability to perform in a safe and reliable manner, and hospitalization. The employee shall provide relevant medical information from their private physician to assist in this determination. The final decision for health-related work recommendations shall reside with the Site Medical Director if a disagreement exists regarding return-to-work suitability.

(f) Termination Health Evaluations. A health status review shall be made available for all terminating employees. Based upon the information obtained, a health examination (the content to be determined by the Site Occupational Medical Director) shall be conducted, whenever possible, on employees with known occupational illnesses or injuries, documented or presumed exposures required by OSHA regulations, or when more than 1 year has elapsed since the last examination. This should include a review of the medical record, associated exposure information, and a signed response by the employee to each of the following questions:

1 Have there been recent occupational illnesses or injuries not previously reported?

2 Have you ever been informed of an exposure to radiation or toxic materials above permissible limits?

3 Do you have any complaints or concerns related to prior illnesses, injuries, or exposures?

4 Do you have any current medical complaints?

c. Diagnosis and Treatment of Injury or Disease.

(1) Occupational Injury or Disease.

(a) The management of occupational injury or disease shall be in accordance with the laws and regulations of the State in which the facility is located.

(b) Diagnosis and treatment of occupational injury or disease shall be prompt with emphasis placed on rehabilitation and return to work at the earliest time compatible with job safety and employee health.

(c) Contractor management has the responsibility to establish procedures to ensure that all employees with occupational injuries or illnesses receive written clearance from the occupational medical department before being permitted to return to work.

(d) The responsible firstline management and health and safety groups (health physics, industrial hygiene, or safety) shall be given notification of unhealthy work situations detected by the occupational medical staff.

(2) Nonoccupational Injury and Illness. Employees shall be encouraged to utilize the services of a private physician or medical facility, where these are available, for care of nonoccupational injuries or illnesses. However, the medical department shall assist employees who become ill at work. Care should be available for what may be judged a short-term, self-limited condition. Such a policy will contribute to containment of medical costs and encourage an atmosphere of trust for employees. The objective is to return the worker to a state of health in the shortest possible time consistent with modern medical therapy. Long-term treatment of nonoccupational injury and illness is not considered to be a routine responsibility of an occupational medical program. NOTE: In emergencies, employees shall be given the necessary care required until referred to a private physician or facility.

(3) Monitored Care. Monitored care of ill or injured employees by occupational medical physicians is highly desirable to maximize recovery and safe return to work and to minimize lost time and associated costs. Contractor management has the responsibility to advise the occupational medical department when an employee has been absent because of an illness or injury for more than 5 consecutive workdays, or has experienced excessive absenteeism. Worker's compensation cases should be monitored when appropriate through frequent return visits and physician-to-physician communication with private physicians where applicable. The goal is to assist the employees in their recovery and to facilitate their return to duty at the earliest practicable time.

Reasonable accommodations or restrictions may be a part of this rehabilitation process and need to be closely coordinated with the human resources department and line management.

(4) Health Care Cost Management. Contractor management of occupational and nonoccupational health care requires knowledge of costs to provide recommendations for cost-effective health care.

(a) When requested, contractor management should provide to the Site Occupational Medical Director information regarding lost-time data, worker's compensation case costs, medical and surgical costs by common diagnosis, and inpatient versus outpatient costs.

(b) The Site Occupational Medical Director should be a resource to contractor benefits personnel in managing health care costs and providing advice on the quality and availability of community health care resources.

d. Employee Counseling and Health Promotion.

(1) EAP and Wellness Program.

(a) The Site Occupational Medical Director shall review and approve the medical aspects which include physical and mental health, stress and emotional/behavioral problems of all contractor-sponsored or supported EAP, as well as alcohol and other substance abuse rehabilitation programs. Program evaluation accountability shall include treatment processes, records, referrals, treatment outcomes, followup (aftercare programs), and staffing.

(b) The Site Occupational Medical Director shall review, approve, and coordinate all contractor-sponsored or supported wellness programs as essential components of a preventive medicine program. Health counseling should be available to all employees. Program evaluation and accountability shall address the training/education opportunities provided, lesson plans, class evaluation records, and referral/counseling sessions.

• U.S. G.P.O.:1992-343-169:80023

(2) Immunization Program.

(a) Tetanus/Diphtheria immunization shall be available for all employees, consistent with Centers for Disease Control (CDC) guidelines.

(b) Employees involved in foreign travel shall be advised to obtain the immunizations recommended by CDC and the Public Health Service of the U.S. Department of Health and Human Services.

(c) In the interest of saving lost time off the job, elective care, such as serial desensitizations for allergy, may be given at the discretion of the Site Occupational Medical Director with the written advice and consent of the employee's private physician.

(d) Using CDC guidelines, influenza vaccine shall be offered to all employees.

(e) Hepatitis B vaccine shall be offered according to CDC guidelines.

(f) The Site Occupational Medical Director shall ensure that immunization programs for bloodborne pathogens and biohazardous waste conform to OSHA regulations and CDC guidelines for those employees at risk to these forms of exposure.

(3) Fitness for Continued Duty Assignment. The occupational medical department has the responsibility to make fitness-for-duty determinations on employees for all conditions that may influence performance or work suitability.

(a) A substance abuse (drug and alcohol) identification and rehabilitation program is an integral part of a comprehensive fitness-for-duty program. Any testing provided shall be in accordance with acceptable practices and applicable regulations. The goal is to promote a safe and healthy work environment and to rehabilitate employees involved with substance abuse.

(b) Employees shall be evaluated for the presence of medical conditions that may be reasonably expected to impair

employee's safe, reliable, and trustworthy performance of assigned tasks and, thereby, affect the acceptability of an employee for a specific job assignment.

(c) Occupational medical personnel shall consider the job duties of any employee seeking medical care to determine if the health condition is job related. In addition, an evaluation should be made of the employee's fitness-to-perform job duties safely and reliably.

(e) Requirements for Medical Records.

(1) Records Maintenance. The maintenance of complete medical records developed by the medical department for each employee from the time of the first examination or treatment is a basic requirement. A personal health record shall be maintained for each employee identifying name, date of birth, and social security number. The contractor may use additional identification systems as desired.

(2) Confidentiality.

(a) The confidentiality of all employee medical records, including the results of health examinations, shall be observed by all members of the occupational medical staff. Such records shall remain in the exclusive custody and control of the occupational medical department. Disclosure of information from an employee's health records shall not be made without written consent, except as permitted by law or Federal regulation.

(b) Computerized or microfilmed medical records and information shall remain under the custody and control of the Site Occupational Medical Director with disclosure as defined in paragraph 11e(2)(a) above.

(3) Access to Employee Medical Records. Access to employee medical records shall be in accordance with: (a) The Privacy Act as codified in 10 CFR 1008.17(b)(1); and (b) "Access to Exposure and Medical Records" as codified in 29 CFR 1910.20 (OSHA Standard).

