Oak Ridge Reservation Health Effects Subcommittee
Centers for Disease Control & Prevention
Agency for Toxic Substances and Disease Registry

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites

Summary Report
December 3 - 4, 2001

Present in the 12/3 and 12/4/01 Meeting of the Oak Ridge Reservation Health Effects Subcommittee (ORRHES) were the following Subcommittee members: Elmer Akin, Bob Craig, Don Creasia, Kowetha Davidson (Chair), Karen Galloway, Jeff Hill, David H. Johnson, Susan Kaplan, Jerry Kuhaida, James F. Lewis, Peter Malmquist, LC Manley, Therese McNally, Donna Mims Mosby, Chudi Nwangwa, Bill Pardue, Barbara Sonnenburg, Brenda Vowell, and Charles Washington, Sr. Other attendees included: LaFreta Dalton (ATSDR Designated Federal Official), Jack Hanley (CDC/ATSDR), Timothy Joseph (Department of Energy), Kendra Myers (Writer/Editor, Cambridge Communications), and Jerry Pereira (CDC/ATSDR).

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Call to Order, Opening Remarks, and Introduction of Subcommittee Members

The Oak Ridge Reservation Health Effects Subcommittee (ORRHES) convened on December 3 and 4, 2001. Dr. Kowetha Davidson, Chair, called the meeting to order at 8:15 am on December 3. She asked that all meeting attendees identify themselves for the record.

Agenda Review, Correspondence, and Announcements

Dr. Kowetha Davidson, Chair
Oak Ridge Reservation Health Effects Subcommittee (ORRHES)

Dr. Davidson reminded the group that the September 11, 2001 meeting had been abbreviated due to the terrorist attacks. Therefore, many agenda items from that meeting had been carried forward to the agenda for December 3-4, 2001. She gave a brief overview of the Subcommittee's agenda, which was adopted as written.

She then directed the group's attention to the following correspondence:

- A letter from Norman Mulvenon, Chair of the Local Oversight Committee (LOC), expressed concern about the Subcommittee meetings which conflict with the LOC meetings. The Subcommittee would avoid these conflicts whenever possible.

- A letter was written to Mr. Patrick Lipford of the Tennessee Department of Health requesting documents that were referenced in the Iodine-131 Dose Reconstruction Report.

Dr. Davidson made the following announcements:

- The workgroup chairs would be available during the lunch hour to discuss workgroup activities.

- Subcommittee members are asked to re-sign lists for workgroups. These lists would be used as the official membership list for the groups.

- A copy of the mailing list would be circulated for updates. If members of the public do not want their information to be viewed by others, then they should notify Marilyn Palmer before the list is circulated..

Ms. LaFreta Dalton made the following announcements:

- Group members should complete the checklist for consensus-building behavior in preparation for the next day's evaluation.

- The hiring freeze at CDC has been lifted, so they are now free to proceed with the selection process for new members for the Subcommittee.

- She directed the group's attention to a handout about the ORRHES meeting minutes. The members of ORRHES voted to use detailed minutes rather than verbatim transcripts. Public comments made during the meeting as well as after the meeting become part of the public record.

- The recommendations regarding an ORRHES Mission Statement were also available.

Discussion Summary:

˜ Mr. James Lewis asked about meeting minutes for workgroups. He felt that workgroups would benefit for some guidance in keeping minutes. Ms. Dalton noted that only Subcommittee meeting minutes are subject to FACA regulations, so each workgroup can create its own system for keeping minutes.

˜ Mr. William Pardue wondered about how to address suggested corrections from the public. Appending these suggestions to the minutes does not indicate whether they are valid.

˜ Ms. Dalton said that based on citizen input during the September meeting and also on information from a presenter, the minutes of the June, 2001 meeting would not be presented for vote. They are in the process of reviewing the tapes and will make appropriate changes for Subcommittee approval.

˜ Ms. Dalton said that public comments become part of the public record and are included with the meeting minutes in the Oak Ridge Field Office. If the minutes include a misstatement from a presenter, then the tapes are reviewed and necessary corrections made in the minutes. This policy is consistent with other FACAs.

˜ Mr. Charles Washington said that statements made in the FACA meetings are part of the public record. Corrections made in writing also become part of the public record, but do not change what was said.

˜ Ms. Dalton noted that public comments regarding the minutes can be shared at subsequent meetings and will thus be part of the public record.

Approval of June, July, and September Meeting Minutes

Dr. Davidson asked the Subcommittee to review the July and September meeting minutes, as the June minutes are still under review.

Motion 1

Mr. Jeff Hill moved that the Subcommittee approved the July and September meeting minutes. Dr. Robert Craig seconded the motion. The motion carried unanimously.

Discussion Summary:

~ Mr. Lewis wondered about an operating procedure and deadline for modifying meeting minutes. He was concerned about leaving the June minutes unapproved.

~ Ms. Dalton replied that the normal time to review minutes and to respond with comments is two to three weeks. The June minutes represent an exception.

Status of Action Items

Dr. Davidson directed the Subcommittee's attention to a table provided by ATSDR that listed the status of action items from the September meeting and from previous meetings.

Discussion Summary:

~ Mr. Lewis commented that action items from the workgroups have an impact on the Subcommittee. He wondered whether there was a mechanism for capturing these workgroup action items. Dr. Davidson responded that the Subcommittee addresses action items for the Subcommittee only. The workgroups address their own action items. Mr. Lewis felt that since many of the action items fall to the workgroups, it would make sense to integrate them.

~ Ms. Dalton noted that the table reflects action items on which ATSDR was asked to act. The table provides a way to track ATSDR's progress. Dr. Davidson added that ATSDR does not respond to action items from the workgroups, but to Subcommittee action items.

~ Mr. Pardue inquired as to how to tell which items are recommendations and which are action items. Ms. Dalton replied that the table includes all items to which ATSDR has responded. In some cases, they are a combination of action items and recommendations.

~ Ms. Susan Kaplan wondered if there is a similar list of major recommendations from other Subcommittees. She was curious as to which ATSDR activities came as a result of requests from the community. Ms. Dalton said that recommendations from the Subcommittee usually come as a result of discussion in workgroups.

~ Ms. Dalton offered to note which items on the chart were recommendations and which were action items. She also offered to include a statement about speakers on the minutes process.

Update on the Health Education Needs Assessment

Dr. Rebecca Parkin
George Washington University

Dr. Parkin presented an update on the Health Education Needs Assessment. She explained that the purposes of the Health Education Needs Assessment are to:

- Identify the community's current health concerns and information needs; and
- Provide a current data summary for the timely implementation of a health education action plan.

There are seven steps in the process, and they are continuing to conduct document reviews and site visits. Key resource interviews were conducted from July through October. Telephone interviews are forthcoming, as are focus groups.

Three Institutional Review Boards (IRBs) are involved in this project:

- George Washington University Medical Center IRB
- The MCP Hanneman University IRB
- The Tennessee Department of Health (which is serving as a repository of information)

These boards ensure that the research is ethical and scientifically sound in its structure and operations. They also ensure the confidentiality and protection of individuals who participate. The initial reviews were done in October, 2000, and final approval for the research methods has been received. The telephone survey questionnaire is under review. The focus group materials are in draft form, as they cannot be finalized without data from the telephone survey.

The goal of the key resource interviews was to reach 25 - 30 people in each of three main categories:

- Health officials
- Healthcare providers
- Key resources in the community

This part of the process is designed to collect information from people who have responsibility in their jobs for health-related issues. 156 individuals were contacted and 74 interviews were completed, as the IRB protocol limits contact attempts to two.

Telephone exchanges to be included in the telephone survey have been identified and the forms have been pre-tested. The questionnaire is being computerized for rapid collection and analysis of the data. There will be a completed rate of 400. The telephone survey is intended to collect a broad view of residents' concerns. The Public Health Assessment (PHA) workgroup has been helpful in shaping the focus group aspect of the Assessment Project. Information from key resource interviews and telephone surveys will feed into the groups. These two methods of collecting information present opportunities to understand residents' issues more deeply. Eight groups will be scheduled in a compressed time period. IRB approval is expected in January, 2002 so the focus groups will likely be held in late February or early March.

The final report will include background information, documentation of methods used, technical results from each of the three research components, and a recommendation for a Health Education Action Plan. The Plan will document current health issues, the views that people have about the issues, the health education information that people are looking for, and how they would like to get that information. Developing an Action Plan includes the following elements:

- Defining the desired outcome(s)
- Identifying forces that can help and limit the Plan's implementation
- Assessing how these forces can be used
- Advising how an Action Plan can be conducted
- Suggesting alternative strategies

The Plan also includes resource and time-frame estimates for recommended actions and evaluation activities. Stakeholders include the Subcommittee, community leaders and other individuals in the community, healthcare providers, and community organizations. Subcommittee and PHA workgroup input on the draft report will be needed.

Discussion Summary:

- Mr. Washington asked if a grid could be created to identify where certain questions came from. For instance, members of some communities might not attribute an illness to their proximity to a nuclear facility. Dr. Parkin answered that the telephone survey will make that information accessible via telephone exchanges. The key resource interviews do not include that information, as the individuals interviewed were assumed to have broad experience. The geographic analysis will depend on the richness of the information. Being too specific with this information runs the risk of identifying the personalities involved in the survey and thus breaching confidentiality.

- Mr. Lewis asked whether the telephone interviews will collect distinctions between residents who are workers, who self-identify as "sick workers," and other types. Dr.

Parkin was not sure that the questionnaire asks whether participants have worked at the site, but there are opportunities within the questions' structure for interviewees to let it be known that they worked at the site. It is important to remember that answers cannot be prompted in the interview in order to ensure that the responses are not biased.

˜ Mr. Lewis commented that the Subcommittee focuses on residents, not on self-identified sick workers. He hoped to gather information on those who feel that their health issues are as a result of being off-site, not on-site. Dr. Parkin replied that the telephone survey will use a random sample of residents, so it is not focused on workers.

˜ Mr. Lewis commented on the word "education" and what constitutes it. An "Education Action Plan" seemed predetermined. Dr. Parkin replied that "education" can be a component of a risk communication strategy. It is a particular method for transferring information from individuals who have special knowledge about a topic of concern to people who want that information.

˜ Ms. Barbara Sonnenburg recalled that part of the project would include concerns that do not involve education. Dr. Parkin answered that the telephone survey includes collecting health issues for individuals and families as well as health education and information concerns.

˜ Mr. Lewis asked about the document review. He wondered if they could capture concerns from this part of the process. Dr. Parkin said that these concerns would be documented in the final report.

˜ Mr. Lewis hoped that the PHA workgroup concerns could be connected to issues of contaminants of concern. Dr. Parkin observed that these issues might not be captured in a telephone survey of limited length. The telephone survey will assess beginnings of concerns about connectedness between health issues and contaminants, and the focus groups will then probe the issues more deeply.

˜ Ms. Sonnenburg hoped that the types of focus groups would be brought to the workgroup before the final decision is made about what the groups are. Dr. Parkin said that they would.

˜ Dr. Davidson asked whether the rationale for selecting focus groups would be shared. Dr. Parkin replied that it would, without revealing results from previous parts of the survey.

Health Needs Assessment Work Group Report

Donna Mosby, Member
Oak Ridge Reservation Health Effects Subcommittee (ORRHES)

Ms. Mosby reported that the Health Needs Assessment Workgroup had assisted in the planning for the needs assessment in the following ways:

- They estimated travel time and distance that people would be willing to travel for focus groups.
- They identified major events in the communities, which will be helpful in planning the focus group meetings.
- They are providing suggestions for appropriate meeting locations in the various communities.
- They are providing input regarding public notification for the focus groups.

Mr. Lewis added that the workgroup had been concerned about the possibility that the focus groups might be too large. Alternatives such as “availability sessions” or a town meeting will assure community input.

Presentation and Discussion: ORRHES Process and Administrative Issues

Dr. Jerry Pereira
CDC/ATSDR

Dr. Pereira described a recent meeting that he, Sandy Isaacs, and Bert Cooper conducted in Oak Ridge. He suggested that the Subcommittee wait to conduct their self-evaluation, as many of the issues that emerged from his meetings were being addressed currently.

The ORRHES is established to advise ATSDR, and possibly other federal agencies. For this function to be effective, the agency should not give a series of presentations to the Subcommittee. The Subcommittee needs good information, but it is also incumbent upon the agency to request input and assistance from the Subcommittee. The agency should take responsibility for achieving closure on these topics.

There should be thought given to collapsing workgroups. Accurate workgroup minutes are important, but the workgroups do not supplant the Subcommittee. Decisions have to be made in the Subcommittee.

Budget talks are beginning, and the funds available for Oak Ridge will not be certain until February or early March. Fiscal responsibility is required. Dr. Pereira said that he would assess the budget available and the needs of the Subcommittee and ask for more funds if they are needed. He will keep the Subcommittee informed.

When the Oak Ridge Field Office was established, the agency selected Bill Murray to be the Field Officer because of his experience and because of the technical issues of Oak Ridge. The agency, however, did not consider the need for administrative and logistical support in the office. Dr. Pereira hoped to establish an absolute process for, and system of, maintaining files and records. There is also the possibility of using a software package for this maintenance. There will be new staff in the Community Involvement Branch in Atlanta, and these staff members might be able to provide additional support.

He explained that Jack Hanley is the lead for this site. Sandy Isaacs and Dr. Pereira have overall management responsibility for the site. Dr. Paul Sharpe is the Senior Health Physicist in Atlanta. Ms. Dalton, as the Designated Federal Officer, advises the Subcommittee regarding the federal aspect of the law. She assists with other tasks, but her key role is this advisory one. Marilyn Palmer is the Committee Management Specialist. Coordination is critical between this Subcommittee and other agencies. Dr. Pereira recommended the following changes in the field office hours:

- Mondays: Noon - 8:30 pm
- Tuesdays, Wednesdays, and Thursday: 10:30 am - 7 pm
- Fridays: 7:00 am - 3:30 pm

The agency will strive to keep the office open in the event of Dr. Murray having to be away.

Subcommittee meetings usually occur every three months. This timing does not lend itself to process or to steady progress. The agency considered benefits and limitations to the current, two-day format for the meetings and has created new formats for consideration. The new options are:

- **Option A:** One, 4-hour meeting per month. This option would be very difficult to manage logistically. It is also not fiscally feasible.

- **Option B:** One, full-day meeting approximately every six weeks. This option this will increase efficiency and put pressure on the agency and the Subcommittee to be prepared.

Dr. Pereira supported Option B and assured the Subcommittee that they would not "stuff the agenda." For instance, if the full Subcommittee does not have a full day of agenda items, then the remaining time could be spent in workgroup meetings. Costs for each option were circulated. Option B was the most cost-effective. Other methods for conserving budget dollars include using a local recorder and meeting in a location that does not charge a fee, such as the YMCA.

He observed that Oak Ridge is the most committed community in which he has worked. Because of that commitment, he is focused on helping the Subcommittee get its work done and on facilitating the workgroup activities.

Discussion Summary:

˜ Ms. Dalton reminded the group that they are paid $250 per day, regardless of the length of the meeting. They cannot pay "half days" at present, but Committee Management is assessing the possibility of pro-rating the salaries. The language in the charter would have to be amended to pay half-days. At this point, however, Option A is not possible. If Option B is selected, and it is possible to hold workgroup meetings on the same day as full Subcommittee meetings, then the workgroups would only have one additional meeting per month.

˜ Ms. Sonnenburg supported Option B, but pointed out that if the Subcommittee's agenda is full, then it will not be possible to hold a workgroup meeting that day. She did not want to meet for more than ten hours in a day. Dr. Pereira agreed, adding that workgroup meetings would only be included if the Subcommittee meeting agenda is not full.

˜ Ms. Sonnenburg asked about the procedure by which the Subcommittee could request, for instance, a person from an agency to speak at a Subcommittee. Dr. Pereira sais that the first question is whether the requested agenda item is germane to the work of the agency and the purpose of the Subcommittee. Dr. Davidson added that the workgroup chairs could communicate these questions to Ms. Sonnenburg as the chair of the Agenda Workgroup. Ms. Sonnenburg wondered whether a Subcommittee vote was needed to set an agenda item. Dr. Davidson replied that a full Subcommittee vote was not necessary.

˜ Ms. Sonnenburg observed that outside consultants had accounted for over half of the past year's budget. She wondered whether the Subcommittee or Agenda Workgroup could be consulted in the future before these consultants were brought on. Dr. Pereira answered that part of the large figure was due to Subcommittee start-up. He expected the figure to drop in the year 2002. Dr. Hanley added that much of the budget was devoted to preparing for the Health Needs Assessment. Dr. Pereira felt that the Subcommittee should approve future expenditures on lecturers or contractors.

˜ Dr. Jerry Kuhaida felt that having an administrative assistant in the field office would have a major impact on the work of the Subcommittee. The ability to keep track of Subcommittee and workgroup progress will help them be prepared for meetings every six weeks. He also offered to suggest meeting locations that were free of charge.

˜ Ms. Kaplan said that the Subcommittee had asked that budget information be made available on the website. Openness in government is crucial to public acceptance. She wondered about other ways to save money, such as not flying consultants in to meetings and having video- or tele-conferences. Dr. Pereira noted that teleconferencing is very expensive, but he appreciated Ms. Kaplan's point. He said he planned to take responsibility for how money was spent and he encouraged the group to focus on getting closure on items.

˜ Ms. Dalton was aware of previous requests for budget information. The agency has to get approval before releasing any of that information. She reiterated that the majority of funds were connected to the Subcommittee start-up. She noted that usually, speakers are invited to the Subcommittee based on requests from the workgroups. These speakers are given an honorarium. If external speakers who require compensation are requested, then Dr. Pereira wants the request to be justified.

˜ Mr. Pardue was encouraged by the proposed changes. He suggested hiring part-time administrative support for the Oak Ridge Field Office. Dr. Pereira hoped to use his existing staff to create a process to manage the office. The possibility of having local, part-time help would be considered, along with the possibility of using Atlanta staff on occasion, when the budget information becomes final in February, 2002.

˜ Mr. Pardue asked about potential disagreements between agency branches, the Subcommittee, or development of the PHA. He wondered whether Mr. Hanley had the authority to resolve discrepancies and budgetary responsibility as a Project Manager. Dr. Pereira replied that Mr. Hanley has a responsibility to complete the Public Health Assessment. Decisions involving personnel, time, or money may require approval.

