# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# CENTERS FOR DISEASE CONTROL AND PREVENTION

**and**

# AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

**convene the**

## OAK RIDGE RESERVATION HEALTH EFFECTS SUBCOMMITTEE

***Oak Ridge, Tennessee***
***April 22, 2003***

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## FINAL RECORD OF THE PROCEEDINGS

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## OAK RIDGE RESERVATION HEALTH EFFECTS SUBCOMMITTEE
## *April 22, 2003*
## *Oak Ridge, Tennessee*

# Final Minutes of the Meeting

The Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), and the Agency for Toxic Substances and Disease Registry (ATSDR) convened a meeting of the Oak Ridge Reservation Health Effects Subcommittee (ORRHES). The proceedings were held on April 22, 2003 at the YWCA, 1660 Oak Ridge Turnpike in Oak Ridge, Tennessee.

### *Opening Session and Introductions*

Dr. Kowetha Davidson, the ORRHES Chair, called the meeting to order at 12:15 p.m. She welcomed the attendees to the proceedings and thanked the ORRHES members for their support and condolences following the recent death of her father. She opened the floor for introductions; the following individuals were present to contribute to the discussion.

**ORRHES Members**

Dr. Kowetha Davidson, Chair
Ms. Peggy Adkins
Dr. Herman Cember
Dr. Robert Craig
Ms. Karen Galloway
Mr. George Gartseff
Mr. Jeffrey Hill
Mr. David Johnson
Ms. Susan Kaplan
Mr. James Lewis
Dr. Anthony Malinauskas
Dr. Peter Malmquist
Mr. L.C. Manley
Ms. Barbara Sonnenburg
Mr. Charles Washington

**ORRHES Liaison Representatives**
Dr. Elmer Akin (EPA)
Mr. Chudi Nwangwa (TDEC)
Ms. Brenda Vowell (TDOH)

**Designated Federal Official**
Ms. LaFreta Dalton, Executive Secretary

**ATSDR Representatives**
Dr. Paul Charp
Mr. Burt Cooper
Mr. Jack Hanley
Ms. Theresa NeSmith
Ms. Marilyn Palmer
Mr. Jerry Pereira
Ms. Lorine Spencer
Ms. Dhelia Williamson

**Guests**
Mr. Gordon Ballock (SENES)
Ms. Kathy Daniels (*The Oak Ridger*)
Mr. Ed Frome (Public)
Dr. Timothy Joseph (DOE)
Mr. Danny Sanders (Public)

## *Agenda Review, Correspondence and Announcements*

Agenda Review. In addition to the project update, work group reports, public comment periods and other standard ORRHES agenda items, Dr. Davidson announced that the following topics would be presented and discussed during the meeting:

- Presentation by Dr. Paul Charp and Mr. Jack Hanley on the Public Comment Draft of the ATSDR Public Health Assessment (PHA) on Y-12 Uranium Releases.
- Presentation by Dr. Charp and Mr. Hanley on ATSDR's minimum risk level (MRL) and cancer comparison values.
- Presentation by Ms. Dhelia Williamson on the health statistics review. This agenda item will be particularly important due to ORRHES's request for cancer data from the Tennessee Department of Health (TDOH).

Ms. Sonnenburg noted that the ORRHES current action items would soon be reviewed. She requested additional time and asked that this topic be tabled until the "Unfinished Business" agenda item during the evening session. In the interim, she asked the members to thoroughly review the list of current action items in preparation for the discussion.

Correspondence. Dr. Davidson received a copy of a letter from Mr. Norman Mulvenon, Chair of the Local Oversight Committee to Mr. Gerald Boyd, Manager of the Oak Ridge Operations Office. The purpose of the letter was to commend diligent efforts in the community by Dr. Timothy Joseph of the U.S. Department of Energy (DOE). He is extensively involved in various committees and advisory boards related to DOE

activities in the Oak Ridge area. Copies of the letter will be distributed to all ORRHES members.

Announcements. The recorder was absent from the meeting due to an unexpected and serious illness in her family. The attendees were asked to state their names and speak clearly into the microphones to ensure all comments were accurately captured and attributed.

## *Review of the March 2003 ORRHES Meeting Minutes*

Dr. Davidson entertained a motion to approve the previous meeting minutes; the following change was noted for the record. Change the sentence on page 11 to "The detailed presentation addressed the East Tennessee Technical Park (ETTP) ..." A motion to approve the minutes as corrected was properly made and seconded by voting members. There being no abstentions, opposition or further discussion, the March 3, 2003 ORRHES Meeting Minutes were unanimously approved.

## *Review of Current ORRHES Action Items*

Ms. LaFreta Dalton, the Designated Federal Official (DFO), and other ATSDR staff provided a status report of pending action items.

1. The Division of Health Education and Promotion should return to a future ORRHES meeting to discuss Phase II activities of the needs assessment. **Status:** ATSDR expects to receive the document from George Washington University on May 30, 2003. Staff will provide copies of the draft document to ORRHES. The members will be given a 30-day review period as requested by ORRHES.

2. The peer review status should be specified for any materials provided to ORRHES. **Status:** This item is ongoing with PHA activities and should be noted as addressed rather than pending.

3. ATSDR should create an article for local media on the screening process. Dr. Joseph should include DOE data on declassified chemicals for the

dose reconstruction. Information about ORRHES accomplishments and changes in the ORRHES process should also be released. This objective may be achieved in an article by the ORRHES Chair. **Status:** This item is to be resolved by the Communications and Outreach Work Group (COWG) and the PHA Work Group (PHAWG).

4. ATSDR should present a review of health effects studies of nuclear shipyard workers, radiation levels of concern, exposures and health effects. **Status:** An agenda item has been scheduled for this presentation.

5. ATSDR should consider the appropriateness of presenting an MRL in the radiation screening process that is less than the annual background radiation exposure of an individual in the United States. **Status:** An agenda item has been scheduled for this presentation.

6. ATSDR should consider and respond to ORRHES's recommendations on the draft PHA of Y-12 uranium releases. **Status:** This item will be addressed in ATSDR's next presentation on the PHA. ATSDR found ORRHES's comments to be extremely helpful in refining and clarifying the public comment draft.

7. ATSDR should review soil and sediment data from the Bull Run and Kingston steam plants in conjunction with PHAWG. **Status:** An agenda item has been scheduled for this presentation.

Regarding action item 1, Ms. Sonnenburg suggested that the Health Education Needs Assessment Work Group (HENAWG) attempt to convene a meeting to review the needs assessment after the document is disseminated on May 30, 2003 and before the next ORRHES meeting is convened on June 3, 2003. Regarding action item 3, Mr. Lewis proposed that a column be added to the list of action items and recommendations identifying responsibility for activities. He was unaware that COWG and PHAWG were expected to resolve this issue.

Regarding action item 3, Dr. Cember requested clarification on the "screening process." Mr. Jack Hanley of ATSDR explained that several detailed presentations on screening of past exposures were made during ORRHES meetings in 2001. ATSDR evaluated screening conducted by TDOH, technical reviewers' comments on this project, and other activities. Based on this assessment, ATSDR developed a preliminary list of contaminants of concern.

Mr. Hanley recalled that ORRHES took a vote to formally approve ATSDR's screening process during the February 2002 meeting. Under the new project plan, the screening of past exposures pre- and post-1990 will be documented in an executive summary of a report that will be presented to ORRHES. The data could be placed in local newspapers at that time, but ATSDR is currently focusing on contaminants of concern only. Mr. Hanley offered to summarize the presentations for new members.

Regarding action item 7, Mr. Lewis asked if ATSDR plans to focus on past releases from the Bull Run and Kingston steam plants. Mr. Hanley explained that ATSDR is charged with evaluating ORR releases and potential public health effects. Environmental samples will be taken and a public health decision will be made based on this assessment. Although uranium is released from the Bull Run and Kingston plants, ATSDR is not mandated to examine the proportion of contaminants from these two sources. The PHA will address the concentration of uranium in soil rather than its source.

Ms. Dalton confirmed that outstanding issues or concerns with the action items would be revisited during the "Unfinished Business" agenda item. Dr. Davidson requested that COWG and PHAWG review the list of action items and recommendations to identify which topics are still of interest to ORRHES. For issues that should be removed, COWG and PHAWG were asked to present recommendations to ORRHES for consideration.

## *Project Update*

Mr. Jerry Pereira, the ORR Project Manager, addressed the following issues in his status report. First, Dr. William Taylor will begin serving in the ATSDR Oak Ridge field office on a full-time basis on May 1, 2003. His expertise in toxicology and community involvement activities will be invaluable to ATSDR and ORRHES. On May 5, 2003, Ms. Melissa Fish will begin a one-year full-time position in the field office as well. She was previously employed in the field office on a temporary basis in the summer and fall of 2002. Her full-time duties will include development of the ORRHES work group meeting minutes, maintenance of the community health concerns database (CHCD), and other clerical and administrative duties.

ATSDR personnel from the Community Involvement Branch and Federal Facilities Branch will continue to staff the field office until the transition is made. Ms. Marilyn Palmer, the ORRHES Committee Management Specialist, will manage the office the

week of April 28, 2003. ORRHES members who are interested in visiting the field office should telephone in advance.

