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# EPA's Draft 2003 Drinking Water Research Multi-Year Plan

*A Review by the Drinking Water Committee  
of the EPA Science Advisory Board*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR  
SCIENCE ADVISORY BOARD

June 8, 2005

The Honorable Stephen L. Johnson  
Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Subject: Review of EPA's 2003 Draft Drinking Water Research Program Multi-Year Plan

Dear Administrator Johnson:

The U.S. EPA Science Advisory Board's (SAB) Drinking Water Committee (DWC) met on May 24-25, 2004 to review the Agency's draft "*Drinking Water Research Program Multi-Year Plan 2003*" (MYP). According to EPA's Office of Research and Development (ORD), this multi-year plan presents its strategy for addressing the highest priority areas of research to support EPA's risk management programs for the next 5-10 years.

The Agency has clearly invested a substantial amount of expertise, time, and energy into developing the MYP. The Drinking Water Research Program logic model and subsequent key scientific questions presented in the MYP should lead to more effective planning and more effective management of scientific programs, with goals, timelines and deliverables. The research products or Annual Performance Measures identified in the MYP address high priority research for each major topic area intended to accomplish ORD's Drinking Water research goals. While establishing the Annual Performance Measures appears to be both a useful and an appropriate approach, there are some areas that the Agency will need to further explore and define. The MYP does not, for example, include the research required to conduct a cost benefit analysis which must consider a variety of health benefits, ranging from lives saved to minor illnesses avoided. Also, more effort is needed to identify human subpopulations that may be more sensitive to non-cancer effects following exposure to drinking water contaminants such as arsenic or microbials.

Exploratory and open-ended research has special value to EPA's mission, especially with respect to emerging issues and new technologies. The SAB believes that this research is significant because it provides support for drinking water issues of interest to EPA that is not always available elsewhere. This research also stimulates activities within the agency, transfers technology and brings new expertise to EPA through EPA conferences and workshops.

Drinking water issues progress from discovery to data collection and regulation followed by monitoring of the effectiveness of the rule. The SAB believes that research resources dedicated to a specific issue should evolve in accordance with this progression. In the early stages, modest research allocation should be dedicated to innovative and forward thinking research. As the agency approaches rulemaking, more resources should be allocated. After the rulemaking is established, the budget should be decreased and focused on assessing the effect of the rulemaking

and the potential for future changes. Examples of mature topics where research may need to be modified are disinfection by-products and the effects of high levels of Arsenic. Examples of issues in their early stages are the contaminant candidate list (CCL), watershed protection and the distribution system.

This leads to one of the SAB's most important comments that elements of the Drinking Water research program may be continuing with diminishing returns. The DWC recommends that Annual Performance Measures be framed in the context of the relative risk posed by target drinking water contaminants. This approach would probably lead to an emphasis in microbials and chemical mixtures, and further de-emphasis of Disinfection By-Products (DBPs), particularly single compound research. The SAB does not believe that DBP research should be discontinued, but encourages a strategic review. The DWC suggests that EPA lead a healthy debate on defining the highest priorities for drinking water contaminants.

Additionally, the SAB believes that a level budget for drinking water research is not sufficient to support ORD's research needs. More resources are required to support the growing research needs of the CCL, the movement toward alternative disinfectants, competing drinking water regulations, increasing concern with respect to source water protection and distribution systems and water reuse and desalination. While the relative allocation of resources across the major components of the drinking water research program may be appropriate based on a consideration of scientific and programmatic needs, the overall resource level is insufficient to address the most important research questions and achieve the intended outcomes of the research program.

Finally, the SAB wishes to strongly encourage ORD to continue to strengthen its multi-year planning activities by increasing the collaboration within ORD, between ORD and other parts of the Agency, and with parties outside the Agency in order to prioritize and communicate research needs. EPA is to be complimented for including organizations, such as, the Global Water Research Coalition in planning efforts and yet resources could also be better leveraged by strengthening formal research relationships with other federal agencies, state agencies, etc. The SAB also wishes to compliment the Agency for its use of the MYP effort to communicate within EPA, as well as, with organizations outside EPA concerning ORD research plans.