˜ Mr. Hill reflected on Option B, suggesting that the days be eight hours long, not ten. He also supported conducting meetings from 12:00 pm until 7:00 pm. A problem with conducting meetings at the YMCA is having adequate time for lunch, as restaurants are not accessible. Also, the meetings do not necessarily have to be in Oak Ridge. If they are held in other communities, then those communities' participation level might go up.

˜ Mr. Lewis complemented Dr. Pereira for capturing key issues that had been addressed at the meetings. He feels that the ability to generate detailed minutes from the workgroups

is critical, and that project planning will help them plan their budgets. He advocated for establishing a community health-related concerns database with sorting capabilities that would allow for links between concerns and findings. He pointed out the difficulty in addressing and closing issues if they have not identified the issues themselves. These issues are integral to having an infrastructure in place and to make their work effective not just for the Subcommittee, but also for the members of community. He suggested that the workgroups comment on the proposed changes before they take effect. He also supported a periodic "lessons learned" meeting with the ATSDR management team.

˜ Dr. Pereira felt that a workgroup should help create the Standard Operating Procedure (SOP) for the field office. There is also the potential for using project management software. He again suggested that the Subcommittee wait to conduct its evaluation.

˜ Dr. Davidson asked the Subcommittee to make a recommendation to ATSDR for their meeting format.

Motion 2

Ms. Sonnenburg moved that the Subcommittee recommend adopting "Option B" to the agency; that is, meeting every six weeks, and that attempts be made to ensure that the meetings last no longer than eight hours. Mr. Hill seconded the motion, and the Subcommittee had the following discussion.

<u>Discussion Summary:</u>

˜ Mr. Hill suggested that the meetings should be held from 12:00 pm until 8:00 pm, or from 11:00 am until 7:00 pm. He also asked for discussion regarding rotating meeting locations.

˜ Mr. Lewis expressed concerned that rotating the meeting locations would conflict with the goal of saving money. The upcoming focus group meetings and other community meetings might capture the issues that would be addressed by rotating the meeting locations. Dr. Davidson said that the purpose of rotating meeting locations was so that community members could be introduced to the Subcommittee process and so that the Subcommittee could see the members of other communities.

˜ Dr. Craig suggested that the motion not demand that meeting locations rotate, but indicate that rotation is a priority.

˜ Mr. David Johnson felt that potential locations should be considered in the nine counties that make up the area of concern. Dr. Pereira said that rotating meeting locations shows good faith on the part of the Subcommittee and the agency.

˜ Ms. Sonnenburg wondered if the motion could incorporate wording to indicate that meetings would move locations occasionally.

˜ Mr. Lewis approved of Option B as an interim measure, but felt that Option A should also be considered as a possibility for the future, perhaps in a workgroup.

˜ Dr. Davidson was not in favor of Option A because of logistical and administrative problems such as filing in the federal register.

˜ Ms. Kaplan said that a workgroup should examine the options, but that the Subcommittee should adopt Option B now, knowing that it could change in the future.

Motion 2 – Amended

This motion was amended as follows: The Subcommittee recommends adopting "Option B" to the agency; that is, meeting every six weeks. The meetings will last from approximately 12 noon until 8 pm, and ATSDR will consider rotating the meeting locations at its discretion. Dr. Davidson called for the vote. The amended motion passed by a vote of 13 in favor and 1 opposed.

Discussion of ORRHES Evaluation

Ms. Jan Connery
Eastern Research Group (ERG)

Ms. Connery addressed the group via telephone, explaining that the self-evaluation would focus on the Subcommittee's function and involve Subcommittee members and liaisons. Ms. Connery offered the following reasons to conduct this evaluation:

‘ The proposed evaluation complements ongoing efforts and contrasts ongoing feedback mechanisms. Often, mechanisms for offering feedback or making changes or improvements rely on spontaneous communication. While this communication among Subcommittee members is important, it may only occur in one workgroup. Not all

members, therefore, have the opportunity to contribute. It is impossible to involve all members in meetings, and comments offered are not anonymous, so some members may not feel comfortable sharing their thoughts. This evaluation would dovetail into the extant mechanisms for gathering feedback. With this system, all Subcommittee members will lend their anonymous input. They will have time to reflect on issues, rather than having to offer their initial thoughts in a meeting.

- Timing is good. The Subcommittee has been in existence for one year and has been able to experience the four stages of becoming a functioning unit:

  - *Forming*: The initial coming-together
  - *Storming:* The difficult stage of getting adjusted and developing ground rules
  - *Norming:* "Getting in the groove" to function effectively
  - *Performing*: When the group is able to produce

  She suggested that the Subcommittee is in the "performing" stage, which lends an opportunity to reflect on the first three stages and to think about how the Subcommittee's function can be improved. As it is still a young group, the Subcommittee is still flexible.

- It is recommended by COSMOS report. The COSMOS report represents a "mega-evaluation" commissioned by CDC. It involved four other subcommittees, and amongst its conclusions was the suggestion that "periodic evaluation of the advisory process should identify areas of concern early (before they impede the advisory process), and, as a result, improve the cost-effectiveness of the advisory process (currently a major concern to agencies)."

There are several goals for the evaluation:

- Obtain constructive feedback
- Generate ideas for improving Subcommittee function
- Give all members a chance to participate
- Provide a baseline

Since the evaluation will include all members' input, the final report will discover themes and similarities in what members feel should be improved and in what works well. If evaluations are done in the future, then this initial report will provide a baseline by which progress and improvement can be measured. The self-evaluation will be open-ended. It will be comprehensive because the questions will prompt feedback in a variety of areas.

The process for the evaluation begins with a collection of proposed areas that it should cover. All Subcommittee members will have a chance to contribute to the evaluation's substance. Then,

ERG creates the format for the evaluation. Subcommittee members complete the evaluation, and ERG creates a summary report from all of the comments, which will be provided at the next Subcommittee meeting. There are three ways to participate in the evaluation so that it will be convenient. Subcommittee members can respond by e-mail, fax, or via telephone with an ERG staff member.

The anonymity of the evaluation is very important, so responses can be sent via postal mail. Further, anonymity will be assured when ERG blacks out identifying information on the responses. The report will not include names or even genders. Copies of individual evaluations will not be available.

Areas that have already been suggested for inclusion in the evaluation include:

- Subcommittee meeting format and procedures
- Effectiveness of the chair
- Effectiveness of workgroups
- Interaction of Subcommittee with ATSDR, liaison members, and members of the public
- The Subcommittee's access to consultants

Next steps for the Subcommittee are to:

- Decide whether the Subcommittee will conduct the evaluation;
- Provide input on evaluation topics; and
- Participate in the evaluation.

As Subcommittee participation is so important, Ms. Connery suggested that voting in favor of doing the evaluation implies a commitment to participate, and she suggested a time-line and provided her contact information.

<u>Discussion Summary:</u>

- Mr. Peter Malmquist observed that the Subcommittee had already conducted a self-evaluation in the meetings with Dr. Pereira and other ATSDR staff. He felt that hiring ERG at this time would be a waste of money. Mr. Lewis agreed that Dr. Pereira had already addressed the Subcommittee's issues that had emerged after the series of meeting. He suggested that the Subcommittee take time to see how the changes work before conducting a self-evaluation.

- Dr. Davidson noted that the work is only proposed at this point, noting that the proposed self-evaluation would have more detail than the meetings with Dr. Pereira. The format also lends itself to getting more feedback from more members of the Subcommittee, as

not all members participated in the meetings. This evaluation would yield a written report that could be used as a baseline.

- Ms. Kaplan complemented the use of the telephone for Ms. Connery's presentation. She also proposed compiling the information from the meetings with ATSDR staff into a report.

- Ms. Connery was not familiar with how the information was captured, but if the notes were written or on tape, she said she could prepare a summary report from them. She asked whether the evaluation with ATSDR was comprehensive.

- Dr. Davidson observed that the meetings were focused on concerns rather than on both positive and negative aspects of Subcommittee function. She hoped that Subcommittee members would evaluate their individual participation.

- Mr. Lewis commented that when the Subcommittee has direct access to consultants, work goes more smoothly. He also felt that workgroup function should be examined.

- Dr. Davidson noted that in the meetings with ATSDR staff, she did not receive feedback on her effectiveness as the chair. Mr. Lewis added that the chairs of the workgroups would benefit from feedback as well. They should consider how to get better participation from all Subcommittee members in workgroups.

- Ms. Dalton said that discussions with ATSDR were helpful, but an evaluation from ERG gives the opportunity to capture everyone's comments and concerns.

- Dr. Kuhaida said that going through another evaluation process would be duplicative. He did not participate in the meetings with ATSDR staff members, but the issues and proposed changes represent a major step for the Subcommittee.

- Dr. Davidson observed that the Subcommittee did not appear to want to pursue the self-evaluation at this time.

- Ms. Connery reflected on the possibility of creating a report from the ATSDR staff meetings. She suggested that such a report could be created and then circulated to members of the Subcommittee for additional comments. With this approach, Subcommittee members who were not at the meeting could provide input. ERG could consolidate those comments into an addendum to the report. This idea relied on clear records from the meetings and on whether Dr. Pereira is willing to share his notes. Mr. Lewis suggested interviewing the ATSDR staff who participated in the meetings to supplement the notes.

~ Mr. Washington felt that having an unbiased person create the evaluation was preferable. He had not known of the ATSDR staff meetings, so his input would not be reflected in the notes from the meetings. He supported adding a sick worker who is receiving Social Security to the Subcommittee. He had participated on FACA committees that included members who were receiving Social Security benefits. Dr. Davidson said that the ATSDR staff visits were announced via e-mail and postal mail. She was sorry that the information had not reached Mr. Washington.

~ Mr. Washington said that e-mail is not a good medium for communication. He noted that members of the public may feel that the Subcommittee is working in areas that are not in the interest of the Oak Ridge communities. Dr. Davidson said that this project is a self-evaluation, so it is conducted only by Subcommittee members.

Motion 3

Mr. Malmquist moved that the Subcommittee not enter into a self-evaluation at this time. The motion received a second.

Motion 3 – Amendment

Ms. Mosby amended the motion, adding that a summary of comments from the ATSDR staff meetings be created, that the Subcommittee assess the effectiveness of the new changes in format and procedure, and that the Subcommittee then evaluate its work in mid-year, 2002. The amendment received a second. The amendment passed with a vote of 12 in favor to 2 opposed.

Motion 3 – Amended

The Subcommittee would not enter into a self-evaluation at this time. Instead, a summary of comments from the ATSDR staff meetings will be created. The Subcommittee will assess the effectiveness of the new changes in format and procedure and evaluate its work in mid-year, 2002. The motion was approved with 11 in favor, 2 opposed, and 1 abstention.

Ms. Dalton reminded the group that workgroup chairs would be available during the lunch hour to discuss ongoing activities and to provide updates.

Dr. Davidson reminded the group to re-commit to the workgroups. Mr. Hill said that

workgroups require a quorum, so he hoped that people who signed up would attend meetings. Mr. Lewis added that workgroup members should take on responsibilities. Mr. Washington noted that any member of the public can become a member of a workgroup.

Work Group Reports

Chair's Presentation

Dr. Kowetha Davidson, Chair
Oak Ridge Reservation Health Effects Subcommittee (ORRHES)

Dr. Davidson began the Work Group Reports with a presentation from the Guidelines and Procedures Workgroup. The Subcommittee did not vote until the next day. The Guidelines and Procedures Workgroup had set to the task of amending the Subcommittee bylaws. This review was scheduled for the September meeting, but was postponed. The first proposed change was in Article 9, Section 4, which currently reads:

> *"The Workgroups shall include the Guidelines and Procedures Workgroup, the Agenda Workgroup, and the Communications and Outreach Workgroup."*

The proposed change:

> *"The Workgroups shall include the Guidelines and Procedures Workgroup, the Agenda Workgroup, the Communications and Outreach Workgroup, the Health Needs Assessment Workgroup, and the Public Health Assessment Workgroup."*

The rationale for this change is that these two additional workgroups will be active for some time.

The second proposed change was to this extant statement:

> *"A quorum at workgroup meetings shall consist of a simple majority of Subcommittee members who are members of the workgroup."*

The proposed change:

> *"A quorum at workgroup meetings shall consist of two Subcommittee present in person at the meeting."*

The rationale for this change comes from the difficulty that some workgroups have experienced in reaching a quorum. This amendment will allow the business of the workgroup to continue even if the majority of Subcommittee members are present. This proposed change is not designed to circumvent establishing workgroup meetings at a time which a majority of members can attend. Meetings are best scheduled after 4:00 pm.

The last proposed change was an addition to Article 9, Section 14 and addressed Subcommittee members who sign up for workgroups but who do not attend workgroup meetings:

> *"Subcommittee members who are absent in person or by conference phone from three consecutive workgroup meetings and who do not provide advance notification of their absence to the workgroup chair shall have their name removed from the roster of the workgroup. The member may be reinstated after providing notification to the workgroup chair prior to the next workgroup meeting of their intention to join the workgroup."*

Subcommittee members should recommit to the workgroups so that there is no question as to the workgroup's membership. Communication with the chair is key.

Discussion Summary:

˜ Mr. Lewis wondered about the possibility of combining some of the workgroups. Dr. Davidson said that if the Subcommittee elects to combine workgroups, then the bylaws can be amended as needed.

˜ Mr. Washington felt that the third change made workgroup functions excessively difficult. Each workgroup should determine its procedures within the purview of the FACA charter. He felt that the simpler the procedures, the more work that can get done.

˜ Dr. Davidson commented that workgroups do not function under FACA, but operate according to guidelines established by the Subcommittee. Few bylaws pertain to workgroups, and the proposed changes offer some structure for them.

˜ Mr. Washington felt that if structure is left to the discretion of the workgroup, then more work will be accomplished. For instance, other FACA groups' workgroups keep detailed minutes.

˜ Ms. Kaplan said that the third change might be irrelevant if the changes in how quorum is achieved are adopted.

˜ Dr. Pereira said that the issue is not how many Subcommittee members attend each workgroup meeting, since Subcommittee members who are not officially members of

workgroups are still welcome to attend workgroup meetings as citizens. The issue is defining the original members of the workgroups.

- Dr. Davidson felt that if a Subcommittee member commits to a workgroup, he or she should take responsibility for participating in the workgroup meetings or at least inform the chair if he or she is unable to attend a meeting.

- Mr. Lewis likes workgroups because they help clarify issues to bring to the Subcommittee for resolution. He feels that workgroups need Standard Operating Procedures (SOPs). Their function will then be more efficient. Dr. Davidson said that workgroups can establish their own SOPs, as the Subcommittee bylaws are general in their guidance.

- Mr. Pardue described the process used by the end-use working group. Any member of the public can participate in meetings, voting and contributing their expertise. The workgroup deliberated on issues. He favored as informal a structure as possible, but recognized that there has to be some structure. The current process works well.

- Dr. Davidson emphasized that these bylaws only apply to Subcommittee members, not to members of the public.

- Ms. Mosby commented that workgroup business cannot be conducted if members are not present. The suggested changes support getting work done in the workgroups.

Agenda Work Group Report

Ms. Barbara Sonnenburg, Member
Oak Ridge Reservation Health Effects Subcommittee (ORRHES)

Ms. Sonnenburg presented a report from the Agenda Workgroup, explaining that she is newly appointed to her position as chair. The group met twice before the current meeting and made few changes, as many of the agenda items were carried over from the abbreviated September 11th meeting. She asked Subcommittee member to approach her with ideas for the agenda, whether specific items or general areas that need to be addressed.

Communications and Outreach Work Group

Mr. James F. Lewis, Member
Oak Ridge Reservation Health Effects Subcommittee (ORRHES)

Mr. Lewis reported that his co-chair in the workgroup had resigned. The workgroup met on November 8th and focused its discussion in three areas:

' The status of website
' The fact sheet
' Concern forms

The workgroup created a recommendation for adopting a website layout and linkages. The fact sheet is intended to describe the essence ORRHES. It includes information about the Needs Assessment, the Public Health Assessment, and how the workgroups work together to get information to the public. Members of the workgroup identified a sample form that could be made available to the public to capture concerns. Approval for these forms is necessary, and work is being done to obtain this approval.

A non-Subcommittee member recommended developing a database to capture concerns that have been raised both by historical work and by ongoing work. It is critical to capture these issues, consolidate them, and provide linkages to resolutions or findings related to them.

Ms. Dalton previously circulated drafts of a fact sheet and a community health concerns sheet. Since then, the Communications and Outreach workgroup developed its own sheet, so they were combined. The concern sheet may not include questions, because it could then be construed as a survey. A draft of the combined sheet would be available soon, including language suggested by the workgroup.

Mr. Lewis commented that the process of creating the website had been frustrating. He hoped that a formal communication strategy could be developed for the workgroup and for the Subcommittee as a whole. There is an existing website that is not an official ATSDR, ORRHES website. It is important, therefore, to get their site "up and running."

<u>Discussion Summary:</u>

˜ Dr. Davidson clarified that ORRHES does not have a website, official or unofficial.

˜ Ms. Dalton indicated that they are awaiting approval from the Subcommittee on the proposed templates for the website. Everyone has had the opportunity to evaluate the draft templates. The Communications and Outreach workgroup recommendations on site maps and templates were indicated in the pre-meeting materials. Once the templates are approved, the contractor has to apply the links, then pilot-testing can begin. She estimated this time at two weeks.

˜ Dr. Davidson reminded them that the workgroup had recommended that the Tennessee Department of Health (TDH) and Environmental Protection Agency (EPA) links be included. Ms. Dalton said that links can be added later, but the larger headings cannot be changed.

~ Ms. Kaplan asked whether budget information could be included. Ms. Dalton replied that information that has been presented as public information could be included.

~ At Mr. Lewis's request, Ms. Dalton described the process by which the site would be controlled and maintained. Once it is finalized by the contractor, it still has to be approved by the internal ATSDR website committee. It can then be included on the ATSDR home-page.

~ Dr. Davidson wondered if the Communications and Outreach Workgroup would consider places in outlying areas where the Subcommittee could put its information.

~ Mr. Lewis suggested that HRSA might be a "related link." Dr. Davidson added that NIH could be included because of their work with iodine.