Second, the upcoming DOE budget will most likely have a negative impact on all ATSDR activities. After actual figures are given to ATSDR, if needed, Mr. Pereira and other managers will discuss options with the ORRHES chair and work group chairs. Mr. Pereira indicated that he was uncertain of the potential impact the reductions in the budget may have on ORRHES.

Third, materials were distributed to ORRHES outlining the majority of contaminants of concern and ATSDR's current progress with the activity. If technical staff determine that the project is behind schedule by two or more weeks, ORRHES will be informed of this problem. Technical staff will be asked to maintain an ongoing record of progress based on the overall project plan.

Fourth, Mr. Pereira's primary role in this effort is to serve as a liaison between ORRHES and ATSDR. He will continue to submit monthly reports to Dr. Henry Falk, the ATSDR Assistant Administrator, about ORRHES's ongoing and completed activities, budget concerns and other issues. He will also continue to interact with ATSDR technical staff, ORRHES members and the DFO. Mr. Pereira will attempt to resolve problems and meet critical needs within ATSDR and ORRHES by immediately discussing these concerns with Dr. Falk.

Ms. Sonnenburg's position was that as the ORR Project Manager, Mr. Pereira should be seated at the table with ORRHES. She asked about the relationship between Mr. Pereira's handouts and a large chart he previously presented illustrating the progress of several activities. She suggested that the handouts be reformatted to show ORRHES's recommendations and actual outcomes. Mr. Pereira clarified that the large chart reflects the status of the overall project. The handouts are a simpler version of the chart that only show the progress of specific contaminants of concern ATSDR is currently reviewing. In terms of actual outcomes, he confirmed that all activities in the overall project are currently on schedule.

Dr. Craig recalled that iodine-131 was the most comprehensive contaminant of concern and generated the most discussion by ORRHES. He noted that ATSDR was scheduled to reconsider this PHA by April 2003 with an analysis of real-time monitoring data from the early 1950s. Mr. Pereira directed Dr. Craig to review two asterisks on the last page of the handouts for an explanation on iodine-131. At a previous meeting, PHAWG discussed several options to address this issue, such as convening an expert panel. An appropriate strategy is still under discussion.

Mr. Lewis conveyed that PHAWG has historically received meeting minutes of high quality. Because the members are charged with addressing highly technical issues, he was concerned that the quality may decrease with responsibility for the meeting minutes shifting to an administrative/clerical staff member. On another matter, Mr. Lewis underscored the need for Mr. Pereira or other appropriate ATSDR decision-makers to attend PHAWG meetings in person or via conference call and become more involved in these activities. For example, additional PHAWG meetings that were held to address issues for which the members could not agree may have been unnecessary if Mr. Pereira had been present to provide clarification.

Mr. Lewis pointed out that Mr. Pereira's involvement, input and guidance as the ORR Project Manager could improve PHAWG's efficiency in problem resolution. To the first comment, Mr. Pereira clarified that ATSDR staff have strongly emphasized the critical importance of the ORRHES work groups to Dr. Falk. The work group chairs, ATSDR staff and Dr. Taylor will review meeting minutes for technical accuracy. However, financial constraints dictate that Ms. Fish be given an opportunity to produce and maintain the work group minutes. To the second comment, Mr. Pereira realized that the ORRHES meeting was behind schedule. He noted Mr. Lewis's concerns and confirmed that a response would be given during the "Unfinished Business" agenda item.

## *Public Comment Draft of the ATSDR PHA on Y-12 Uranium Releases*

Mr. Hanley briefly outlined ORRHES's activities related to the PHA. During the November and December 2002 PHAWG meetings, ATSDR reviewed the list of references and data sources; asked the public to submit any new information; presented the preliminary PHA; and discussed informal comments, concerns and issues raised by the public. The initial data validation version of the PHA was released in January 2003 to ORRHES. PHAWG extensively discussed the document over a series of meetings and obtained comments from other ORRHES members and the public.

PHAWG compiled and presented this feedback to ORRHES; a formal recommendation was forwarded to ATSDR based on ORRHES's deliberations during the March 2003 meeting. Dr. Charp and Mr. Hanley reviewed the comments and revised the draft PHA based on recommendations to clarify text, provide explanations and add new material. Comments from ORRHES and the public played a critical role in significantly improving the document. The current version is easier to read and more effectively communicates data, but ATSDR is now requesting additional technical comments from ORRHES. ATSDR also developed a nine-page briefing document for ORRHES that highlights key points of the PHA.

The public comment draft was released on April 22, 2003; the 45-day public comment period will officially begin on May 5, 2003 and end on June 20, 2003. Copies of the document would be distributed to ORRHES before the meeting was adjourned. Mr. Hanley explained that the rationale for ATSDR to use the PHA process is fourfold. First, offsite populations that may have been exposed to hazardous substances at levels of health concern are identified. Second, public health implications of the exposure are determined. Third, health concerns of persons in the community are addressed. Fourth, follow-up public health actions or studies to address the exposure are recommended.

The basic components of the PHA process are environmental data, exposure data, health outcome data and community concerns; exposure and health effects evaluations; and public health conclusions and recommendations. All of these factors lead to public health actions. Environmental data used in ATSDR's PHA of Y-12 uranium releases included past exposures from 1944-1995. The PHA's major data source for past exposures was the TDOH screening evaluation of uranium releases. The data were submitted for peer review before being included in the document. Current exposures from 1995-present are based on monitoring and sampling data, primarily from Scarboro. ATSDR recently identified data from other sources and included these sites in the PHA as well.

The PHA's four major data sources for current exposures were the Florida A&M University (FAMU) Scarboro Community Environmental Study conducted in 1998; the 2001 Scarboro Community Sampling Report developed by the U.S. Environmental Protection Agency (EPA); annual monitoring data from the DOE-Oak Ridge Environmental Information System; and monitoring data by TDOH. The previous PHA discussed Y-12 uranium, but the current document discusses uranium without identifying sources. However, ATSDR acknowledges in the PHA that uranium is present from local power plants and other sources.

Scarboro was selected as a reference location in the Oak Ridge dose reconstruction (ORDR) because the offsite population was likely to receive the highest exposures to past releases from the Y-12 plant. This finding was based on air dispersion modeling results collected during the TDOH screening evaluation. The ORDR report stated that "while other potentially exposed communities were considered in the selection process, the reference locations represent residents who lived closest to the ORR facilities and would have received the highest exposures from past uranium releases. Scarboro is the most suitable for screening both a maximally and typically exposed individual."

Based on these conclusions, ATSDR determined that exposures are not likely to be present in other Oak Ridge communities if no problems are detected in Scarboro. Results in the ORDR report regarding exposures to Scarboro residents are also

applicable to other residents living near the Y-12 plant. With respect to potential exposure pathways, ATSDR evaluated air, water, soil, biota, vegetables and fish.

Another important data source for the PHA on Y-12 uranium releases was community concerns. ATSDR compiled, tracked and maintained >1,800 concerns in the comprehensive CHCD developed for ORR. Community concerns about uranium, other contaminants, diseases and specific geographic areas around the Y-12 plant were extracted from CHCD and are addressed in the PHA. Data input into CHCD were submitted to ATSDR from a variety of sources:

- ORRHES and PHAWG meetings from 2000-present.
- The "Save Our Cumberland Mountain" letter in 2001.
- The ORR Public Health Working Group sponsored by ATSDR in 1999.
- The door-to-door Scarboro Community Assessment Report developed by the Joint Center for Political and Economic Studies in 1999.
- Concerns about the Scarboro environment collected by the community from 1997-1999.
- The CDC/TDOH Scarboro Community Health Survey conducted in 1998.
- The Scarboro residents' letter written to the *Oak Ridger* in 1998.

To better inform ORRHES about ATSDR's extensive efforts to evaluate, consider and include all pathways and community concerns in the PHA, Mr. Hanley played a videotape of a *Good Morning America* broadcast that focused on issues related to the Y-12 plant. Key concerns ATSDR gathered from diverse sources and evaluated for the PHA included play in the East Fork Poplar Creek (EFPC) flood plain soil and water; contact with Scarboro soil and water; inhalation of dust or particles containing uranium from the Y-12, Bull Run and Kingston plants or other sources in the area; and consumption of fish from EFPC, vegetables grown in the area, and meat or milk from cows raised in the EFPC flood plain.

In terms of health outcome data, ATSDR relied on the 1998 health investigation of the Scarboro community. CDC and TDOH conducted the actual study, while EPA and FAMU performed sampling. These activities were conducted in response to the *Good Morning America* broadcast and other media articles. Based on door-to-door survey results, the agencies clinically examined ~20 children who appeared to be healthy with no problems requiring urgent management. The clinical examinations did not indicate unusual morbidity patterns among Scarboro children. Illnesses that were detected were not found to be atypical or more severe than those found in other communities.

Dr. Charp discussed the PHA of Y-12 uranium releases from the perspective of modeling data, concentrations, doses, exposure pathways, and the comparison of doses to ATSDR's screening values. For its toxicological profile, ATSDR established a

uranium MRL at a value of 0.008 mg/$m^3$ of air. The MRL is defined as the lowest baseline figure for which non-cancerous adverse health effects are not expected to occur. Based on 1944-1995 data from the ORDR Task 6 Report, average annual air concentrations of total uranium in Scarboro were estimated at ~1,000 times lower than the ATSDR MRL. This dose is from the intake of chemicals and would primarily affect the kidney.

