B·O·S·C

BOARD OF SCIENTIFIC COUNSELORS

REVIEW OF THE OFFICE OF RESEARCH AND DEVELOPMENT'S DRINKING WATER RESEARCH PROGRAM AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY

Final Report

BOSC SUBCOMMITTEE ON DRINKING WATER RESEARCH

Gary S. Sayler (Chair) – University of Tennessee, Knoxville
James H. Johnson, Jr. (Vice-Chair) – Howard University
Chi-Hsin Selene Chou – Agency for Toxic Substances and Disease Registry
James Raymer – RTI International
David L. Sedlak – University of California, Berkeley
Mary H. Ward – National Cancer Institute NIH/DHHS (Consultant)

October 27, 2005

This report was written by the Drinking Water Research Subcommittee of the Board of Scientific Counselors, a public advisory committee chartered under the Federal Advisory Committee Act (FACA) that provides external advice, information, and recommendations to the Office of Research and Development (ORD). This report has not been reviewed for approval by EPA, and therefore, the report's contents and recommendations do not necessarily represent the views and policies of the EPA, or other agencies of the federal government. Further, the content of this report does not represent information approved or disseminated by EPA, and, consequently, it is not subject to EPA's Data Quality Guidelines. Mention of trade names or commercial products does not constitute a recommendation for use. Reports of the Board of Scientific Counselors are posted on the Internet at http://www.epa.gov/osp/bosc.

TABLE OF CONTENTS

I. SUMMARY 1
- I.1 Introduction 1
- I.2 Review of Objectives and Charge 1
- I.3 Findings 2
- I.4 Conclusions and Recommendations 4

II. REVIEW OF THE DRINKING WATER RESEARCH PROGRAM 6
- II.1 Introduction 6
- II.2 Objectives 7
- II.3 Long Term Goal 1: Regulated Contaminants 7
  - II.3.1 Introduction 8
  - II.3.2 Surface/Ground Water Rules and Distribution Systems 8
  - II.3.3 Arsenic 11
  - II.3.4 Disinfection Byproducts (DBPs) 12
- II.4 Long Term Goal 2: Unregulated Contaminants 13
  - II.4.1 Introduction 13
  - II.4.2 Contaminant Candidate List 14
  - II.4.3 Source Water Protection 18

III. QUALITY 20

IV. SCIENTIFIC LEADERSHIP 22

V. COMMUNICATION AND COORDINATION 24

VI. APPENDIX A: DRAFT CHARGE QUESTIONS FOR ORD'S DRINKING WATER RESEARCH PROGRAM REVIEW 26

VII. APPENDIX B: DRINKING WATER SUBCOMMITTEE MEMBER BIOGRAPHIES 28

VIII. APPENDIX C: LIST OF ACRONYMS 31

I. SUMMARY

I.1 Introduction

The U.S. Environmental Protection Agency (EPA) Office of Research and Development (ORD) is responsible for the conduct of research to strengthen the Agency's science base and to provide critical data, information, and tools to EPA's program and regional offices to support the development and implementation of environmental policies, regulations and practices. The principal statutory authority driving ORD's Drinking Water (DW) research is the Safe Drinking Water Act (SDWA) of 1974, as amended in 1986 and 1996, with a requirement for regulations to be based on sound and objective science.

ORD conducts both problem-driven and core research in drinking water, largely in support of the needs of the Office of Water (OW) as its principal DW client. In June 2005, ORD sought an independent Board of Scientific Counselors (BOSC) expert review of its Drinking Water Research Program (DWRP). This is, in part, driven by the need to prepare for performance and accountability reports to Congress under the Government Performance and Results Act (GPRA) of 1993.

The DW research program contributes mainly to EPA's Strategic Goal 2 for Clean and Safe Drinking Water, as described by the Agency's 2003-2008 *Strategic Plan*. The DWRP mirrors the Agency's 2003 Draft Multi-Year Plan (MYP) for Drinking Water Research focusing on two modified Long Term Goals (LTGs). These LTGs are prescribed by the SDWA. LTG 1 is inclusive of the regulated contaminants, the 6-year review cycle for contaminants, and water distribution systems. LTG 2 focuses on unregulated contaminants and the Candidate Contaminants List (CCL) process and is inclusive of source water protection.

After consultation with the Agency, the BOSC established the BOSC Drinking Water Research Subcommittee to review and evaluate the ORD DWRP. The Subcommittee members communicated through an administrative conference call followed by two formal conference calls that were open to the public. The Subcommittee met with ORD staff, the Acting National Program Director (NPD) for DW, individual researchers, Science To Achieve Results (STAR) grantees, program clients and stakeholders, and the public on June 21-23, 2005, in Cincinnati, Ohio, to conduct the review and draft a review report for BOSC Executive Committee approval.

I.2 Review of Objectives and Charge

The specific objective of this BOSC review was to evaluate the relevance, quality, performance, and scientific leadership of ORD's DWRP. This review was anticipated to assist ORD in program enhancement, comparative analysis with other similar programs, intermediate mid-term investment decisions, GPRA reporting, and response to the Program Assessment Rating Tool

(PART) process. The Subcommittee was asked to respond to six multi-component charge questions. These charge questions are summarized below and are provided in entirety in **VI. Appendix A** (see page 23).

1. **Program Relevance**. Is the DWRP focusing on EPA's strategic goals, and are potential public benefits clearly evident?

2. **Program Design**. Is the program design logical, with goals and priorities clearly identified and with the MYP describing an appropriate flow of work?

3. **Progress on Key Scientific Questions and Client Needs**. Has progress been made toward the LTGs while addressing key science questions in a rational and clearly articulated manner? Has the research met the clients' needs in a timely fashion with outcomes identifiable in environmental decisions, regulations, and technical assistance?

4. **Scientific Quality**. What is the scientific quality of the research product, and is it ensured through competitive merit-based funding? How is quality maintained, and how are funds allocated for non-competitively awarded projects?

5. **Scientific Leadership**. Have the program and/or individual ORD researchers demonstrated or played a leadership role in drinking water research, problem-solving, or advancing the frontier of science?

6. **Coordination and Communication**. Does the program effectively engage scientists and managers from both ORD and DW in planning and identifying key gaps? Is the process open to all stakeholders and the science community? How effective is interagency interaction in advancing EPA's research agenda, and are there effective mechanisms for research communication?

Through the course of this review, the Subcommittee was focused keenly on the issues of research "outcomes," that being the use, impact, or application of the research at a higher level than preparation of a report or publication of a scientific article. To assess the translation of outputs into outcomes, the Subcommittee conducted its review with careful consideration of communication within and among agencies, stakeholders, and the public and how this was used to ensure that the ORD DWRP contributed to EPA's long-term goals.

I.3 Findings

The BOSC Subcommittee finds that the DWRP is relevant and critically important to EPA's mission in protecting human health and the environment. The program is focused on high quality research of national importance in support of OW, and in particular EPA's Strategic Goal 2 for Clean and Safe Water.

Research projects within the DWRP are timely and consistent with the MYP for Drinking Water Research. In particular, research progress for regulated contaminants (LTG 1) has been

excellent. There also has been good progress on the CCL (LTG 2). Innovative research and methods development, a second component of LTG 2, has allowed ORD to stay involved in rapidly evolving areas, such as genomics and proteomics, bioinformatics, computational science, and toxicology, as they relate to DW problems and research needs. The STAR grants program continues to play an important role in bringing in new and needed expertise and vigor to enhance the overall performance of the DWRP.

Scientific leadership by ORD staff members has been significant in the past; but, both reduced funding and data and information mandates imposed by the SDWA threaten ORD's broader leadership role. Research funding, which has decreased in recent years after accounting for inflation, is not keeping pace with the challenges associated with protecting public health. The diminished resources are likely to limit ORD's ability to maintain broad scientific leadership in the DW field without extensive partnering and leveraging with other agencies and nongovernment organizations (NGOs). Individually, some ORD researchers will continue to provide strong scientific leadership, but ORD's leadership may only be sustainable in certain pockets if this issue is not addressed soon.

It is clear that research outputs from the DWRP are leading to important outcomes with respect to OW and other clients, including the states, and stakeholders such as the drinking water utilities. It often is difficult, however, to quantify specific outcomes within the current structure of ORD. There appears to be a need to enhance the accounting metrics, visibility, and communication of the DWRP outputs contributing to these outcomes.