We look forward to working with ORD to improve these efforts in the future.

Sincerely,

/signed/

Dr. Granger Morgan, Chair  
EPA Science Advisory Board

/signed/

Dr. Rhodes Trussell, Chair  
Drinking Water Committee  
EPA Science Advisory Board

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## EXECUTIVE SUMMARY

On May 24-25, the Science Advisory Board (SAB) Drinking Water Committee (DWC) met to review the “*Drinking Water Research Program Multi-Year Plan 2003*” (MYP) developed by the U.S. Environmental Protection Agency’s (EPA) Office of Research and Development (ORD). The MYP describes the drinking water research activities and plans for fiscal years 2003 - 2010. It focuses on four major drinking water research areas: 1) Regulated and Unregulated Pathogens, 2) Regulated and Unregulated Chemicals, 3) Source Water Protection and Distribution Systems, and 4) Innovative Approaches and the Six-Year Review. The DWC has therefore provided comments and recommendations based on these four areas of research to address the charge questions.

ORD requested that the DWC review and provide advice on the Drinking Water MYP with respect to its overall organization, rationale and content. The specific charge, as created by ORD, to the DWC was as follows:

- *Does the MYP provide a logical framework for organizing the drinking water program to best meet EPA’s needs? For each major topic area addressed by the research program (e.g., Disinfection Byproducts, CCL Pathogens, Distribution Systems), do the research goals (APGs) represent logical progressions of activities and intended outcomes?*
- *Do the science questions identified in the MYP address the most important research issues for each of the major research topic areas?*
- *Do the research products identified in the MYP focus on the highest priority research for each major topic area? Do the sets of APMs under the APGs appear both necessary and sufficient for accomplishing the intended goals?*
- *Is the relative allocation of resources across the major components of the drinking water research program appropriate, based on a consideration of scientific and programmatic needs? Is the overall resource level generally sufficient to address the most important research questions and achieve the intended outcomes of the research program?*

The Agency has clearly invested a substantial amount of expertise, time, and energy into developing the MYP. The Drinking Water Research Program logic model and subsequent key scientific questions presented in the MYP will lead to more effective planning and more effective management of scientific programs, with goals, timelines and deliverables.

Overall the DWC agrees that the MYP provides a logical framework for organizing the drinking water program to meet EPA’s Drinking Water research goals. The use of Annual Performance Goals as milestone markers en route to achieving Long-Term Goals is a valuable approach and the entire process is beneficial as it increases the transparency of EPA decision-making. The rationale for where the Annual Performance Goals appear in the timeline in Figures 1 through 3 is, however, not well articulated. Additionally, the origins of the process that led to the logic model were also not clear. The DWC does not challenge the logic model, rather the way it is presented in the MYP.

The DWC suggests that the MYP be presented as a stand-alone document. The MYP primarily focuses on the research activities in ORD and does not provide a full account of other research activities in other parts of the Agency. While this is reasonable for an ORD research review, it does not provide the reviewer with a complete view of all the research. A more

transparent and comprehensive representation of the research program would provide a significant improvement.

The DWC supports and encourages the continued development of the Environmental Information Management System (EIMS) as it represents an important contribution to transparency. The EIMS stores, manages, and delivers descriptive information for scientific documentation that can be easily accessed with standard Web browsers. Having direct access to descriptions of ongoing or planned research activities, through EIMS links, was extremely helpful.

In general, the science questions identified in the MYP do address important research issues for each of the major research topic areas. However, some of the questions are not clearly articulated and recommendations for revisions can be found in the body of the report. The DWC recommends that the contextual background be provided for each key question so that they can be more easily understood and the relationship between Long-term Goals, Annual Performance Goals, and Annual Performance Measures can be readily discerned. Finally, with regard to the key scientific questions, the MYP should provide a distinction between natural or accidental contamination and intentional contamination, for example, storm events or wastewater spills versus bioterrorism events.