Public Health Assessment (PHA) Work Group Report

Mr. Bill Pardue, Member
Oak Ridge Reservation Health Effects Subcommittee (ORRHES)

Mr. Pardue referred to a memo which summarizes the workgroup's recent activities. They meet twice a month and the meetings are well-attended. Meeting summaries are available, as Ms. Galloway has served as their recorder. Having a defensible, factual, permanent record will be important as the group will work for some time and have personnel changes.

Their work began by examining the PHA process. They also considered the technical issues associated with the Iodine-131 reconstruction part of the PHA. After an epidemiological workshop, the workgroup engaged in a "dry run" evaluation of an epidemiological report by Dr. Joseph Mangano. Dr. Mangano's report concludes that increases in cancer rates in Oak Ridge are attributable to radiation releases from the Oak Ridge Reservation. Dr. Lucy Peipins led the workgroup through an evaluation of that report, which led to the workgroup's assessment that the information in the report does not support the conclusions reached.

The PHA group also developed a case history file, which is a systematic capturing of concerns that the public brings to the Subcommittee. Mr. Lewis added that this approach provides summaries of their efforts, including reports. When conclusions are reached, it will be possible to retrace the logic and process that led to them.

Mr. Pardue listed the PHA's recommendations:

- The Mangano paper should not be considered in the development of the Public Health Assessment.

- EPA is undertaking a soil sampling program in Scarboro. The Subcommittee was under the impression that a wider program would cover a larger community area, which most citizens seem to support. The status of this larger program is still uncertain. Therefore, the PHA workgroup has drafted a letter to Dr. Koplan, Director of CDC/ATSDR, which includes recommendations as to how that program should be designed and conducted.

- The PHA workgroup supports the need for administrative help in the Oak Ridge Field Office, particularly in maintaining files and records.

Discussion Summary:

- Mr. Washington commented on the range of uncertainty in the data used in the Mangano report due to the time that numbers of deaths in Oak Ridge began to be counted. There are also uncertainties in exposure numbers. He asked about how decreases in cancer deaths in Oak Ridge compare to the general population of the United States. Mr. Pardue replied that he did not have the exact numbers. Dr. Davidson added that in the evaluation, they did not use numbers or information that was not included in the report.

- Mr. Pardue explained that the workgroup considered the reasonableness of the interpretations made in the report. Deficiencies in the report were included in a matrix. Some members of the workgroup had consulted the National Cancer Institute (NCI) website to gather other data regarding cancer deaths. Mr. Washington noted that data regarding cancer deaths in the Oak Ridge vicinity have just recently been kept. Mr. Pardue said that the workgroup pointed out that data were uncertain in the 1950's.

- Ms. Kaplan commented on the workgroup's struggle with finding a person to keep their minutes. She expressed her appreciation for Ms. Galloway's work.

- Mr. Washington wondered about the appropriate level of detail for workgroup meeting minutes. Dr. Davidson replied that workgroups decide the level of their minutes. Mr. Pardue said that the PHA workgroup had opted for detailed minutes because of the complexity of the technical issues that they address.

- Dr. Akin asked that he be copied on the memo to Dr. Koplan. Dr. Davidson apologized for the oversight.

~ Mr. Lewis expressed hope that by documenting technical issues in detailed minutes, issues can be captured in a database and eventually resolved.

Ad Hoc Mission Statement Work Group Report:

Ms. Karen Galloway, Member
Oak Ridge Reservation Health Effects Subcommittee (ORRHES)

In the July meeting, it was decided that the Subcommittee needed a mission statement, said Ms. Galloway. An ad hoc committee comprised of Subcommittee members and members of the public held three meetings to answer this need. Using a model from another group, they developed a draft of a vision statement, a mission statement, goals, and objectives.

The workgroup has offered a vision, mission, and goals. The vision statement is the absolute or ideal perception for the group. The mission statement addresses the scope and purpose of the Subcommittee's work. Goals are broad statements of how the Subcommittee will achieve its mission, and the objectives identify measurable ways in which the goals are achieved. The objectives will require more refinement to make them measurable.

The draft mission statement is:

> "To provide ATSDR and CDC with advice regarding public health studies and activities relating to people who may have been exposed to radioactive and chemical emissions from the ORR."

The draft vision statement is:

> "To promote the health and well-being of all residents in the communities surrounding the ORR."

The draft goals are to:

> "Conduct an unbiased and objective review of the previous studies;
>
> "Evaluate information on the release of hazardous substances into the environment from the ORR;
>
> "Assess current or future impacts on public health;
>
> "Identify, review, and advise on follow-up studies and actions needed;

"Review the Public Health Assessment document; and

"Assure that information is made available to the healthcare providers as well as the public to allow them to make informed decisions about health issues that may be related to their off-site exposures from the ORR."

Discussion Summary:

˜ Dr. Davidson felt that the statements should be kept general. She commended the Ad Hoc Workgroup for their efforts.

˜ Mr. Pardue suggested eliminating "well-being" from the vision statement, as "well-being" includes issues such as finances that are outside the scope of the Subcommittee. He also suggested adding "affected by ORR activities," as the Subcommittee focuses on residents of the community that have been affected by releases.

˜ Mr. Lewis commented that the goals and objectives have to be linked.

˜ Dr. Craig did not feel that one of the Subcommittee's goals was to conduct the review of previous studies or to assess the PHA. The Subcommittee is assisting ATSDR in these efforts. He also offered that part of the Subcommittee's mission is to identify health issues and to assess health needs in the community affected by releases.

˜ Ms. Mosby observed that in the self-evaluation in mid-year 2002, it might be possible to measure progress on some of the goals. Either the Communications and Outreach Workgroup or an ad hoc workgroup could meet to formulate some measurable objectives. Dr. Davidson added that other work groups might want to formulate objectives as well, such as the PHA Work Group.

˜ Mr. Washington said that the affected communities should be named and it should be specified whether they were addressing 5, 7, or 9 counties. Dr. Davidson noted that the Subcommittee had voted on a map of the potentially affected area. There are portions of eight counties included on the map on which they are basing their work. Mr. Washington added that the counties should be identified in the statements.

˜ Ms. Sonnenburg was hesitant about adopting the goals, but was prepared to adopt the vision and mission statements. She suggested that the committee review the goals further, offering the following potential goal: "to conduct a review of the delivery of medical services and any real or perceived obstacles to this delivery."

- Dr. Davidson said that some goals could be adopted while others could be sent back to the work group for further refinement. Additional goals could also be added at a later time.

- Dr. Akin commented on the last goal, which he read as a "watchdog" function. He felt that if they plan to provide information to the public, then they should also take steps to ensure that the maximum amount of information is made available to the public and to practitioners.

- The group offered ideas for wording. Mr. Lewis advised them to be careful with the words that they choose, considering what information is reasonable and adequate.

- Dr. Akin reworded the goal to read as follows: "to assure that comprehensive (or another modifier) information is made available to the healthcare providers and the public to the end that information decisions may be made about health issues that may relate to off-site exposures to the ORR." He was not sure about separating the public and healthcare providers, Dr. Davidson noted that this goal relates to the Health Education Needs Assessment output.

- Ms. McNally felt that the last goal was one of the most important. She suggested that educating healthcare providers be listed as a separate goal from educating the public, as they are two different issues. If the healthcare providers are educated and informed, then the public will be able to rely on them to be knowledgeable about their problems so that their concerns will be heard. Ms. Kaplan related a recent experience with her doctor in which she mentioned her exposures to see how he reacted. He ignored her concern and did not try to educate her.

- Mr. Lewis wondered about the definition of the "public" and whether it referred to the general public or to individuals. Dr. Akin reflected on the line between the general public and individuals. The extent to which individuality can be addressed by a public, government-funded activity is an age-old question that is central to public health and medical practice.

- Dr. Davidson understood that the amount information needed would be included in the Health Needs Assessment process, which would result in recommendations regarding what education is needed, where it is needed, and where it should be targeted.

- Mr. Lewis recalled a community member's suggestion that the Subcommittee present information in a manner similar to the way that the Surgeon General presents information.

~ Dr. Creasia noted that the idea of "sufficient data" is difficult to use, as data changes and grows over time. Also, better information about chemicals of concern will likely emerge in the future.

Update on the Scarboro Soil Sampling Project

Cheryl Smith
Environmental Protection Agency (EPA)

Ms. Smith told the group that EPA is starting to get raw data packages from the Scarboro sampling effort that occurred on September 24th. It is the intent of the agency to present this information in January, 2002. This presentation will not be a final report, but an update to the Subcommittee and perhaps to the public in general. The timing and format of this update has not been decided. There will then be an opportunity to compare these initial findings to the May 1998 sampling performed by the Department of Energy (DOE).

Discussion Summary:

~ Mr. LC Manley asked whether EPA had enough preliminary data to tell whether there is any difference between the samples. Ms. Smith replied that the evaluation had not yet been made.

~ Mr. Lewis expressed hope that, if there is a major discrepancy between the efforts, DOE and EPA would be available to discuss it at the same time to achieve closure. Ms. Smith said she did not have the authority to make such a commitment, but she felt that the idea was sound. EPA's sampling effort was independent, so comparisons will come from EPA's technical expertise. DOE will receive EPA's results. She emphasized that EPA's work was in response to requests from the public and was not designed to show that "anything was wrong" with the DOE work.

~ Dr. Akin volunteered to take the suggestion to the people who would be responsible for this coordination. He agreed that if there are discrepancies, a coordinated response from the agencies will be less confusing to the community. As the EPA work was not an attempt to verify the DOE work, it was done at similar, but not identical locations. The samples could be different and both be right. The agencies could then present reasons for discrepancies.

~ Mr. Manley asked how differences could be explained, since differences will be perceived as one agency being "right" and the other being "wrong." Dr. Akin replied that

they would assess the known variables that might lead to different answers. For example, the sampling could have been done at different depths. There may be samples that cannot be explained, but the agencies will offer their best scientific guesses.

~ Mr. Pardue commented that DOE had been offered the opportunity to participate in the EPA soil samplings. Ms. Smith responded that DOE had accepted the opportunity, sending an off-site DOE representative to conduct split samplings.

~ Dr. Davidson said that the Subcommittee members would be interested in attending the January public update. She asked when the final report would be completed. Ms. Smith anticipated completion by May, including input from the public, stakeholders, and DOE.

~ Mr. Lewis noted that no transcript of minutes from the Scarboro effort was provided. He suggested that the next meeting be recorded.

Public Comment

Ms. Linda Gass
Member of the Public

Ms. Gass addressed the group, pointing out that the Subcommittee still needs to have a member with a history of interacting with sick workers. These stakeholders have not been represented. The Subcommittee also needs a member with a history of interacting with sick residents. An explanation for not having these representatives, that the White House liaison will not allow it, does not make sense. She commented on having a waiver so that a disabled person can serve on the Subcommittee. She introduced an example of a prior FACA committee which interacted with Social Security to get a waiver. She felt that this step would be reasonable on the path to creating fair and balanced representation on the Subcommittee.

She later showed the group the *Phase One Report, Volume Two, Part A of the Dose Reconstruction Feasibility Study: Tasks One and Two, Summary of Historical Activities, Emphasis on Information Concerning Offsite Emission of Hazardous Material*. The report was prepared by ChemRisk. She thanked Mr. Hanley for helping her to obtain the report after much effort. She has been through several requests for information. Some people in the public do not want much information, but Ms. Gass is a member of the public who appreciates background information and who checks references.

She said that it is extremely important to realize the “company town” effect in Oak Ridge given that, in Oak Ridge, there is not only the “company town” effect contributing to the suppression of information, but there is also the effect of DOE’s role as a long-term, major player in the

economy of the entire state of Tennessee. She posed the question, "How do you get to the truth, when the employees being interviewed have strong disincentives to reveal information about releases that could affect their careers as well as their bosses' careers and the state of the contractor?" Employees could even be considered to be unpatriotic if they talk about these facilities.

The state of Tennessee commissioned the Dose Reconstruction Study, and the Oak Ridge Health Agreement Steering Panel (ORHASP) worked for nine years. Ms. Gass told the PHA workgroup that she wanted to check these references before there was more discussion on the Iodine-131 Dose Reconstruction. She was asked to put this suggestion in writing and to make it a motion. The next meeting was in violation of the spirit of FACA. She was not asking for a "stop work" order; she only wanted access to the interviews to check the references. It was decided that she had the right to check the references, and she thanked Dr. Albert Brooks for supporting her in her efforts. The integrity of the Dose Reconstruction rests on these interviews with company employees.

Iodine-131 discussions have run their course, and Ms. Gass was concerned about setting a precedent for efforts regarding other contaminants of concern. She was told that the state of Tennessee contracted with ChemRisk to conduct these interviews. Subsequently, primary sources were destroyed. She has continued to ask for the interviews. If they are not headed toward a "whitewashed report," she said it was unclear to her why she could not get those interviews. She then read from the *Phase One Report, Volume Two, Part A, page 59: Personnel Interviews, "Interviews have conducted as of September of 1993 with approximately 50 individuals with extensive experience at the Oak Ridge reservation."* Ms. Gass noted that eventually, over 150 people were actually interviewed. *"The names of initial interviewees were provided by facility managers for key functional areas identified by ChemRisk."* Ms. Gass commented that if facility managers provided the interviewees, then there are questions about whether the interviewees had strong disincentives for information on releases to emerge.

"Each interviewee identified additional points of contact. Candidates for interviews were also identified from association with key historical documents. Some have not yet been located, and not all desired interviews have been completed at this time." Ms. Gass added that more interviews were done. *"While several individuals thought it necessary to obtain approval from Martin/Marietta and DOE, or from their current employer prior to consenting to an interview, only one individual has declined to be interviewed. Notes taken in the course of the interviews were reviewed by appropriate classification reviewers. The information obtained in the interviews is being summarized and entered into the project repository and the associated database."* She has tried to get those interviews, and has been told different things in trying to gain access to the project repository mentioned about.

Upon thanking the people who had helped her so far, she listed some of the places where she had been told to go for the interviews, including OSTI. The documents are public and owned by the state of Tennessee. History Associates, Inc. (HAI) was a DOE contractor that did work on missing mercury information. She has been able to get some response from them, and she implored the Subcommittee to help her get the interviews.

Discussion Summary:

- Ms. Dalton pointed out that as the CDC hiring freeze has been lifted, the procedure is underway to advertise for and select new members for the Subcommittee. She then addressed the topic of a waiver. Anytime a worker proposes to participate in the Subcommittee, the agency recommends that the individual seek legal counsel and make a decision based on his or her situation. It would not be ethical or legally practical to predict what benefits or compensation to which a person may or may not be entitled in the future. Issues with Social Security, for instance, should be addressed individually. In the past, such an individual was approved for the Subcommittee, but declined the position.

- Dr. Davidson emphasized that individual members of the Subcommittee should encourage people to apply for membership on the Subcommittee. Members of the public are also encouraged to apply.

- Ms. Dalton described ATSDR efforts to locate the documents in question. A letter to Patrick Lipford at the Tennessee Department of Health formalized these requests. The Communications Work Group forwarded a recommendation to ATSDR in September.

- Ms. Gass noted that part of the documents have been in Nashville and parts have been at OSTI. She recognized state budgetary problems that could be a contributing factor, but she reiterated that she had never gotten any interviews.

- Dr. Timothy Joseph offered insight into potential problems with the ChemRisk records. When the interviews started, each individual being interviewed had the right to say anything, classified or not. If the interviews contained classified information, or if the interviewee did not want his or her name associated with what was said, then there could be complications in getting the interviews.

- Dr. Albert Brooks noted that this situation was the first time that he had not been permitted access to information based on a reasonable request. Some of the operational staff of the project were interviewed and asked to give their impression as to the efficiency of the scrubber. Sometime later, they were interviewed again, and they reduced their numbers. Without knowing why these interviewees changed their numbers,

it is impossible to give an opinion regarding the validity of the conclusions that were drawn. The interviews are still important, but even more important is the perception that this information is being suppressed. If the information is classified, then that should be made known and the non-classified information should be released.

˜ Dr. Davidson presented an action item for ATSDR, asking that they continue to make a concerted effort to obtain the references that Ms. Gass has requested.

˜ Ms. Gass said that the list on the table was not complete, as she had been told that she had to request all items separately. She said that she wanted all of the interviews: the list on the table is an example. She was recently told by the state of Tennessee that not all materials were kept. In addition, the ORHASP meeting minutes indicate that classification issues have already been resolved.

˜ Ms. Kaplan served as chair of the liaison subcommittee of the Local Oversight Committee in 1995. She took on the task of interacting with retirees and requested those interviews from Tom Widner, from ChemRisk. He had the information, and she offered to locate it in her records.

˜ Ms. Sonnenburg wondered about an appropriate contact at the state level to get the issue resolved. Ms. Dalton replied that Patrick Lipford was the contact with the state, and a letter to him was included with the pre-meeting packet.

˜ Mr. Lewis recalled his work in checking and validating records. Sometimes, there are record retention clauses in the body of contracts. If the right clause is not in the contract, then even professionals may discard even primary sources. It might be possible to assess what was in those contracts.

˜ Dr. Creasia pointed out that often, materials get thrown away for other reasons, such as moving or retiring. He asked Dr. Brooks to provide more detail on the scrubbers who changed their numbers.

˜ Dr. Brooks replied that the same people were interviewed twice. Apparently, they were presented with other opinions or calculations that caused them to change their minds. It is important to learn what they were told and why they changed their minds. On the topic of data availability, he felt that there can be no report without backup data.

Motion 4

Mr. Pardue moved that the Subcommittee recommend that ATSDR continue to pursue this information in all possible manners. The motion received a second, and discussion continued.

~ Ms. Dalton noted that a recommendation from the July 31st Subcommittee meeting resulted in the responses that she had described.

~ Mr. Lewis commented that a properly-worded letter that goes through the appropriate system channels can force actions. The letter should ask a specific question and expect a detailed response.

~ Ms. Dalton reviewed the July 31st recommendation, which asked ATSDR to pursue Iodine-131 references from the Tennessee Department of Health. The ATSDR responded at the September meeting, and Ms. Dalton and Mr. Lipford had been in communication since August.

~ Ms. Kaplan pointed out that the list of requested references came under pressure. Those references should be in an archive.

~ Dr. Brooks asked about the state's response. Ms. Dalton replied that the state is working with ChemRisk to locate several of the documents. ATSDR has been searching for some of the documents on the list as well. Due to matters at another site, the principals at ChemRisk have not been able to locate this information yet.