A major departure from the draft MYP for Drinking Water Research has been the consolidation of three LTGs into two. LTG 3 in the MYP, which comprised both distribution systems and source water protection research, now is nested within LTG 1 (distribution systems) and LTG 2 (source water protection) in the DWRP. Ultimately, these are both important topics from the near- and long-term perspectives of safe drinking water including the homeland security perspective. The BOSC Subcommittee was asked to comment on this change of collapsing three LTGs into two and whether, within these two goals, sufficient attention was being directed at the research priorities of former LTG 3.

High quality research is being conducted in the areas of source water protection and distribution systems. Based on reviews of research posters and discussions with researchers, it appears that STAR grant recipients are being relied upon for more fundamental work and research that fills critical information gaps in a particular project area, while internal ORD work represents application of results from other researchers. There is evidence of good collaboration between ORD and other agencies and private firms to address homeland security issues of source water monitoring and early warning systems. This collaboration is being promoted through ORD's National Homeland Security Research Center and the Testing and Evaluation Facility in Cincinnati, Ohio.

The exact rationale for collapsing three LTGs into two remains somewhat elusive. While the placement of the former LTG 3 efforts into LTGs 1 and 2 makes some rational sense (regulated versus unregulated contaminants); the fit is not perfect, and it is worrisome to the Subcommittee that the two topical areas of research (source water protection and distribution systems)

ultimately may be underrepresented in the DWRP research portfolio. It is recognized that relatively limited resources are being applied to these areas and, consequently, reorganization of the LTGs may not have resulted in a significant decline in the priority of these research topics.

I.4 Conclusions and Recommendations

1. The decision to consolidate three LTGs into two is not well justified. Although it may lead to a streamlined research plan, it also may result in an unintended de-emphasis of source water protection and distribution systems research. Given budget constraints this may be unavoidable, but it is likely that these research areas will continue to grow in importance, partly as a result of homeland security issues and the further recognition of the impact of source water on drinking water quality.

   The ORD/DWRP should continue to evaluate the question of whether the two LTGs can accommodate the source water protection and distribution systems research needs adequately.

2. The SDWA and rules drive the MYP for Drinking Water Research; this in turn, guides research efforts and investment in the DWRP, which further constrains the scope of research and limits the magnitude of "anticipatory" research the program can support.

   ORD should evaluate strategies that could be implemented to encourage more cutting edge research to identify and circumscribe issues, problems, and solutions that impact safe drinking water. One such strategy could be to invest greater resources in the STAR Program for an enlarged anticipatory research effort.

3. EPA's role as a science leader is multifaceted and is perceived differently by differing constituents both within and outside the Agency. In a pure research context, however, ORD's historical leadership role in drinking water research is eroding. While it is expected that islands of science and scientific leadership will be maintained, resource availability and federal regulatory mandates will define those areas where ORD will have recognizable international leadership.

   ORD is strongly encouraged to develop a "Science Leadership" mission statement and to identify those areas it believes it is capable of establishing or sustaining international leadership over the long term. This will be challenging, given the dynamics of such issues as homeland security or global change as they are superimposed on more conventional topics and mandates in drinking water research. Without such a vision, however, ORD runs the risk of becoming too applications-oriented and implementations-oriented in its DWRP, with little direction for individuals to strive for scientific leadership.

4. ORD's DWRP has had significant outputs that have been translated by its clients into outcomes, largely in support of its principal client, OW, but also in support of states and industry. Unless the client is active in attributing ORD's research contributions to outcomes, these contributions are difficult to identify and quantify.

ORD needs to be proactive in developing metrics to document and support its assertion that translation of its research outputs is making significant contributions with respect to downstream outcomes as part of the overall logic model. If "outcomes" are indeed an important GPRA and PART process metric, then a focused effort is needed to make the process of outputs-to-outcomes transparent.

5. The CCL process is challenging, given the potential for large numbers of contaminants. Additional resources ultimately will be needed by ORD to respond adequately to this mandate.

   ORD is strongly encouraged to aggressively pursue partnering with other agencies and NGOs to ensure that the CCL needs are addressed adequately.

6. The STAR Program remains critical to EPA's overall research strategy and capabilities. The program lends diversity and vigor to ORD's research mission.

   To anticipate new problems in drinking water contamination, treatment, distribution, and source water protection, the Agency should consider STAR solicitations that are somewhat more open ended. In particular, research contributing to the CCL process could benefit from greater levels of anticipatory/exploratory research.

II. REVIEW OF THE DRINKING WATER RESEARCH PROGRAM

II.1 Introduction

A BOSC Subcommittee was established to respond to ORD's request for an independent review of the DWRP. This Subcommittee was comprised of Dr. Gary Sayler (Chair), University of Tennessee; Dr. James H. Johnson, Jr. (Vice Chair), Howard University; Dr. David Sedlak, University of California, Berkeley; Dr. Chi-Hsin Selene Chou, Agency for Toxic Substances and Disease Registry (ATSDR); Dr. James Raymer, Research Triangle Institute; and Dr. Mary Ward, National Cancer Institute. Dr. Ward's official capacity was as a consultant to the Subcommittee.

The Subcommittee was provided with extensive Agency and program documentation and background information that included the EPA *Strategic Plan* (2003-2008) Goal 2; the 2003 Draft MYP for Drinking Water Research; ORD's organizational structure, facilities, and priority-setting strategy; the program logic model and LTGs; and a compilation of references and sources useful to responding to specific charge questions. Two pubic teleconferences were held with the Subcommittee and ORD administrators and managers to review the documentation and receive briefings on the DWRP structure and goals and the PART process. The Subcommittee also was able to request and receive supplemental information, such as the Science Advisory Board (SAB) Drinking Water Committee 2004 Review Report of the DW MYP. All of this information was provided to the Subcommittee prior to the formal onsite review, which was held in Cincinnati, Ohio, on June 21-23, 2005.

The onsite review was a public process, consisting of overview and explanatory presentations from the Acting Deputy Assistant Administrator for Science, ORD; various Acting Directors from the research laboratories and centers, as well as the Acting NPD, ORD Drinking Water Research. The Subcommittee was able to question the presenters fully, and several requests for further documentation and clarification were made through the Subcommittee Chair and the Designated Federal Officer (DFO) for the Subcommittee. ORD administrators were responsive to these requests.

A significant effort was devoted to the Subcommittee's review of poster presentations by ORD researchers, collaborators, and STAR grantees. The poster presentations were organized around LTGs 1 and 2 of the DWRP. There was excellent turnout and ample opportunity for Subcommittee discussion of the research goals, outputs, and potential outcomes with ORD researchers and poster presenters. Agency program offices as well as state and research partners, such as the American Water Works Association Research Foundation (AwwaRF), provided their perspectives on the relevance of the DWRP. There also was an opportunity for public comment, and, at the conclusion of the meeting, the Subcommittee provided an out-briefing of the general findings and impressions gathered during the course of the reviews.

During the review, the Subcommittee requested specific documents to clarify the following questions:

1. How do ORD laboratories prioritize and implement their intramural DW research programs?

2. Following peer review, how are meritorious proposals selected for award, given that available funding can only support a very limited number of awards?

3. To what extent does the National Program Director (NPD) have budgetary authority for DW resource allocation across the ORD program?

4. What is the review and evaluation process to ensure quality science for contractors and cooperative agreements?

The information provided to the Subcommittee and the onsite responses to the first three of these questions were adequate to assist the Subcommittee's review of these issues. An oral response was provided for the fourth question, but was left somewhat ambiguous in terms of a concise ORD response.

II.2 Objectives

The objective of the Subcommittee review of the ORD DWRP was to evaluate of the relevance, quality, performance, and scientific leadership of the program. Specific charge questions focusing on these issues and to be addressed by the review are listed in **VI. Appendix A**; however, each of these charge questions will be reiterated for LTG 1 and LTG 2 research results and outcomes independently.