No average annual doses of uranium from soil and surface water pathways were found at the lowest observed adverse effect level (LOAEL) of 0.06 mg/kg/body weight/day based on 1994-1995 data from the ORDR Task 6 Report. Based on this finding, ATSDR toxicologists and external peer reviewers developed a uranium MRL for an ingestion intake of 0.002 mg/kg/body weight/day. EFPC flood plain soils and water were the basis of this chemical risk exposure. ATSDR also used the ORDR Task 6 Report to estimate the chemical dose to several persons who may have ingested this material, including an adult male and female and children 6 and 12 years of age.

During the time period from 1952-1973, most of the study population was above an MRL for adverse kidney effects from ingestion of contaminated soils and water from the EFPC flood plain. These persons were also above the ATSDR MRL from 1944-1947. However, none of these intakes were above the LOAEL at any point in time from 1944-1995. Total past uranium radiation doses to the Scarboro community were calculated in the ORDR Task 6 report. The 52-year period of time in which persons could have been exposed to uranium released from the facility was estimated to be 1944-1996. Some values were multiplied by 52 for the total 52-year time period; the results showed a dose of ~84 mrem/year.

ATSDR developed a similar calculation, but divided 70 by 52 to examine doses for a 70-year period. The results showed a dose of ~155 mrem/year to the entire body from uranium ingestion based on the sum of doses from air, surface water and soil exposure pathways. The 155 mrem/year dose is slightly above the regulation for public exposure of 100 mrem/year established by the Nuclear Regulatory Commission. The ORDR Task 6 Report showed the following results. Of the total radiation dose from surface water, 59% was from EFPC fish consumption; 5% was from milk consumption from dairy cows drinking EFPC water; and <1% was from EFPC water by immersion, incidental ingestion or consumption of meat from livestock drinking EFPC water.

Of the total radiation dose from soil, 73% was from consumption of vegetables grown in contaminated soil and 5% was from inhalation of resuspended dust. When the ORDR Task 6 Report was released in 1996, the Scarboro community expressed great concern with the FAMU sampling activity. As a result, EPA collected additional samples in 1998. In a comparison of these results, the EPA and Scarboro findings are essentially identical for both uranium-235/238. FAMU did not sample for uranium-234. The

amount of uranium-235/238 in the flood plain was found to be ~20 times higher than levels detected in the Scarboro community by EPA and FAMU.

This finding indicates flood plain soils are contaminated downstream and Scarboro soils have lower levels. If flood plain soils are used as a surrogate for Scarboro soils, doses could perhaps be an order of magnitude to ten times higher than levels detected by EPA and FAMU. To evaluate total uranium concentrations in air, sampling locations were established at several locations: Bear Creek Road/Scarboro Road intersection, Bull Run Steam Plant, Fort Loudon, Freel's Bend, Kingston Steam Plant, Morgan County at Norris Dam, Pine Ridge, the Turnpike, Tulane Road and Scarboro.

All sampling locations were found to be ~1 million times lower than the ATSDR uranium MRL of 0.008 $mg/m^3$ for air inhalation. Scarboro was found to be slightly higher than background locations, but the source of concentrations in this area was not identified. Figures from the FAMU and EPA studies were used to determine the uranium dose following ingestion of Scarboro soils. The EPA *Exposure Factor Handbook* was used as the basis to select food ingestion rates from the Southeastern part of the country and increase the body weight from 70 kg to 80 kg. Doses for an adult male and female and children 6 and 12 years of age were found to be ~140 lower than the uranium MRL of 2 mg/kg/body weight/day for soil ingestion.

In evaluating total uranium dose following ingestion of vegetables grown on- and offsite of ORR, ATSDR learned that DOE planted vegetable gardens co-located with sampling sites at some air monitoring stations. Comparisons were made of food grown in a private garden in Scarboro, onsite at the Y-12 plant, in Scarboro, at Norris Dam and in Claxton near the Bull Run Steam Plant. Data showed that the total uranium dose at all locations was ~100 times lower than the ATSDR MRL. Scarboro doses were found to be slightly lower than the Y-12 plant and fairly similar to Claxton and the DOE air monitoring location.

For total uranium concentrations in EFPC and Bear Creek, comparisons were made to the ATSDR Environmental Media Evaluation Guide (EMEG) of 20 μg/L and the EPA maximum contaminant level (MCL) for uranium of 20 μg/L. However, the EPA MCL will be slightly modified in December 2003. Mean concentrations were found to be 0.197 μg/L in offsite Scarboro drainage ditches; 12.8 μg/L at a Lower EFPC offsite location; 8.4 μg/L at a Lower EFPC onsite location after joining with Bear Creek; 33.5 μg/L at an Upper EFPC onsite location; and 159 μg/L at a Bear Creek onsite location.

To estimate a current whole-body radiation dose to the Scarboro community, ATSDR summed an air inhalation rate based on air monitoring data; soil ingestion by a Scarboro resident 1 year of age; and vegetable consumption from a private garden near Scarboro consistent with a rate in the Southeast. The whole-body radiation dose was ~0.2 mrem;

the organ dose to bone was ~21 mrem. This calculation equates to <1 mrem/radiation over 70 years. To determine whether Scarboro soils are different than typical Oak Ridge soils, ATSDR analyzed the percent of uranium per gram of soil using Scarboro soil samples collected by both EPA and FAMU. However, ATSDR acknowledged uncertainties with these data.

Uranium-238 accounts for ~99.3% of uranium found in nature; uranium-234/235 are responsible for the remainder. A comparison of all Scarboro soils collected by EPA and FAMU showed essentially no differences in background concentrations. The average levels of uranium-235 levels appeared to be elevated, but no statistically significant differences were seen between Scarboro soils and natural concentrations when data were adjusted for uncertainties. However, uranium-235 appeared to be slightly enriched in the Chattanooga-Shell area. Statistically significant differences between background concentrations in Scarboro and uranium-234 levels were not seen as well.

ATSDR also made a comparison between uranium in Scarboro soils and naturally occurring uranium using a ratio method. Uranium-234 and -235 concentrations were divided by uranium-238. The values showed 1.16 for uranium-234 and 0.096 for uranium-235. Although typical concentrations in Scarboro are 0.97 for uranium-234 and 0.047 for uranium-235, no statistically significant differences were seen when data were adjusted for uncertainties in the measurements. Overall, ATSDR's evaluation of past and current uranium exposures to offsite populations concluded that no public health concerns exist from air, surface water or soil exposure pathways.

In response to Dr. Cember, Mr. Hanley confirmed that Y-12 uranium releases are documented; modeling data are based on outcomes after uranium was released; and actual amounts of releases are known. Ms. Kaplan pointed out that in addition to modeling data, assumptions were also made to select Scarboro as the reference location. She inquired about methodologies used to ensure these assumptions were correct because inaccurate hypotheses have been generated in the past. For example, Tennessee Valley Authority stacks were initially believed to contribute the greatest impact to nearby communities, but effects were later detected at sites farther than the local area. Ms. Kaplan asked to review data used to support assumptions for the Scarboro location.

Mr. Hanley committed to reviewing the assumptions, discussing this issue with TDOH technical staff who conducted the dose reconstruction, and sharing the information with ORRHES. He conveyed that TDOH used EPA's standard and conservative model in the screening analysis. During this review, Ms. Adkins asked Mr. Hanley to also determine whether TDOH considered erratic patterns of underground crevices and various formations of limestone slabs. She was interested in whether Scarboro or other

communities shared a limestone slab with a dumping site or burial ground. These issues may have left some communities with contaminated groundwater.

Mr. Hanley explained that the uranium species used by the Y-12 plant typically did not travel far in groundwater. However, ATSDR plans to evaluate groundwater at the reservation in a separate and specific PHA. In the Y-12 uranium PHA, washed-off uranium from the bone yard, burn yard and S-3 Ponds that migrated into Bear Creek surface water was considered, evaluated and included. Mr. Hanley raised the possibility of adding a section in the PHA to clarify these issues.

Several ORRHES members expressed concern with the 1998 CDC/TDOH health investigation in the Scarboro community. Ms. Adkins questioned whether Scarboro children were examined prior to 1998. She raised this issue because many residents who lived in her previous community during the 1950s-1960s have died. If a study was conducted at this site now, no health effects would be detected. Ms. Adkins mentioned that missing information on historical exposures and deaths may cause data gaps in the PHA.

Dr. Craig inquired about the 16 children who resided on Benedict Avenue and were found to be ill. Mr. Lewis reported that all of the children's illnesses identified in the study were previously diagnosed by their pediatricians. At the time of the investigation, the ill children were already being treated for asthma or other respiratory effects. He pointed out that the CDC/TDOH study validated efforts in the community. Mr. Washington conveyed that the health investigation did not acknowledge the number of ill children who were tested at the University of Tennessee Hospital. His position was that the study results were not justified since this information was excluded.