The research products (i.e., Annual Performance Measures) in the MYP focus on EPA's identified high priority research for each major topic area and provide a useful and appropriate approach for addressing accomplishments toward meeting the intended goals. The MYP does not, however, include the research required to conduct a cost-benefit analysis which must consider a variety of health benefits, ranging from lives saved to minor illnesses avoided. Also, more effort is needed to identify human subpopulations that may be more sensitive to the non-cancer effects following exposure to drinking water contaminants such as arsenic or microbes. Exploratory and open-ended research also has special value to EPA's mission, especially with respect to new issues and new technologies. The DWC believes that this research is significant because it provides support for drinking water issues of interest to EPA that is not available elsewhere. In addition, this research stimulates activities within the agency, transfers technology and brings new expertise to EPA through EPA conferences and workshops. EPA is to be complimented for its cooperation in the Global Water Research Coalition and yet resources could also be better leveraged by strengthening formal research relationships with other governmental agencies (e.g. NIEHS, NSF, USGS, CDC, NCBI (bioinformatics), state agencies, etc.)

One of the DWC's most important comments is that elements of the Drinking Water research program may be continuing with diminishing returns. The DWC recommends that Annual Performance Measures be framed in the context of the relative risk posed by target drinking water contaminants. This approach would probably lead to an emphasis on microbials and chemical mixtures, and de-emphasis of Disinfection By-Products (DBPs), particularly single compound research. EPA should lead a healthy debate on defining the highest priorities for drinking water contaminants. The DWC does not believe that DBP research should be discontinued, but encourages a strategic review.

Finally, in view of the growing research needs to support the CCL, the movement toward alternative disinfectants, competing drinking water regulations, increasing concern with respect to source water protection and distribution systems and water reuse and desalination, the DWC believes that a level budget for drinking water research is not sufficient. While the relative allocation of resources across most of the major components of the drinking water research program may be appropriate based on a consideration of scientific and programmatic needs, the overall resource level is insufficient to address all the important research questions and achieve the intended outcomes of the research program. One area where a shift of funds may be needed, as new issues arise, is for Distribution Systems. For Distribution Systems, the overall allocation of resources and timing appear to be insufficient and lag behind the drinking water program timeline. The DWC believes that research resources dedicated to a specific issue should evolve in accordance with their progression. In early stages, modest research allocations should be dedicated to reconnaissance and forward thinking research. As the agency approaches rulemaking, more resources should be allocated. After rulemaking, the budget should be decreased and focused on assessing the effect of the rule and the potential for future changes.

## INTRODUCTION

This report was prepared by the Science Advisory Board (SAB) Drinking Water Committee (DWC) in response to a request by EPA's Office for Research and Development (ORD) to review the *Drinking Water Research Program Multi-Year Plan 2003* (MYP)<sup>1</sup>. ORD describes the MYP as EPA's drinking water research activities and plans for 2003 - 2010. In partnership with the Office of Water (OW), ORD developed this MYP which will link research plans that support EPA's annual budget request with EPA's strategic plan. The MYP was developed as a tool for planning and communication; it provides: (1) a context for annual planning decisions and a basis for describing the impacts of these decisions; (2) a framework for integrating research on common issues across the ORD laboratories and centers, as well as across the various Agency Goals established under the Government Performance and Results Act (GPRA); and (3) a resource for communicating ORD research plans and products within ORD, with EPA programs, with the Regions and with interested parties outside of EPA.