The PART review is used by the Office of Management and Budget (OMB) to evaluate program effectiveness in areas of Purpose/Design, Strategic Planning, Program Management, and Program Results. The BOSC Subcommittee review is an external evaluation that contributes to the Strategic Planning and Results evaluation section of PART. Results are linked to Annual and Long-Term Performance Goals with an emphasis on "outcomes." Results represent 50 percent of the PART score, and the Strategic Planning and Results combined account for 60 percent of the score.

Quality, relevance, and performance are key research and development PART issues used to guide OMB/Office of Science and Technology Policy Investment Criteria. Thus, a primary output of this BOSC review is not only to assist the Agency in evaluating the DWRP science, but also to provide the mandated external independent evaluation for the PART process.

II.3 Long Term Goal 1: Regulated Contaminants

ORD's stated, outcome-oriented, LTG 1 is **"Office of Water and other key clients *use* ORD's new scientific data and leading-edge approaches in the Agency's Six-Year Review decisions."**

II.3.1 Introduction

LTG 1 encompasses research related to future changes in regulations pertaining to drinking water contaminants that already are regulated under the SDWA and related regulations. In particular, research is being conducted on arsenic, disinfection byproducts (DBPs), and priority contaminants undergoing 6-year reviews, such as lead and copper. LTG 1 also includes research on drinking water distribution systems, which originally was included under LTG 3.

The research program has been designed to address the largest uncertainties associated with future regulatory decisions. The research provides critical data needed to assess the occurrence of contaminants in drinking water, their human health effects, and the efficacy of treatment technologies. ORD has a long history of research on these topics and, as a result, there is considerable expertise in the various laboratories. The research program timing and focus is closely connected to regulatory mandates. ORD staff members have established collaborations with federal researchers outside of EPA (e.g., Centers for Disease Control and Prevention [CDC]) and with academics through cooperative agreements. These collaborations have expanded the expertise of the Agency into new areas.

II.3.2 Surface/Ground Water Rules and Distribution Systems

Program Relevance

Surface/Ground Water Rules
Subsequent to an outbreak in Milwaukee, Wisconsin, affecting 400,000 people in 1993, considerable attention was focused on the risks posed by *Cryptosporidium* in surface waters. The greatest challenges associated with the development of regulations to protect public water supplies from *Cryptosporidium* were related to the absence of good monitoring techniques, data on the infectivity of different strains of the organism, and its fate in different types of treatment systems. Much of ORD's research in support of surface and ground water rules was related to addressing these critical issues.

In addition to *Cryptosporidium* in surface waters, several other pathogens posed challenges to public water supplies. ORD has supported research on other pathogens in ground water and drinking water distribution systems by developing improved methods for microbial risk assessment and epidemiological studies targeted at determining the frequency and causes of outbreaks.

Distribution Systems
The 6-year review requires an evaluation of regulated contaminants of concern. In particular, research has focused on lead and copper. In most cases, lead and copper are derived from the water distribution system or plumbing within homes. ORD research is addressing the effect of residual disinfectants (e.g., chloramines) on the leaching of lead, copper, and arsenic in distribution systems important to safe water. This research is particularly relevant because aging infrastructures are more susceptible to leaching of metals. Furthermore, changes in treatment processes may mobilize contaminants from within the distribution system. Recent work has begun to investigate the release of organotin compounds from polyvinyl chloride (PVC) pipes in home plumbing. ORD also conducts research on biofilms in distribution systems because the biofilms can contribute to corrosion and can serve as reservoirs for pathogens. These issues will become more important as the infrastructure continues to age and as pathogens from the CCL become more of a concern in drinking water. Finally, distribution systems are critical to homeland security, and ORD's research on distribution systems has important implications for researchers focused on terrorist threats to water distribution systems.

Program Design

Surface/Ground Water Rules
Research being conducted on pathogens in support of surface and ground water rules closely follows the schedule described in the MYP. The research on *Cryptosporidium* follows a logical progression from detection to infectivity and then to treatment. The research on *Cryptosporidium* inactivation and removal in drinking water treatment processes was not a major focus of the MYP. It is a meritorious topic, however, and fits into the overall research objectives. This research demonstrates that ORD is able to support relevant projects that are not articulated fully in the MYP. The Subcommittee believes that the MYP should guide ORD's research program, but the program should retain the flexibility to include different projects as opportunities arise or as new research becomes available.

Distribution Systems
ORD has developed expertise in the area of corrosion and biofilms. The corrosion research is linked to lead, copper, DBPs, and arsenic, while the biofilm research is linked mainly to pathogens. The Subcommittee believes that there may be advantages associated with better integration of research that is more inclusive of all elements of the distribution system (e.g., evaluating how biofilms affect corrosion or how corrosion products affect pathogen populations in biofilms).

The Subcommittee is uncertain of the merits associated with placing distribution systems research in LTG 1, an area that ORD has projected to become less important over time. Issues related to the management of distribution systems are likely to become more important in the near future and may merit more resources. For example, the American Society of Civil Engineers (ASCE) has projected that more than $11 billion per year will be needed to maintain and rehabilitate aging water distribution systems. It may be possible to extend the lifetime of aging distribution systems through different management approaches. Research is needed to determine the costs and public health implications associated with different options for maintaining distribution systems. Grouping distribution systems research with LTG 1 may prove

to be counterproductive, especially if it means that research in this area will continue to be subject to the current inadequate level of funding. The Subcommittee suggests that ORD consider restoring LTG 3 from the MYP and allocating additional resources to distribution systems and watershed protection commensurate with the needs in these two critical areas.

Current research on distribution systems is timed to coincide with 6-year reviews of lead and copper rules. Although it is important to coordinate research with rulemaking, the Subcommittee also sees merit in research that is not directly tied to the 6-year review. For example, ORD research has demonstrated that changing residual disinfectants from free chlorine to chloramines may have played a role in recent increases in lead in the water distribution system of Washington, DC. It may be appropriate to conduct research after new regulations are implemented to assess the impacts of changes in treatment methods on water quality.

Some of the current research on distribution systems relies upon dedicated facilities or long-term contracts to conduct field work through contractors. For example, the contract for the Testing and Evaluation Facility in Cincinnati, Ohio, has been used to conduct research on chlorine and DBPs in distribution systems. Research also is being conducted at a dedicated pipe loop facility. The pipe loop research has considerable overlap with research conducted at a similar facility in Montana (run by one of the investigators associated with ORD's facility), and the contributions of the EPA facility are incremental at best. Furthermore, biofilm research at actual field sites, where pipes have been aged in the presence of biofilms, may have more merit than the controlled conditions of a pipe loop. This type of research (i.e., long-term commitments for fixed facilities) provides ORD with little benefit compared to the amount of resources allocated. Given the limited funding available to ORD's DWRP, a reallocation of resources to areas with a higher return might be appropriate.

Progress

Surface/Ground Water Rules
The research program for *Cryptosporidium* has made significant progress in addressing the water quality challenges posed by the presence of the pathogen in water supplies. In particular, the research on *Cryptosporidium* infectivity and removal has provided information that is useful in the protection of public health and the design of treatment systems. The new analytical methods developed for *Cryptosporidium* measurement will be crucial to the implementation of the Information Collection Rule and will provide numerous future benefits.

Distribution Systems
The research focused on the fate of metals in distribution systems has been a highlight of ORD's mandate to minimize human exposure to toxic metals. The theoretical studies on the chemistry of metals in distribution systems have provided a new understanding that will be useful in managing distribution systems. The research in this area also has shown tangible outcomes, such as the contribution of ORD's research team to identifying the causes of elevated lead concentrations in Washington, DC's, water supply.

Strengths

The *Cryptosporidium* research has been highly responsive to the Agency's objective of ensuring safe drinking water. ORD has played a leading role in a comprehensive research program that integrates expertise from the National Exposure Research Laboratory (NERL), the National Risk Management Research Laboratory (NRMRL), and the STAR Program managed by the National Center for Environmental Research (NCER). The progress in this area is particularly noteworthy in light of the interdisciplinary nature of the problem.

In the distribution system area, ORD has made good progress in developing a better understanding of corrosion and its role in the release of contaminants.

Opportunities

Surface/Ground Water Rule
ORD and the scientific community have identified a need to conduct comprehensive epidemiological studies to understand the sources of disease outbreaks and the efficacy of different actions that can be taken to prevent outbreaks. The funding levels for ORD projects typically are too small and the timeframes too short to complete these studies. ORD may need to increase STAR grant funding and the grant performance period and/or partner more effectively with other federal agencies or stakeholders to make progress in the area of epidemiology.