(4) Identification of Medical Records. It shall be the responsibility of contractor management to provide the Site Occupational Medical Director with information to enable the coding or flagging of records to reflect current job titles, specific job certifications or limitations, assigned work areas, and work hazards.

(5) Work Restriction Registry. The Medical Director will advise contractor management of appropriate work restrictions. Contractor management should maintain a central work restriction registry.

(6) Retention of Medical Records. All employee health records shall be retained in accordance with DOE 1324.2A. However, inactive records may be retired to low-cost storage in an onsite records holding area or a Federal Records Center. To protect the confidentiality of the records, the shipping cartons shall be sealed and the transfer documents shall note that access to the records is limited to personnel of the Contractor Medical Department. If resources are available, the files may be microfilmed and the paper records destroyed.

f. Emergency and Disaster Preparedness.

(1) Integrated Emergency and Disaster Preparedness Planning. The Site Occupational Medical Director is responsible for the development of the medical portion of the site emergency and disaster plan. This input shall be closely integrated with, and made a part of, the overall site emergency and disaster preparedness plan in accordance with DOE 5500.1B. It will require coordination and cooperation with management, emergency preparedness coordinators, safety, health physics, the industrial hygiene, fire and rescue units, security organizations, and offsite medical facilities.

(2) Integration with Community Emergency and Disaster Plans. The occupational medical portion of the site emergency and disaster plan shall also be integrated with surrounding community emergency and disaster plans to the extent consistent with the development of a mutual aid and assistance capability.

(3) Preplanning Requirements.

(a) The medical portion of the site emergency and disaster response capability shall be adequate to meet the type and severity of accidents and trauma dictated by the character and history of plant operations and conditions.

(b) Preplanning and prearrangements are key factors vital to the effectiveness of the medical portion of the site emergency and disaster plan and shall provide the following:

1 Onsite capabilities for medical aid and triage, and personnel decontamination by trained, qualified personnel which shall include onsite capability for cardiopulmonary resuscitation, cardiac defibrillation and advanced cardiac life support;

2 Services of health physicists and industrial hygienists to evaluate any associated radiological or chemical hazards affecting the environment, the casualties, or the general public, and to assist rescue and medical personnel;

3 Arrangements for hospital care shall include the capability to evaluate and treat injuries resulting from exposure to radiation and/or toxic materials, including internal and external contamination, as appropriate;

4 Services of medical specialists and consultants;

5 Services of rescue squads, ambulances (ambulance personnel shall meet the U.S. Department of Transportation guides or State requirements), and helicopters, as needed, with capability for handling radioactively contaminated casualties;

6 Medical aid coverage during evacuation operations from facilities and the site; and

7. Communication links between medical aid and triage teams, fire and rescue units, hospitals and hospital teams, local and State police, and DOE Emergency Operating Center.

g. Organizational and Staffing Guidelines for Contractor Occupational Medical Programs.

(1) Site Occupational Medical Director.

(a) Shall be a physician who is a graduate of an accredited school of medicine or osteopathy and who meets the licensing requirements applicable to the locations in which the physician works. Board certification in occupational medicine is preferred.

(b) Shall report directly to the Contractor Site Manager, appropriate Laboratory Director, or another management level with sufficient authority to ensure program effectiveness.

(c) Shall participate in health and environmental issues at the policy-making levels.

(d) Shall be responsible for the development, interpretation, implementation, and administration of the occupational medical program.

(e) Should have opportunities for continuing medical education, attendance at national occupational medical meetings (including DOE-sponsored meetings and health seminars), and access to medical journals. The physician should also be afforded the opportunity for membership in professional organizations.

(2) Occupational Medical Physicians.

(a) Shall be graduates of accredited schools of medicine or osteopathy and meet the licensing requirements applicable to locations in which they work. Training and experience in occupational medicine are preferred.

(b) Shall be directly responsible to the Site Occupational Medical Director or designee.

(c) Should have opportunities for continuing medical education, attendance at national occupational medical meetings (including DOE-sponsored meetings and health seminars), and access to medical journals. They should also be afforded the opportunity for membership in professional organizations as approved by the Site Occupational Medical Director.

(3) Occupational Health Nurses.

(a) Shall be graduates of accredited schools of nursing, registered, and legally qualified to practice nursing where employed. Training and experience in occupational health nursing are desirable.

(b) Shall be directly responsible to the Site Occupational Medical Director or designee.

(c) Should be afforded opportunities for continuing nursing education, including attendance at professional meetings, and access to nursing journals as approved by the Site Medical Director. They should also be afforded the opportunity for membership in professional organizations as approved by the Site Occupational Medical Director.

(4) Clinical Psychologists.

(a) Shall be graduates of accredited schools of clinical psychology and hold a valid license as required in the State where they work. A Doctor of Philosophy or a Doctor of Psychology degree with training and experience in clinical occupational assessment and treatment is highly desirable.

(b) Shall be directly responsible to the Site Occupational Medical Director or designee.

(c) Should be afforded opportunities, as determined by the Site Medical Director, for continuing psychological education related to services provided on the site, including use of psychological evaluation. Psychologists employed fulltime shall be afforded opportunities for membership and participation in professional associations.

(5) Counselors (i.e., Substance Abuse, Mental Health).

(a) Shall have the training appropriate to their specialty and be certified or licensed as required by the State in which the facility operates.

(b) Shall be responsible to the Site Occupational Medical Director or designee.

(c) Counselors employed fulltime should be afforded opportunities for continuing education, membership, and participation in professional associations as approved by the Site Occupational Medical Director.

(6) Physician Assistants.

(a) Shall be: 1 graduates of physician assistant programs accredited by the American Medical Association Committee on Allied Health Education and Accreditation; 2 certified by the National Commission on Certification of Physician Assistants; 3 and licensed/certified as required by State law. Specific training in an occupational medical specialty or experience in an occupational setting is desirable.

(b) Shall be responsible to, and work under, the supervision of the Site Occupational Medical Director or designee.

(c) Should be afforded opportunities for continuing medical education, including attendance at professional meetings and access to medical journals, as well as organizational memberships as determined by the Site Occupational Medical Director.

(7) Nurse Practitioners.

(a) Shall be graduates of an approved nurse practitioner training program with licensing/certification as required by State law. Specific training and experience in occupational health nursing are desirable.

(b) Shall be responsible to the Site Occupational Medical Director or designee.

(c) Should be afforded opportunities for continuing medical education, including attendance at professional meetings and access to journals, as well as organizational memberships as determined by the Site Occupational Medical Director.

(8) Other Occupational Health Personnel.

(a) Shall have the appropriate training and be certified or licensed as required by the State in which the facility operates.

(b) Shall be responsible to the Site Occupational Medical Director or designee.