Dr. Akin noted that the CDC/TDOH investigation was flawed because the investigation was conducted at another point in time when disease rates may have been different. Moreover, the sample size of 20 children was extremely small and would not have shown statistically significant results in the reference population. Mr. Hanley responded to ORRHES's concerns about the CDC/TDOH health study of the Scarboro community as follows. Illnesses detected in children were not found to be more severe than any other community. The study only focused on children in Scarboro at that time because the community was concerned with this particular period. Potential exposures, impacted populations, doses and health outcomes from a historical perspective were addressed in the ORDR. Past exposures from this data source were included in the PHA. Mr. Hanley committed to distributing the CDC/TDOH study at the next meeting for ORRHES's review.

Mr. Gartseff asked about ATSDR's process to identify data gaps in potentially exposed communities or individuals. Mr. Hanley responded that ATSDR attempts to identify data

gaps with its two databases for current exposures and community concerns. Moreover, the PHA Guidance Manual outlines a standard protocol each health assessor must follow to locate data. However, ORRHES should feel free to inform ATSDR about additional issues that should be addressed in the final PHA. Data gaps that cannot be filled will be noted in the document. ATSDR will also consult with DOE, EPA and TDOH about appropriate steps that should be taken if a determination cannot be made. Mr. Hanley acknowledged that ATSDR has released "indeterminate" PHAs due to data gaps.

In response to Dr. Cember, Dr. Charp was not aware of any autopsy data on the amount of uranium found in various organs of Scarboro residents and the use of this information to validate intake estimates and doses. Ms. Kaplan requested additional details on uncertainties associated with estimated average annual air concentrations of total uranium in Scarboro monitored from 1944-1995. These uncertainties would impact all of ATSDR's data and may decrease the distance between concentrations and the MRL. Dr. Charp agreed with this observation because uncertainties can fluctuate to a great degree. Most notably, detection methods applied in 1999 were significantly different than those currently used. He committed to obtaining more detailed information about the uncertainties from the ORDR Task 6 Report or ChemRisk, the company that analyzed the data.

Dr. Charp explained that in some instances, ChemRisk estimates were five times higher than DOE releases. However, levels would still be 10 times below the MRL even if the uncertainties were found to increase concentrations by an order of magnitude. Mr. Hanley added that an appendix in the ATSDR PHA points out the ChemRisk calculations of air concentrations were overestimated based on modeling used. Ms. Adkins noticed that some communities may be more impacted by uranium releases than Scarboro if natural ridge pathways, underground limestone slab formations, official and unofficial burial sites of toxins, and the incidence of illness are collectively considered and analyzed.

To address this issue, Dr. Charp confirmed that ATSDR can apply groundwater monitoring data to geo-locate these points. After all data are collected, efforts can also be made to overlay groundwater locations with air monitoring stations to identify a correlation with illnesses. He acknowledged that communities in the northeast or southwest end of Bear Creek Valley may have been more adversely impacted. To account for uncertainties, Dr. Cember inquired if values were multiplied by a factor of ~3-10 when LOAELs were adjusted to the MRL. Dr. Charp replied that LOAELs were divided by uncertainty values to account for variations in species, particularly when extrapolating data from animals to humans.

## *Public Comment Period*

The Chair called for public comments; no attendees responded.

## *ATSDR MRL and Cancer Comparison Value*

Dr. Charp reported that the PHA explains ATSDR's total dose and the methodology used to reach this conclusion. The approach was taken to identify no apparent health concerns, health hazards or doses of concern that would be sufficiently high to warrant a public health advisory. In this instance, ATSDR and CDC would issue a public health advisory for EPA to take appropriate actions. Of 30 public health advisories ATSDR has issued to EPA to date, five were related to radioactive contamination in the environment.

ATSDR may also be required to conduct further evaluations with site-specific parameters, specific conditions, scientific evidence and epidemiological investigations to determine if the dose is related to adverse health effects. This issue is explained in detail in an appendix of the PHA. The General Accounting Office (GAO) reviewed the literature and held discussions with federal agencies and outside experts to show that whole-body doses of >10,000 rem are well-known adverse health effects or in the range of well-verified effects. Whole-body doses of 5,000-10,000 rem are unknown, while those <1,000 rem are nearly impossible to verify.

ATSDR defines the MRL as the estimate of a daily human exposure to a substance that is likely to be without an appreciable risk of adverse non-cancerous health effects over a specific duration of exposure. Time periods for the MRL are categorized as an acute exposure of $\leq$14 days, an intermediate exposure of 14-365 days or a chronic exposure of $\geq$365 days. Studies used to derive the MRL were based on non-cancerous health effects rather than cancer impacts. For research designed to determine if radiation induced cancer, this effect would not have been reviewed because the purpose of the studies was to detect cancer problems. Locating radiation studies that focus on health effects other than cancer is extremely difficult.

During its evaluation, ATSDR found no data indicating that whole-body chronic exposures over 50-70 years cause cancer unless the dose was >5,000 mrem over this time period. ATSDR planned to conduct a more in-depth analysis of adverse health

effects potentially associated with whole-body doses that were found to be above the comparison value of 5,000 mrem over 70 years. With the exception of the thyroid, this approach was important for uranium and other contaminant pathways. ATSDR's comparison value was based on the following peer-reviewed literature:

- ATSDR toxicological profile of ionizing radiation.
- Conclusions from the GAO literature review.
- Study of nuclear shipyard workers.
- Research on the radium dial worker who did not develop bone cancer until doses reached >200 rad; 20,000 rem to the bone was used as the effective dose.
- Studies of nuclear medicine patients who received cardiac stress tests.
- Studies of nuclear workers in Canada, the DOE complex and the United Kingdom in which film badge data showed no whole-body adverse health effects until doses exceeded 3-4 rem.

In addition to these data sources, ATSDR applied EPA guidance from the Comprehensive Environmental Response, Compensation and Liability Act. The regulation requires radiologically contaminated sites to be cleaned to a risk-based level of $10^{-6}$-$10^{-4}$. These figures equate to 1/10,000-1/1 million cancers; a dose of 15 mrem/year; a risk of ~5 x $10^{-4}$/rem; and a dose of 1,000 mrem over 70 years. ATSDR considered using a probability of causation to establish the comparison value, but two problems were identified. First, probability of causation is used to adjudicate worker compensation claims after a disease is diagnosed, but the comparison value is used to establish risk before disease develops.

Second, the relationship between radiation exposure and cancer risk must be known. Based on these issues, ATSDR used a whole-body dose of 5 mrem. During its meeting on the previous day, PHAWG asked ATSDR about the appropriateness of applying whole-body doses when certain organs receive much more of a radiation dose. The members pointed out that based on whole-body calculations, the radiation dose can be diluted over the entire body and would decrease. PHAWG also noted that the limit to any particular organ should not exceed 50 rem.

To address these concerns, ATSDR reviewed new weighting factors to particular organs, such as 20% to gonads, 12% to red bone marrow, 5% to the thyroid and 0.01% to bone surface. In applying the weighting factors to certain organs, the whole-body dose would be multiplied by 20 to estimate a dose to the thyroid and multiplied by 100 to estimate a dose to bone. ATSDR could not definitively determine whether a whole-body dose of 5,000 mrem would be sufficient or too high because bone may receive a dose of 500,000 mrem. ATSDR was also unable to inform PHAWG if the whole-body

dose is protective of public health because some values are as much as 100 times higher to individual bone.

ATSDR's screening value of 5,000 mrem was reduced to 500 to estimate uranium concentration in bone. The whole-body dose to a Scarboro resident was calculated in the PHA as <1 mrem. Applying the weighting factor and multiplying the dose by 100 would result in <100 mrem. The figure is below the ATSDR MRL of 100 mrem and the organ dose limit of 50,000 mrem. If a Scarboro resident exceeds the 5,000 mrem dose, ATSDR acknowledges that the entire PHA will need to be recalculated.

Ms. Adkins remarked that the PHA reflects exposure to a single contaminant, but persons most likely had cumulative exposures from uranium, nickel, mercury, lead and other metals. She asked if ATSDR plans to analyze synergistic effects from multiple exposures in one body. Dr. Charp confirmed that this methodology can be applied by adding doses for each individual isotope and then totaling all isotopes. Radiological doses from synergistic effects can be developed for the whole body and each organ. However, this strategy will be much more difficult for chemicals because an analysis to combine radiological and non-radiological doses has only recently been developed. Dr. Charp planned to forward Ms. Adkins's request to ATSDR toxicologists.

Dr. Craig did not believe synergistic effects play a role in the PHA of Y-12 uranium releases. Scarboro was defined as the most exposed population, but the community is only at 1/100$^{th}$ of an action level. Moreover, the data showed that concentrations were within natural background. Mr. Hanley added that ATSDR responded to a previous action item to distribute literature references to ORRHES on the effects of mixture contaminants. The data showed that chemical mixtures do not always result in synergism and additive effects. If ATSDR evaluates more contaminants in the PHA, he raised the possibility of Dr. Karl Markiewicz presenting this issue at a future ORRHES meeting.

Mr. Lewis announced that Dr. Cember was absent from the PHAWG meeting the previous day. He asked that Dr. Cember be allowed to weigh in on outstanding issues from the technical deliberations. Dr. Charp requested Dr. Cember's opinion on the screening dose that should be used to calculate a whole-body or organ dose and determine health effects. Dr. Cember would use an effective whole-body dose for prospective screening and an organ dose for retrospective screening. However, he clarified that unlike an organ dose, an effective whole-body dose is not an actual dose and cannot be measured. Dr. Cember provided additional details about the weighting factors referenced in Dr. Charp's presentation.