~ Dr. Bill Murray said that he has contacted Mr. David Hamrin at the Oak Ridge National Central Laboratory files. Mr. Hamrin has records of what references are available at the DOE Reading Room and at the IRC. Dr. Murray has nine memoranda resulting from this search, which he will copy and provide to Ms. Gass. He has been told that the other references are in the DOE Reading Room.

~ Dr. Akin understood that the original request was not a comprehensive list of documents. He suggested that the request should be made again, including a complete list of documents. The importance of acquiring these documents should be re-emphasized.

~ Ms. Dalton reiterated that ATSDR had been working to obtain the documents, but that ATSDR policy is to make documents that they have generated in the past available. Requests for documents from other agencies are referred to that generating agency. They will do everything they can to request documents.

~ Dr. Akin wondered if the request could come from the Subcommittee, not from ATSDR.

~ Mr. Lewis suggested that they invite Mr. Patrick Lipford to address the Subcommittee on the issue.

Motion 4 – Amended

Dr. Davidson proposed a re-wording of the motion: ATSDR, at the recommendation of the Subcommittee, should pursue to the extent possible the whole list of references for the interviews from the Dose Reconstruction Study. Those interviews should be placed in the Oak Ridge Field Office. After the following discussion, the motion and amendment were withdrawn and replaced.

~ Ms. Mosby commented that if they cannot get a few of the references, it was unlikely that they would be able to get them all.

~ Dr. Akin felt that this issue was critical to the credibility of the Subcommittee and was unclear about why the information could not be requested from the Tennessee Department of Health. If the request could not or should not be made by ATSDR, or put the agency in an awkward position, then the Subcommittee should devise another way to make it.

~ Dr. Davidson said that the Subcommittee cannot make direct requests to the Tennessee Department of Health, but it can make requests through ATSDR staff or through Dr. Koplan.

~ Ms. Dalton noted that ATSDR had acted on the recommendation from July 31st as it was written. The new recommendation represents an expansion on the old one, and the request would be forwarded.

~ Dr. Davidson commented that another way to pursue the documents is to direct the request to the heads of the agencies involved: Dr. Koplan and the head of the Tennessee Department of Health.

~ Ms. Mosby said that more than one avenue should be pursued to get the documents. They could work as individuals, as members of the Subcommittee, or other ways.

~ Dr. Pereira advised that the list of documents requested and the reason for requesting them be forwarded to the director of DHAC for Dr. Falk’s signature. From Dr. Falk, the

letter would then go to the director of the Tennessee Department of Health. Justifying why the documents are needed is key to get the proper signature.

˜ Dr. Pereira also reflected on the mentality of a "company town," in which the tendency for workers to want to protect their jobs is a reality. He urged the Subcommittee and the public to judge the credibility of the information in the interviews based on what they know about the community.

˜ Mr. Pardue asked whether FACA prevents the Subcommittee from making a request from another agency. Dr. Pereira did not see a problem with the Subcommittee writing a letter, but added the risk that the Tennessee Department of Health might not recognize what ORRHES is, and therefore not respond to the letter.

˜ Ms. Sonnenburg suggested that Dr. Al Brooks write the letter and copy it to the Tennessee Governor's Assistant.

˜ Mr. Pardue retracted his motion and its amendment.

˜ Ms. Kaplan said that the request for the interviews is not just for the data or to assess the credibility of the report. The request is also a process issue, as taxpayers spent a great deal of money on the ORHASP committee. If that committee could not maintain the integrity of their references, then how could other committees expect to.

Motion 5

Ms. Mosby moved that the Subcommittee recommend that ATSDR continue to pursue the request for all interviews. A letter should be written to the heads of the agencies in question. The ORRHES should also issue a letter requesting all interviews. The letters should include rationales for why the information is requested. The following discussion ensued.

˜ Dr. Davidson was concerned about potential redundancies in the different methods for requesting.

˜ Ms. Kaplan wondered whether they were also asking for references. Dr. Davidson said that the request was for the interviews. She suggested that the Subcommittee forward this request to Dr. Falk.

˜ Ms. Mosby was concerned that Dr. Falk might not sign the letter or that action might not occur. Dr. Davidson said that their request could not be ignored, and that if their rationale is strong for the information, then they will get whatever action Dr. Falk can

accomplish. Ms. Mosby favored more attempts to get action.

~ Dr. Brooks suggested that the rationale include the statement that the credibility of the state is in question.

~ Dr. Davidson suggested that the PHA workgroup work with the details of the letter. She also asked that the motion ensure that the letter is drafted, finalized, and sent.

~ Ms. McNally reminded the group of the suggestion that the Subcommittee send its own, direct request to the Tennessee Department of Health. Dr. Pereira did not recommend that the Subcommittee ask Dr. Falk to sign a letter and then send one of their own that is, essentially, requesting the same thing. He suggested that the letter go through Dr. Falk. If Dr. Falk does not respond to the letter, then Dr. Pereira will inform the Subcommittee, but he expected that Dr. Falk would respond.

~ Dr. Bob Peele responded to the discussion, as he is a former ORHASP member. The committee wanted all records kept in this area. Mr. Lipford worked on an agreement for storage, but was not able to form an agreement, so the information is in Nashville. There have been other complications, such as a flood in the building where the records were kept. It is unfortunate that the records are not all in one, easily accessible place, as was ORHASP's intention.

~ Ms. Barbara Brooks of the Department of Energy, also a former member of ORHASP, described efforts to locate the information requested by Ms. Gass. As ORHASP had intended for the information to be available, copies of their materials and references were kept in the public document room. The materials were organized in a database of information about them and also scanned into electronic form. They are available on the Internet with a permanent URL. The descriptive database is bibliographic. The interviews are a small part of the information used by the researchers. Now, all materials belong to the state, other than what is kept in the public reading room. The public reading room is under-staffed and not policed, making it difficult to find materials there. She was not sure if more than what exists in that public database exists, and in what form. In the next week, the state has asked that Tom Widner come and organize all of the paper materials. She wondered whether this activity would make it possible for Mr. Lipford to respond to the original letter from ATSDR.

~ Mr. Malmquist called for the question.

Motion 5 – Amended

The PHA workgroup of ORRHES will draft, finalize, and send a letter for Dr. Falk's signature requesting all interviews used in the Dose Reconstruction Report. This letter will include rationales for why the information is requested. The motion passed with a vote of 10 in favor and 1 opposed.

Presentation and Discussion: Epidemiology Workshop Part II: Discussion of the Mangano Report

Dr. Lucy Peipins
Dr. John Merckle
Dr. Albert Brooks

Dr. Peipins spoke about how to evaluate and critique an epidemiologic study. She reminded the group that every scientific study and its scientific analyses are built on a body of knowledge and conducted to expand that body of knowledge. What is already known determines what needs to be known – studies "fill in the gaps." The body of knowledge represents the consensus of science. Once a study is completed, the author of the study and analysis publishes the results. The purpose of scientific publication is to present a new finding or insight into a problem. The results are shared and debated with scientists and the public.

Publication also demonstrates the quality and validity of the study by presenting the study's methods, design, analysis, and interpretation. This information allows other scientists and the public to judge the quality of the study. Authors are responsible for providing information on each component of the study so that readers can adequately evaluate the study. All assumptions and references must be justified and stated in the article. Epidemiologists have criteria to judge the quality of an epidemiologic study. There is no "perfect" epidemiological study. There are even limitations to clinical studies. The better the study meets the criteria, the more likely the readers are to accept the author's conclusions.

The author submits an article to a medial journal, which forwards the article to its peer reviewers. Peer review is an essential component of scientific work. These reviewers read the article and recommend whether it should be published. They can request additional information as well. The author must address all peer review comments before the article is published.

To illustrate the principles of evaluating an epidemiological study, Dr. Peipins used the article, "Cancer Mortality Near Oak Ridge, Tennessee" by J. Mangano, published in the *International Journal of Health Services*. These criteria should be applied to every article that is evaluated:

- Why was the study done?
- What hypothesis did the author have?

The question is usually found in that article's title or in the introduction. The main purpose of the Mangano article was to examine change in cancer mortality in 94 counties located within 100 miles surrounding Oak Ridge, Tennessee. Change from 1950 to 1952 was compared to changes from 1987 to 1989. That magnitude of change was then compared to change in the United States as a whole and the Southeast. The exposure of interest was radiation from Oak Ridge weapons production, which began in the early 1940's. Mangano included more specific hypotheses

Hypothesis 1:
An increase in all cancer mortality near Oak Ridge should be larger than the national and regional areas due to this radiation.

The following issues arise with regard to the first hypothesis:

- What type of study is this?

  - A descriptive study describes the health outcomes alone and answers the questions, what is the disease? Who got it? When were they sick? Where were they sick?

  - An analytic study attempts to answer the question of why one population gets a particular disease. The Mangano study is essentially descriptive, as exposure is largely based on location or residence in a county. However, because the study compares the rate of change in cancer mortality to the United States and to the Southeast, it also has an analytic component.

- Who was in the study? The Mangano population was the white population living less than 100 miles from Oak Ridge, in the 94 counties specified, between 1950 and 1952 compared with 1987 - 1989. The comparison population was the white population in the Southeast and the United States in that period.

- What was the exposure of interest? The article mentions several exposures from radiation, including chronic, low-level, ingested, emissions, and more. There are a variety of pathways and types of exposure.

- How is exposure defined and measured? Mangano did not measure exposure per se; however, exposure was defined as residents in a county near the weapons plant, residents in mountainous counties, residents in downwind counties, and residents in rural counties. Exposure measurement is often the "weakest link" in epidemiological studies. An individual can be assigned an exposure number anywhere along the pathway from when the radiation is emitted to when it is taken into the body. The goal is to have the most precise measure of exposure to reduce mis-classification. Residents in a geographical area is considered the poorest approximation to actual exposure on the hierarchy of exposure measurement. The numbers can be further refined with proxy measures such as drinking water use or length of time lived in an area. The best measurement is quantifiable personal measurement. The Mangano article exposure characterization is based on residence in a county in proximity to sites.

- What are some limitations or criticisms to how exposure was measured? Residence in a county is a poor measure of exposure. In the Mangano study, everyone who lived in the 94 counties was assigned the same exposure. It is assumed in the comparison with the rest of the United States that everybody was not exposed. In considering proximity, Mangano did not clearly define distance from the site. Roane County was not included, and the counties chosen for comparison were unclear. There was no justification for why these counties were chosen. Different pathways of exposure may exert a stronger influence than vicinity alone. The author assumes that rainfall may affect exposure, so he compares mountainous with non-mountainous counties. This approach seems general, as there is a great deal of variation in the rainfall in mountainous counties. These counties also have residents living in the valleys, so there is a mix of exposures. No previous studies were cited to support these assumptions in the article.

Hypothesis 2:
Within the Oak Ridge area, increase in cancer mortality should be greatest in rural areas, near the weapons plant, in mountainous areas, and downwind of the weapons plant.

The second hypothesis addresses differences between exposures in urban versus rural areas, but the author provides no rationale for the assumptions in the article. There is no rationale for not including Kentucky and Virginia. Rural areas are not free of risk. Information from dose reconstructions contradicts some wind patterns assumed in the article. It may be reasonable to assume that downwind counties will have higher cancer rates, but there are wind patterns affecting the four quadrants differently. The following issues arise with regard to the second hypothesis:

- What is the health outcome? The outcome of interest in the Mangano study was deaths from all cancers among whites in the specified counties in the specified times, compared with cancer deaths among whites in the United States and in the Southeast during the same times. It is important to measure outcome accurately. The study collected data from NCI. The study looked at all cancer mortality rather than specific cancers. Cancer is not one disease, but different types of diseases. Grouping them together may not get the appropriate information. There are a number of causes for cancers, and not all of them can be linked to the environment. Death certificate data are easily available, but there are problems with accuracy. This accuracy varies by causes of death and by regions of the country, according to who fills out the certificate. Accuracy varies by time as well: it is likely that cancer was under-reported in the earlier time frames.

- Was there selection bias in this study? Mangano used existing data, so this question is not relevant to this article. In evaluating other studies, however, it is important to discern how get into the study. Recruitment is particularly important, particularly if the exposed group is included on a volunteer basis and the unexposed group is not.

- Was there information bias in this study? Information bias concerns how information is collected on individuals. Questions must be asked and data must be collected in the same way for everybody. This aspect is not directly relevant to the Mangano study, but it should be recognized that the accuracy of cause of death certification can vary by region.

- What were the confounding factors? There is a possibility that the relationship shown in the study could be due totally or in part to other differences or risk factors between the two study groups. The author must address confounders and can do so in a number of ways. The study can be restricted to certain types of people or other risk factor information can be collected, for instance. Because Mangano's study was based on extant data, these measures were not possible. The potential confounders associated with cancer risk, then, are large. The author said that there was little or no migration in this area, and yet there was a large influx of people into the area when the plant first opened, and then a decline in population. Regional differences in life expectancy are another confounder. There are other regional sources of environmental contamination that might account for differences in mortality rates. The author should adjust or control for these confounders, and Mangano could not in this study.

- What statistical analysis was conducted? What method was used to measure the relationship between exposure and disease? In this study, the author calculated age-adjusted mortality rates for selected counties in the hypotheses area and compared them to the Southeast and the United States. The article provided little information on the actual statistical analysis or the justification for it. The selection of years was not

justified, nor was the choice not to evaluate specific cancers as opposed to all cancers.

With regard to the results, Mangano found positive results for each of the hypotheses. Given other concerns with the study, though, these conclusions may not be justified.

A 1965 article by Sir Austin Bradford Hill, called "The Environment and Disease: Association or Causation?" presents a number of criteria by which to judge a body of evidence or study. These criteria are guidance for understanding a study and include:

- Strength of association. How strong is the relationship between exposure and disease? In the Mangano study, there is a large difference.

- Consistency with the weight of evidence. Has this association been seen in other studies with different study designs? Has this relationship been seen in different populations? The association between radiation and cancers have been studied, both among workers and residents near sites.

- Is there a biologically plausible explanation between the exposure and the disease? In this case, there is: ionizing radiation mutates DNA and causes cancer. However, county of residence was used as a surrogate for radiation. The radiation was never measured for these individuals.

- Does risk of the disease increase with increasing exposure? As no doses were calculated in the Mangano study, it is not possible to see this association.

- Temporality: has the exposure occurred before the disease? This point is critical to understanding a study. This study cannot address this issue because it is impossible to assess whether individuals moved into the area and had cancer, or moved out of the area and had cancer.

The final questions that one must ask when evaluating a study are: Has the author convinced us of his conclusions? Does this study advance our knowledge about the relationship between exposure and disease? Some of the guidance criteria were met; however, the article includes no exposure measurement. The study also focuses on all cancers rather than on specific cancers. Use of death certificate data and the lack of potential confounders further limit the study. Because of these limitations, this study does not demonstrate a relationship between cancer mortality and radiation exposure as effectively as it could. This conclusion does not mean that the relationship does not exist, but this study fails to provide strong evidence for that relationship.

Dr. Merckle then addressed the group regarding statistical issues with the Mangano report. An Oak Ridge resident and retired civil engineer, he became interested in the Mangano report after reading an article in the *Oak Ridger*. He stressed that an important question to ask at the beginning of an epidemiological study is: Are the differences involved in the measurements likely random, or are they likely not random? This procedure is called "testing the null hypothesis."

Dr. Merckle spoke to Dr. Mangano to obtain more information with which to evaluate his statistical analysis. Dr. Merckle used Dr. Mangano's rates and populations to re-do the statistical analyses. He gave the group an overview of how he conducted these analyses. In the early 1950s, he concluded, the differences between cancer mortality rates in the Oak Ridge area and in the Southeast could have been, and likely were, due to randomness. In the late 1980s, however, the differences in cancer mortality rates appear not to be random.

The differences in the rates are very small, he reminded the group. These numbers must be approximate because the populations are not stratified by age, gender, length of exposure, or according to other contributing factors. These calculations are important to consider in evaluating studies, and Dr. Merckle advised the group to ask qualified epidemiologists or statisticians to assess the figures in studies.

Dr. Brooks then addressed the group on the topic of wind patterns. There is no actual measurement of exposure in Mangano's work: the same results would be obtained regardless of what the cause was assumed to be. Mangano assumes an airborne release and a wind effect from the southwest to the northeast. Oak Ridge wind patterns have been studied in detail by NASA and are well understood. They are probably 2/3 to the northeast and 1/3 to the southwest; therefore, Mangano's assumption that "downwind" is one direction is erroneous.

The rates of cancer mortality from 1990-1994 in the different counties do not seem to correlate to wind direction. The rates are the lowest "downwind" to the northeast and to the southwest, and highest to the northwest and the southeast. Counties also appear to be "skipped." Knox County has high rates, Cox County has low rates, then Greene County rates are high again. The study's presumptions are not borne out by other information that is available. Mangano would have to explain why wind patterns lead to mortality figures that are different from what is expected.

<u>Discussion Summary:</u>

~ Dr. Brooks inquired about the variance of the difference between Oak Ridge 5 and Southeast 5. He pointed out that if C was the average, and the average rate were zero, then the variance would be zero independent of the scatter of the data, which is not correct, because they are measured rates, not true rates.

~ Dr. Merckle replied a binomial distribution was assumed. Dr. Brooks pointed out that when numbers are large, a binomial distribution approaches a normal distribution. Dr. Merckle noted that the variance of a linear combination of these variables is taken as the sum of the variances of the individual terms for a normal distribution. The derivation comes from epidemiologic books.

At this point, members of the public were invited to comment.

~ Ms. Gass understood that a null hypothesis can never be proven. It can only be rejected at a certain level of probability, which is frequently .01. Dr. Merckle replied that a range of ratios must be established. If a difference is random, then 95 percent of the differences will fall between the limits. The reversal of the logic indicates that if the difference falls within the limits, then it is most likely random. There is a 5 percent possible error in that a number could fall outside the limits and still be random. The calculation cannot reveal the relative probabilities of randomness and non-randomness in a given situation.