(9) Professional Staffing.

(a) General. The proper ratio of physicians and nurses to the employee population is related to many factors, including the following:

1 Size of employee population;

2 Geographical distribution and location of employees;

3 Shifts worked;

4 Rate of employee turnover;

5 Age and sex distribution of the employee population;

6 Extent of occupational hazards and associated medical surveillance requirements;

7 Types and complexities of job tasks and operations performed;

8 Total number of all health examinations required;

9 Degree of isolation of worksites from community and other medical services; and

10 Degree of employee utilization of occupational health services.

(b) Minimum Physician Staffing. For sites with employee populations greater than 2,500, the Medical Director shall not be included in meeting the physician staffing requirement.

1 At least 1 part-time physician for employee populations between 300 and 1,000;

2 One full-time physician for employee populations over 1,000 and under 1,500;

3 One full-time and 1 half-time physicians for employee populations over 1,500 but under 2,000;

4 Two full-time and 1 half-time physicians for employee populations over 2,000 but under 2,500; and

5 An additional physician for each additional increase of 1,000 to 1,500 employees.

(c) Minimum Nurse Staffing.

1 One part-time nurse for up to 100 employees;

2 One full-time nurse for employee populations over 100 and up to 300;

3 Two full-time nurses for employee populations over 300 and up to 1,000;

4 Three full-time nurses for the first 1,000 employees;

5 One additional full-time nurse for each additional 1,000 employees up to 5,000; and

6 One additional full-time nurse for each additional 2,000 employees over 5,000.

(d) Minimum Requirements for Worksites not Covered by a Physician or Nurse. At worksites with employee populations not warranting a full-time nurse or physician (i.e., less

than 100 employees), management shall ensure at least one employee on duty is trained and currently qualified in first aid and cardiopulmonary resuscitation.

(e) Ancillary Staffing. The number and qualifications of physician assistants, nurse practitioners, and other ancillary medical personnel shall be determined by the Site Occupational Medical Director as required to support the occupational medical program. Utilization of these personnel may partially offset the prescribed staffing levels of physicians and nurses.

(f) Psychological Staffing. The Site Occupational Medical Director shall establish consulting relationships with psychiatrists or psychologists as required by the demands of the program. At sites with 2,000 or more employees, 1 full-time equivalent clinical psychologist and/or psychiatrist is suggested. The option of contracting for the services of a part-time clinical psychologist or psychiatrist for facilities with fewer than 2,000 employees or to supplement existing services is acceptable.

h. Occupational Medical Facilities and Equipment.

(1) Occupational Medical Facilities. General design criteria for occupational medical facilities are contained in DOE 6430.1A. Specifically, these facilities:

(a) Shall be located in areas readily accessible to employees and to transportation. Accessibility of the occupational medical department is a key factor in employee utilization of medical services and is very important to the overall effectiveness of the program.

(b) Shall be sufficiently spacious, well lighted, and ventilated with appropriate climate control.

(c) Shall include waiting, consultation, examining and emergency treatment areas, toilet, and shower or tub facilities adequate to ensure privacy and comfort.

(d) Shall have necessary medical and laboratory equipment with adequate decontamination facilities.

(e) Shall include a rest or recovery room, dressing rooms, and facilities for the laboratory and radiological examinations performed in the department.

(f) Shall include ambulance services and equipment that meet applicable State or Federal regulations. It is not necessary to assign responsibility for ambulance and rescue personnel, operations, and equipment to the Site Occupational Medical Director.

(g) Shall have access to medical information through a library and/or computerized information systems.

(h) Dispensing, storing and disposing of pharmaceuticals shall be in accordance with appropriate Federal, State and local law.

(2) Equipment.

(a) The Site Occupational Medical Director shall ensure that the medical department equipment is adequate in terms of present-day accepted standards of medical practice and that it is maintained in good working order and is properly calibrated.

(b) The selection of specific kinds and brands of medical office and laboratory equipment shall be determined by the Site Occupational Medical Director. Preference should be given to devices that can provide direct input to computerized data systems. The following minimum items should be included:

1 Standard distant and near visual acuity eye charts or optical testers;

2 Standard color vision plates (Ishihara, Dvorine, or American Optical);

3 Audiometer with a testing booth which meets OSHA standards;

4 Electrocardiograph equipment;

5 Pulmonary function equipment;

6 Cardiac defibrillation and related monitoring equipment adequate for portable use;

7 Suction equipment;

8 Pulmonary resuscitation equipment;

9 Adequate equipment for monitoring, handling, and decontamination of radioactively contaminated or chemically contaminated casualties;

10 Physiotherapy equipment as needed; and

11 Emergency power supply.

i. Quality Assurance. Each Site Medical Director shall develop a written quality plan. Personnel, equipment, procedures, and documentation will be considered, using applicable standards and accepted practice.

12. RESPONSIBILITIES AND AUTHORITIES.

a. Assistant Secretary for Environment, Safety and Health (EH-1) shall:

(1) Advise the Secretary on occupational health;

(2) Develop and promulgate relevant Departmental policies; and

(3) Ensure conformance with applicable laws and regulations.

b. Deputy Assistant Secretary for Health (EH-40) shall:

(1) Develop and recommend policies and standards;

(2) Maintain a health surveillance system; and

(3) Ensure implementation of all aspects of Departmental occupational health programs.

c. Director, Office of Occupational Medicine (EH-43) shall:

(1) Develop policies and standards related to occupational medicine;

(2) Provide assessment and oversight of contractor occupational medical programs to ensure implementation of standards and policies;

(3) Ensure the development of effective preventative medical and health maintenance programs;

(4) Establish and manage applied research in areas relevant to this Order;

(5) Provide for and assist in training activities associated with this Order; and

(6) Provide advice and guidance on all aspects of the occupational medical program for all elements of DOE and contractors.

d. Program Secretarial Officers shall receive and review occupational medical appraisal reports for facilities under their program responsibility with the exception of an exemption for the Director of the Naval Nuclear Propulsion Program.

e. Director of the Naval Nuclear Propulsion Program through Executive Order 12344, statutorily prescribed by Public Law 98-525 (42 U.S.C. 7158, Note), establishes the responsibilities and authorities of the Director of the Naval Nuclear Propulsion Program (who is also the Deputy Assistant Secretary for Naval Reactors within the Department) for all facilities and activities that comprise the Program, a joint Navy-DOE organization. These executive and legislative actions establish that the Director is responsible for all matters pertaining to naval nuclear propulsion, including direction and oversight of environment, safety, and health matters for all program facilities and activities. Accordingly, the provisions of this Order do not apply to the Naval Nuclear Propulsion Program.

f. Heads of Departmental Elements (the senior ranking DOE official at a DOE office location) shall include in a procurement request package, for each procurement requiring the application of this Order, the following:

(1) Identification of the Order;

(2) Identification of the specific requirements with which a contractor or other awardee is to comply, or, if this is not practicable, identification of the specific paragraphs or other

portions of this Order with which a contractor or other awardee is to comply;

(3) Requirements for the flowdown of provisions of this Order to any subcontract or subaward;

For application to awarded management and operating contracts, Heads of Departmental Elements may set forth this information in a written communication to the contracting officer rather than in a procurement request package.

g. Managers of DOE Field Offices and Energy Technology Centers shall:

(1) Review policies and standards of this Order and ensure contractor implementation;

(2) Receive and review occupational medical appraisals of sites under the jurisdiction of the field office or center; and

(3) Implement recommendations.