The figures were developed to establish radiation safety standards for various substances and are not designed to retrospectively estimate the contribution of dose to

illness. The dose amount taken into the body was used to calculate the probability of dying from cancer; the probability was then limited to a well-defined number of 1/10,000. The weighting factors represent a best estimate of the relative susceptibility of various organs to cancer based on excess cancer deaths among atomic bomb survivors. The sum of all weighting factors provides an overall probability of cancer death. If the acceptable intake for preventing or minimizing the probability of cancer death led to an organ dose that was sufficiently high to cause damage to the organs, the permissible intake would then be reduced.

If the acceptable intake for preventing cancer led to a large organ dose, the factor that limited intake on the material would be the threshold effect on the organ rather than cancer. From the perspective of establishing radiation safety standards, conservative estimates that yielded a lower intake were used. Dr. Charp inquired about the cut-off point between health issues and non-health effects for a particular organ.

Dr. Cember was not aware of any situations in which detrimental impacts occurred at non-cancerous doses of <50 rad. However, he acknowledged that health effects cannot be verified and may be masked by background noise during screening. His position was that 5 rad is a reasonable cut-off point for screening non-stochastic effects to organs. He explained that a stochastic effect can randomly develop whether or not exposure to an agent occurred. A non-stochastic effect will only develop with a minimum dose or if a threshold level of exposure to an agent occurred.

## *Health Statistics Reviews (HSRs)*

Ms. Dhelia Williamson of ATSDR provided an overview of this activity because the possibility of conducting an HSR in Oak Ridge is currently being considered. ATSDR uses HSRs to determine whether higher rates of a specific disease occurred at a particular site. To achieve this objective, ATSDR compares disease occurrence in the community of concern to county or state rates. For example, cancer rates in Oak Ridge would be compared to those in Tennessee or a particular county in the state. To obtain these data, ATSDR examines the number of persons who actually have the disease versus the number of cases expected in the area.

HSRs are conducted to respond to community concerns; provide specific information on the health status of a community; and examine outcomes associated with exposures to chemicals. State health departments may provide annual summaries on the rates of asthma, cancer, diabetes and other diseases to provide communities with the health status in a particular area. In developing HSRs, ATSDR only uses previously collected

data, such as cancer, birth defects and other registry data as well as birth certificates, death records and other vital statistics. Data in registries are reported by physicians and hospitals to health agencies.

ATSDR acknowledges that each data source contains strengths and limitations. For example, only physical birth defects seen at delivery are reported by physicians. Malformations or internal health conditions are not captured on birth certificates. Death records only list the actual cause of death. For example, an individual with cancer who dies in an automobile accident would not be reported to the cancer registry. To conduct an HSR analysis, ATSDR examines the ratio between the observed number of cases in the area of concern and the expected number of cases based on county or state data. Particularly for cancer, the analysis accounts for age, race and gender.

HSR results provide data on the number of persons in an area who have or died from a specific disease. The findings also determine whether more cases are present in the area than would be expected in comparison to the county or state. HSRs have both strengths and limitations. One the one hand, HSRs respond to community concerns about disease occurrence in the area; specify particular geographic locations and disease outcomes to examine; and use established methods to conduct analyses. On the other hand, HSRs rely on available data; cannot determine the cause of disease; do not identify other risk factors that may be associated with the disease; provide no information on length of residence or occupational exposures; and generate unstable estimates due to a small number of cases.

## *HSR of Tennessee Cancer Registry Data*

Mr. Lewis outlined PHAWG's rationale for ATSDR to conduct an HSR in Oak Ridge. Based on community concerns and other issues listed in the CHCD, many residents believe Oak Ridge has higher cancer rates and certain counties have an increased cancer incidence. To address these concerns, efforts will be made to examine the TDOH Cancer Registry and identify cancer incidence in particular counties or plume areas that may be associated with releases. PHAWG has discussed the possibility of TDOH presenting cancer statistics for the target counties.

Mr. Lewis asked Ms. Williamson to provide input on three issues of key interest to PHAWG: utilization of anecdotal data; ATSDR's role in special testing on exhumed bodies; and the need for symptoms and disease prevalence studies. To fulfill its charge of developing recommendations to compile cancer registry data and analyze communities of interest, PHAWG reviewed or referenced several data sources to

support the ORDR, including an HSR of concerns by Oak Ridge physicians and an HSR of mortality rates. No recommendation was made in the ORDR to perform an epidemiological study, but PHAWG has discussed the feasibility of revisiting this issue since more data on cancer incidence and other issues have now been generated.

PHAWG also reviewed the New York State web site and found age-adjusted county data on the incidence of thyroid cancer among females in the area from 1992-1996. The county figures are categorized as below, within or above a certain percentage of state rates. New York State released a brochure to compliment the study and inform the public about reading cancer maps and interpreting graphs. The study can be accessed at www.health.state.ny.us.

PHAWG hopes that after ATSDR collects HSR data from TDOH, a similar product can be developed for Oak Ridge. This information can assist ORRHES members and the lay public in better understanding the process to resolve problems in a specific geographic location. PHAWG recognizes that epidemiologists and other scientists are concerned about effectively applying and interpreting raw data.

Based on a previous presentation, PHAWG agrees that data should follow a continuum of decisions to actions. Data can be generated in the form of formal studies, television broadcasts, newspaper articles or other mechanisms. PHAWG's interest in symptoms and disease prevalence studies was triggered by articles published in the *Tennessean*. The reports were based on hundreds of interviews of residents in Oak Ridge, Paducah, Kentucky and other sites.

To further support the HSR, Mr. Lewis cited several requests outlined in a letter from Tennessee Senator William Frisk to former HHS Secretary Donna Shalala: assess the quality or usefulness of data on which reports are based; examine data for any illness patterns and evaluate whether sufficient data exist to establish a relationship to nuclear plants; summarize HHS studies currently underway at 11 sites; identify a process to address key questions raised by the newspaper articles in a study; and describe existing federal programs that may assist in addressing medical needs of persons living near the plant.

In response to the first request, Mr. Lewis reported that data in the *Tennessean* articles were not compiled from an epidemiological study and have many limitations. For example, calculating rates for reported illnesses, determining whether illness rates were abnormal, and relating excess illness to specific nuclear plants are nearly impossible to calculate. The primary exposure was found to differ among plants. In response to the second request, Mr. Lewis noted that tabulating data collected in a non-standardized manner and assessing illnesses and symptoms based on limited diagnostic information are not acceptable from an epidemiological perspective. Determining whether data in

the report represent a new or unusual occurrence of symptoms in the population is not possible.

Mr. Lewis confirmed that Senator Frisk's letter will be incorporated into a case file of all data PHAWG has reviewed; the document will also be disseminated to ORRHES. The time-line of the project is proposed as follows. PHAWG has asked Ms. Williamson to examine county data and gather records from TDOH to analyze areas of concerns. Zip codes will also be evaluated to identify health effects. ATSDR will combine the county and zip code data to demonstrate whether releases of uranium or other contaminants may have contributed to increased cancer rates in the area.

After the conclusions are presented to ORRHES, PHAWG will submit the data to technical experts for a formal evaluation. Beyond the HSR, Mr. Lewis mentioned that PHAWG also discussed other potential uses of epidemiological data, such as individual behavioral changes, societal benefits or educational purposes. His position was that the lowest level to apply this information will be in zip codes where persons do not live in the respective regions.

## *Recommendations on Health Outcome Data*

Dr. Malmquist called ORRHES's attention to a handout that was distributed in support of Mr. Lewis's presentation. The document outlines PHAWG's draft recommendations that are being proposed as a three-tier project. In Phase I, the TDOH Cancer Registry would conduct an HSR of cancer incidence in eight counties surrounding ORR. In Phase II, the TDOH Cancer Registry would use zip codes or census tracts and provide this information to ATSDR. PHAWG is requesting that the HSR be performed at this level because some cancer clusters may be overlooked at the county level.

In Phase III, ATSDR would obtain these data from TDOH and conduct the HSR in the event TDOH is unable to complete the activity. Dr. Malmquist announced that PHAWG unofficially asked TDOH to supply these data, but the information has not been received to date. As a result, PHAWG is asking ATSDR to officially request the data.

If ORRHES approves the HRS, Dr. Craig advised ATSDR to be mindful of other limitations of TDOH data. Most notably, data reporting is variable among counties and the quality of data submitted differs as well. Ms. Williamson responded to PHAWG's requests outlined in Mr. Lewis's presentation as follows. First, anecdotal data are included in ATSDR's PHA. The information is captured as community concerns and statements by residents about the higher incidence of disease in a particular area.

However, anecdotal data are typically not representative of the total community. As a result, the Tennessee HSR would be based on established data from disease registries and vital statistics.

Second, ATSDR's mandate is limited to living persons in communities; the agency has no role in conducting special testing on exhumed bodies. Third, ATSDR has been reluctant to perform studies on symptoms and disease prevalence after the 1990s. These activities were extremely frustrating to ATSDR and communities because the results merely showed that certain symptoms or diseases were more prevalent in a particular area. Fourth, an analysis of cancer incidence data will address concerns about current cancer rates in the area, but the information cannot determine rates from historical exposures.