Distribution Systems
Research on distribution systems has not received the same attention as some of the other areas. The issues pertaining to distribution systems need to be better integrated (e.g., chemical and biological processes should be considered together). Furthermore, ORD should not restrict research on distribution systems to contaminants listed under LTG 1. The distribution system is relevant to many of the issues addressed in LTG 2.

A separate but important issue related to LTG 1 is the question of whether too much focus on regulatory determinations can be a handicap. There are real issues related to the Agency's goal of safe drinking water that are not addressed effectively by LTG 1 and LTG 2. For example, how are ORD staff members anticipating new problems outside of CCL issues? Where does water reuse fit into the research program? Anticipatory research may fit well with the STAR Program rather than with proscriptive Requests for Proposals (RFPs).

II.3.3 Arsenic

Relevance

Arsenic is an element that is widely distributed in the earth's crust, and is a natural contaminant of water. Humans may be exposed to arsenic in air and from food and water. Arsenic is toxic and carcinogenic in humans. Information from recent studies has raised concerns about adverse human health effects from chronic exposures. EPA set a new maximum contaminant level (MCL) for arsenic of 10 ppb in 2001. The Arsenic Rule is subject to reviews in 6-year cycles.

The ORD DWRP for arsenic directly supports the Agency's strategic goals for Clean and Safe Water to protect the public health by ensuring the safety of the nation's public water supply. The research on health effects would strengthen the quantitative assessment of relationships between low dose (in the 10 ppb range) exposures and health effects. The research on treatment technology provides technical assistance that helps small systems and other stakeholders develop cost-effective strategies for implementing the new drinking water rule for arsenic.

Program Design

The ORD arsenic research program addresses the scientific questions pertaining to the implementation of the new rule and supports the 6-year reviews of the rule with a focus on research to improve the arsenic risk assessment.

Progress

Excellent progress has been made in characterizing arsenic exposures, biomarker development, and health effects evaluation in studies in human populations and in laboratory studies of toxicity, metabolism, mode of action, and pharmacokinetic modeling to support the new rule.

Much progress also has been made in conducting full-scale treatment technology/engineering demonstrations at 40 sites nationwide, developing guidance documents, and establishing outreach programs in support of timely implementation of the new rule.

Strengths

The research scientists are well qualified with proper expertise capable of conducting cutting-edge research and applying best available technology. The program includes human studies in the United States and in other countries. The program develops sensitive human biomarkers and addresses health effects from arsenic exposure in sensitive subpopulations.

Opportunities

The potential and possible need exist to develop a strategy to manage arsenic in residual wastes from treatment on a long-term basis. The magnitude of the problem scope has not been delineated fully. Technically, it may represent a significant issue, and there is a mandate to manage arsenic in residual wastes.

II.3.4 Disinfection Byproducts (DBPs)

Program Relevance

The DBP rule is designed to provide public health protection against waterborne pathogens while minimizing the risks posed by exposure to DBPs. ORD has a long history of conducting research on DBP exposure, health effects, and treatment. More recently, the research has focused on the remaining critical issues, including reproductive effects of specific DBPs and

DBP mixtures, health risk from exposure to byproducts generated from alternative disinfectants, and source waters of different quality.

Program Design

The research focuses on characterizing health effects of high priority byproducts and DBP mixtures and evaluating risk from alternative disinfectants (other than chlorine alone) and varying raw water quality in support of the implementation of the rule and to improve the science base for future reviews as required by the SDWA.

Progress

Excellent progress has been made in: (1) evaluating DBP reproductive/developmental effects, (2) developing methods for integrating multi-route exposures and dose-response data to evaluate exposure to complex mixtures of drinking water contaminants, (3) developing methods to monitor formation and occurrence of DBPs from source water of different quality, (4) developing methods to screen and detect DBPs produced from alternate disinfectants, and (5) awareness of unintended DBP perturbations from processes tailored to minimize a particular class of DBPs. When disinfection processes are changed to minimize one class (e.g., avoiding chlorination to minimize trihalomethanes [THMs]) other classes become more significant (e.g., brominated compounds as a result of ozone/chloramines). The new compounds could have toxic effects that need to be investigated.

Research results from ORD ultimately supported a regulatory outcome for a decrease in the total THM standard stage 1 DBP rule from 100 ppb to 80 ppb. ORD research data on the nonlinear cancer risk assessment of chloroform was used as basis for support changing the chloroform MCL goal (MCLG) from 0 ppb to 70 ppb in the proposed stage 2 DBP rule. ORD data on chronic effects of bromate were critical to the EPA non-cancer and cancer risk assessments presented in the EPA Integrated Risk Information System (IRIS) database.

Strengths

The DWRP is highly responsive to DBP issues. ORD is recognized internationally as a leader in DBP research. The DWRP draws expertise from broad areas of discipline inside ORD and has achieved successful team efforts as demonstrated by the four laboratory studies of DBP mixtures arising from chlorination. The research program also leverages and expands resources and expertise through productive collaboration with other agencies and organizations, such as the National Toxicology Program, the CDC, and the Department of Homeland Security.

Opportunities

Opportunities exist to develop research to fill data gaps in potential health risks and treatment technology of newly identified DBPs in drinking water treated with chlorination, such as haloacetonitriles, in addition to dibromoacetonitrile.

II.4 Long Term Goal 2: Unregulated Contaminants

ORD's stated, outcome-oriented LTG 2 is **"Office of Water and other key clients *use* ORD's relevant, timely, and leading-edge data, tools, and technologies in decisions leading to a scientifically sound Contaminant Candidate List process."**

II.4.1 Introduction

LTG 2 encompasses issues related to unregulated contaminants and is focused on the CCL and source water protection. Source water protection research formerly was included under LTG 3 in the MYP. Research on exposure and potential health effects of CCL chemicals and pathogens provides the scientific basis to support the 1996 SDWA Amendments, which require EPA to establish a list of unregulated contaminants to consider for regulation. The first CCL was finalized in 1998, and EPA is required to make regulatory determinations on at least five contaminants every 5 years. In 2002, EPA announced a determination not to regulate nine contaminants, which included eight chemicals and one pathogen. The second CCL (CCL2) was finalized in early 2005, and subsequent CCLs are scheduled every 5 years. The regulatory determinations for CCL contaminants can be to develop a drinking water standard, to provide a health advisory, or to decide not to regulate.

With regard to source water protection, the key scientific questions fall into four general areas: water quality criteria, source water assessments, prevention measures to address sources of contamination, and contingency planning (e.g., early warning systems). Source water protection research relates to the CCL research area, in that source water assessments are key to understanding the potential for future changes in contaminant occurrence and human exposure.

II.4.2 Contaminant Candidate List

Relevance

The CCL research program clearly is responsive to the Agency's strategic goal of Clean and Safe Water. The process of making regulatory decisions about contaminants on the CCL2 and evaluating additional contaminants for possible listing is one of the most challenging areas in the DWRP. Because this research effort is relatively new and many data gaps still exist, the potential public health benefits are not yet evident in some areas. Future outcomes of the CCL research program, however, may result in many public health benefits.

Program Design

The difficult charge of developing future CCLs drove ORD and OW to seek expert advice from the National Research Council (NRC) and the National Drinking Water Advisory Council (NDWAC). The NRC recommended a two-step approach of developing a CCL from a universe of contaminants that have the potential for human exposure, health effects, or both. The NDWAC report (May 2004) made specific recommendations for the implementation of the two-

step approach. As a result of this input from the NRC and NDWAC, identification of gaps in the data required to make CCL regulatory decisions occurs via a two-phase process. In Phase 1, analytical methods are developed and used to screen for the chemicals and pathogens on the CCL. Additional information is sought through a more detailed risk assessment/risk management process. The outcome leads to a regulatory determination or a decision to move a contaminant to Phase 2. During Phase 2, a more comprehensive database on analytical methods, occurrence, exposure, and treatment is generated. The research needs are specific to a chemical or microorganism.