BY ORDER OF THE SECRETARY OF ENERGY:

DOLORES L. ROZZI
Director of Administration
and Human Resource Management

APPENDIX Q

CONTENTS OF THE APRIL-JUNE 1992 EPI-LOGS

REVIEW OF WORKER STUDIES USING EPI-LOGS

EPI-LOGS are quarterly reports of the activities of the Center for Epidemiologic Research of ORISE (Oak Ridge Institute for Science and Education) in Oak Ridge Tennessee

Reports include the following categories of information. A brief description of the type of information included in each of the categories (from the April-June, 1992 Report) is included under each category.

Report from the Epidemiology Group

During this period, the epidemiology group responded to a request from U. S. representative John D. Dingell to provide all studies, reports, memoranda, and correspondence dealing with metal toxicity/contamination among/DOE MMES employees at Oak Ridge as well as other studies, reports, memoranda dealing with research on health effects arising from exposure to radiation or heavy metals among Oak Ridge employees or residents.

Staff met with Martha Chow of Rep. Dingell's office to discuss Dr. Reid's allegations.

A symposium was held in Oak Ridge to familiarize faculty and students of member organizations with the ORAU's long-term epidemiologic studies of workers at contractor-operated DOE facilities.

A meeting at Lawrence Berkeley Lab of the Information Systems Working Group was attended to discuss the Comprehensive Epidemiologic Data Resource.

The IARC requested essentially the same files used by Dr. Steve Wing in his updated study of ORNL white males.

A request was received that originated in Senator John Glenn's office for information about exposure monitoring data at all three oak Ridge facilities and the Feed Materials Production Center.

One request for medical records for a former worker at the Y-12 plant during WWII was processed.

Population Studies

Activities related to three uranium dust site studies are described.

(1) Feed Materials Production Center, Fernald

A request from NIOSH to supply a list of deceased persons with their dates of death for workers included in the mortality investigation of the Fernald population. NIOSH was responding to a request from the president of the Fernald Atomic Trades and Labor Council.

(2) Mallinckrodt Chemical Workers

Exposure files were matched to identification files and a report was generated containing frequencies of years exposed from MCW workers exposure files.

(3) Uranium Dust Lung Cancer Study
Statistical Analyses have been completed using a 10 and 20 year lag with cumulative internal radiation exposure and average internal radiation exposure as the exposure of interest, both unadjusted and adjusted for covariables which included smoking, pay code, and duration of employment. The only significant findings related to smoking.

Activities related to 2 external radiation site studies are described.
(1) Oak Ridge National Laboratory
Only the annual external dose are available for the pre-1956 ORNL population. Discussions continue regarding the procedure to employ for adjusting the data. UNC requested grids on several individuals in the ORNL cohort.

(2) Savannah River Site
A portion of the exposure data for Savannah Rive site workers was received. Linking of the exposure data was started.

Six Combined Population studies are described
(1) Oak Ride Facilities Comparison Study (ORFCOM)
Graphs and tables were created showing the relationship between internal and external personal monitoring data. A second series of personal monitoring data analysis files is being planned that will use average readings for adjacent years for missing years. An adjustment will be made for ORNL for 194-1955 when the policy of the weekly readings of dosimeters was thought to have affected annual doses.

(2) Greater then 5 rem study
Progress on software enhancements was reported.

(3) Pinellas Plant
Staff of ORISE visited Pinellas to examine the records in the Records Retention Center.

(4) Sheet Metal Workers Study
226 contact letters were mailed to study members (179) or next-of-kin (47). A total of 142 study members have responded and 108 have participated in the study, forty responses were received from next-of-kin and 29 agreed to be interviewed. 137 telephone interviews have been completed.

(5)Y-12 Beryllium Worker Enhanced Medical Surveillance Program
Collection of Phase I questionnaires continues, Currently, a total of 6,731 questionnaires have been obtained. Approximately 300 employees who should e surveyed have not been. The beryllium roster now contains the names of 972 deceased former beryllium workers. Several activities are underway to validate the completeness of the beryllium roster. To date, 115

beryllium workers have completed physical exams. Approximately 200 chest radiographs of current y-12 Beryllium workers have been interpreted by a NIOSH certified reader and results have been returned to the medical division.

(6) Centrifuge Worker Study
More than 850 centrifuge workers and an equal number of non-centrifuge workers wee interviewed. Data has been entered ad preliminary data review is in progress.
Report from the Epidemiology Support Section

Epidemiology Support Section Report

Three primary activities are described. One is the routine matching of death certificate information with records for former employees. A second is an agreement between ATSDR and the DOE Oak Ridge Field Office for ORISE to identify and abstract death certificate data for ATSDR. Data for 291 of the original submission of 334 records have been returned to ATSDR. The third includes the activities of the information and nosology resources unit. The status of the validation of ICD codes on the death file is provided, progress on development of a computerized bibliography is described, and progress on filming old Oak Ridge Hospital medical records ins reported.

Computer Sciences

The section describes progress and problems in developing software and operating and maintaining hardware that support ORISE activities.

Hazards and risk assessment

An evaluation of background radiation doses was completed on the Y-12/TEC, MCW and FMPC Uranium dust lung cancer study. A dosimetry file containing annual external exposure for 8,708 workers of the Savannah Rive Site study population was completed. Members of the Hazards Assessment Group completed considerable evaluation of the Y-12 Beryllium workers enhanced medical surveillance program data.

Biostatistics and methodologic studies
Investigations into different perspectives for including time related variables in data analysis are continuing.

Abstracts, Papers and Presentations
This section describes abstracts and papers prepared and presentations by ORISE staff during the reporting quarter.

Attendance at meetings, conferences, and seminars
This section describes meetings, conferences, and seminars attended by ORISE staff

Visitors
This section describes who visited ORISE and for what purposes.

Personnel
This section provides information on new employees and employees who have terminated employment.

Recent additions to the epidemiology reading room
This section describes new publications that have been placed in the epidemiology reading room.