Ms. Williamson confirmed that ATSDR can use the PHA to closely collaborate with PHAWG and ORRHES in analyzing exposures, examining mortality rates and developing appropriate follow-up recommendations. Strategies to effectively implement these activities are currently being discussed by ATSDR. Ms. Sonnenburg inquired whether PHAWG has established a particular time period for data to be collected. She pointed out that the correct spelling of one of the counties in the recommendations is "Meigs." Dr. Malmquist replied that the request for data will be consistent with the time period of TDOH's existing computerized records.

Ms. Williamson added that the cancer registry maintains incidence data from 1990-1998. In ATSDR's formal letter of request to Dr. Toni Bounds, the TDOH Cancer Registry Director, the time period and census tracts of interest will be clearly specified. Dr. Cember advised PHAWG to revise the recommendations with accurate language. For example, "cancer incidence" should be replaced with "cancer prevalence." Ms. Williamson clarified that the use of "cancer incidence" in the document is correct because TDOH data are newly reported cases. Mr. Hill also made suggestions to refine the document: add "a possible" before "increased rate(s) of cancer" and include the zip code for each county listed.

Dr. Malmquist explained that zip codes were intentionally excluded from the recommendations because TDOH will not conduct a study in a population smaller than a county. Ms. Adkins mentioned that data sources for the HSR exclude topography and other factors to increase risk. As a result, TDOH or ATSDR will most likely conclude no health effects exist in Oak Ridge. Given the strong possibility of this outcome, she was uncertain about the rationale to undertake the study. Dr. Davidson reported that the HSR is being proposed in direct response to an ORRHES request. After Dr. Bounds's presentation at a previous meeting, the members asked TDOH to provide data on cancer rates within the counties of concern.

Ms. Sonnenburg asked if data have been collected on the number of residents who moved into and from communities of concern over the past 50 years. For exposures that occurred in the 1950s or another time period, past residential status would play a critical role in addressing Ms. Adkins's concerns and making the results more statistically significant. Ms. Williamson replied that information on historical residential status has not been collected. Another limitation in conducting the HSR will be mortality data due to the long latency period for cancer. For example, exposure may have occurred in the 1950s, but the disease could have been diagnosed several years later.

Mr. Johnson inquired about the feasibility of using both census data and TDOH records to cross-reference historical residential status. Ms. Williamson confirmed that ATSDR will use 1990 census data because the HSR will rely on TDOH Cancer Registry records. She remarked that the population within the target area will be considered during the analysis. In conducting the HSR, Ms. Brenda Vowell of TDOH advised ATSDR to also be aware of the fact that 1992 data are not as complete as 1997 information. If the HSR is approved, Ms. Adkins suggested that ORRHES play an active role in its design. For example, the members could select certain communities with the maximum air or water flow and pinpoint specific target populations that were most likely to receive the highest exposures.

## *Public Comment Period*

Mr. Danny Sanders has been an Oak Ridge resident since his birth in the area in 1955. He was personally interested in the ongoing studies and the proposed HSR because both his parents died from cancer. He has attended ORRHES and PHAWG meetings over the past two months to learn more about historical exposures when ORR was initially established. His parents moved to the area in 1942 and lived in Happy Valley; the community was onsite at the K-25 plant.

Mr. Sanders was initially unable to locate data about the community, but PHAWG assisted him in this effort. However, he needs more assistance in locating additional data to address his concerns about cancer-causing agents. In conducting the HSR, Mr. Sanders urged ATSDR to historically research records to the extent possible. Due to TDOH's data gaps, he acknowledged that a wealth of information will be missing. In a personal effort, he has been attempting to locate residents who lived in Happy Valley at the same time as his parents.

In addition to conducting the HSR and other formal studies, he encouraged ATSDR to also collect qualitative data by interviewing persons. This approach can assist in

identifying health effects among current and future residents in communities of concern. He also asked ATSDR to refrain from limiting the HSR to 1990 census data. In response to Dr. Davidson, Mr. Sanders confirmed that he completed and submitted a concerns form to Ms. Dalton to be entered in the CHCD.

In response to Dr. Akin, Mr. Sanders commented that identifying a potential correlation between his parents' cancers and the environment is important due to his concerns about historical health effects, future generations and a potential predisposition to the disease. Most notably, his two siblings who were born in Happy Valley in 1945 and 1947, respectively, may develop health impacts in the future. Dr. Davidson noted that Mr. Sanders's concerns were consistent with ORRHES's mission to address future health effects. Dr. Craig reported that ATSDR is scheduled to conduct a PHA of pollutants from the K-25 plant; the evaluation will include Happy Valley. He raised the possibility of placing this activity on a faster time-line to more quickly address Mr. Sanders's concerns.

Mr. Ed Frome is a former ORRHES member. In support of the proposed HSR, he referenced an e-mail he transmitted to Mr. Hanley in August 2001 discussing the 1994 paper by Mangano on cancer mortality near Oak Ridge. The paper was also distributed to ORRHES members and ATSDR staff at that time. The study raises several statistical questions about the process to appropriately establish, design and implement an analysis. The communication was submitted into the record and is appended to the minutes as Attachment 1.

Mr. Frome offered to attend a future PHAWG meeting to answer questions or provide more information about the Mangano paper. Dr. Davidson confirmed that she would ensure Mr. Frome's name is still included on the PHAWG e-mail distribution list. Dr. Akin emphasized the need for ORRHES to clearly delineate whether its focus is on historical exposures or protection of the current community. Dr. Davidson commented that the community is concerned with both issues. Dr. Malmquist's position was that ORRHES should focus on whether Oak Ridge is currently a safe place to live.

Mr. Lewis provided additional details on PHAWG's rationale for recommending that ATSDR conduct an HSR in Oak Ridge. Based on concerns raised by the community, issues documented in the CHCD and the lack of data in the ORDR, the need to gather additional information, conduct the HSR and address community concerns within the ORRHES charter is evident. The overall purpose of the activity will be to answer questions by the lay community on whether cancer rates in the area are higher than others based on a comparison of data from the TDOH Cancer Registry. Mr. Lewis added that the HSR will reflect a combination of environmental and occupational exposures.

Mr. Sanders pointed out that dose reconstructions are based on historical events and are performed to address public concerns about the cause of cancer among individuals. To achieve this goal in Oak Ridge, historical exposures will need to be traced to the initial establishment of ORR. If ORRHES attempts to determine whether past events during the years of maximum exposure in the community resulted in cancer or other diseases with a long latency period, Dr. Akin agreed efforts should be made to locate persons who lived in the area at that time. These individuals should serve as the study population. However, he was uncertain whether the study could be designed in this fashion.

## *Work Group Reports*

Agenda Work Group (AWG). Ms. Sonnenburg announced that AWG had no activities to report.

Guidelines and Procedures Work Group (GPWG). Ms. Galloway announced that GPWG had no activities to report.

COWG. Mr. Lewis reported that COWG has held several meetings to address specific issues. First, a matrix was developed to identify recipients of correspondence, appropriate persons to notify for particular activities and communication actions to take within COWG. However, the distribution list does not satisfy the need to create an ORRHES listserv, post the document on the web site and obtain commitment to maintain and update the database as needed. COWG has raised the possibility of holding a meeting with ATSDR management to discuss actions that should be taken to begin developing the ORRHES listserv.

Second, ATSDR's nine-page briefing document of the PHA was reviewed and well-received by COWG. The summary is succinct and contains color pictures that will be easily understood by the lay public. Mr. Lewis commended ATSDR on this effort. COWG is now asking ORRHES to endorse the overall concept of the document if similar summaries will be disseminated to the community in the future. The briefing document should also be incorporated into the overall project plan with a clearly defined time-line for completion and distribution that is consistent with the release of the PHA.

Third, COWG has added key points and made other refinements to the community health concerns comment sheet. The document is expected to be highly effective. Fourth, a clear and transparent process must be developed to capture all action items. Mr. Lewis acknowledged that some recommendations raised during COWG and

ORRHES meetings are not transferred to the formal list. For example, Dr. Cember was concerned that presenting data in the PHA in units of rem, mrem and rad will be too technical for the lay public.

To respond to this issue, ATSDR developed a thermometer graph to illustrate the units of measure. COWG also learned that Dr. Malinauskas wrote a paper on this issue for the Three Mile Island incident. A recommendation was made to obtain the study for inclusion into the formal ORRHES record. Mr. Lewis underscored the need for solid scheduling, accurate record keeping and management support to effectively and efficiently implement action items.

HENAWG. Ms. Theresa NeSmith of ATSDR reported that completion and release of the draft needs assessment to ATSDR is scheduled for May 30, 2003. The document will be disseminated to HENAWG for review and comment; HENAWG will then formulate recommendations for consideration by ORRHES. In response to Ms. Sonnenburg's concerns, Ms. NeSmith confirmed that the draft will be sent to HENAWG via FedEx prior to May 30, 2003 if ATSDR receives the draft before this time.

Dr. Davidson agreed with Ms. Sonnenburg's comments. HENAWG will be extremely burdened by receiving the draft needs assessment after May 30, 2003, thoroughly reviewing the document and then developing formal recommendations for ORRHES to consider at the June 3, 2003 meeting. She suggested that HENAWG's recommendations be tabled until the following ORRHES meeting on July 29, 2003.