As stated in the MYP, the overall organization of the drinking water research program is represented in the context of EPA's Strategic Goals and Objectives, and ORD's Long-Term Goals (LTGs), Annual Performance Goals (APGs) and Annual Performance Measures (APMs). The MYP establishes three Long-Term Goals in the following areas: (1) regulated contaminants; (2) unregulated contaminants and innovative methods; and (3) source water protection and distribution systems. Annual Performance Goals within each of these Long-Term Goals is represent as milestones along the path toward attaining the long-term outcome.

Accordingly ORD identified key scientific questions for each of the major components of the research program discussed in the MYP to focus research on their highest priority issues. Annual Performance Measures in the MYP are presented in the form of research outputs, such as, new data, tools, technologies, databases, models, or assessments that are considered necessary for accomplishing a particular goal (APG). The MYP also identifies several synthesis documents, which integrate and summarize new research findings on a particular topic. The MYP does not, by design, provide detailed information on specific research activities and products represented by Annual Performance Measures. Nevertheless, a general evaluation of the research program outputs was made via the Annual Performance Measures titles and the supplementary information on near-term Annual Performance Measures through linkages to the drinking water research tracking system. Some budgetary information was provided to the DWC for their consideration of resource allocations within the drinking water research program. The development of the MYP was based on an assumption of level resources over the period covered by the plan.

In the MYP, ORD has stated that research is an iterative process for which the results are not certain until the work is completed. Research findings may identify additional needs or provide new tools which can be used to pursue other lines of inquiry that may not have been anticipated or possible when the original research was planned. In addition, unexpected changes may occur in available resources or strategic priorities. For these reasons, ORD intends to update the MYP on a biennial basis (NEXT UPDATE TO OCCUR IN 2005) to provide opportunities for making the necessary adjustments to the research program.

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<sup>1</sup> The MYP document can be found at the following URL: <http://www.epa.gov/osp/myp/dw.pdf>

## **GENERAL RESPONSE AND RECOMMENDATIONS**

The DWC wishes to compliment ORD on the quality of the MYP and on the serious investments ORD is making in the multi-year research planning process. The identification of EPA's key scientific questions should lead to more effective planning and management of scientific programs, with goals, timelines and deliverables. Such efforts help ORD staff to focus on their highest priority areas of research and to understand management decisions that influence their activities. Documents of this kind also help both internal and external organizations understand where ORD intends to focus its research effort. The DWC supports and encourages the continued development of the Environmental Information Management System (EIMS) as an important contribution to transparency. Direct on-line access, through the EIMS links to descriptions of the ongoing research activities in ORD, was extremely helpful. The DWC also strongly encourages ORD to continue to strengthen its multi-year planning activities. Better coordination between ORD and other parts of the Agency will produce a MYP that is more useful in identifying the Agency's most urgent research needs and setting research priorities.

The current MYP does not include all the drinking water-related research and data-gathering activities supported by EPA or its partners. Using the available information, the DWC has reviewed and addressed the approach of the program overall in meeting EPA's general needs and has offered recommendations and suggestions to improve future iterations of the MYP. Perhaps one of the DWC's most important criticisms is that elements of the Drinking Water research program may be continuing without clear benefit. This comment is explained in greater detail under Charge Question 2 later in the report. As ORD intends to update the MYP on a biennial basis (NEXT UPDATE TO OCCUR IN 2005), the opportunities for making the necessary adjustments to the research program can now occur in a more timely fashion.

Charge questions, as created by ORD, are provided below and are followed by the DWC's specific responses and recommendations for each charge questions. The responses focus on the four key research topic areas addressed in the MYP. These include: 1) Regulated and Unregulated Pathogens; 2) Regulated and Unregulated Chemicals; 3) Source Water Protection and Distribution Systems; and 4) Innovative Approaches and the Six-Year Review.