APPENDIX R

TENNESSEE BIRTH DEFECTS REGISTRY

DEVELOPING A BIRTH DEFECTS REGISTRY FOR TENNESSEE

In July of 1991, an agreement was signed between the State of Tennessee and the United States Department of Energy that provides the State financial support to coordinate independent health-related studies to assess the potential for human health risks resulting from past releases at the Oak Ridge Reservation in east Tennessee. One of the primary provisions in the five year, 12.4 million dollar Health Studies Agreement is financial support to develop and maintain a statewide birth defects registry.

The Tennessee Birth Defects Registry is a population-based, statewide registry covering birth defects occurring to infants of residents of the State in a given year. The first year of data includes infants born to Tennessee residents during 1991.

The first step in development of the statewide registry was to identify the intent of data utilization. Data are needed that will be useful for

- monitoring birth defects to detect changes or unusual patterns in incidence that may suggest an environmental influence,
- developing hypotheses for analytical epidemiological studies related to birth defects, and
- planning and evaluating services available to infants and parents of infants with birth defects.

Rather than instituting a new reporting requirement in the State, the decision was made to use data presently being reported to or collected by the Tennessee Department of Health. The surveillance system is, therefore, a passive one which relies on existing data bases to identify cases of birth defects. All cases identified from these data bases will be verified prior to inclusion in the Registry. The design and development of the Registry in Tennessee are the joint responsibility of the Office of Health Statistics and Information and the Division of Environmental Epidemiology in the Department of Health.

To define the specific data elements maintained in the Registry, a review was completed of the elements that were maintained in other state registries. Elements that were consistently maintained in those registries were included in the Tennessee Registry. Some additional elements were included based on particular needs of the State. The resulting data set was then compared with the recommended data sets for birth defects from the Centers for Disease Control and Prevention Birth Defects Monitoring Program and the National Center for Health Statistics. All of the recommended data elements from both of these sources were included in the Tennessee data set. The data set was reviewed by the State's Genetics Advisory Committee.

The data bases from which cases of birth defects are being identified include:

1. Vital Records data, including birth certificate, death certificate, and fetal death report files,

2. Tennessee Medicaid Management Information System enrollment files and claims for infants with birth defects,

3. Children's Special Services files providing information on children with diagnoses of birth defects or disabilities that entitle them to services directly provided or funded by the State,

4. State laboratory newborn screening data, including results of laboratory tests for phenylketonuria, hypothyroidism, galactosemia, and sickle cell anemia which are required to be performed on every child born in the State by T.C.A. 68-5-401, and

5. Cost Containment Information System data, providing data on diagnoses and procedures related to birth defects based on hospital insurance claims data.

With the exception of some Cost Containment Information System data and the fetal death files, all of the cases in the Birth Defects Registry include demographic and medical data obtained from the infant's birth record. The Cost Containment Information System does not include patient names, but it does include a patient control number which is the same as the patient's medical record number located at the hospital where the information originated.

The Cost Containment data base is of great importance to Tennessee's Birth Defects Registry as it is the only source of data to identify birth defect cases not found (1) during newborn screening prior to completion of the birth certificate (2) as a result of health department service delivery, or (3) as a result of receiving Medicaid assistance. The Children's Special Services database is the only source of information for cases with defects that were neither identified at birth nor subsequently hospitalized.

The Department of Health has contracted with the Center for Epidemiologic Research of the Medical Sciences Division of Oak Ridge Associated Universities (ORAU) for verification of the registry cases. All cases will be verified through the review of patient hospital medical records in hospitals across Tennessee. Verification of the 1991 cases will begin in September 1993, and will be completed by June 30, 1994.

The verification process will also include some case-finding efforts. Medical records related to other adverse reproductive outcomes including fetal deaths, infant deaths, and very low birth weight infants of Tennessee residents will be reviewed, even if the fetal death report, death certificate or birth certificate does not mention any type of defect.

Cases included in the Birth Defects Registry will be limited by age and diagnosis. These two criteria are not independent. The age limit directly influences which types of defects can be monitored as some defects, such as developmental disabilities and mental disorders, are not obvious until later in the child's life. The Tennessee Registry will include all defects diagnosed up through age one as is customary in most state birth defects registries.

As for diagnoses included in the Registry, the majority of the defects are International Classification of Diseases (Ninth Revision) codes 740.0 to 759.7. Each birth defect is classified as major or minor, which will influence its inclusion in the registry. Major birth defects are defined as those that affect survival and require substantial medical care or result in marked physiological or psychological impairment. They will always be included in the registry. Birth defects defined as "minor birth defects" will be included only if they occur in combination with a major defect.

It is essential to initially include identifiers in the original data to allow matching of records to birth records and to identify appropriate hospital medical records for verification. Likewise, it is necessary to preserve identifiers in order to complete studies that would require obtaining additional data about cases. However, all data are confidential and will be maintained in accordance with Department of Health regulations concerning medical data that include individual identifiers.

APPENDIX S
SCOPE OF THE CANCER QUALITY IMPROVEMENT AND BIRTH DEFECTS VERIFICATION PROGRAM

MANAGEMENT OF THE PROJECT

The project will be conducted under the oversight of the two senior epidemiologists at the Center for Epidemiologic Research. The epidemiologists will review all procedures to be implemented in the course of the contract specifically ensuring that there is no possibility for bias or improper quality control procedures in the data collection activities. It is anticipated that after the start-up period the involvement of the senior epidemiologists will be minimal. However, they will be available for consultation and decision making during the entire course of the contract.

All hospital contacts and scheduling will be performed by the project manager. She will be in charge of four teams of workers who will travel to the hospitals and perform the required records reviews and data abstraction tasks that are detailed below. Each team of workers will consist of a person with records experience (designated as the ORAU records specialist) and a person with data collection experience (designated as the ORAU data specialist). Each team will be expected to complete approximately 35 hospitals each year of the contract. Hospitals will be assigned to the teams by region in order to minimize travel time. Support staff at ORAU will include two data entry clerks and a programmer analyst.

The initiation of the project will begin with hospitals in and around the Oak Ridge area in order to send all teams to complete at least two hospitals under the direct supervision of the senior epidemiologists and the project manager. This will ensure that procedures are working as anticipated and will allow the epidemiologists and senior personnel to observe the teams for adherence to procedures. The senior epidemiologists and the project manager will accompany the teams approximately twice a year to observe the conduct of the field work.

Subsequent to the initiation phase, the hospitals in the state will be completed in an east to west manner so that travel time will be minimized. All hospital visits will be coordinated with the State.

In this section, and in the remainder of the document, the attachments provided with the State RFP will be referenced as "State Attachment N." We will use all forms as designed by the State and have not included them in this response except by name.