~ Ms. Gass recalled Dr. Peipins' stress on the importance of data quality in evaluating an epidemiological study. She was concerned because the Mangano report uses county data: sometimes epidemiological studies springboard other studies, so there are other implications for the study. There does not seem to be another study to which the Mangano study could be compared, nor does it seem that any other studies have "spring-boarded" from the Mangano study. Dr. Peipins said that there have been other studies of populations around nuclear facilities, but none that have resulted from the Mangano study. The Mangano study is rarely cited anywhere, she added, and the journal in which it was published is not in MedLine.

~ Ms. Gass observed that a large amount of time was spent on proving that the study was based on weak data, which was established at the beginning of the process. She asked for comment on the availability of data, particularly the fact that county of residence is the most readily available research opportunity for an epidemiologist. Dr. Peipins agreed that the county data is easily available, which contributes to its attractiveness to a researcher. There are always trade-offs, though. Her purpose was not specific to the Mangano article, but to provide criteria for evaluating other epidemiologic studies and interpreting different data based on different exposures. All studies will have limitations.

~ Ms. Gass asked how to design a better project to measure radiation dose and to develop data on an outcome and what such a study might cost. It did not seem feasible to her. Dr. Peipins agreed that such a study would be difficult. Ms. Gass acknowledged that the Mangano study is based on weak data, but it is all that they have so far, as it has not inspired further studies.

˜ Ms. Gass emphasized that cancer is not the only outcome from radiation exposure. The Iodine-131 work is almost entirely focused on cancer as the only endpoint, but cancer is not the only health concern that people have in Oak Ridge. She suggested that ATSDR solicit community people by advertising: "Exposure Health Concerns?" Many people in the community are not aware that the issues are being discussed or that the field office exists. She read the following from minutes from a Subcommittee meeting from the previous year: *"In response to Subcommittee questions, Mr. Williams explained the following points: what interactions among chemicals is ATSDR exploring? Work is beginning on mixtures of contaminants within different media."* The listed chemicals are only 275 out of the thousands used, but they are the most prominent at the sites. She observed that often, they are told that work is "beginning." She asked what work is beginning. She was particularly concerned about chemicals and the interactive effects with radiation and repeated a comment that she had made when ATSDR staff was in Oak Ridge, conducting meetings. The toxicological literature includes information on work with synergistic effects that should be coming to the Subcommittee. These data gaps are critical data.

˜ Dr. Davidson commented that in working with mixtures and synergistic action with chemicals, they can be additive or antagonistic. In this work, the particular chemical mixture of interest must be examined, as information about another chemical mixture does not provide enough information. Ms. Gass felt that the toxicologists on the Subcommittee should bring this information to the Subcommittee and that it would be helpful in the area of health concerns to keep the Subcommittee informed.

˜ Mr. Hanley said that the Division of Toxicology puts out "Tox Profiles." Mixtures, synergism, and additive effects in environmental toxicology is in the infancy stage. He did not know how much was available. A toxicologist works with ATSDR, and as the screening process begins and the contaminants of concern are evaluated, they will see other compounds that may have an impact or an additive effect. First, they will evaluate individual compounds, then as part of the health implications, other compounds will be assessed as well. He said that he would follow up with the Division of Toxicology to ascertain to what Mr. Williams was referring in those comments.

˜ Dr. Creasia has been working on synergism for some time. Toxicological studies include dose-response studies, which almost always show that a single compound is synergistic by itself unless the dose has an exponent of one. Very few chemicals have a toxicological exponent of one.

˜ Dr. Brooks reported that in the early 1970's, ORNL started the Mao study to determine the effects of low-level radiation. This study was to involve a million mice and was

carefully controlled and designed. Before the experiment was completed, funds for the work were redirected to the war in Vietnam so that the number of mice was reduced so far as to be insignificant. Any epidemiological study that hopes to take a definitive look at low-level radiation will have to include approximately one million people. Normal, background radiation in the Oak Ridge area is approximately 300 milli-rems. The maximum airborne exposure outside the plant area is usually less than one milli-rem. There is no way that a study will be able to detect the effect of the normal, airborne radiation releases compared to background radiation on the general public.

~ Ms. Sonnenburg shared a response from Dr. Mangano. She had felt that it was fair to ask him to provide with a chance to comment on his report and on their assessment of his study. She called Dr. Mangano and mailed him the minutes from the workgroup meeting as well as the matrix. In addition, she asked for the new data to which he referred in his letter to the editor in the *Oak Ridger*. His response asked the committee to look at the changes that have taken place in his figures. Rates have increased in the counties around the Oak Ridge area in relation to Tennessee and the rest of the United States. She pointed out that the one column adds population for five years, and the other the population for four years. The cancer rates for the four-year time are higher, even with one less year in the count. He also separated data by age and lung versus non-lung cancer. She also has the raw data available.

Dr. Davidson thanked Dr. Peipins. She reminded the group to complete their checklists for consensus-building. She noted that the Communications and Outreach Workgroup needs more members and asked Subcommittee members to sign up for that workgroup. With that, the meeting was adjourned at 6:15 pm.

End of Day 1

Day 2: Opening Comments

At 8:19 AM on Tuesday, December 4, 2001, Dr. Davidson welcomed the group to the second day of the Oak Ridge Reservation Health Effects Subcommittee meeting. The Subcommittee did a "roll call," and there was a quorum present.

Presentation and Discussion:
Community Health Centers: Needs and Strategy

Dr. Robert Jackson
Associate Director for Primary Care
Southeastern Regional Field Office
Health Resources Services Administration (HRSA)

Dr. Jackson addressed the group on the topic of Community Health Centers, explaining that HRSA is the arm of HHS that is concerned with personal care, access to care, and disparities between and among population groups. The agency provides leadership for ambulatory care, primary care, and other special healthcare needs around the country. HRSA is leading the Health Centers Presidential Initiative and covers all 50 states and the territories.

For the first time in a long time, significant new resources are being devoted to community health centers and related organizations. There is not yet a budget for the fiscal year. Given the times, reductions in the number of new clinics and in the amount of money available are possible. To date, about 10.5 million people receive care from HRSA's various enterprises. There are well over 3000 access points. Instead of general primary care, some clinics have begun to address management of specific issues, such as diabetes, high blood pressure, and trying to improve pregnancy outcomes.

The National Health Services Corps is the clinical work force of HRSA. They offer scholarships and professional training through a popular program called loan repayment. Through prior agreement, clinicians work in under-served areas and in addition to compensation, receive a certain amount of dollars to retire their education-related loans. HRSA is also responsible for Title V of the Social Security Act, which makes dollars available to states to improve pregnancy and the general health status of infants and toddlers. HRSA also operates the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act.

The southeast is one of the fastest-growing areas in the discovery and confirmation of new infections. CDC is the main organization for developing prevention programs, but when prevention is no longer possible, HRSA ensures that service and availability is at a proper level of quality in the community. A growing program at HRSA is in rural health, where outreach grants in states and communities support primary care clinics. Each state has an Office of Rural Health, and this program will likely continue to grow due to the difficulty of maintaining healthcare services in rural areas when the population is so migratory and more health professionals prefer to live in urbanized areas. There is no shortage of clinicians. The distribution of those physicians and other clinicians, however, is an issue. HRSA's programs provide scholarships for people entering clinical training and loan repayment for people who are completing their training. The production of health professionals and clinicians lies within states as states take responsibilities through various universities, colleges, and professional schools. HRSA works with states regarding how many clinicians are needed, where they need to be, and what incentives need to be developed to influence how they locate themselves.

Because of increasing attention to healthcare quality, the National Data Bank of Practitioners is the authoritative database of clinicians in the country who have been involved in malpractice difficulties and credentialing. HRSA is also responsible for organ procurement, transplantation, and vaccine injury. The many programs of HRSA work together to provide supportive services in states. HRSA is working with ATSDR to assess whether situations at Oak Ridge require HRSA's particular attention and resources. Understanding the Oak Ridge situation will require a great deal of discussion and understanding what HRSA can and cannot do because of their legislative mandates. Dr. Jackson noted that he had researched the Oak Ridge situation and did not have a "ready-made answer" regarding the possibility of HRSA's involvement there.

Discussion Summary:

˜ Ms. Kaplan observed HRSA's special initiative areas include women's programs. Women are disproportionately affected by Iodine-131 exposures. Also, rural areas are disproportionately affected by the placement of hazardous facilities because of their low population density. It is important to understand that traditional healthcare services are not working in the Oak Ridge area, where residents have been saying for some time that they are not well-treated by their healthcare providers.

˜ Dr. Jackson said that nothing in HRSA's legislation speaks to environmentally or occupationally challenged or damaged individuals. There is a piece under the Department of Energy that includes a very specific, industry-related, limited entitlement. He asked about the status of the needs assessment for the Oak Ridge area. HRSA is concerned with the number of people in need and their particular needs, including the clinical and technical expertise needed. The HRSA programs for women are driven by

pregnancy, not by the woman's overall needs. He could not find legislation that would authorize ongoing clinical oversight of people who have been in communities and environments that raise questions of risk and potential damage. Dr. Davidson replied that the Health Education Needs Assessment is being conducted. It encompasses not only Oak Ridge, but the areas around it. The study is projected to be completed in May 2002.

˜ Dr. Jackson said that the number of people in need makes a great deal of difference. All pieces of legislation are specific about who has eligibility to receive services, and over what length of time. There is a Worker Health Protection Program under the Department of Energy in several communities, including Oak Ridge, with a specific list of benefits. He noted that in 1982, HRSA administered the Black Lung Program at a clinic for coal miners in Oak Ridge. This program ended in 1986 and there was no successful effort to retain the program. There is no law requiring retention of records from 1986, so it was not possible to say why the clinic closed, but Dr. Jackson surmised that the reason concerned the declining number of people who make their living from working in coal mines.

Mr. Lewis then offered a series of questions to Dr. Jackson from concerned citizens:

<u>What kinds of health clinics does HRSA usually establish to meet community needs?</u>

Dr. Jackson answered that HRSA usually provides generalized, primary care services; that is, a clinic is intended to meet the needs of anyone who visits it. Their interest is in the primary healthcare "safety net." In order to provide clinics to respond to specific needs in Oak Ridge, those needs must be expressed by a needs assessment. Mr. Lewis noted that the Subcommittee's efforts have not yet defined those needs. Dr. Jackson understood, and was therefore hesitant to provide details about what HRSA can do.

<u>What kind of medical clinics can HRSA establish to meet the expressed Oak Ridge needs?</u>

Dr. Jackson responded that HRSA is legally authorized to do general primary care, not specific programs for people with particular needs such as environmental damage or occupational medicine. They are, however, open to the possibility. He said that the only occupational group for which HRSA specifically provides funding is migrant farm workers.

<u>If HRSA cannot meet the Oak Ridge needs, what other avenues are open to the community to obtain the desired clinic or clinical services?</u>

Dr. Jackson said that the Department of Energy's program is very focused, and does not include families. Traditionally, the government has been reluctant to take on the obligations of family members in addressing an issue that is perceived to be occupationally-related, wherein workers

are at risk, not families.

Could diagnosis, treatment, and research be facilitated by a cooperative agreement between some Oak Ridge or Knoxville health entity and existing, appropriate clinics? Can HRSA mediate such agreements?

Dr. Jackson felt that HRSA's responsibility was to mediate discussions that might be helpful. He was obliged to be alert to funding needs. HRSA can help the community make beneficial alliances, but devoting money requires "jumping hurdles related to legislation." These pieces of legislation are very detailed and specific. He believed that they should address the following question aggressively: Is there a need for generalized primary care in the Oak Ridge area? The foundation of most available money is in general primary care. It is widely perceived that Oak Ridge is not a medically needy area. Measures will determine whether communities are eligible or competitive for grant dollars. The Bush administration has been vocal about its wish to expand personal health services at the community level, so the discussions should increase in intensity.

If the needs assessment suggests a need, and a response is desired by the community, then HRSA can assist in convening a meeting with the parties that can facilitate the process, said Dr. Jackson. It is possible to create a clinic that is a "satellite" of another eastern Tennessee clinic. This process is less competitive and more flexible than other programs. The Oak Ridge community needs to meet the medically under-served designation for HRSA to be able to act.

The general discussion then continued:

˜ Ms. McNally noted that there is no federal legislation to investigate and protect communities such as Oak Ridge and Hanford that have been contaminated by problems from activities during the Manhattan Project. With more political activism, this area could become a focus in the future. She asked whether this movement could come as a result of the state of Tennessee becoming more active. Dr. Jackson replied that such a movement would be ideal. In this era, activity is moving to different levels of the government. He has been impressed by local community initiatives and innovations, which are politically viable.

˜ Ms. Sonnenburg emphasized that their ongoing assessment is for health education needs, not healthcare needs. This study was arranged before the Subcommittee formed. The community of Oak Ridge is well-educated. HRSA works to assure access to comprehensive, quality healthcare to all, and a group of people do not have comprehensive, quality healthcare available to them. She pointed out that workers are tested via a program in which a van comes to town for testing. If a the workers are deemed to need healthcare, then they are sent to out-of-town hospitals.

˜ Mr. Pardue recalled that the first step toward a clinic is to identify a need. Assuming that the Subcommittee recommends a clinic and HRSA is able to mediate or assist in that project, he asked whether the Subcommittee could interact directly with HRSA, or if they had to work through ATSDR. Dr. Jackson replied that ATSDR, HRSA, and whatever other agency might be identified to assist would join in the dialogue. He assured the group that they could rely on HRSA to be responsive.

˜ Mr. Hill commented that the Employees Medical Screening Program in Oak Ridge is not available to all employees. It is only available through the Pace Union through the AFL-CIO building. It is not available to the workers at the ORNL, at Y-12, or to the guards. When workers are sent to out-of-town hospitals, as Ms. Sonnenburg had mentioned, that work is diagnostic and treatment is not provided.

˜ Mr. Hill recalled learning at an earlier meeting that Hanford had a medical monitoring program that provided periodic medical evaluations. Dr. Jackson was not sure about the clinic situation at Hanford. The phenomenon of providing a diagnostic exam and then referring to the primary source of care has been the pattern for years. There are many people who do not qualify for Medicare or Medicaid and who also are not insured. Community health centers and those primary programs assure people that they get what they need, but it is hard to reach all of those people.

˜ Mr. Malmquist reflected on the numbers of people needed to qualify for a program. In Roane County, they had hoped for a veterans' clinic, but the Veterans Administration would not operate a clinic unless there were at least 3500 active cases in the service area. He asked if HRSA had such a specific number requirement. Dr. Jackson answered that the programs managed by HRSA assume at least 2500 people. In addition to people who have the issues and concerns that they had been discussing, they should consider the number of people in the Oak Ridge area who are likely to use a clinic because they are uninsured or because it is more convenient. A clinic's existence does not guarantee that people will use it. HRSA tries to buy into communities that have energy and organization to sustain the clinics.

˜ Dr. Davidson commented that Oak Ridge is an "oasis" within the area of interest. The outlying areas do not resemble Oak Ridge. She wondered about the proximity of a rural community to a town or city that would be considered under-served. Dr. Jackson replied that the criterion for unacceptable availability is 20 miles or 30 minutes of driving time. The residents of the nearby county are crucial to whether the area should receive a satellite clinic of an ongoing enterprise. There is a greater likelihood of building a patient load quickly in this option. It would be preferable to have the clinic next to the hospital, but there are many issues to be resolved. For instance, is the area inhospitable to the

clinic because of the number of physicians' offices nearby? Also, the closer the clinic is located to groups of physicians, the more difficult it is to prove a need for additional resources.

˜ Mr. Johnson wondered about HRSA's receptiveness to working in collaboration or partnerships with grassroots communities, initiatives, and healthcare providers. He also asked how sustainability and self-sufficiency relate to attracting a clinic to the Oak Ridge area. Dr. Jackson said that HRSA has become very interested in partnerships. They encourage partnership development not just because of resources, but also because of validity in the community. He said that on the average, their clinics get approximately 45 percent of their annual revenue from a grant and 55 percent from patient fees, reimbursements, write-offs, et cetera. Factors such as the number of people who bring insurance and local support from laboratories and hospitals also contribute.

˜ Dr. Creasia asked whether Anderson County, in the Oak Ridge area, is medically under-served. Dr. Jackson replied that there is a primary care community health center grant in this part of state which includes part of Anderson County as its service area. That group might be one to consult in the process of seeking a clinic.

˜ Dr. Akin asked whether HRSA's legislation distinguishes between clinical services and medical monitoring facilities or capabilities. Dr. Jackson answered that the HRSA legislation calls for services. Monitoring is included as a form of service.

˜ Dr. Akin clarified that "clinic" typically includes a broad category of services for many medical needs. "Monitoring" implies more focused efforts; that is, monitoring for a specific reason such as exposure or another condition in the community. Around hazardous waste facilities, "medical monitoring" indicated a focused service for people who feel that they have been exposed. Dr. Jackson felt that the terms should not be distinguished. In offering primary care to populations, these services blend together. "Monitoring" to him applies to clinical outliers. They should focus on services, which include monitoring people with occupational or environmental history.

˜ Mr. Washington commented that Oak Ridge has been described by Margaret Mead as "an island of plenty surrounded by a sea of poverty." If a clinic must be located in a medically under-served area, then it probably could not be located in Oak Ridge. The surrounding communities may represent a better choice. One of the justifications for a clinic could be related to blood pressure, which could be related to occupations in this area such as heavy metals affecting kidney functions over long periods of time. There are several dialysis clinics in the area, and so a combination of these factors might lend to the possibility of a clinic. Oak Ridge is not so much under-served as residents do not have confidence that the medical community is aware of, or well-trained in, occupational

illnesses that related to the diseases associated with facilities in Oak Ridge. Another possibility is HRSA's responsibility for organ procurement and transplantation. Their effort should center on a real needs assessment of a geographical area. Black lung disease still occurs in the area as well.

˜ Ms. Kaplan called the group's attention to the efforts of a local activist. His wife worked at ORNL and passed away, and he has become involved in issues regarding a clinic at the facility. Legislation is being introduced into the state that would force the plants' clinics to be operated independently. This effort might be a good partner.

˜ Mr. Lewis said that some community members have identified Oak Ridge as a "company town." There is also a feeling that physicians are "on the take." The perception is that a clinic would be independent of the current healthcare provider structure. He wondered if similar situations have been used as the basis for establishing a HRSA clinic. Dr. Jackson said that HRSA clinics allow for a certain autonomy and independence because community-based organizations are not beholden to public agencies or to private interests. He offered to provide examples of similar efforts after some research and clearance.