The program design is logical, and goals and priorities are identified clearly. The research appears to follow the MYP closely. The framework for addressing the CCL research includes two scientific issues: (1) identifying data gaps on occurrence and health risks of exposure for at least five chemicals and pathogens on the CCL, and (2) development of innovative approaches for identifying and prioritizing unregulated contaminants for possible listing on the CCL.

Occurrence data for CCL contaminants are primarily obtained through the Unregulated Contaminant Monitoring Rules (UCMR). ORD's intramural and STAR research support this mandatory data collection through the development of measurement methods. Treatment studies to evaluate the effectiveness of routine treatment practices for removing CCL chemicals and killing pathogens are an important part of the CCL research program.

Progress

Research on CCL2 contaminants has taken on increasing importance within ORD, as proscribed by the mandated regulatory decisions and their associated timeline. The research budget allocation shifts from LTG 1 to LTG 2 reflect this change in recent years.

ORD is developing new analytical methods in support of the UCMR and is making those validated and detailed methods available to the research community. Excellent progress has been made for high priority pollutants, such as perchlorate. Good to excellent progress also is being made on treatment technologies. Laboratories are evaluating current treatment methods to determine their effectiveness in removing more than 35 CCL-related contaminants (e.g., endocrine disruptors, pharmaceuticals and personal care products [PPCPs], pesticides, and their breakdown products). A database that contains the efficacy of current treatment technologies to address CCL contaminants is being developed.

Research on innovative approaches has focused on developing methods for using genomic, proteomic, and cell-based assays to classify unregulated contaminants. There is, however, some disagreement on the most appropriate choices of gene arrays in genomics studies; such choices should be considered carefully. The aim of the research is to use these technologies to understand biological effects and modes of action by which a contaminant produces an adverse health effect. Although progress is being made in gearing up for the "omics" revolution, this progress is "catch-up" in nature with respect to ORD's capability in the drinking water area. This approach, which includes the development of biomarkers linked to health outcomes, then would be used for risk prioritization and screening of a large number of contaminants.

The Computational Toxicology Program of ORD's National Health and Environmental Effects Research Laboratory (NHEERL) is being used to develop models, including quantitative structure-activity (QSAR) models, to predict health effects to aid the development of future CCLs. To date, much of the research is focused on questions regarding unregulated DBPs and endocrine disruptors. The plan is to extend this approach to other CCL contaminants. Research using computational toxicology and QSARs for predicting contaminant behavior and health effects is ongoing. Several studies also are investigating the biological effects of mixtures.

New chemicals that can arise from new treatment schemes to address specific contaminant reduction problems are being investigated. For example, new DBPs arising from chloramination are being characterized. Research in this area follows closely from the experience with the regulated DBPs and the experience gained from these efforts should be translatable to other CCL contaminants.

For microbes, the research plan focuses on developing microorganism-specific information on serology, infectious dose, and surveillance. Research is focused on priority CCL pathogens including *Mycobacterium, Helicobacter*, and microsporidia. DNA microarrays are being developed for detecting multiple pathogens in water, and virulence factors are being evaluated for their usefulness in characterizing CCL pathogens. Another major problem area is the determination of the nature and magnitude of endemic and epidemic waterborne disease. This research involves both surveillance activities and community intervention studies to evaluate the risk of disease from waterborne microbes. These efforts involve extensive partnering with CDC and the National Center for Infectious Disease.

Studies are underway to evaluate the risk to susceptible subpopulations (immunocompromised individuals) from CCL microbes. To date, research has focused on *Mycobacterium avium intercellulare* (MAC) and, in the future, it also will be important to develop research programs for other potential pathogens to improve estimates of potential adverse health effects in susceptible subpopulations. Well-designed epidemiologic and human biomonitoring studies can play an important role in this effort.

Good to excellent progress is being made on understanding the nature and magnitude of endemic and epidemic illness caused by waterborne microbes. Research on endemic illness is focused on gastrointestinal illness. Epidemiologic studies to evaluate the risk of disease are key to this research area. Progress on assessing waterborne disease outbreaks through collaboration with CDC has been good.

Strengths

CCL contaminant research represents the most challenging area of ORD's DW research effort. A particular strength of the research program design is the use of experiences in the area of byproducts of disinfection to inform the research plan for CCL contaminants. The development of innovative methods for identifying, characterizing, and prioritizing contaminants is underway. Research is at the early stages and is innovative and showing reasonable progress. The development of screening methods is ongoing.

ORD has made excellent progress in the development, standardization, and dissemination of methods for high priority pollutants. For example, the perchlorate method development and standardization was useful in bringing common tools to bear for the affected stakeholders. The treatment technology database for CCL contaminants is an important resource for identifying and prioritizing CCL research. This area is particularly important because contaminants with treatment issues are the focus of additional research into treatment methods and will move into the next steps of risk characterization.

Research into the development of innovative methods for identifying, characterizing, and prioritizing contaminants is in the early stages. The research appears to be innovative and is showing reasonable progress to date. Good research progress is leading to improved methods in detecting and describing the spatial and temporal occurrence of cyanotoxins in aquatic environments.

It also appears that important contributions are originating from DWRP research to quantify levels of microbial pathogens and relative risks to susceptible subpopulations, such as the immune-compromised.

A major strength of the DWRP is the ongoing collaborative effort with CDC and STAR grantees to assess endemic and epidemic disease caused by waterborne microbes in distribution systems.

Opportunities

There are many challenges related to the CCL research program. Specifically, the anticipation of new CCL issues will require an understanding of likely trends in drinking water source use and source water assessments. There will be new chemicals, new endpoints (e.g., reproductive effects, endocrine disruption) and new treatment technologies that need to be evaluated. A potential mechanism for addressing these challenges could be to have more open-ended calls for STAR grants on CCL-related topics. The broad scope of the CCL research program and limited funding for this research means that partnering and value-added research will be critical to meeting the research aims of LTG 2. Anticipating potential future unregulated contaminants and prioritization of research on the current CCL will be aided by good communication and responsiveness between OW and ORD and stakeholders (i.e., utilities) and other agencies.

The use of computational toxicology and QSAR approach for evaluating potential health effects of CCL contaminants and screening future chemicals may be useful; however, caution should be used to ensure these methods are validated in some way and are not used in isolation.

In some areas, such as 1, 4-dioxane and in the early stages of perchlorate and methyl tertiary-butyl ether (MTBE) problem definition, one could argue that the ORD DWRP was late-to-the-table. It appears that EPA needs some way to respond quickly to the detection of new contaminants. At this time, it is not clear as to the degree that new “omics” will contribute to these efforts. Recent experience shows that identification of new contaminants requires followup on unusual observations and support for research that is not centrally planned 8 years in advance.

The problem associated with health effects of mixtures is acknowledged and is deserving of additional research. ORD has contributed to understanding the issue of mixture toxicity, and the complexity of this issue is far ranging. The issue extends beyond simple acute or chronic toxicity to complex synergies and antagonisms to the integrative effects in reproduction and developmental biology. This is expected to continue to grow as an area of priority concern and could be prime territory for STAR solicitations and multi-agency programmatic thrusts, which the ORD could lead.

Continuing research on waterborne disease requires ongoing surveillance efforts and long-term epidemiologic studies. Challenges in this area include the limited research budget for conducting the longer-term epidemiologic studies required. Additional opportunities should be sought for partnering with academic institutions and other government agencies.

The budget for CCL research has increased and now represents approximately one-half of the ORD DW research. The scope of the mandated research effort is considerable, however, and it will be important to prioritize research areas carefully and to ensure that maximum efforts at partnering are made.

II.4.3 Source Water Protection

Relevance

The changing geographic distributions of the U.S. population and depletion of ground water is leading to increases in surface water use; however, this issue does not appear to be well documented. Because surface water is impacted by human activities to a greater extent than ground water, source water assessment and protection should play an increasingly important role in the future. Research in these areas, as well as contingency planning to prevent terrorist attacks on drinking water supplies, is directly relevant to EPA's goal for clean and safe water. Additionally, source water assessment and prevention research is directly relevant to the evaluation of additional contaminants for possible listing on the CCL.