1.0 Site visit procedures and work flow--Including time estimates

It is ORAU's intention to complete Tasks 1-3 within the course of one hospital site visit. Therefore, contact of the hospitals will be accomplished simultaneously for all tasks detailed later in this proposal. The contact letter will describe the scope of the work to be performed and will contain a listing of the medical records and other records that will need to be available for the team's review at the time of the visit. As discussed above, after the initiation of the project, a team of two ORAU employees will arrive at a scheduled hospital prepared to complete all tasks in an efficient manner. Also, in the second year of the contract, the Children's Special Services Clinics will be visited for completion of Task 3.

1.1 Task 1 - Casefinding

After meeting briefly with the cancer reporting contact person at the hospital, the ORAU records specialist and the ORAU data specialist will work together on the casefinding study. One person will read names from the hospital lists that are to be reviewed, and the other person will scan the list provided by the State to determine if the name appears on the list. If a name is not located on the State list, the name and other information will be entered on the Casefinding Study

Worksheet (State Attachment 12). At the completion of the review of all hospital source documents, the ORAU records specialist will mark the appropriate sample of names and request the cancer reporting contact person at the facility to pull the records for these persons for review. While awaiting the charts to be pulled, the ORAU records specialist will begin to work on Task 2 - the reabstraction study. The ORAU data specialist will begin on Task 3 - the birth defects records verification.

When the ORAU records specialist completes Task 2, she will review all newly pulled records for possible missed cases, complete appropriate documentation, and discuss all cases with the cancer reporting contact person as necessary.

It is anticipated that the casefinding study will require approximately 12 hours for the ORAU records specialist and 8 hours for the ORAU data specialist.

1.2 Task 2 - Reabstract study

The ORAU records specialist will perform all of the work for the reabstraction study after the casefinding work has been completed and while the cancer reporting contact person is locating records that must be reviewed in order to complete the casefinding study. It is anticipated that each record will take approximately 30 minutes to review and abstract.

Coding of all records will be performed at the Center for Epidemiologic Research by the Senior Nosologist at a rate of approximately 2 minutes per record.

Data entry for the reabstract records will be performed at the Center for Epidemiologic Research. Double entry will be performed at a rate of approximately 15 minutes per record per entry person. Therefore, 30 minutes of data entry clerk time will be required per record.

1.3 Task 3 - Birth defects activities

The ORAU data specialist will begin abstracting records for Task 3 upon completion of the initial casefinding activities. The data specialist will continue until all records have been abstracted and/or verified.

The ORAU records specialist will assist the data specialist in completion of the work for Task 3 upon completing all work for Tasks 1 and 2.

It is anticipated that each record in Task 3 will require approximately 30 minutes to abstract and/or verify.

All coding will be performed at the Center for Epidemiologic Research by the Senior Nosologist at the rate of 2 minutes per record.

Data entry for the birth defects registry records will be performed at the Center for Epidemiologic Research. Double entry will be performed at a rate of approximately 10 minutes per record per entry person. Therefore, 20 minutes of data entry clerk time will be required per record.

1.4 On-site quality control for abstracted records

The ORAU records specialist and the ORAU data specialist will check the abstracting forms completed on-site by trading forms and checking work performed by the other person before leaving the facility. This check will include the following specific requirements: 1) Is the form completed in a legible manner? 2) Are all the required elements completed or if not completed, is there a note detailing why the element is not complete?

2.0 Records security

All records abstracted for any task addressed in this proposal are considered to be confidential records. The personnel proposed to work on this project have all worked with confidential records and are aware of the sensitive nature of these types of records. The CER facility is a secure facility with entrance limited to those who have a key and to those who formally sign in at the front desk. The facility has specially designed vault areas that are halon fire protected, double walled, and security protected by combination locks on the door to each room as well as connection to a central 24-hour-a-day security facility. The vaults were specially designed to meet the security needs for storing DOE facility medical records and death certificates. All personally identifiable data for this project will be stored in the vault areas when not in use for data entry.

When travelling, ORAU personnel will not leave any records in hotel rooms while they are working at an area hospital. The records will be secured in the trunk of the car or maintained with the ORAU personnel until return to CER.

At the termination of this contract, all records will be returned to the State or disposed of according to the requirements of the State. It is our policy to make a copy of all materials that are mailed that contain irreplaceable data. Upon notification of safe receipt of the data at its destination, the copy may be shredded, or the computer tape may be erased according to the requirements of the State.

TASK 1 - CASEFINDING STUDY FOR THE QUALITY IMPROVEMENT PROGRAM

The casefinding study has been designed by the State of Tennessee to "review hospital casefinding procedures and assess whether cases meeting the TCRS requirements are being abstracted." ORAU proposes to implement the casefinding study as described below.

1.0 The facility survey

The first step to implementing the casefinding study will be to survey all hospitals that will be visited for casefinding purposes. A draft hospital survey has been prepared (Appendix E) that will ascertain the availability and format of the records necessary to perform casefinding activities. The survey will be computerized upon completion and a statewide data base will be created that will be updated yearly during the course of the contract and will be turned over to the State at the termination of the contract period. The survey will facilitate planning for hospital casefinding visits. Information to be obtained on the survey will identify procedures established in the facility to obtain reports necessary for casefinding. For each type of casefinding source list (e.g., pathology logs, outpatient department logs, etc.), the survey will ascertain how long the logs or lists are maintained by the cancer reporting contact person prior to being discarded. Availability of the information collected in the survey prior to a hospital visit will allow ORAU to categorize each hospital according to whether the lists required by the State are available or whether an exception to the casefinding procedures will have to be devised.

The cancer reporting contact person at each hospital will be re-contacted by phone between May 15 and June 30 of each year of the contract to update data provided the previous year. This yearly contact will identify personnel changes and data format changes prior to hospital site visits.

2.0 Notification of the facility

Each year, the State will provide to ORAU a complete listing of cases to be included in the casefinding study by facility. This list should be provided in electronic format so that it may be sorted and reformatted for most efficient use in casefinding comparisons. The listing will cover a specific time frame (i.e., all cases whose discharge date is December 1991) and should include all demographic and identifying data available to TCRS. ORAU will separate hospitals into two categories based on availability of necessary casefinding records. The first category will be hospitals that have available all of the listings necessary to complete the casefinding study. The second category will be hospitals that do not have available all of the listings necessary to complete the casefinding study. The first category hospitals will be scheduled immediately for completion of the casefinding steps outlined below. The second category hospitals will be scheduled for a telephone information gathering call that will involve an epidemiologist and the project manager to explore alternate approaches to the casefinding activities. A written recommendation will be developed for alternate casefinding methods to be used for each second category hospital. This recommendation will be provided to the State and will be implemented upon written approval from the State. After approval, the hospital will be scheduled for the casefinding study.

Each facility will be notified of the visit from the casefinding team and requested to make available to the team all materials necessary for completion of the study. These materials will include: medical records disease index for the time period of the study, pathology logs (including tissue reports, cytology reports, bone marrow reports--by date the tissue was resected or date of service within the study period), and outpatient department logs if the facility has oncology, radiation therapy, chemotherapy, outpatient surgery, and/or other outpatient clinic sources. Specific criteria for casefinding in each of these sources

are discussed later in this proposal. Requests for materials will be revised for those hospitals where alternate casefinding methods have been approved.