˜ Mr. Pardue suspected that a large problem with establishing a clinic is cost. A clinic for this area would be large and include a great deal of expensive equipment. He wondered about an approach that would use the Methodist Medical Center equipment and facilities so that there would not be duplication. There are concerns about physicians employed by Methodist Medical Center, but independently-funded, public health service doctors could see patients and perhaps conduct research. The community has good research facilities, and grants could come from a government agency or from the Department of Energy at ORNL. Dr. Jackson felt that an approach that utilizes and perhaps augments existing resources was logical and rational. The problem is not with the model, but in its implementation, as HRSA does not have the legislative authority to purchase the high-tech equipment that might be involved. HRSA has experience with using the resources of an existing facility, but they do not advocate for that approach because of the many problems with the process. It is difficult to be independent when working in another group's facility.

˜ Dr. Pereira asked whether HRSA requires a specific format for its needs assessment. Dr. Jackson said that HRSA has certain needs assessment issues that have to be addressed and he said that he would provide them to the Subcommittee.

Public Comment

- Ms. Cheryl Smith asked about the clinic in the Hanford area. Dr. Jackson replied that to the best of his knowledge, that clinic is not a HRSA-funded operation. He would follow up to make sure.

- Ms. Janice Stokes was concerned that discussion about a clinic was too focused. She asked the Subcommittee to consider a wider focus that would not only test for one or two contaminants in the body. Proper and thorough testing should be done, as a simple blood test will not identify all toxins and the "body burden." Many people will test below "permissible limits." A clinic must be operated independently and carefully and test properly. Her mother has tested positive for lead and arsenic at high levels, but they cannot get treatment for her. Toxicologists have recommended treatment, but the state is taking the licenses of the few doctors who will treat for metal poisoning.

- Ms. Gass mentioned a new test for PCBs in human tissue. She asked if HRSA has had experience with that test or with testing for heavy metals or cyanide in humans. Dr. Jackson was careful about making a generalization, as HRSA has 3000 clinic sites. He suspected that they had experience, but planned to investigate the issue. The question is interesting because of the primary care clinics that operate around various industrial plants on the eastern seaboard.

- Ms. Faye Martin observed that there is a high frustration level because of a lack of action. For several years, the community has wanted clinics. She suggested that they form a committee that will raise funds for a clinic. There are doctors all around that area, sick people, and buildings: what else do they need?

- Dr. Davidson wondered if such a group in Oak Ridge and the surrounding areas could partner with HRSA.

- Mr. LF Raby addressed the group about Tennessee Senate Bill 280. This bill requires the Department of Energy to operate the medical clinics at ORNL, Y-12, and K-25 with private contracts so that the medical clinics can be independent. The occupational medicine in Oak Ridge is nonexistent through DOE. There is no Medical Director for occupational medicine and they have no oversight in Oak Ridge. He is in meetings to gather support to get the bill passed. He offered to provide updates on the effort and gave his contact information: 865-435-1152.

- Ms. Gass also gave her contact information: 898-4263 linda99@mindspring.com

~ Ms. Sonnenburg asked members of the public to comment on the necessity of an independent clinic and to share the experiences that have made them support an independent clinic.

~ Mr. Raby said that his wife worked for DOE for 23 years and had her annual physicals at ORNL. The doctors did not pay attention to her blood work. Her cell lines decreased continually for ten years and she was never informed that she had a problem. He asked the Medical Director for a meeting, but was refused. The Medical Director would not discuss his wife's medical records: their primary interest was to protect the contractor, at that time, Lockheed Martin. If the clinics are operated independently, then this situation will not occur. DOE facilities operate in this manner in other locations, and have since 1965. There is legislation in Washington requiring them to do that.

~ Ms. Stokes said that in the past month, two physicians have been called before the State Board of Medical Examiners because they have addressed the fact that heavy metals exist in bodies. The Tennessee State Department of Health is stopping physicians from treating patients with heavy metal poisoning. These actions are a travesty of justice and inhumane treatment. In 1993, Ms. Stokes went to a toxicologist who verified that the toxic level of nickel in her was moderate, which meant that if she did not eliminate the nickel from her body, she would eventually die. Within a year, that physician was no longer practicing in Tennessee. If the Subcommittee is interested in helping people, then they must stop any entity that is interfering with poisoned citizens' access to healthcare.

~ Ms. Gass wondered if it would be appropriate to ask the Tennessee Department of Health liaison for the Subcommittee could bring information to the process. She had asked for the liaison roles to be clarified. Ms. Brenda Vowell offered to assess the situation, contacting people in charge of licensing at the State Board of Medical Examiners. She said she was not sure that the rest of the Subcommittee felt that it was appropriate to address requests for information directly to the liaison members. Occasionally, questions should be addressed to the Department of Energy, and the day before, a DOE representative had responded at the public microphone. The role of liaisons had never been properly clarified, but she appreciated that sidebar conversations had stopped. She hoped that there could be a process for addressing questions of DOE, particularly how the members of the Subcommittee and the public could interact with DOE representatives, one of whom was seated at a side table with the writer/editor.

~ Dr. Davidson noted that Ms. Brenda Brooks of DOE had volunteered to gather information, which was appreciated. The liaisons communicate with their agencies about Subcommittee activities and can respond to specific requests, such as Dr. Akin's working with EPA's soil sampling work. The Subcommittee's recommendations go to ATSDR

and CDC, not to other federal or state agencies, but ATSDR acts for the Subcommittee in requesting and obtaining information. Dr. Joseph of DOE was present at the meeting as a member of the public, and could sit anywhere in the room save at the table with the Subcommittee.

˜ Ms. Stokes said that she was almost sorry for bringing up the situation with doctors being called before the State Board of Medical Examiners. The last issue that she had brought to the Subcommittee was the Mangano study, which the Subcommittee "beat ... pretty bad." When the state intervenes with physicians who are trying to treat patients, the rationale is that the physicians are not toxicologists. She had challenged the state to replace those physicians, if they are not qualified, to replace them with physicians who are qualified. She hoped that those physicians would not be embarrassed because of her comments, as Dr. Mangano was. They are loving humans are trying to help people and who are being stopped for political reasons, and she did not want to see them "trashed" in the Subcommittee. Ms. Stokes said that the issue would be taken up be some person or some agency at the recommendation of the Subcommittee. The Subcommittee took on the Mangano paper as an academic exercise and spent a great deal of money on the effort. She would not provide the Subcommittee with the physicians' names because she was concerned that the Subcommittee would somehow discredit them, which would be "in poor taste." In the past, she said, the Subcommittee has accused her of having poor taste, being incompetent, and not being credible. If the physicians are "raked over the coals," then she would respond in the press.

˜ Dr. Davidson responded that the Subcommittee would not become involved in discussions of individual physicians and how they treat their patients. She apologized if the Subcommittee had caused problems for her or made statements to her. She could not recall making such statements. The activities of individual Subcommittee members outside the Subcommittee setting is not controlled by the Subcommittee.

˜ Ms. Stokes felt that since the Subcommittee members are paid by ATSDR, then there was control over them. Dr. Davidson replied that there was no control over members outside the meetings. Ms. Stokes responded that the Mangano report was discussed in Subcommittee meetings and in sanctioned settings. Any review of any paper will reveal missing details. They should not take a similar approach to the issue with the physicians. Instead, they should take the positive approach of trying to get trained toxicologists who can helate them and make them better rather than "defending [their] toxins."

˜ Mr. Lewis said that if the Subcommittee wants comments and support from DOE, then DOE ought to be at the table. That issue should be evaluated. He asked for clarification on disease and symptom prevalence studies, which are defined as: "A study designed to measure the occurrence of self-reported diseases that may, in some instances, be validated

through medical records or physical examinations, if available, and to determine those adverse health conditions that may require further investigation because they are considered to have been reported at an excess rate. This study design can only be considered as hypothesis generation." They hear about self-reported diseases and linkages, and people want to pursue these linkages via clinics. This issue might relate to a clinic in Oak Ridge.

˜ Dr. Peipins said that the issues in these studies are related to study design. The crux of the matter is that a study that looks at symptoms and diseases must include how well they are characterized, case definitions, how they are well measured, and whether they can be equally measured in exposed and unexposed populations. A valid study requires identical measuring. A unified case definition is also required to count the diseases in the same way and to evaluate relative risk.

˜ Dr. Jackson said that this question related to the questions and concerns that he had tried to express. What real symptoms could be identified and differentiated, and what would it take to treat them? A needs assessment may not answer these questions, but the questions must be implied and acknowledged. In many cases, there is no experiential answer.

Presentation and Discussion: State of Tennessee Screening Process for Past Exposure

Mr. Jack Hanley
CDC/ATSDR

Mr. Hanley recalled the January 18, 2001 meeting in Oak Ridge, at which Ms. Janice Stokes asked a question about clinics. At that time, the Deputy Assistant Secretary of DOE answered the clinic question from DOE's perspective. One of the key points in the transcript is that there has to be a strong case for the existence of sick workers in the community who were not being appropriately compensated. The needs assessment must be done. The Associate Administrator of ATSDR responded to the question as well, giving an example of an ATSDR medical monitoring program in Libby, Montana. At this site, there was long-term, documented asbestos exposure with outcomes seen in the community.

There are often questions about why the state and ATSDR focus on environmental data in their public health assessments. The PHA process is used to evaluate environmental data, community concerns, and health outcome data, with a focus on the environmental data. These data are used to identify people off-site who have been exposed to a specific contaminant or contaminants at a level of health concern. When the contaminant and its pathway are identified and a dose to the population is estimated, the likely health outcome can be determined. At that point, they make a

recommendation and create a public health action plan. Follow-up occurs with many other agencies and may include medical monitoring, surveillance, health education, and advisories, if the situation is severe. Follow-up can also include exposure investigations and health studies. The criteria for these measures can be addressed as the PHA process is underway.

Mr. Hanley then the presented an overview of the screening process that ATSDR will use in the health assessment at Oak Ridge as well as how ATSDR will use the state of Tennessee's screening to focus their evaluation on the contaminants of concern. There are two screening processes taking place:

- Past exposure
- Current or recent-past data

Past exposure concentrates on the years 1940 - 1990. The state of Tennessee conducted two studies in this time. The contaminants that were deemed potential candidates for further evaluation would be put through the ATSDR screening process, which would be explained to the Subcommittee in a later presentation. Current or recent-past data includes data from 1990 - 2001, which is mostly electronic. The DOE information system here will be used and the information will be put through the ATSDR screening process.

The first study conducted by the state was a feasibility study. The findings from this study went into the dose reconstruction study. Other contaminants required further evaluation and screening, so they were taken through another screening. The purpose of this work was to help the state focus its resources on the most important contaminants. The feasibility study for dose reconstruction included many tasks, four of which focused on the screening of the contaminant. Task One was an extensive historical review of the operations and releases from all three facilities. Task Two incorporated an inventory of the vast amount of environmental data and contains abstracts. The state used this information to identify the operations that did not have the potential for releasing contaminants off-site. The study focused on the quantities used, the source, and how they were used. A qualitative evaluation was made. For instance, releases of volatile organics were small and not associated with possible off-site health effects. There is a great deal of Freon, but it has low toxicity. Acids and bases dilute quickly, so they were also eliminated as priorities.

Tasks Three and Four identified contaminants that were at a high priority for further study. The study included a quantitative evaluation which estimated, based on source data, quantities that could have gotten off-site and compared them within different media, across media, and to each other. The contaminants were then placed in a ranking order. The radiological contaminants were compared to each other, and Iodine was considered to have the highest hazard ranking. All contaminants then had dose reconstructions, except for protactinium 233, which had a low relative hazard ranking. Mr. Hanley shared the list of contaminants, including which ones were

screened out and which were included in the dose reconstruction. For the highest-priority contaminants, sources, releases, the transport medium, and the basic pathway of exposure were identified.

After completing the feasibility study, the state was able to conduct dose reconstruction studies on iodine, mercury, PCBs, uranium, and White Oak Creek releases. A group of contaminants needed further study, so they were evaluated in another round of screening, including a qualitative evaluation, a threshold quality approach, and a quantitative, two-level screening evaluation. This list grew as the program extended and as certain contaminants became declassified.

The qualitative approach was used in the beginning to identify contaminants that likely posed an off-site health hazard. The screening also identified contaminants that were not likely to get off-site or to be at sufficient levels to cause a health hazard. The quantities of some contaminants were still classified, so the state used "reverse engineering" with the threshold inventory approach. They estimated the level that would cause a health hazard off-site and then how much would have to be released from the stacks to reach that level. Then, they estimated the inventory required to yield that amount. The result was an estimation of quantities needed on-site, and the quantities on-site were not at those levels.

The first level of the quantitative portion began with quantitatively and conservatively estimating the off-site individual with the highest exposure, using the maximum concentrations detected off-site and the upper parameters in other pathways such as fish consumption and length of exposure. Using this "worst-case scenario," they identified contaminants that were below a minimum level of health concern. Level two used slightly less conservative and more realistic parameters, but there was still conservatism built into the screening. Exposures for most people were overestimated in this phase, but underestimated for any individual, highest-exposed person. This process eliminated all but the following eight contaminants:

- Beryllium
- Chromium
- Copper
- Lithium
- Nickel
- Technetium
- Arsenic
- Lead

ATSDR will put those contaminants through their screening process. The previous work not only identified the contaminants of highest priority, but also the pathways. 80 to 90 percent of the exposures came from vegetables and fish. Milk and beef ingestion were a dominant pathway for one of the contaminants.

Discussion Summary:

~ Mr. Lewis asked whether, since vegetables and fish are the dominant pathways, people who live downstream are at higher risk. Mr. Hanley replied that the risk depends on the facility. The state used reference populations for estimating and identifying contaminants. The models were conservatives. The technical reviewers for this study commented on the conversion factors of how much contaminant is absorbed by the vegetables or the fish. There are new, updated bio-transfer factors available from the EPA that should be used in the ATSDR process.

~ Mr. Lewis reflected on the "reverse engineering" approach and the concept of secrecy regarding contaminants. He understood that there are ways, despite secrecy, to eliminate items, and the facilities have cooperated with these efforts. Mr. Hanley agreed, observing that ORHASP has worked to release as much information as possible to the public.

~ Dr. Creasia asked whether the evaluation of toxicity considered peak exposures, such as when certain plants will burn inventory that has "outlived its life." These peak exposures are more severe than regular exposures. Mr. Hanley was not sure whether the study had taken peak exposures into consideration. The study used the maximum identified concentration of contaminants in the initial screening. Volatile organics were in small quantities at the plants, but it was feasible that they were released at once, resulting in these peak exposures. He offered to look into the issue.

~ Dr. Creasia asked about the conservative estimates at the beginning of the screening. Later in the process, the estimates became more liberal or typical. Mr. Hanley agreed, adding that the study used the same, conservative bio-transfer factors in the screening, which were over-estimates.

~ Mr. Washington felt that the screening process was wrong. Y-12 is a manufacturing plant. Millions of gallons of Benzine, Xylene, and Toluene were used there. He noted that fluoride gas does not remain fluorine for long; it converts to HF, which penetrates through the skin to the bone. Mr. Hanley replied that fluorine was added to the list of issues that ATSDR would investigate.

~ Y-12 has been in place for more than 50 years, Mr. Washington continued, and the area around it is contaminated. T-Male, a classified product, was not included as a contaminant of concern, even though its TLV is in the PPB range. He had made the compound, and workers could not remain in the room for more than an hour because of its toxicity. When the bombs are torn down and the material is re-used, there is another exposure in the community as there are releases from the stacks. Savannah River has a project in which there is an uptake of mercury in some plants. During the transferation process, metal mercury is transpired onto the leaves of plants. In making metals, too, other elements are added that are released into the atmosphere. He encouraged ATSDR to look at the big picture, that Y-12 uses all of the naturally-occurring elements on the periodic chart, up to element 92, and all of those elements are then present in the air. The steam plant burns coal, he added. Mr. Hanley replied that arsenic is listed because of the coal facilities at K-25 and Y-12. Most of the classified contaminants are unique to making metals. Mr. Washington was not sure that anyone has a good idea of how many of these elements are used, and how they are used.

~ Mr. Hanley commented that the form and manner of use of materials was considered as well as quantities to determine what elements might have an impact off-site. Mr. Washington added that the compounds can remain in the atmosphere or make other compounds as they react with UV light.

~ Dr. Akin asked about DOE's approach toward chemicals that are classified and on which there is no information. Mr. Hanley understood that the state, contractors, and members of ORHASP could look at all of the data, classified and non-classified. By the end of the process, the names of all materials were declassified, but some of the quantities are still classified and some contaminants and the building in which they are used are not connected.

~ Dr. Timothy Joseph clarified that this issue emerged often during the study process. DOE declassified the names of all compounds and elements in all facilities. The classification issue arose regarding the building and the process used. Several members of the ORHASP panel were Q-cleared to see the quantities and buildings with any compound.

~ Dr. Akin asked whether Oak Ridge citizens found this point to be an issue. He observed that they had an opportunity to move this issue off of the table and to clarify the issue with the Oak Ridge citizenry.

~ Mr. Washington said that three compounds were classified and not included on the list. Dr. Joseph assured him that there were no classified compounds.

˜ Dr. Davidson noted that the name of all compounds were not included on the provided sheet because the sheet was about the screening process, not about which compounds were classified and listed. Mr. Hanley confirmed the observation, using the example of cadmium, which is not on the list. Sampling may reveal that cadmium was released and exists in the environment. Based on the volume of historical data, certain compounds and elements were screened out.

˜ Dr. Akin said that the ATSDR process is the same process that EPA uses for its risk assessment at any Superfund site, whether federal or private. The Subcommittee needs to understand the process thoroughly, and he was sorry that some of the community members were not in attendance for the presentation, as the process should also be understood by the community. The process is open for criticism, should there be any. Site characterization and toxicity information could be questions, as are exposure pathways and data gaps, that the Subcommittee and the community should address at these opportunities so that they can make progress. Mr. Hanley added that the details of the process were reviewed in the PHA workgroup. Outstanding issues could be addressed there. In the end, the process leads to focusing on contaminants of the highest priority.

˜ Dr. Davidson commented that the PHA workgroup would continue to look at this issue. They can then bring any outstanding issues back to the Subcommittee.