Based on Dr. Davidson's observations, Ms. NeSmith summarized the revised time-line. ATSDR will send the draft needs assessment to HENAWG via FedEx no later than May 30, 2003. HENAWG will be provided a comment period from time of receipt of the document until July 29, 2003. The draft will be circulated to the full ORRHES prior to the July 2003 meeting to prepare for HENAWG's recommendations.

PHAWG. Dr. Craig reported that PHAWG's ongoing activities were extensively discussed in previous presentations, *i.e.*, input on the public comment draft of the ATSDR PHA on Y-12 uranium releases; review of screening levels; and initial planning of the HSR. However, the mercury PHA is another current PHAWG project that was not mentioned. The members held a meeting to preliminarily discuss this issue; development of the mercury PHA by ATSDR is currently underway.

PHAWG

- **Recommendation 1:** ORRHES should adopt PHAWG's recommendations to the TDOH Cancer Registry on health outcome data.

  Discussion: Phase I of the HSR will be designed with a narrow scope that will only focus on cancer incidence in the eight counties. Census tracts and zip codes will be examined in Phase II of the study. At that time, plumes and other events can be analyzed as well. The recommendations should be revised as follows: change the sentence to "ATSDR will provide the Cancer Registry with specific census tracts...;" change the sentence to "cancer incidences for all types of cancer."

  Vote: A motion to approve the recommendation was properly made and seconded by ORRHES voting members. The motion carried with 13 votes in favor, no opposing votes, no abstentions and no further discussion. The recommendations as amended by ORRHES are appended to the minutes as Attachment 2.

- **Recommendation 2:** ORRHES should adopt PHAWG's recommendation for ORRHES to draft a letter to the DOE-Oak Ridge Operations (ORO) Office Manager requesting DOE's continued commitment to support the involvement of Dr. Joseph, the DOE liaison to ORRHES. The resolution was drafted in response to consideration by DOE-ORO to completely eliminate or limit Dr. Joseph's involvement with ORRHES.

  Discussion: The recommendation may be more effective as an unsolicited acknowledgment of DOE's valuable contribution of providing outstanding support to ORRHES. The resolution should be rewritten as a positive thank-you letter to DOE by removing the entire "Background" section; encouraging Dr. Joseph's continued involvement; and deleting "and not vacate your responsibility to provide competent DOE liaison to ORRHES." PHAWG should draft the letter and submit the document to Dr. Davidson for her signature.

  Ms. Sonnenburg suggested that the letter be submitted to the local newspaper. Dr. Akin pointed out that Dr. Joseph is not seated at the ORRHES table as an official liaison. He raised the possibility of ORRHES reconsidering Dr. Joseph's role; Mr. Lewis wholeheartedly agreed with this

proposal. Mr. Hill was not in favor of either of these suggestions. His personal belief was that ORRHES should not publicly thank DOE in a letter published in the newspaper. He reminded the members that ORRHES has taken many votes on whether or not to appoint DOE as an official liaison. Ms. Kaplan also did not support DOE serving as an official ORRHES liaison. Ms. Sonnenburg rescinded her suggestion; agreement was reached to address the issue of DOE as an official liaison in a separate discussion.

Vote: A motion to approve the recommendation was properly made and seconded by ORRHES voting members. The motion carried with 13 votes in favor, no opposing votes, no abstentions and no further discussion. The letter as amended by ORRHES is appended to the minutes as Attachment 3.

The AWG, COWG, GPWG and HENAWG Chairs made no recommendations.

## *Unfinished/New Business and Outstanding Issues/Concerns*

Dr. Charp reported that Dr. Cember did not notice any time frames on graphs illustrating the ingestion and inhalation MRLs. The ingestion MRL is based on a chronic lifetime intake over 365 days/year, while the inhalation MRL is based on an intermediate exposure for the most insoluble form of uranium. Before the PHA is finalized, these data will be referenced in the document in tables or footnotes as appropriate.

Mr. Hill suggested that the next ORRHES meeting be held in the mall because the YWCA facilities are continuing to worsen. For the next ORRHES meeting, Ms. Dalton announced that DOE offered its offsite conference facility to ATSDR at no charge. She asked the members to weigh in on this proposal. Mr. Hanley added that the DOE Information Center is located on the Turnpike and is designed to comfortably accommodate public meetings. Mr. Hill's position was that ORRHES meetings should not be held in any DOE facility based on the agency's image and history with the Oak Ridge public.

Mr. Washington conveyed that the Oak Ridge Site Specific Advisory Board (ORSSAB) holds its meetings at the DOE Information Center. He agreed with Mr. Hanley that the accommodations are excellent and easily accessible to the public since visitor's badges are not required to enter the building. As another advisory group chartered under the Federal Advisory Committee Act (FACA), ORSSAB has received no negative feedback

from convening its meetings at the facility. Mr. Washington mentioned that DOE has no presence in the building.

Ms. Kaplan disagreed with Mr. Washington's comments because DOE controls the ORSSAB agenda and enforces its 66% voting requirement. To maintain a high level of credibility in the community, Dr. Craig acknowledged that ORRHES activities should remain separate from DOE. This independence will continue to be critical to assure the public that DOE has no control or influence over ORRHES. Dr. Akin asked if free use of the DOE facilities could be used as leverage against DOE reducing the ORRHES budget in other areas.

Mr. Pereira remarked that the YWCA charges ATSDR $300 for ORRHES meetings, while the mall requires at least $500. Although the charges for both locations are nominal, meeting expenses quickly increase when multiplied by several ORRHES meetings per year. ATSDR staff who visited the DOE conference facility were extremely impressed; he planned to make a site visit to the building as well. In response to ORRHES's concerns about its autonomy, Mr. Pereira was confident that the members will continue to generate independent, credible and meaningful products regardless of the meeting location.

Mr. Lewis announced that the DOE building also has video conferencing facilities. This technology could play a critical role in more effectively communicating technical information, increasing public involvement in activities and enhancing ORRHES's overall function. With the more modern facilities, Mr. Lewis indicated that television stations could broadcast meetings. Although concerns about ORRHES's independence from DOE are valid, his position was that advantages in terms of message dissemination to the public far outweigh disadvantages of a particular meeting location.

Mr. Hill followed up on some of the comments. DOE made the decision for ORRHES to be autonomous by authorizing and funding ATSDR to independently perform studies and conduct other activities at ORR. As the funding agency, DOE could have had oversight for ORRHES without ATSDR and held meetings at its onsite facilities. Mr. Hill asked the members to be mindful of the fact that DOE's establishment of ORRHES as a separate body was based on concrete reasons.

Dr. Davidson provided clarification on the overall process. The ORRHES agenda, activities and operations are determined by the collective members and bylaws that can only be amended by the collective members. ORRHES's only limitation is its requirement to operate within FACA guidelines. Dr. Davidson emphasized that DOE cannot control ORRHES's agenda or operations under any circumstances. As another option to consider for a future meeting location, Ms. Sonnenburg announced that the

Community Center has a large conference room. She committed to providing ATSDR with contact information for the facility.

Ms. Dalton called for a non-binding straw vote on whether or not the next ORRHES meeting should be held in the DOE Information Center. ORRHES's comments, ATSDR's budget constraints and other potential locations will be taken into consideration during the decision-making process. ATSDR will consult with ORRHES during this time. Nine members voted in favor of the DOE facility, four voted against and none abstained from voting.

## *New Action Items*

Ms. Dalton reviewed the action items raised during the meeting.

- Mr. Hanley to follow up on the logic or rationale associated with the Scarboro modeling.
- Mr. Hanley to distribute CDC's 1998 health investigation of the Scarboro community at the June 2003 ORRHES meeting.
- Dr. Charp to provide ORRHES with data on the uncertainties for air releases modeled in the ORDR Task 6 Report.
- Ms. NeSmith to send the needs assessment to HENAWG via FedEx when the document becomes available.
- Mr. Hanley to provide ORRHES with the letter by former HHS Secretary Shalala responding to requests made by Senator Frisk.

Mr. Hanley mentioned that the CDC study is included into the PHA and will be distributed to ORRHES by mail. The study contains an extensive discussion on the outcomes from the 1998 health investigation of the Scarboro community. Dr. Davidson requested details on ATSDR's process to announce and disseminate the PHA to the public. Mr. Hanley replied that the document will be mailed to each individual on ATSDR's comprehensive distribution list, but a review will be conducted to determine whether additional names should be added. The PHA will also be distributed as an electronic version on the ATSDR web site and by CD-ROM. Mr. Hanley made note of the members who asked for a hard copy or CD-ROM of the PHA.

Ms. Dalton added that ATSDR will issue a press release providing guidance to the public on the correct process to submit comments on the document. The notice for the current ORRHES meeting announced that the public comment draft of the PHA will be released in May 2003 and more details will be provided in the future. The meeting notice also directed the public to check local media sources for updates.