3.0 Comparison of the case listing provided by the State with the listings provided by the facility

The objective of this comparison activity is to identify names that appear to be within the time frame of the casefinding study that are on the hospital listings, but not on the listing of cases provided by the State. Each name on each listing provided by the facility will be searched on the listing provided by the State.

3.1 The casefinding lists to be reviewed

3.1.1 The hospital disease index. The hospital disease index will be examined for the time frame of the study and all records coded to 140-208 or 230-234 or V10.0-V10.9, V58.0-V58.1, or V67.1-V67.2 will be checked against the list of names provided by the State.

3.1.2 The pathology log and/or tissue reports. Malignant diagnoses will be identified by using the TCRS Manual guidelines which require reporting of the primary site and the specific morphology (or cell type). The International Classification of Diseases for Oncology (ICD-O) codes will be used to distinguish reportable neoplasms by including all cases which have a morphology code with the 5th digit behavior code of '2', '3', '6', or '9' (except squamous or basal cell carcinomas of the skin).

3.1.3 The outpatient department registrations. Some hospitals will have facilities for outpatient treatment for some or all of the following areas: oncology, radiation therapy, chemotherapy, and/or outpatient surgery. The registrations or logbook for the dates

within the time frame for the casefinding study will be reviewed to ascertain possible reportable cases not on the TCRS case listing.

3.2 Missed case reports

All possible missed reportable cases ascertained through review of the appropriate listings in each of the general areas listed under 3.1 above will be recorded on the Casefinding Study Worksheet (State Attachment 12). Upon completion of the review of all possible sources of case ascertainment for the time frame of the study, the complete listing of possible missed cases will be reviewed. If the listing contains between 1 and 25 cases, every other record will be marked for medical records review. If the listing contains 26 or more cases, every 4th record will be marked for medical records review.

The facility cancer reporting contact person will be given a listing of the possible cases whose records need to be reviewed. The contact person will be expected to provide the records to the ORAU records review person in a timely manner.

4.0 Review of the sample of possibly missed reportable cases

The ORAU records review person will review each of the records in the sample of possible missed cases to determine if the cases meet the requirements for reporting to TCRS. The broad requirements that will be examined are outlined on page 13 of the TCRS 1991 Abstract Procedure Manual. These requirements specify that the case must have been diagnosed only at the facility during the time frame, or diagnosed and treated at the facility, or diagnosed elsewhere but come to the facility to receive all or part of the first course of treatment.

5.0 Reporting missed cases

If the case meets the requirements for reportability, it will be determined to be a missed case and a missed case report (State Attachment 13) will be completed. All missed cases will be discussed with the cancer reporting contact person after completion of the missed case report. Subsequent to this discussion, it may be determined that some of the missed cases are not reportable, and a note will be made on the missed case form detailing the reason the case was not eligible for reporting.

Those cases in the sample that still meet the reportability requirements after review by the ORAU medical records specialist and the facility cancer reporting contact person will be reported to TCRS within 10 working days of the last day of the facility site visit. The list will also be given to the facility cancer reporting contact person who will be responsible for abstracting and reporting the case to TCRS within 30 days. The facility will provide the data to TCRS with a casefinding transmittal form.

Within 20 days of the last day of the facility site visit, ORAU will complete the Facility-Specific Final Report (State Attachment 14) detailing the number of missed cases, source of missed cases (if generalizable), and recommendations for resolutions of systematic casefinding problems at the facility. This report will also be provided to the facility cancer reporting contact person and discussed with that person by ORAU by phone.

A statewide casefinding report will be prepared yearly within 45 days of the last hospital casefinding visit. The statewide report will compile all the data obtained from all facilities visited during the year. Descriptive analyses will also be provided that may give TCRS staff information that will be valuable in decision making regarding how to decrease missed cases in the future. The report will examine demographic characteristics of the missed cases such as age, race, sex, diagnosis, and region of the state.

TASK 2 - REABSTRACTING STUDY FOR THE QUALITY IMPROVEMENT PROGRAM

The reabstracting study has been designed by the State of Tennessee to "assess the agreement between data originally reported to the Tennessee Cancer Reporting System and actual information found in the reporting facility's medical record(s); and to identify problems in data collection and interpretation based on the guidelines and definitions stated in the Tennessee Cancer Reporting System Manual." The study has the potential to identify areas of the formal guidelines and definitions that are not being properly interpreted as well as identifying areas that are not written in a sufficiently rigorous manner. It is important for the TCRS to obtain objective information regarding interpretation of the guidelines so that, if necessary, additional examples and definitions can be added to the guidelines that will enable two different abstracters to provide identical information after reviewing the same medical record.

ORAU will ensure that all persons proposed to work on this project be made available to TCRS personnel for the purpose of training sessions for cancer reporting activities. We propose to video tape these training sessions so that we can hold yearly retraining sessions and can train staff replacements in the same manner as original staff if necessary during the period of the contract.

1.0 Notification of Reporting Facilities

At the same time that the letter of notification is sent regarding the visit for the purpose of the casefinding study, the letter of notification will be sent regarding the reabstracting study. The letter will review the purpose of the study and will identify the list of cases that are to be reabstracted by the ORAU staff during the site visit. A follow-up telephone call will be made so that specific arrangements can be made for work space and to ascertain the need for and availability of special equipment such as microfilm readers. Also, the date of the visit will be

confirmed so that the facility records contact will have a sufficient amount of time to locate and pull the records that are needed for the study.

2.0 Reabstracting the record

The ORAU records specialist will arrive at the facility with a listing of the cases to be reabstracted. This listing will have been previously provided to the facility for the purpose of pulling the records for these cases prior to the arrival of the ORAU records specialist. Although the State will have provided ORAU with the entire case report, the ORAU records specialist will have only the portion of the report that will allow identification of the proper record for abstraction. This information will include only hospital record number and full name.

The ORAU records specialist will work sequentially through each medical record as though it were a new case to be reported to the TCRS following all guidelines and definitions stated in the TCRS Procedure Manual, SEER Summary Staging Guide, and the appropriate ICD-O manual.

The ORAU records specialist will review each medical record chronologically looking for the first admission that identifies the individual to be a cancer case. This will be considered to be the index admission and all pertinent information for the TCRS abstracting form will be derived from tests and diagnostic procedures occurring during the course of this admission. This procedure will allow for verification of the case report that was originally made to TCRS, and it will also allow identification of cases that may have been late reports of prevalent cases.