˜ Mr. Manley offered a "facetious" comment, rescinding his offer of vegetables from his garden, from which he has been eating for 40 years.

˜ Mr. Lewis asked EPA to endorse the process that Mr. Hanley described. He hoped to avoid confusion or argument between agencies in the future.

˜ Dr. Akin confirmed that the screening process was included in guidance documents for both ATSDR and EPA. The sheet of specific contaminants would not be endorsed by EPA, but the process used to arrive at them was a common process used to define chemicals that need to be studied further. Many chemicals are found in the environment, so the environmental media must be analyzed to name contaminants that may lead to health problems. Every aspect of the process has limitations in knowledge, but science must use a framework to focus on those chemicals that require immediate action. The ATSDR PHA process will lead to a list of chemicals that are still a problem today. EPA will address the chemicals, as a Superfund site, by making decisions about remediation that may need to be done about chemicals that remain and may be causing harm. There are gaps and questions in the process, and the Subcommittee and community must focus

on those questions and gaps. Mr. Hanley pointed out that the quantitative analysis portion of the process used to use an EPA reference dose for comparison and would use new EPA bio-transfer equations. There are many standard equations.

˜ Mr. Lewis reiterated that an endorsement of the process would help the community.

˜ Mr. Hanley asked whether EPA uses a qualitative judgement process in preliminary assessments. Dr. Akin replied that the science is not well-developed in that area, so there is often not clear information. For example, metals can be in different forms, which are related to their bio-availability. These issues are often not clear. Issues such as these and such as interactions must be addressed in a qualitative way, so that the judgement allows work to move ahead without the ideal, exact science.

˜ Dr. Davidson asked Dr. Akin to provide the Subcommittee with EPA's screening process to be compared to the ATSDR process. Dr. Akin replied that he would.

˜ Mr. Pardue said that in recent years, the question of whether all classified materials have been identified has been raised often in public meetings. It is a continuing issue in the community, as evidenced by the fact that not all Subcommittee members were aware that the materials had been declassified. He encouraged Dr. Joseph to make a public statement to this effect to eliminate the question.

˜ Mr. Pardue also commented that public acceptance of the screening process was key to the success of the PHA. He noted that their current audience was not representative of the public, so he suggested that they make an announcement in the *Oak Ridger*. Almost everyone in the community reads the newspaper, particularly the editorial and front pages. The "guest commentary" is an opportunity for ATSDR to publish this process and to solicit questions from the community. If the process is understood and known in advance, then there is less likely to be negative reaction after the fact. Dr. Davidson supported the idea, particularly because not all members of the public have access to the ATSDR website.

˜ Ms. Kaplan also encouraged a press release that addresses the changes that have been made in the Subcommittee's work. She knew of plans at the newspaper to publish an article about the Subcommittee's one-year anniversary. The changes that resulted from Subcommittee and public input are very important.

˜ Ms. Kaplan asked whether EPA was in charge of remediation decisions in the off-site communities as well as at Superfund sites. Dr. Akin said that EPA responsibilities are separate at public and federal sites. At private Superfund sites, the site is a moving definition that includes any area into which a site contaminant is released. Therefore, a

neighborhood that is contaminated by a Superfund site becomes part of that site for EPA to assess risk and conduct clean-up, if needed. At federal sites such as Oak Ridge, DOE is the lead agency and EPA provides oversight.

- Mr. Hill approved of the idea of a news article and suggested that all community papers be included in such an effort, including the Roane County News. The release should include information about the next Subcommittee meeting as well.

Motion 6

Mr. Hill moved that the Subcommittee recommend that ATSDR create an article for local media on the screening process. It is further recommended that information from DOE, via Dr. Joseph, be included regarding information about declassified chemicals for the dose reconstruction. The motion received a second. After discussion, it was added that information about Subcommittee accomplishments and changes in Subcommittee process should also be released.

- Ms. Dalton said that ATSDR would do its best to coordinate its effort with DOE. The information might need to be presented in two articles rather than in one.

- Ms. Mosby felt that the articles should be released as soon as possible.

Dr. Davidson opened the meeting for public comment. As there were no immediate comments from the public, discussion among the Subcommittee for Motion 6 continued.

- Mr. Hanley asked whether the Subcommittee preferred an editorial article or a press release. Dr. Davidson and Ms. Mosby said that the suggestion was for a “your views” part of the newspaper, which is longer than a letter to the editor.

- Dr. Kuhaida asked what newspapers should be included. Mr. Hanley replied that ATSDR usually contacts the *Oak Ridger*, the *Clinton Courier*, and the *Roane County News*. They used to advertise in the *Knoxville News-Sentinel*, but now they send that paper press releases.

- Dr. Murray suggested that the motion include specifics about which newspapers should be included.

- Ms. Dalton said that the agency typically uses press releases, not paid advertising. They do buy space in the *Oak Ridger*, the *Clinton Courier*, and the *Roane County News* to announce Subcommittee meetings.

~ Dr. Davidson did not think that a paid advertisement was part of the recommendation.

~ Dr. Kuhaida reflected that there are three separate opportunities: one, sharing information about the screening process; two, changes in the Subcommittee that came as a result of input and evaluation of Subcommittee activities, which shows that the Subcommittee is active and responsive; and three, the issue of declassified contaminants, a significant issue in the community. He felt that these issues should be addressed separately because they are so important. Dr. Davidson repeated the three issues, and Ms. Mosby added that they should also include the Subcommittee accomplishments along with the changes. Dr. Davidson held the vote to allow for public comment.

~ Dr. Peele commented that when he entered the ORHASP panel in 1994, a number of members of the panel felt that no report could ever be issued due to classification and the resultant lack of information. Other panel members felt that a partial report and a classified report could be issued. As time passed, policies in changed as there was a national opening of information. The contractors learned how to make valid screening estimates based on the limited amounts of data that were declassified. It is possible to make correct analyses without using classified information. The final report stated that none of the conclusions were hampered by classification of information. He offered examples of public comments on and criticisms of the screening process that had been heard over the years. The first complaints regarded pathways. ORHASP did not estimate exposures for pathways that did not exist, such as for a river that people did not use. There were also doubts expressed about the lack of knowledge about the quantities of contaminants that were released. Some people doubted the standard coefficients, which may change over time. The most significant complaint regarded the confluence of various contaminants, or the "multiple exposure problem." There is no coefficient for this phenomenon. It is not possible to assess the toxicity of all known compounds, never mind of their combinations. The most obviously-suspicious cases were exposures to PCBs and mercury, in which similar symptoms occurred elsewhere in the country. Dr. Peele felt that interactions in the body have not been studied and understood, but he also felt that they were not likely. An analogous situation is with interactions of medicines.

~ Other doubts were expressed about whether the transport of materials was considered properly. In most cases, these factors were well-assessed. Another problem was as a result of poor monitoring where people lived, such as a lack of measurements of ground water. In some instances, especially 40 years ago, it was not known that these compounds were toxic, so it is understandable that these measurements did not take place. The panel was forced to create some complicated extrapolations due to this lack of monitoring data.

Dr. Davidson called for the Subcommittee to vote on Motion 6, however, discussion continued.

~ Ms. Mosby wondered whether a Subcommittee member should write one of the articles, rather than ATSDR because of possible questions of credibility.

~ Ms. Dalton encouraged the Subcommittee to spread its own message about its accomplishments. It is important for the community to hear about Subcommittee activities from its local members.

~ Mr. Pardue felt that the statement on declassified materials should be made by DOE. While the PHA workgroup is contributing to the screening process, ATSDR should write the article on that subject, which can indicate that the process has been endorsed by the Subcommittee, if that is the case. He suggested that the chair of the Subcommittee should write about the Subcommittee's accomplishments and changes.

~ Ms. Dalton mentioned that ATSDR has provided the *Oak Ridger* columnist with the Subcommittee changes. ATSDR can collaborate with the Communications and Outreach workgroup to ensure that all Subcommittee accomplishments are included.

~ Mr. Hanley said that his next step was to put the screening process into writing for the PHA. He would keep his document concise and readable, then presenting it to the Subcommittee.

~ Ms. Mosby felt that the articles should not be combined, but released in three separate efforts.

Motion 6

Mr. Hill moved that the Subcommittee recommend that ATSDR create an article for local media on the screening process. It is further recommended that information from DOE, via Dr. Joseph, be included regarding information about declassified chemicals for the dose reconstruction. The motion received a second. After continued discussion, it was added that information about Subcommittee accomplishments and changes in Subcommittee process should also be released. Dr. Davidson called for a vote on the motion. The motion carried with a vote of 13 in favor and none opposed.

Public Comment

Ms. Gass
Member of the Public

Ms. Gass reminded the group that the state of Tennessee spent $15 million on the dose reconstruction, and she has reviewed meeting minutes from this time. Some of the same discussions have been going on throughout the process that are going on now. She reflected on the pathways that Dr. Peele had addressed. The biggest difference between Hanford and Oak Ridge is rainfall, and one of the biggest exposure pathways at Hanford was irrigation using the Columbia River and the subsequent uptake into produce. Oak Ridge does not have that exposure, but rain has a more negative than a positive effect on exposure in East Tennessee, which should be remembered when comparing the two locations.

She recalled a lawsuit over medical monitoring in Hanford, and Hanford had public interest attorneys, which are not available in Oak Ridge. Another difference, which has been noted by other committees, is the existence of environmental organizations at the grassroots level in the West. In contrast, East Tennessee has never had an appreciable degree of environmental grassroots organizations. She referred to a draft of time-lines for the three facilities and asked Mr. Hanley when their final versions would be available. Mr. Hanley did not have a specific date, but said that they would be finalized as he makes progress on the screening and receives input from the workgroup.

Ms. Gass noted that the time-lines were all historical information. Mr. Hanley replied that the work was done as part of the Task Two feasibility study. Most of the sampling studies included on the time-lines came from the feasibility study. Ms. Gass said that the books were difficult to acquire. Mr. Hanley said that the feasibility study was on a CD-ROM, which is why the state was not printed them any longer, which was available in the library.

She observed that the information in the feasibility study anticipates that more work will be done during the ORHASP process. In some cases, due to time pressure, activities were not completed or followed-up. She said that the time-lines were mostly focused on releases. She wondered if person within ATSDR other than Mr. Hanley was working on verifying releases for the PHA. Mr. Hanley said that state studies were being used to examine historical releases. ATSDR evaluated the data to assess whether it could be used in the PHA, and concluded that the data could be used in the PHA.

Ms. Gass asked whether technical reviewers recommended using the data. Mr. Hanley answered that the reviewers provided input into the data. The conclusions were that there were limitations and weaknesses, which is the case with all studies. The reviewers helped ATSDR to identify those weaknesses and limitations so that the findings could be used appropriately. In response to a question from Ms. Gass, Mr. Hanley added that his responsibility was not to assess whether all releases are included.

Unfinished Business: Update on Subcommittee Nominations and Update on ORRHES Website

Ms. LaFreta Dalton
ATSDR/Designated Federal Official

Ms. Dalton gave the group an update on Subcommittee nominations. The nomination process can begin and will be followed by Subcommittee member selection and placement. She has been working with the ATSDR website to have the Subcommittee nomination information included on the ATSDR homepage and available for direct printing. The nomination process will begin when the ATSDR website committee approves the posting.

Packets will also be mailed to everyone on the mailing list, and copies will be placed in libraries and other public buildings, as well as at the Oak Ridge Field Office. She asked for more suggestions for locations for the information. A press release will go to local newspapers. ATSDR will work with the Communications and Outreach Workgroup to advertise the nominations in additional ways. It is critical that Subcommittee take an active role in announcing the nominations to the community. She does not have firm dates for when the process would begin, but the nominations will be open for at least 30 days and perhaps longer because of the holidays.

Ms. Dalton also gave an update on the website. The Communications and Outreach Workgroup would present recommendation on the site map and template. The next step in process is for the contractor to incorporate links. Content can always be added to the site. When the links are incorporated, the pilot-testing will begin. Two pilot tests are planned, and then ATSDR has to give final approval before the page is added to the ATSDR site.

<u>Discussion Summary:</u>

~ Ms. Sonnenburg asked whether an effort would be made to replace Subcommittee members who had resigned, such as a doctor. Ms. Dalton replied that one Subcommittee place was reserved for a sick worker. For the other three positions, preference for a self-

identified ill resident and consideration to replacing the doctor was suggested.

- Mr. Lewis commented on Subcommittee balance and representation. It might not be necessary to be sick or ill to represent the sick or ill, he noted. ATSDR had kept diversity in mind in its initial selection of Subcommittee members, and he hoped that ATSDR would consider filling slots based on the caliber of individuals that had been on the Subcommittee in the past. Ms. Dalton replied that ATSDR always hoped to have Subcommittee members of high caliber who represent the community at large. It does depend on who applies, and they also have the option of re-considering the pool of applicants that applied for the Subcommittee the first time. They are hoping to match the talent and expertise that the Subcommittee lost.

- Ms. Mosby asked about the length of the new members' terms. Ms. Dalton replied that the new members' term would expire at the same time as current members, in 2004. If an applicant does not come forward for the sick worker position, then the position will remain open until the end of the term.

- Mr. Hill asked for clarification on the term "sick worker." He assumed that the term was defined as a worker who believes that he or she has had a health impact from their employment. Ms. Dalton agreed, adding that the applicant can be a past or current worker who has an illness that is believed to be associated with the Reservation.

- Mr. Lewis wondered about the procedure if a current Subcommittee member self-identified as a sick worker. He said that there is a difference between a sick person who acts as a representative for a group of people and someone independent who fulfills that category. Ms. Dalton replied that such an issue would have to be discussed by the Subcommittee, as the Subcommittee stated that an ill worker representative would be needed. She said she understood that the consensus was to solicit an ill worker.

- Mr. Hill noted that all Subcommittee represent themselves only; therefore, a sick worker would not be representing all sick workers, but their viewpoints only. Ms. Dalton agreed.

- Ms. Mosby commented that a drawback associated with a Subcommittee member self-identifying as a sick worker would be criticism and the perception that they are trying to circumvent process.

- Mr. Lewis asked whether an individual who resigned from the Subcommittee could reapply for membership. Ms. Dalton replied in the affirmative.

- Dr. Davidson noted that the Subcommittee had been operating for a year with no members being specified as ill workers and that the process would not be expedited by

such an identification now.

˜ Mr. Manley asked what constitutes sickness in a worker. For instance, welders have a tendency to lose their eyesight. Would this person be a sick worker? Ms. Dalton replied that the individual's view of him- or herself is the deciding factor.

˜ Mr. Washington clarified that a sick worker is a person who feels that he or she came into contact with some contaminants while working in a facility that affected his or her health. There are some illnesses that have not yet been characterized, but when a number of people who worked under the same conditions have the same symptoms but no disease is named, then each individual is responsible for deciding his or her status as an ill worker. He added that people will always represent their own interests, even if they are members of specific groups.

˜ Ms. Kaplan commented that welders have trouble with their eyesight, but they also breathe fumes that may include contaminants.

New Business/Issues/Concerns:
Workgroup Recommendations and Future Meeting Dates

Dr. Davidson began by reviewing the recommended amendments in the Subcommittee bylaws. Several motions were raised.

Motion 7

It was moved and seconded that the following amendment be made to the Subcommittee bylaws: "The Workgroups shall include the Guidelines and Procedures Workgroup, the Agenda Workgroup, the Communications and Outreach Workgroup, the Health Needs Assessment Workgroup, and the Public Health Assessment Workgroup." The motion passed unanimously.

Motion 8

It was moved and seconded that the following amendment be made to the Subcommittee bylaws: "A quorum at workgroup meetings shall consist of two Subcommittee present in person at the meeting." The motion passed unanimously.

Motion 9

It was moved and seconded that the following amendment be made to the Subcommittee bylaws: "Subcommittee members who are absent in person or by conference phone from three consecutive workgroup meetings and who do not provide advance notification of their absence to the workgroup chair shall have their name removed from the roster of the workgroup. The member may be reinstated after providing notification to the workgroup chair prior to the next workgroup meeting of their intention to join the workgroup." The motion with a vote of 11 in favor and 2 opposed.

The following discussion resulted as a result of Motion 9:

~ Ms. Sonnenburg clarified that Subcommittee members can inform the chair why he or she is missing the meeting. Dr. Davidson agreed, saying that there may be legitimate reasons for missing meetings. Dr. Craig added that the three missed meetings without informing the chair have to be consecutive.

~ Mr. Johnson commented that it might be difficult to get in touch with the workgroup chair, but Subcommittee members can call the field office to say that he or she will not be present. Dr. Davidson agreed and said that a person who would miss a meeting could also inform another workgroup member of his or her impending absence.

~ Dr. Davidson then turned the discussion to the mission statement. Ms. Galloway had spoken to other members of the ad hoc committee and attempted to make adjustments in the mission, vision, goals, and objectives of the Subcommittee in accordance with the previous day's discussion. The committee members were not in agreement about the goals, but were ready to propose the mission and vision for ratification. Dr. Davidson suggested that the Subcommittee vote on the vision and mission statements and that the ad hoc committee reconvene to work on the goals and objectives.

Motion 10

Ms. Galloway moved that the following vision statement for the Subcommittee be adopted:

"To promote the health of potentially impacted residents in the 8-county region surrounding the Oak Ridge Reservation."

She further moved that the following mission statement for the Subcommittee be adopted:

"To provide ATSDR and CDC with advice regarding public health studies and activities relating to people who may have been exposed to radioactive and chemical emissions from the ORR."

The motion received a second, and discussion ensued.

Discussion related to this motion was as follows:

˜ Mr. Johnson wanted the 8 counties to be named in the mission statement. Ms. Galloway said that the ad hoc group had discussed having a watermark of the map of the affected area. Mr. Lewis wondered how the counties could be named, since portions of the counties are included in the affected area.

˜ Dr. Davidson supported maintaining general language in the mission statement. There is also ongoing discussion about the counties in the area.

˜ Ms. Mosby said that the vision is the ideal perception for the Subcommittee. The ideal would be for all residents in the surrounding area to have good health. She supported the original wording for the vision and mission.

˜ Mr. Johnson commented that in Knoxville, there are "9 counties, one vision." The counties should be included. Ms. Mosby suggested that the specifics be addressed in the goals.

˜ Dr. Davidson suggested only voting on the mission statement. Ms. Mosby felt that the vision and mission pieces should go together, as the goals and objectives go together.