## *Housekeeping Issues*

Ms. Dalton announced that the Oak Ridge field office will be closed the remainder of the week of April 22, 2003, but will be reopened at 2:00 p.m. on April 28, 2003 by Ms. Palmer. The office is in operation from Monday-Thursday 9:00 a.m.-6:00 p.m. and is closed on Fridays. Dr. Taylor is expected to report to the office the week of April 28, 2003. Any ORRHES member who is not a member of a work group can still attend meetings and participate as a non-compensated member of the public. In response to Ms. Sonnenburg, meeting notebooks can be returned to the field office for recycling by ATSDR.

## *Closing Session*

The ORRHES members presented Dr. Davidson with a dogwood tree and two peonies to express their sorrow on the recent death of her father. The next ORRHES meeting will be held on June 3, 2003 beginning at 12:00 p.m. The location will be determined and announced by ATSDR.

There being no further business or discussion, Dr. Davidson adjourned the ORRHES meeting at 6:15 p.m.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

_____ _____

Date

Kowetha A. Davidson, Ph.D., D.A.B.T.
ORRHES Chair

**ATTACHMENT 1**

FYI — This is for the ORRHES April 22, 2003 public comment record.

— Original Message —
From: E. L. Frome [mailto:FromeEL@ornl.gov]
Sent: Wednesday, April 23, 2003 10:20 AM
To: Kowetha Davidson
Cc: Palmer, Marilyn; jah8@cdc.gov; James Lewis
Subject: [Fwd: 1994 paper by Mangano]

Kowetha,

RE: Statistical Issues Related to "Health Statistics Review"

The discussion that I heard at the April 22 meeting and review of notes from the March 17, 2003 meeting of the Public Health Assessment Work Group indicate that a geographically base study (most likely at the county level) of cancer incidence and/or mortality is being considered. If such a study is undertaken then some of the details of data organization and statistical analysis should be discussed. I indicated some of my concerns in the following e-mail that was sent to ORRHES and ATSDR staff Aug, 2001. Since Dhelia Williamson has probably not seen my concerns about statistical analyses, and because of the time limitations I decided to limit my comments at yesterdays meeting. I would be glad to discuss my concerns with the Public Health Assessment Work Group.

Best,

Ed Frome

P.S. Would you please forward this e-mail to Dhelia.

On Tue Aug 28, 2001 Ed Frome wrote:
To: Jack Hanley
CC: ORRHES ATSDR-Staff

Jack,

RE: Cancer Mortality Near Oak Ridge Tn, 1994 paper by Mangano

As I indicated in our phone conversation last week this paper by Mangano uses a statistical method, *i.e.* age adjustment using the direct method, that in my opinion is not appropriate.

This method of analysis implicitly assumes that there is no "interaction" between age and other explanatory variables of interest, *i.e.*, the relative difference among groups does not change with age at risk. Mangano gives no indication that this possibility has occurred to him or that he had undertaken preliminary analysis to justify this strong assumption. This and related issues, as well as more appropriate statistical methods are discussed (see in particular Eqns 7 and 8 and related discussion) in Frome, E. L. and Checkoway, H. (1985), "The Use of Poisson Regression Models in Estimating Incidence Rates and Ratios," American Journal of Epidemiology, 309-323.

These methods and the necessary computer resources for a more appropriate analysis have been widely available since the mid80s and are described in the well know textbook by Breslow & Day. In particular, Example 2.5 page 61 of Breslow & Day illustrate this point with an example from the Connecticut Tumor Registry.

"Fig 2.3 shows age-adjusted rates ... calculated by the direct method relative to 1950 US population. While they show a smoothly rising incidence over the 40-year period, they miss an important feature of the data for females. Fig 2.4 shows age-specific rates to illustrate the problem ..."

N. E. Breslow and N. E. Day. Statistical Methods in Cancer Research, Volume II: The Design and Analysis of Cohort Studies. Number Scientific Publication 82. International Agency for Research on Cancer, Lyon, 1987.

On the issue of "causal inference" you may find the recent review by M.A. Hernan "Causal Methods for Longitudinal Studies" Vol 2001 No 1, in the Statistics in Epidemiology Report from Section on Statistics of the American Statistical Association of interest. This is available at in PDF format at URL http://www.csm.ornl.gov/asasie/ newsletter/ click on "Summer 2001."

I see little point in trying to evaluate this paper since the methods used can lead to biased results of an unknown direction and magnitude based on statistical issues alone.

Best of luck,

Ed

P.S. On July 23, 2001 at http://www.csm.ornl.gov/~frome/orrhes/FINAL.html I wrote:

I will be glad to follow the activities that are described on the OFFICIAL ORRHES web site, and if there are items on the agenda for a work group meeting that involve statistics or epidemiology I will try to participate in these discussions. I have checked the ORRHES web site and see no indication of any meetings.

On August 25 I received your letter data Aug 22, 2001 concerning the discussion of this paper. When this paper was mentioned at earlier meetings I had come prepared to explain the above issues and to discuss direct age adjustment, but time was not available. In your letter you indicated that there is a PHAWG meeting tonight, from 5:30 to 8 p.m. I do not feel my participation in this meeting would be helpful since I could add nothing to your discussion beyond the above.

**ATTACHMENT 2**

Public Health Assessment Work Group (PHAWG) Draft Recommendations:

to the Oak Ridge Health Effects Subcommittee (ORRHES)

April 22, 2003

The ORRHES recommends the following:

Phase I.

To address the community concerns about a possible increased rate of cancer in communities surrounding the DOE Oak Ridge Reservation, the ORRHES requests that the Tennessee Department of Health Cancer Registry conduct a health statistics review of cancer incidences for all types of cancers in the State's cancer registry for the eight counties which surround the Oak Ridge Reservation (Roane, Anderson, Knox, Morgan, Loudon, Blount, Rhea, and Meigs).

Phase II.

To address community concerns about possible increased rates of cancer in the geographic areas identified in the Public Health Assessment (PHA) where exposure to hazardous substances may have occurred, the ORRHES requests that the Tennessee Department of Health Cancer Registry conduct a health statistics review of the incidence of cancer in those identified geographic areas of concern. ATSDR will provide the Cancer Registry with the specific census tracts that make up the geographic areas of concern, as well as the types of cancer to be examined.

Phase III.

If the Tennessee Department of Health Cancer Registry is unable to conduct the above mentioned health statistics reviews, the ORRHES requests that the Cancer Registry provide the pertinent data to ATSDR to conduct the health statistics review using the data provided by the Tennessee Department of Health.

**ATTACHMENT 3**

## RESOLUTION

The Public Health Assessment Work Group (PHAWG) recommends to the Oak Ridge Health Effects Subcommittee (ORRHES) that ORRHES draft a letter to the Department of Energy, Oak Ridge Operations (DOE-ORO) Office Manager regarding the continued commitment of DOE to support the involvement of its liaison to the ORRHES.

ORRHES Position

Dr. Joseph is an exceptionally useful asset to the ORRHES whose role it is to provide public involvement and community guidance to the Agency for Toxic Substances and Disease Control's (ATSDR) independent assessment of the health effects of the DOE's past and present operations in Oak Ridge. Dr. Joseph's professionalism and candid responses to questions and requests for information have greatly improved the efficiency of the subcommittee's deliberations, the quality of information provided to the public and the community satisfaction with the ORRHES/ATSDR process. On more than one occasion Dr. Joseph has volunteered facts and provided a perspective that resolved serious misunderstandings regarding DOE's policies and past actions. Dr. Joseph has provided DOE credibility in the community that has been here-to-fore lacking. Because of his continuous involvement throughout the health effects investigations in Oak Ridge he has a unique perspective and irreplaceable corporate knowledge of what has transpired to bring us to the present conditions. Dr. Joseph represents DOE extremely well in one of its primary public interfaces and he provides an invaluable service to the citizens of Oak Ridge. We urge you to adhere to your office's commitment to support the ORRHES mission.

**Glossary Key**

| | | |
|---|---|---|
| ATSDR | — | Agency for Toxic Substances and Disease Registry |
| AWG | — | Agenda Work Group |
| CDC | — | Centers for Disease Control and Prevention |
| CHCD | — | Community Health Concerns Database |
| COWG | — | Communications and Outreach Work Group |
| DFO | — | Designated Federal Official |
| DOE | — | U.S. Department of Energy |
| EFPC | — | East Fork Poplar Creek |
| EMEG | — | Environmental Media Evaluation Guide |
| EPA | — | U.S. Environmental Protection Agency |
| ETTP | — | East Tennessee Technical Park |
| FACA | — | Federal Advisory Committee Act |
| FAMU | — | Florida A&M University |
| GAO | — | General Accounting Office |
| GPWG | — | Guidelines and Procedures Work Group |
| HENAWG | — | Health Education Needs Assessment Work Group |
| HHS | — | Department of Health and Human Services |
| HSRs | — | Health Statistics Reviews |
| LOAEL | — | Lowest Observed Adverse Effect Level |
| MCL | — | Maximum Contaminant Level |
| MRL | — | Minimum Risk Level |
| ORDR | — | Oak Ridge Dose Reconstruction |
| ORO | — | Oak Ridge Operations |
| ORRHES | — | Oak Ridge Reservation Health Effects Subcommittee |
| ORSSAB | — | Oak Ridge Site Specific Advisory Board |
| PHA | — | Public Health Assessment |
| PHAWG | — | Public Health Assessment Work Group |
| TDEC | — | Tennessee Department of Environment and Conservation |
| TDOH | — | Tennessee Department of Health |