Program Design

Source water protection research questions address four primary areas: methods development for characterizing sources of contamination, fate and transport of contaminants, evaluation of best management practices on source water protection, and the development of early warning systems for alerting utilities of contaminant incursions in source water. The research program on source water protection has relevance to the CCL research program design. The research efforts in these areas are relatively modest at this time and do not necessarily represent a coherent vision of the areas that pose the greatest potential threats to public health. The area of source water protection is interdisciplinary in nature and overlaps with OW research on aquatic ecosystems and ORD research on homeland security.

Progress

There is an ongoing effort to develop methods to detect cyanotoxins, which are increasing either in incidence or general reporting in source water. Future plans are to generate better information on occurrence and spatial and temporal fluctuations in toxin concentrations. Progress in other areas includes development of methods to track fecal pollution sources, methods for delineation of source water protection zones for public water supplies, and the evaluation of best management practices. ORD intramural activities and STAR grants are being used to develop research in these areas.

Improved surveillance methods for detecting epidemics will supplement work within EPA and CDC on protecting water systems from terrorist attacks.

Strengths

The Agency is moving forward to embrace new molecular methods for source identification of fecal organisms. Progress in this area is good and will contribute to understanding total maximum daily loads (TMDLs) and, ultimately, to assist in source water protection.

Opportunities

Water reuse continues to grow as an area of importance and potential for risk to human health. This is a future source of drinking water with broad applications in the South and Southwest. ORD should find water reuse to be an issue on the near-term horizon and, a strategic research plan for this area will have to be developed in the near- to mid-term.

The research efforts in the area of source water protection are relatively small. Interagency collaborations (e.g., with the U.S. Geological Survey [USGS]) to address source water protection and assessment goals will be important toward meeting research goals. The SDWA well-head protection program is an important part of EPA's efforts at source water protection; however, little documentation nor a description of this program were available; also, the obvious links to homeland security issues were not documented. The need for a thorough evaluation of this program for protecting ground water resources may be a priority item**. Furthermore, it appears that ORD should not restrict research on source water protection to contaminants listed under LTG 2 as source water protection research is relevant to some regulated contaminants in LTG 1.**

III. QUALITY

Scientific Quality Questions and Overview

A. What is the scientific quality of the DWRP's research products (including consideration of peer-review process)?
B. Is high quality research ensured through competitive merit-based funding?
C. For non-competitive funds, what process is used to allocate funds, and does it ensure that quality is maintained?

In general, the mechanisms for ensuring quality are relatively consistent, regardless of whether research is being directed toward LTG 1 or LTG 2. STAR grant support is through a peer-review process, with laboratory and program directors ultimately prioritizing and selecting projects for funding based on preconceived needs of the overall Agency research plan. Cooperative agreements resulting in intramural collaboration receive internal peer review but are not open to an extensive outside review process. This may tend to perpetuate some research efforts that are past their prime and may leave the Agency open to concerns of "cronyism." **ORD could consider a streamlined external review process that could make suggestions to improve the quality and/or timeliness of the cooperative venture.**

Candidate Contaminant List

Research related to the CCL is an applicable model for describing the overall objectives for insuring research quality.

The scientific quality of the CCL research is good. High quality research is ongoing and is maintained through the use of partnering with other agencies, intramural research efforts, and the STAR grants program. CCL research is particularly challenging given the large number of contaminants to be evaluated and the mandatory timeline for review. The STAR program is a competitive, merit-based mechanism and has been used to develop important research areas with respect to CCL contaminants. **ORD should consider more open-ended calls for STAR grants on CCL-related topics to provide quality research on emerging issues.**

The process of allocating non-competitive funds for CCL and source water protection research lies ultimately with the NPD for DW Research, who recommends budgetary allocations to the laboratories and centers. ORD Laboratory and Center Directors are responsible for implementing the research programs with their prescribed budgets. In addition, the Laboratory and Center Directors provide input as to the impact of the budget allocations on their research

and business plans. The overall requirement is that DW research must be focused on research products that address the MYP and other near-term needs of the program and the clients. Research plans to implement MYP research undergo extensive internal and external peer review. In general, this process appears to be working to produce high quality research in support of the CCL and, to a lesser extent, source water protection**. ORD should consider that further efforts to integrate research on source water protection with the CCL research would be advantageous.**

IV. SCIENTIFIC LEADERSHIP

Scientific Leadership Question A

Has the program played a leadership role in contributing to advancing the state-of-the-science and solving drinking water research problems?

The issue of leadership relative to the charge question appeared to be perceived somewhat differently on the part of the Subcommittee compared to the Agency's program directors who spoke to the issue. It was apparent that leadership from an Agency perspective was viewed in a management context. For example, it was argued that leadership is demonstrated by the Agency or individual directors in their ability to function as conveners to bring disparate or partner groups to the table to focus on overarching issues, perhaps even larger than the Agency's agenda. An example provided was the Agency's role in managing the perchlorate in drinking water issue, which extends into the interest area of many stakeholders, industry, government agencies, and the public.

Clearly this is an important leadership area, and it may reflect a synthesis of science and risk management approaches noteworthy to the Agency. It does not necessarily speak to being the science leader *per se*. For example, in the area of DBPs, EPA has been viewed, internationally, as a science leader. As this is a maturing research area, EPA still holds some leadership credentials such as in the critical issue area of "mixtures." In other areas, however, such as the occurrence of unregulated contaminants in drinking water sources (e.g., pharmaceutically active compounds), researchers from USGS, Western European agencies, and academia have taken leadership roles. It appears that where statutory mandate and rules require focused Agency resources, ORD can maintain a science leadership; however, in rapidly evolving fields in which regulations have not been promulgated, ORD may not be responsive enough to take on a leadership role. In light of the narrowing resource base (i.e., not keeping up with inflation) and an ever expanding problem set, it seems likely that the ORD research leadership will become narrow compared to its former level of prominence.

It also was noted by the Subcommittee that many of ORD's key administrative and science managerial posts, including that of the NPD for the DWRP, are filled by interim or acting directors. This leads to some concerns over the long-term issues of leadership, morale, and program direction within the Agency, as well as the national science agenda. It is accepted that many of these positions are in somewhat continuous flux, and it is unknown as to the extent, if any, that this introduces uncertainty into the management structure and leadership. Although it is difficult to influence the process that leads to the formal appointment of research and administrative directors, **ORD is strongly encouraged to continue to press for timely appointments to these key leadership positions.**

Scientific Leadership Question B

Have ORD scientists demonstrated leadership in the field of drinking water research?

The Subcommittee was provided several sources of information as evidence of the manifestation of the scientific leadership of the DWRP scientists. The information included posters and poster abstracts, biosketches of the DWRP researchers and managers, biosketches of postdoctoral and visiting scholars, overview presentations, testimonial presentations, and scientific awards and leadership positions of DWRP researchers and managers. Examination of the material indicates the program has been a leader in the development of state-of-the-science research in areas that are related directly to the SDWA and its amendments and mandates (e.g., arsenic, ground water pathogens, mixed contaminants). Several individuals and groups are known internationally for their work. The bibliometric analysis shows 19 publications during the past 10 years in the most highly cited category (i.e., the top 1%) per the Thomson's Essential Science Indicators (ESI). Approximately one-half of the lead authors are internal researchers. This is indicative of recognized good research across many aspects of the DWRP.

The stellar performance and recognition of the research, however, is not uniform throughout the program. Although it is somewhat difficult to compute, an analysis of the publication records of the DWRP researchers, managers, and STAR grant participants indicates the average publication rate for peer-reviewed and total publications per person per year over the last 10 years is less than 1.0. The Subcommittee views this as below the expected publication rate of a program that aspires to be a leader in drinking water research.

The Subcommittee is concerned about the potential conflict of the goal for scientific leadership in the DWRP and the need to be responsive to mandates per the SDWA and its amendments. If the goal of scientific leadership is to be achieved and maintained, the Subcommittee recommends consideration of a program that would allow a group of researchers to pursue fundamental research that may not be driven exclusively by the SDWA but is in the drinking water arena and the Agency's long-term objective of providing safe drinking water. In such a program, the research would investigate emerging issues (e.g., indirect potable water reuse, seawater desalination), and the researchers would be expected to be nationally and internationally renowned for the work, as evidenced by publications, citations, invited talks, membership in honorific societies, etc. Models currently exist in other federal agencies, such as USGS.