It is possible that some of the records to be reabstracted will be out of the medical records department during the period of the site visit, particularly if the patient is an inpatient at the time of the visit. Within the guidelines of the hospital, the ORAU records specialist will be available to travel to the location of the record for the

purpose of abstracting. However, we do recognize that there may be times when the record to be abstracted is not available to the ORAU abstractor during the site visit. These circumstances will be documented and every effort will be made to make a return visit to abstract the record.

All elements of the TCRS Abstract will be filled out by the ORAU records specialist, although it is recognized that some elements are not required. Since the ORAU records specialist will not know whether some of the optional elements were abstracted and coded in the original case report, this complete abstracting effort will be necessary and will provide a check of the completeness of reporting specific data elements on the TCRS abstracting form.

3.0 Coding and computerization of the reabstracted record

In order to minimize the amount of time ORAU personnel are in the facilities, both coding and computerization of the reabstracted records will be accomplished at our facility in Oak Ridge at the completion of the reabstracting visit.

A special data entry program will be written that will perform range checks on the data entered in order to provide an extra level of validation of the data entered. Also, each record will be entered twice by separate data entry clerks, and the files will be compared after entry. Discrepancies between the two entry files will be resolved by a third person. The final clean, verified and validated data file will be compared field by field with the original case report that was supplied by the TCRS.

4.0 Comparison of the original case report with the newly abstracted record

A field by field comparison will be made by the ORAU project manager. If the ORAU records specialist abstracted an optional field that was not supplied in the original case report, this will be noted, but it will not be considered to be a serious discrepancy. All other differences will be

considered to be discrepancies in the full report that will be prepared and submitted to the State within 20 days of completion of the reabstraction study. The discrepancies will be categorized as major and minor according to the definitions found in the Table of TCRS Definitions of Major and Minor Discrepancies (State Attachment 15). The ORAU computer utilizes the Statistical Analysis System (SAS) on a mainframe IBM system that is described in the introduction to this proposal. The SAS system has a procedure called PROC COMPARE that will be used for this comparison activity.

5.0 Provide the State with a written report within 20 days

The results of the reabstracting study will be provided to the State within 20 days of the last day of the facility visit. The raw data will be provided on a case by case basis with all discrepancies clearly marked. Each discrepancy will be discussed. Where possible, patterns will be identified in data items that may lead to recommendations for revisions of the guidelines and definitions stated in the TCRS Procedure Manual. We will also supply information provided by the ORAU abstractor regarding abstracting or coding activities that were difficult to complete because more direction was needed in the guidelines and definitions document.

The ORAU project manager will review all discrepancies and abstraction problems and prepare a comprehensive reabstraction report by facility. At the conclusion of a complete round of reabstracting (i.e., all 150 hospitals) the project manager will prepare a complete report of all discrepancies from all hospitals. This is necessary because the small volume of records abstracted at some facilities will not allow a valid statistical analysis based on a single facility at a time.

Although the aggregate results will not identify any facility-specific results, these results should be stratified by the hospital size and number of cases reported in a typical reporting year. Because of more day to day

abstracting and coding experience, larger hospitals may have more opportunity to report cases that do not strictly follow the guidelines and definitions. Therefore, these hospitals will tend to be more familiar with exceptions and special cases of reporting. Small hospitals will not have the volume of reporting and may have difficulty interpreting and applying rules that pertain to some reporting situations. We recommend that this final annual report be stratified by hospital size to see if there are differences in the type of discrepancies by size.

Also, it is important to point out that some discrepancies may not be discrepancies. It is our experience in working with records that involve the possibility for human error that a person's social security number may be different depending on the document from which the number is abstracted. Also, data such as birth date and occupation vary depending on the informant. It is possible that the ORAU records specialist may abstract a piece of data from the record that is valid, but not equivalent to the data that was originally abstracted. The two discrepant pieces of data may actually exist within the same medical record. The resolution of this type of error is not addressed in the RFP.

TASK 3 - BIRTH DEFECTS REGISTRY

The records review for the Birth Defects Registry has been designed by the State of Tennessee to "verify suspected cases of birth defects identified by the State and to collect additional information from the medical records of infants with birth defects and other adverse reproductive outcomes." The State will provide pre-printed forms that will be used to verify data that have already been collected and to abstract data not previously collected.

A recent publication (Piper, JM et al, Validation of 1989 Tennessee Birth Certificates Using Maternal and Newborn Hospital Records, American Journal of Epidemiology, Vol. 137, No.7, pp 758-768, 1993) found that birth certificates, which provide a significant proportion of the information on abnormal conditions of the newborn and congenital anomalies, should be used with caution when trying to assess infant health issues. The positive predictive value of birth certificate data was shown to be variable, ranging from 0% for renal agenesis to 100% for fistula atresia/stenosis and polydactyly/syndactyly. Although other sources of ascertainment for birth defects will be used by the State, the data presented in the recent publication underscore the importance and potential benefit of completion of the work outlined as Task 3 - Birth Defects Registry.

1.0 Notification of the Director of Medical Records

Prior to the facility visit, a listing of all the records that need to be reviewed will be provided to the Director of Medical Records at the facility. The cover letter will explain the purpose of the abstraction exercise and the proposed date of the site visit.

2.0 Verification of the data

The ORAU data specialist will begin the verification process by matching the identifying information on the Tennessee Birth Defects Registry Birth Verification Form (State

Attachment 7) and/or the Tennessee Birth Defects Registry Death Verification Form (State Attachment 8) and/or the Tennessee Birth Defects Registry Diagnosis Verification Form (State Attachment 9) and/or the Tennessee Birth Defects Registry Verification Form (State Attachment 10) to information in the medical record to verify that the record pulled is for the correct individual. If the record is correct, the data specialist will proceed to verify all pre-printed information on the forms. It is recognized that the death verification information will not be necessary for all cases in the registry. The clerk will be instructed to begin with the first admission in the chart and to review each admission for information that may be used to verify the pre-printed information. All discrepancies will be noted on the form. If the information on the form is verified by one record, but another record is found that contradicts the information, notations will be made on the abstracting form. For example, the last name may be listed as "Witherspoon" on the first admission, but later may be spelled as "Whitherspoon". ORAU data abstraction clerks have many years of experience verifying computer listings by looking at the hard copy source records.

As the chart is being reviewed, the data specialist will abstract any new data from the record that was not previously completed. All completed records will be reviewed by the ORAU records specialist for completeness before leaving the facility. All coding and coding verification will be performed at ORAU after the verified and newly abstracted records are brought back to Oak Ridge.

3.0 Computerization of the data

The State will provide the format for the data entry that is necessary after the completion of the verification and abstraction of data at the hospitals. ORAU data entry personnel will utilize a double entry verification system to ensure quality control for the data entry. All discrepancies will be resolved by a third person.

Electronic files containing the corrections and the data obtained will be forwarded to the State within 30 days of the last day of a hospital data gathering site visit.

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