˜ Dr. Davidson recalled a suggestion from the previous day's discussion, which was "to promote the health of all residents in the community affected by the Oak Ridge Reservation." There was general approval of this wording.

˜ Mr. Washington did not support that wording because the emissions from the facilities affect Kentucky and other areas, both due to airborne emission and by contaminating waterways downstream. Dr. Davidson felt that if their work helped the communities surrounding them, then other areas will benefit as well.

˜ Ms. McNally recommended the word "directly" so that the statement would address residents in the communities directly affected by the Oak Ridge Reservation. Naming the specific counties could be problematic in the future if other effects are found in other places.

˜ Dr. Akin observed that the discussion seemed to indicate that the original vision statement was their most appropriate choice, as each modifier used leads to a semantic debate.

Dr. Davidson called for a straw vote to determine the wording, and amended Motion 10 to reflect the consensus of the Subcommittee:

Motion 10 – Amended

The vision statement for the Subcommittee was amended as follows:

"To promote the health of all residents in the community surrounding the Oak Ridge Reservation."

The mission statement remained unchanged:

"To provide ATSDR and CDC with advice regarding public health studies and activities relating to people who may have been exposed to radioactive and chemical emissions from the ORR."

The motion carried with a vote of 12 in favor and 2 opposed.

The vision and mission statements were adopted, and the goals will go back to the ad hoc committee. The committee will also develop appropriate objectives and present both at the next meeting.

Mr. Pardue then offered three recommendations from the PHA workgroup.

Motion 11

Mr. Pardue moved that the Subcommittee approve a resolution from the PHA workgroup recommending that the Mangano paper not be used as a basis for the Oak Ridge Reservation Public Health Assessment. The motion received a second and passed with a vote of 10 in favor and 2 opposed. Discussion ensued.

Discussion of the motion was as follows:

~ Mr. Pardue clarified that the Dr. Mangano's written response to the evaluation included new facts, but did not question the evaluation or its judgements. The new information should still be evaluated, but did not have any impact on the recommendation.

~ Dr. Davidson further clarified that the recommendation only applies to the report that is in the open literature.

Motion 12

Mr. Pardue moved that the Subcommittee approve a letter to Dr. Koplan, administrator of ATSDR, which addresses the topic of sampling environmental media in the Oak Ridge area, requesting that ORRHES have input into the process and that the process be better developed and explained to the public. Dr. Davidson added that Dr. Elmer Akin would be added to the list of people who receive the letter. The motion received a second and carried with a vote of 13 in favor and 1 opposed.

Motion 13

Mr. Pardue moved that the PHA workgroup draft a letter to Dr. Henry Falk, assistant administrator of ATSDR, requesting provision of administrative support in the Oak Ridge Field Office to improve efficiency. There was a second. The motion passed unanimously.

The discussion was as follows:

- Dr. Pereira suggested that the letter go to Dr. Falk through Bob Williams, for protocol.

- ***Action Item***: Mr. Lewis suggested that Dr. Lucy Peipins be thanked formally for her efforts in helping the Subcommittee learn more about epidemiology and assisting with the evaluation of the Mangano paper.

Motion 14

Mr. Lewis moved that Design Number Three be approved as the ORRHES homepage and site map. There was a second and the motion passed unanimously.

Mr. Lewis then introduced the second recommendation from the Communications and outreach Workgroup, which addressed capturing current and historical concerns into a database. With this system, there will be a formal list of the issues that are being addressed. There can then be a link between those concerns or issues and the resultant resolutions or findings. The recommendation came to the workgroup from a non-Subcommittee member.

Motion 15

Mr. Lewis moved that an ATSDR employee read the Oak Ridge Health Assessment Steering Panel's meeting minutes and put concerns into the present format to capture the concerns for ORHASP. The definition of "format" refers to the comment sheet being used. This motion was amended following further discussion.

The following discussion was held regarding Motion 15:

- Dr. Davidson wondered whether all meeting minutes were expected to be reviewed, and wondered whether the feasibility of this activity should be assessed, since the volume of minutes was not specified. Mr. Lewis understood that there were a number of meeting minutes. He agreed about assessment of reviewing the minutes, adding that once the process begins, then the feasibility of gathering concerns from other sources can be assessed.

- Dr. Pereira suggested that in workgroup meetings, when a topic of concern is raised but not fully discussed as part of the agenda, it should be captured in a condensed, "parking lot" form. With this approach, there can be no interpretation issues.

~ Mr. Lewis added that there should be a standard operating procedure to capture these concerns. The workgroups should capture concerns, he agreed. The larger problem is with historical records. There is a history of issues in the community. They should be captured and addressed.

~ Ms. Mosby recalled the request from the workgroup meeting. She had not supported it because she found it to be a tedious task that was too nebulous. The idea has merit, though, because the historical concerns need to be captured. She suggested looking at the feasibility of the project before making a recommendation about it: its size, where the records are located, and how it might be accomplished.

~ Dr. Davidson commented that database development can continue, and noted that concerns in Subcommittee and workgroup meetings can be captured on an ongoing basis.

Motion 15 – Amended

Mr. Lewis amended his motion to read, the Subcommittee recommends that ATSDR move ahead with a database that captures community concerns and issues which has links to the resolutions that are associated with them. There was a second, and the motion passed with a vote of 13 in favor and 1 opposed.

General discussion continued:

~ ***Action Item***: The Subcommittee recommended that ATSDR look at the feasibility of reviewing ORHASP minutes to capture historical concerns of the Oak Ridge community.

~ Ms. Mosby hoped that this action item would have closure at the next meeting.

~ Mr. Lewis pointed out that the needs assessment would be another source for these community issues and concerns.

~ ***Action Item***: Mr. Lewis had another recommendation from the Communications and Outreach Workgroup, but he suggested taking it back to the workgroup for further refinement and review it, in light of recent changes.

~ Mr. Pardue commented that a FACA group just like the Subcommittee wrote a letter recommending a clinic to the Secretary of Energy four years ago. The letter was developed in a workgroup with broad representation from sick workers and residents as well as people who were not convinced that there were ill people. While he liked to see

the idea of a clinic being strengthened, it would be remiss not to acknowledge the work of the other group and its letter, which he believed led to the establishment of this Subcommittee.

˜ The Subcommittee turned to a consideration of future meeting dates. They considered conflicts with other groups that meet in the area. They also noted the need for planning and preparation.

Motion 16

It was moved and seconded that the next ORRHES meeting be held in Oak Ridge on January 11th after a straw vote was conducted to assess consensus. The motion passed unanimously.

The Subcommittee then tentatively marked meeting dates through June, 2002. They can revisit whether the format is working in the future, and the dates can be adjusted.

- February 11, 2002
- March 26, 2002
- May 6, 2002
- June 18, 2002

There was discussion about when new Subcommittee members would be selected. The hope was to have them selected by the March meeting. The approval process is lengthy enough that it was unlikely that they would be confirmed by then, pointed out Dr. Murray. They could, however, attend meetings as non-paid, non-voting members.

Ms. Dalton then introduced the ethics video, ***The Ethical Choice: Ethics for Special U.S. Government Employees***.

Public Comment

Ms. Gass
Member of the Public

Ms. Gass showed the group a poster that is a draft of the time line. There is quite a bit of information on the poster, and it is an attempt to summarize historical information. Also, it should be noted which processes are well-defined and over. For example, the 13-year time period for Iodine-131, in the late 1940s and early 1950s, coincides with the large "baby boomer" birth cohort being exposed in early childhood. That process is clearly defined, and its end is

clearly documented. The poster indicates that some processes are ongoing, or their end is not clearly defined. They should have as good an understanding as possible of historical data and of ongoing processes such as current releases, current processes, and work that is still ongoing. EPA is charged with reviewing ongoing and future concerns, but not historical data .

She observed a great deal of change in the past year. As recently as a few months ago, the thought of having a clinic in Oak Ridge was not even discussed. She believed that it was good for the Subcommittee to discuss a clinic openly. She is more optimistic and has some hope that things could be turned. It will take a great deal of effort to turn the momentum from its original direction. The "unofficial website" has been the source of formative information for the process. It has not been open and receptive to people coming forward with concerns. She recalled the day's discussion, which had included the point that if a person works in a place long enough, he or she will experience health-related problems. Nobody in Oak Ridge has an idea of how many people have been affected, she said. Some of the health concern are at a deep level.

Ms. Gass offered an example of a citizen who had told her about how her husband prematurely died of cancer. They had both been well-positioned in Union Carbide and her husband continued working into Martin Marietta. When he was dying, he did not want questions to be asked about the connection between exposure and his illness. Ms. Gass said that she had told this lady to be true to her husband's memory. If he did not want that connection made, then his widow had to honor that wish. This example illustrates that many people will not bring their concerns forward. In some cases, the people are dead or they or their heirs have given up. Ms. Gass did have hope, though, because discussion about a clinic would not have been possible six months ago, when "the c-word" was taboo. The process has been opened up and she has the hope that several people on the committee are open-minded and want to do the right thing for the community, getting to the truth of the matter. The question now is what to do at the end of the process, when the truth comes out. She hoped that they would not worry about legal implications and suppress information. She also had hope that people who need help would get help.

<u>Discussion Summary:</u>

˜ Dr. Davidson thanked Ms. Gass for her comments and assured her that "the c-word" would re-surface in Subcommittee and workgroup discussions.

˜ Mr. Lewis commented that it was helpful when people from the community take the time to review documents and to bring issues to the Subcommittee members' attention, challenging the Subcommittee. The efficiency of their overall operation should improve to get more information to the public in a structured way.

Identification of Action Item Assignments/Closing Comments

Dr. Kowetha Davidson, Chair
Oak Ridge Reservation Health Effects Subcommittee (ORRHES)

Dr. Davidson led the group in a final discussion. She reviewed the list of action items for the Subcommittee, reading them into the record. A complete list of these items, with the motions posed and voted upon included, is attached to this summary document. She reminded the Subcommittee that workgroup meetings should be scheduled through the field office.

<u>Discussion Summary:</u>

~ Ms. Sonnenburg, the chair of the Agenda Workgroup, suggested that their next meeting be on Thursday, January 3rd, at 4:00 pm.

~ Mr. Pardue, chair of the PHA workgroup, proposed that the next meeting would be Monday, December 10th, at the Oak Ridge Field Office at 5:30 pm. Major topics for the agenda included the upcoming visit from an ATSDR representative regarding current screening for contaminants.

~ Dr. Murray ensured that everyone had received copies of the draft minutes from the last workgroup meeting of November 5th. He offered to send the minutes to any new workgroup members and confirmed that his phone number was 865-220-0295.

~ Dr. Davidson reminded Subcommittee members that additional members are needed for the Communications and Outreach Workgroup and that they should sign up for the Guidelines and Procedures Workgroup, even though that group did not have a task.

~ Dr. Tim Joseph addressed the group. He had first seen the list of missing interviews and requested documents the previous day. Thanks to Steve Wylie at Y-12 and good record-keeping on the part of Senes, he was able to obtain the interviews, which he provided to the Subcommittee chair. They were not the interviews that Dr. Joseph had thought they were; they are interviews that were conducted in Oak Ridge by Senes during their modeling. The interviews are public information. He was also able to get an additional interview.

~ Ms. Gass said that she had already asked Senes for the over 150 interviews, and Senes did not have them. Dr. Joseph said that he could try to get other interviews. Dr. Davidson said that copies of the interviews would be made available to Ms. Gass and that the originals would be kept in the Oak Ridge Field Office.

~ Ms. Mosby suggested that the Needs Assessment Workgroup meet on Monday, December 17th at 6:00 pm. The field office would not be available on that day, so an alternate location would be chosen and the meeting would be coordinated through the field office.

~ Dr. Joseph noted that workgroups needing space to meet could consider doing so at the guard houses, which have been renovated and are open for the public's use, free of charge.

~ Mr. Washington reviewed a statement of his from the September 11th meeting, in which an EPA presentation resulted in his approval of having an EPA representative on the Subcommittee. Consequently, he made the following motion:

Motion 17

Mr. Washington moved that the Subcommittee recommend to ATSDR that a DOE liaison be included as a member of the Subcommittee. Mr. Lewis seconded the motion. After discussion, the motion was withdrawn.

The discussion continued:

~ Mr. Hill offered a difference of opinion. The Subcommittee has to weigh the pros and cons that come with inviting DOE to participate in the Subcommittee. If there is a benefit to the community and the Subcommittee, then they should vote. A large population of the community have concerns about DOE being on the Subcommittee. There are even concerns that DOE is funding the Subcommittee, thereby making it biased. He did not feel that the Subcommittee is biased, but the perception of the Subcommittee in the community is crucial. DOE has separated itself from the Subcommittee, which he felt has been beneficial. He would support any Subcommittee decision, but did not feel that the Subcommittee has lost flow of information without having a DOE representative at the table, especially given the good information provided by Dr. Joseph.

~ Dr. Craig agreed that Dr. Joseph had done an outstanding job of providing the Subcommittee with information, and that DOE participation was a matter of perception. For the Subcommittee to maintain its credibility and have its results viewed as independent and worthwhile, it must remain separate from DOE. He did not believe that it was in the best interests of DOE to participate on the Subcommittee and urged DOE not to come to the Subcommittee. Ms. Kaplan agreed and pointed out that no other Subcommittee includes a DOE representative.

~ Ms. Sonnenburg felt that the topic should be discussed at the next meeting, as it is such an important topic that was not on the agenda. She hesitated to vote on the topic without prior notice. She offered a counter-motion:

Motion 17A

Ms. Sonnenburg moved that the topic be moved to the next meeting. The motion received a second and was amended after discussion.

Discussion continued:

~ Dr. Davidson suggested that if discussion on the topic is postponed, then an ad hoc group should examine it and bring a report to the full Subcommittee at the next meeting. Ms. Mosby felt that if the topic is tabled, then more information on it should be gathered before the next meeting. Dr. Davidson noted that the Subcommittee seemed to feel that the topic needed more time for consideration and discussion.

~ Mr. Washington, as the maker of the first motion, offered his rationale for having DOE representation on the Subcommittee. All other entities, such as EPA and TDEC, have liaisons at the table. He had initially not supported their participation because of community perception. As much as these entities are part of efforts in Oak Ridge, then they should be at the table, and the Subcommittee can hold them accountable to provide information to help them make decisions. EPA representation on the table resulted in benefit to the Subcommittee at the September 11th, when a high-level official addressed them.

~ Mr. Lewis said that if a smaller group meets to consider this topic, then the proceedings should be documented so that their logic can be documented and clear action can be specified. He also noted that this issue should be resolved before new Subcommittee members are selected.

~ Dr. Davidson recommended that the topic should be discussed fully with time in the agenda at the next Subcommittee meeting. The full Subcommittee should participate in discussion on this topic, not just a sub-group. Dr. Creasia agreed.

~ Dr. Craig pointed out that Dr. Joseph can get information for the Subcommittee, as proven by his acquisition of the interviews, without the Subcommittee having to suffer any negative perceptions from the community by having a DOE representative serve as a liaison on the committee.

Motion 17A – Amended

Ms. Sonnenburg amended Motion 17 to read that the topic be reviewed by the Communications and Outreach Workgroup and then brought to the full Subcommittee for discussion at the next meeting. The motion was withdrawn after discussion.

Discussion continued:

~ Dr. Davidson strongly recommended that the topic be brought to the full Subcommittee for discussion in a specific time on the agenda.

~ Ms. Mosby noted that bringing the issue to a workgroup would collect input from a wide variety of people. It would also provide a chance to articulate the pros and cons of having representation.

~ Ms. Sonnenburg withdrew her amended motion, asking Ms. Mosby to restate it. Mr. Washington withdrew his original motion and offered a new motion.

Motion 18

Mr. Washington moved that the Communications and Outreach Workgroup study the issues surrounding, and conduct a full discussion of, bringing a DOE liaison to the Subcommittee. Time on the next Subcommittee meeting agenda should be devoted to deliberating the Workgroup's information and to full Subcommittee discussion of the issue. The motion received a second. The motion failed with a vote of 5 in favor and 6 opposed.

Discussion continued:

~ Ms. Kaplan felt that sending the issue to a workgroup would be divisive. The workgroup is an uncontrolled, small group environment. There is a great deal of emotion involved in this issue, and she strongly encouraged that it be discussed fully in the more formal setting of the Subcommittee.

~ Dr. Davidson requested that the Agenda Workgroup put the issue on the agenda for the next Subcommittee meeting.

~ Mr. Pardue wondered whether, since Dr. Joseph was working to get the documents requested, a letter from the PHA Workgroup requesting the interviews was still necessary. Dr. Davidson decided that the letter-writing should be postponed to see what Dr. Joseph could produce.

~ Dr. Joseph pointed out that the interviews are a small component of the list, which contains many other documents and items that are not DOE-owned. He would do his best to get as many of the items as possible, but they are not all his responsibility. Mr. Pardue said that they would write the letter and then see if it was necessary to send it.

Evaluation Consensus-Building Process

Mary Ann Downey
Consensus Building Presentation

Ms. Downey addressed the group regarding their work with the Consensus Building Process. She said she appreciated everyone's frustration and encouraged them all to take care of themselves. She provided them with a handout and said that Ms. Dalton would send them all a copy of the evaluation summary. In essence, she said, they "are doing it right." She would also provide the results of the individual evaluation of the Subcommittee.

She asked the group whether they felt that they were ready to begin working in small groups, bringing that information back to the Subcommittee. According to her evaluation, the group was at that point. They should work at both levels, gathering information and opinions in a workgroup setting and then bringing that "homework" to the full Subcommittee.

Mr. Lewis advocated for developing a process for evaluating things. Without these processes, a conclusion might not be possible on any issue. Ms. Downey agreed, and then addressed the concept of consensus. She works with troubled youth in Atlanta on consensus, and she keeps the ideas basic:

- Speak out
- Listen up
- Go for diversity
- Teamwork
- Pull together on a plan

She felt that the Subcommittee had consensus "right." She asked Dr. Craig to read a story about how geese operate in a collective and what humans can learn from these facts. Ms. Downey concluded by sharing motivations that she had found from walking a marathon. She ended the session by playing a folk song from coal miners in Kentucky.

With no further business posed, Ms. Dalton thanked the group for their participation. With that, the meeting was adjourned.

End of Summary Report

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