As an alternative, the DWRP could revise the goal of scientific leadership to something more in harmony with its need to respond to SDWA mandates. For example, the use of a modifier such as "in selected areas" could be inserted in the existing goal.

The Subcommittee also is concerned about the program's lack of stable leadership. The reason for this concern is the perception that uncertainties over changing authority or management may create difficulty in championing the program or capitalizing on opportunities, as well as protecting budgets and priorities in research direction. Currently, the NPD and the leaders of the LTGs are acting in their positions. **The Subcommittee believes there is need to fill the acting positions to solidify the program's leadership as soon as possible.**

V. COMMUNICATION AND COORDINATION

Communication and Coordination Questions

A. *To what extent has the program coordinated with and used other agencies (inside and outside the government) in advancing EPA's research agenda? Are there important interagency collaborations that should and can be improved to advance the Agency's research agenda?*

B. Does the program use effective mechanisms for communicating research activities and results, both internally and externally?

Information on communication and coordination was provided to the Subcommittee both as a section of the notebook and in the form of presentations at the review meeting. From this documentation, it was clear that the DWRP has established internal efforts for coordination and communication, including the Water Research Coordination Team, to facilitate communications across the ORD laboratories and centers, OW, and the regional offices. Members of this team have worked to develop the Drinking Water Research MYP, held annual DW progress reviews, held annual ORD/OW senior management meetings, held annual Deputy Assistant Administrators meetings, and have held at least 18 *ad hoc* meetings and conference calls.

The DWRP also has established relationships with various outside organizations, including the Global Water Research Coalition, the AwwaRF, the WaterReuse Foundation, the Water Environment Foundation, the CDC (National Center for Environmental Health and National Center for Infectious Diseases), and the National Toxicology Program at the National Institute of Environmental Health Sciences (NIEHS). During the review, there were several testimonials about the interactions of the DWRP and other organizations (inside and outside the government). Work with OW was shown and involves ORD closely (e.g., arsenic, DBPs, Surface Water and Ground Water rules, CCL). OW is satisfied with interactions and outputs. Given the performance measures in place, the Subcommittee believes that ORD should develop a means to track and assess how outputs are used in the formulation of outcomes beyond ORD control. ORD's work with AwwaRF has been "satisfying" to AwwaRF. The states (Texas was represented) are appreciative of the support and guidance provided by ORD; however, some concern was expressed that the states' needs and issues were not heard as well as they could be. **The Subcommittee believes there is a need to develop partnerships with regard to CCL issues (e.g., selection, evaluation) with both governmental and non-governmental organizations. The Subcommittee also thinks that coordination with other governmental agencies can be enhanced to leverage the outputs of ORD efforts. For example, studies can be designed jointly with CDC, NIEHS, National Cancer Institute, and others to address an issue more completely than individual agencies could do alone.**

Communication of research activities and results uses several mechanisms. Journal articles describing research results are published in peer-reviewed journals. DWRP scientists actively make oral and poster presentations at national and international conferences. At least 18 internal meetings and 35 meetings with external organizations or experts have been held since 1999. These meetings are designed to both provide and receive information. In addition, at least 17 meetings have been hosted by EPA/ORD that indirectly support the DWRP. These meetings have included STAR seminars/program meetings and science forums. Several Web sites have been established to facilitate access to EPA activities, scientific/technical work products, publications, and EPA organizations.

VI. APPENDIX A: DRAFT CHARGE QUESTIONS FOR ORD'S DRINKING WATER RESEARCH PROGRAM REVIEW

The following charge questions were developed by ORD to help evaluate the relevance, design, performance, quality, and scientific leadership of its DWRP:

1. **Program Relevance Questions:**
    A. Is the focus of ORD's Drinking Water Research Program responsive to the Agency's strategic goal for Clean and Safe Water?
    B. Are potential public benefits of the program clearly evident?

2. **Program Design Questions:**
    A. Is the program design logical? Are the program goals and priorities clearly identified?
    B. Does the MYP describe an appropriate flow of work (i.e., the sequencing of related activities) that reasonably reflects the anticipated pace of scientific progress and the timing of client needs?
    C. Do the two LTGs provide a logical framework for organizing and planning the research and demonstrating outcomes of the program?
    D. Does the research program use the MYP to help guide and manage its research?

3. **Program Progress in Addressing Key Scientific Questions and Meeting Client Needs Questions:**
    A. Has the program made significant progress toward each of the LTGs?
    B. How well has the research program addressed the key scientific questions?
    C. Is the rationale for the research clearly articulated?
    D. Has the program met client needs in a timely and useful way through its scientific products?
    E. Have clients applied the program's research in environmental decisions and regulations?
    F. Has the program been successful in providing technical assistance to the Office of Water, regional offices, states, municipalities and water utilities?

4. **Scientific Quality Questions:**
    A. What is the scientific quality of the program's research products? (This includes a consideration of the peer review process employed.)
    B. Does the program ensure high quality research through competitive, merit-based funding?
    C. If funds are not competitively awarded, what process does the program use to allocate funds? Does this process ensure that quality is maintained?

5. Scientific Leadership Questions:

A. Has the program played a leadership role in contributing to advancing the state-of-the-science and solving important drinking water research problems?

B Have ORD scientists demonstrated leadership in the field of drinking water research?

6. Coordination and Communication Questions:

A. Has the program effectively engaged scientists and managers from ORD and the Office of Water in its planning?

B. Does the program identify key research gaps and update the research agenda through an established process that considers the input of the scientific community and stakeholders?

C. To what extent has the program coordinated with and used other agencies (inside and outside the government) in advancing the EPA's research agenda? Are there important interagency collaborations that should and can be improved to advance the Agency's research agenda?

D. Does the program use effective mechanisms for communicating research activities and results, both internally and externally?

VII. APPENDIX B: DRINKING WATER RESEARCH SUBCOMMITTEE BIOGRAPHIES

Gary S. Sayler, Ph.D.
Dr. Sayler is Distinguished University Professor of Microbiology, and Ecology and Evolutionary Biology, and Director of the Center for Environmental Biotechnology at the University of Tennessee. He received his Ph.D. in 1974 from the Department of Bacteriology and Biochemistry at the University of Idaho and did postdoctoral research at the University of Maryland. He received his B.S. in Bacteriology from North Dakota State University in 1971. Dr. Sayler has more than 30 years of experience in multidisciplinary laboratory and field environmental research and biodegradation of organic pollutants. He has pioneered the development of environmental molecular diagnostics, including the extraction and analysis of nucleic acids from soils, bioluminescent bioreporter technology, and the first field release of a genetically engineered microorganism for bioremediation purposes. This research has resulted in more than 275 technical publications and monographs, more than 350 invited presentations at the national and international level, and 9 patents. He is a member of American Society for Microbiology (ASM), American Chemical Society (ACS), American Association for the Advancement of Science (AAAS), Society for Industrial Microbiology (SIM), Society of Environmental Toxicology and Chemistry (SETAC), and SPIEE, has served on five editorial boards, and currently is an associate editor of the journal *Environmental Science & Technology*. Dr. Sayler is a Lifetime Fellow of the American Academy of Microbiology. He was the recipient of the 5-year U.S. Public Health Service Research Career Development Award from NIEHS, the recipient of the Procter & Gamble Award in Applied and Environmental Microbiology from the ASM, The University of Idaho Distinguished Alumni Award, and the SPHERE award from the Dow Foundation. He has directed the research of more than 50 Ph.D. and M.S. candidates. Dr. Sayler currently serves on the Drinking Water Committee of the EPA Science Advisory Board (SAB) and is an Executive Committee member of the EPA/ORD BOSC.