## **SPECIFIC RESPONSES AND RECOMMENDATIONS**

### **CHARGE QUESTION 1**

The Research Program Design Logic Model on page 3 of the MYP presents the overall organization of the drinking water research program in the context of EPA's Strategic Goal and Objective, and ORD's Long-Term Goals (LTGs), Annual Performance Goals (APGs) and Annual Performance Measures (APMs). The MYP establishes three Long-Term Goals in the following areas: (1) regulated contaminants; (2) unregulated contaminants and innovative methods; and (3) source water protection and distribution systems. Annual Performance Goals

within each of these Long-Term Goals are represented as important milestones along the path toward accomplishment of the Long-Term Goals and long-term outcomes.

- *Does the MYP provide a logical framework for organizing the drinking water program to best meet EPA's needs?*
- *For each major topic area addressed by the research program (e.g., Disinfection Byproducts, Contaminant Candidate List (CCL) Pathogens, Distribution Systems), do the research goals (APGs) represent logical progressions of activities and intended outcomes?*

#### **COMMITTEE RESPONSE TO THE FIRST QUESTION IN CHARGE QUESTION 1**

- *Does the MYP provide a logical framework for organizing the drinking water program to best meet EPA's needs?*

The MYP does provide a logical framework for organizing the research intended to support the drinking water program. The delineation of three areas of Long-Term Goals (as opposed to one), better reflects research needs and allows better coordination with rule development, implementation and review. Further delineation would be helpful in the future. For example, the DWC recommends that distribution systems and source water protection not be combined as they deal with different aspects of water research.

The MYP identifies critical issues and provides a roadmap which describes the path that ORD is following to achieve its research goals. ORD has taken great effort to organize the plan and its work products. This is significant because of the breadth of the research needed to support the goals. The changes that have been made from previous plans are excellent improvements.

The MYP was developed, in part, as a vehicle “*for integrating research on common issues across the ORD laboratories and centers, as well as across the various Agency Goals established under the Government Performance and Results Act (GPRA) and a resource for communicating ORD research plans and products within ORD, with EPA programs, with the Regions and with interested parties outside of EPA*” and as such presents research that supports regulatory activities of the Office of Water (OW) and addresses EPA’s and ORD’s strategic plans. It reports ORD activities and the interaction between the five ORD laboratories (National Exposure Research Laboratory, National Health and Ecological Effects Laboratory, National Risk Management, National Center for Environmental Assessment Laboratory, and the National Center for Environmental Research) involved with various goals. However, the MYP did not include all of the water-related research projects. Additional ORD water-related research programs are reported under different MYPs. The MYP does not capture all the research activities under OW or those of non-Agency partners such as the American Water Works Association Research Foundation (AwwaRF). Any other water-related research and data gathering activities which supplement ORD research should be explicitly recognized in the MYP, with links whenever possible. The framework should explicitly address the Drinking Water Program’s response and approach to incorporating the needs of stakeholders and refer to the Global Water Research Network and interactions with other programs to leverage resources.

The DWC recommends that future versions be a self-contained document; (i.e., it should include all the information a reviewer would need to be able to fully assess if the research program meets EPA’s needs). Specific suggestions are given below.

EPA research provides the scientific underpinning for regulation. For the water research program, there are numerous regulations, each including multiple deadlines. These have been incorporated into the three Long Term Goals and their Annual Performance Goals and Measures. The reader needs a deep understanding of OW’s various and vast regulatory deadlines, more than that which is included in the MYP, to comprehend the nuances of the different milestones captured as Annual Performance Goals. The logic model presented in figure 1 could be improved by showing the linkages either graphically or through narrative, without going to Appendix A, between the Long-Term Goals and the following items:

- Statutory drivers (i.e., which statutes and time frames are each of the Long-Term Goals designed to respond to?);
- Long-Term Goals in other MYPs.

There should be more discussion about the relationship between the Annual Performance Goals, the Annual Performance Measures and the scientific questions, including: a brief discussion of the issue; the current state of knowledge; and an indication of knowledge gaps. The key questions can then be derived from those gaps, ordered by regulatory priority or by scientific need. This discussion should include an assessment of the likelihood that the goals set forth in each APG will be met.