James H. Johnson, Jr., Ph.D.
Dr. Johnson is a professor of Civil Engineering and Dean of the College of Engineering, Architecture and Computer Sciences at Howard University. Dr. Johnson received his B.S. from Howard University, M.S. from the University of Illinois, and Ph.D. from the University of Delaware. Dr. Johnson's research interests include the treatment and disposal of hazardous substances, the evaluation of environmental policy issues in relation to minorities, the development of environmental curricula and strategies to increase the pool of underrepresented groups in the science, technology, engineering, and math disciplines. He is the Chair of the EPA/ORD BOSC, a member of EPA's SAB, and the co-principal investigator of the Department of Energy (DOE)-sponsored Historically Black Colleges and Universities/Minority Institutions

(HBCU/MI) Environmental Technology Consortium. Currently, he is a consultant to the Office of the President, University of California, as a member of the Environmental, Health, and Safety Panel monitoring activities at the three DOE national laboratories operated by the University of California. From 1989-2002, he was the Associate Director of the EPA-sponsored Great Lakes and Mid-Atlantic Center for Hazardous Substance Research; from 1996-2002, he oversaw the activities of the Engineering Coalition of Schools for Excellence and Leadership in Education, a National Science Foundation (NSF)-funded consortium. Dr. Johnson is a member of the NRC's Board on Environmental Studies and Toxicology, SECME, and the Engineering Deans Council of the American Society for Engineering Education. Other recent service activities include NRC's Board on Radioactive Waste Management, the Board of Directors of the Civil Engineering Research Foundation (CERF), and the Space Day Foundation. He also serves on several university and private sector advisory committees. Dr. Johnson has authored more than 50 scholarly articles, contributed to three books, and co-edited two books. He is a fellow of the American Society of Civil Engineers (ASCE) and a member of the American Association of Environmental Engineering and Science Professors, American Water Works Association, American Society for Engineering Education, and Tau Beta Pi. Dr. Johnson is a registered professional engineer in the District of Columbia and a diplomate of the American Academy of Environmental Engineer. He is the 2005 recipient of the National Society of Black Engineers Lifetime Achievement Award in Academia.

Chi-Hsin Selene Jen Chou, Ph.D.
Dr. Chou is an Environmental Health Scientist at the Agency for Toxic Substances and Disease (ATSDR), Division of Toxicology and Environmental Medicine (DTEM), Prevention, Response and Medical Support Branch, Scientific Assessment and Consultation Team, in Atlanta, Georgia. Dr. Chou's major activities include human health risk assessment, Chair of the ATSDR Minimal Risk Level Workgroup, Co-Chair of the DTEM Health Effects Review Workgroup, and Chemical Manager of ATSDR's toxicological profiles for arsenic, hydrogen sulfide, chloroform, and pyridine. Dr. Chou received her B.S. degree in chemical engineering from National Taiwan University, Taipei, Taiwan, and a Ph.D. in physical chemistry from Emory University, Atlanta Georgia. She also received postdoctoral training in biochemistry and neurochemistry at Northwestern University, Evanston, Illinois, and Emory University School of Medicine, Atlanta Georgia, respectively.

David L. Sedlak, Ph.D.
Dr. Sedlak is a Professor of the Department of Civil and Environmental Engineering at the University of California, Berkeley, Dr. Sedlak received his B.S. degree in Environmental Science from Cornell University in 1986. He received his Ph.D. in Water Chemistry from the University of Wisconsin in Madison in 1992, and served as a postdoctoral researcher at the Swiss Federal Institute for Environmental Science and Technology (EAWAG) from 1992-1994. He has received several notable awards, including the Paul Busch Award for Innovation in Water Quality Engineering in 2003, the NSF CAREER Award in 1997, and the Hellman Family Faculty Award in 1996. His areas of research interest include analytical methods for measuring organic compounds in water, fate of chemical contaminants in water recycling systems, metal speciation and its effect on metal uptake and reaction, and environmental photochemistry.

James H. Raymer, Ph.D.
Dr. Raymer is Senior Program Director for the Exposure Analysis Research Program at RTI International, Research Triangle Park, North Carolina, and has been responsible for scientific and financial management of a variety of projects utilizing analytical chemistry for both government and commercial clients. These projects have involved the development and application of separation techniques, including capillary gas chromatography, supercritical fluid chromatography, supercritical fluid extraction, high performance liquid chromatography, liquid chromatography/mass spectrometry, capillary gas chromatography-Fourier transform infrared spectroscopy, and capillary gas chromatography mass spectrometry to the quantitative and qualitative analysis of various chemical classes, including pesticides, water DBPs, and volatile and semi-volatile analytes, in biological and environmental samples. Most of these projects have been geared toward a greater understanding of human exposure to toxic chemicals or the biological responses of animal models to such exposures and have included the development of methods for analysis that are then applied in the studies. Recent projects have focused on improving the understanding of exposures of children to environmental contaminants through air, food, water, and dust, including potential pesticide exposure via interactions with surfaces. Both activities and metabolic effects have been considered in these recent studies as they relate to dose. Responsibilities also have included experimental design, modeling of experimental data, proposal and report preparation, and preparation of articles for publication. He received a B.A. in Chemistry at SUNY College at Brockport, Brockport, New York, in 1979, and a Ph.D. in Analytical Chemistry (Minor: Biochemistry), Indiana University, Bloomington, Indiana, in 1984

Subcommittee Consultant:

Mary H. Ward, M.S., Ph.D.
Dr. Ward is an environmental epidemiologist and tenure-track investigator in the Occupational and Environmental Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institutes of Health, in Bethesda, Maryland. She received a M.S. degree in Ecology from the University of Tennessee in 1983. She received her doctorate in Epidemiology from Johns Hopkins University, School of Hygiene and Public Health, in 1994. Dr. Ward's research has focused on environmental and occupational epidemiology, with special emphasis on pesticides and N-nitroso compounds (NOC). She has examined the role that NOC and NOC precursors, particularly drinking water and dietary sources of nitrate and nitrite, may play in the development of cancer through studies of non-Hodgkin's lymphoma and cancers of the bladder, brain, colon, esophagus, stomach, and pancreas. She has developed interdisciplinary collaborations to use Geographic Information Systems for exposure assessment of environmental contaminants, including pesticides and nitrate and she received a Division of Cancer Epidemiology and Genetics Intramural Research Award in 1999 and a NIH Merit Award in 2000 to continue her research in this area.

VIII. APPENDIX C: LIST OF ACRONYMS

AAAS	American Association for the Advancement of Science
ACS	American Chemical Society
ASCE	American Society of Civil Engineers
ASM	American Society for Microbiology
ATSDR	Agency for Toxic Substances and Disease Registry
AwwaRF	American Water Works Association Research Foundation
BOSC	Board of Scientific Counselors
CCL	Candidate Contaminants List
CDC	Centers for Disease Control and Prevention
CERF	Civil Engineering Research Foundation
DBP	Disinfection Byproduct
DFO	Designated Federal Officer
DHHS	Department of Health and Human Services
DOE	U.S. Department of Energy
DTEM	Division of Toxicology and Environmental Medicine
DW	Drinking Water
DWRP	Drinking Water Research Program
EAWAG	Swiss Federal Institute for Environmental Science and Technology
EPA	U.S. Environmental Protection Agency
ESI	Essential Science Indicators
FACA	Federal Advisory Committee Act
GPRA	Government Performance and Results Act
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
IRIS	Integrated Risk Information System
LTG	Long-Term Goal
MAC	*Mycobacterium avium intercellulare*
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MTBE	Methyl Tertiary-Butyl Ether
MYP	Multi-Year Plan
NCER	National Center for Environmental Research
NDWAC	National Drinking Water Advisory Council
NERL	National Exposure Research Laboratory
NGO	Nongovernmental Organization
NHEERL	National Health and Environmental Effects Research Laboratory
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NOC	N-Nitroso Compounds
NPD	National Program Director
NRC	National Research Council
NRMRL	National Risk Management Research Laboratory

NSF	National Science Foundation
OMB	Office of Management and Budget
ORD	Office of Research and Development
OW	Office of Water
PART	Program Assessment Rating Tool
PPCPs	Pharmaceuticals and Personal Care Products
PVC	Polyvinyl Chloride
QSAR	Quantitative Structure-Activity Relationship
RFP	Request for Proposals
SAB	Science Advisory Board
SECME	Science, Engineering, Communication, Mathematics Enhancement Program
SDWA	Safe Drinking Water Act
SETAC	Society of Environmental Toxicology and Chemistry
SIM	Society for Industrial Microbiology
STAR	Science To Achieve Results
THM	Trihalomethane
TMDL	Total Maximum Daily Load
UCMR	Unregulated Contaminated Monitoring Rules
USGS	U.S. Geological Survey