The tables are an integral component of the MYP and list the Annual Performance Goals and their associated Annual Performance Measures. The figures provide the broad context. The rationale for placement of the Annual Performance Goals in the timeline in Figures 1 through 3 is not well articulated. Annual Performance Goals in the figures should also be numbered and more specifically and succinctly labeled. The tables should provide sufficient information for the reader to grasp the context of the Annual Performance Goals and the content of the Annual Performance Measures. As an example, for Annual Performance Goals addressing a Six-Year Review, the scheduled completion date for the review should be given. For Annual Performance Goals addressing a rule revision or implementation, further details (e.g., “possible revision to the [add specific name] final rule to be issued on...”) should be provided. The Committee found the Environmental Information Management System (EIMS) links to be very useful and encourages ORD to include them for all the Annual Performance Measures.

#### **COMMITTEE RESPONSE TO THE SECOND QUESTION IN CHARGE QUESTION 1**

- *For each major topic area addressed by the research program (e.g., Disinfection Byproducts, CCL Pathogens, Distribution Systems), do the research goals (APGs) represent logical progressions of activities and intended outcomes?*

The MYP presents three Long-Term Goals that address regulated contaminants, new (unregulated) contaminants, and protection of source water and distribution systems. They were

developed with Annual Performance Goals and Annual Performance Measures, which are intended to measure the outcomes. We noted that arsenic and DBP research priorities have changed from those given in previous research plans. It would be useful to elaborate on such changes.

#### **Arsenic Rule:**

As envisioned *a priori*, the Annual Performance Goals for the arsenic rule represent a logical progression. First, research is conducted to develop and evaluate treatment technologies to aid in implementation of, and compliance with the current MCL. Then risk-related research to support OW's initial six-year review of the current MCL and its second six-year review of that, or a different MCL (pending the outcome of the initial six-year review).

There is a significant concern about the numbers of projects or Annual Performance Measures that are behind schedule and whether there will be a sufficiently robust body of new health effects and exposure data available by 2006 for OW to perform its first six-year review of the current MCL in a credible way.

#### **Disinfection By-Products:**

These Annual Performance Goals are reasonable for supporting future regulatory review, although they are not necessarily sequential, nor do they appear to be progressing towards the regulatory review or action. It is not obvious that the earlier Annual Performance Goals are setting the groundwork for remaining Annual Performance Goals or providing specific information that is needed for intermediate decision points. The MYP would benefit from including a decision analysis approach wherein the data gaps are clearly laid out and prioritized.

#### **CCL Pathogens:**

The Regulated Pathogens include: *Cryptosporidium*; *Giardia*; *Legionella*; viruses in surface water and groundwater; and pathogens on the CCL. Microorganisms should be viewed as a high health risk priority, due to the acute nature of the impacts. Deaths are often associated with microbial contamination events. Among health risks the high priority of microbial contaminants should be clearly stated in the MYP. Microbial issues focus on microbial contamination of source water, treatment to remove microbes, and the distribution system, both as a protector of the water's integrity and as a potential habitat for opportunistic pathogens. The MYP should include efforts to develop techniques for measuring pollution sources and the efficacy of prevention measures for watershed protection; verifying small treatment system performance; and examining health risks. Where pathogens are concerned, the focus on the small systems is especially important given the high number of outbreaks that occur in small communities where they are more likely to be recognized than in more diffusely spread populations.

For microorganisms, data, tools and techniques as well as assessment are the key descriptors in each of the goals (APG) and final management strategies (LTG). These descriptors in each of the goals and final management strategies may be seen as occurrence (data), methods (tools), environmental assessment (survival & transport), health assessment (risk), and water treatment (management), which should be explicitly addressed in more detail in each long-term goal.



The Annual Performance Goals for Long-Term Goal 1 include: implementation of the rules; implementation for small systems; and a general category on health, exposure, treatment and assessment. Long-Term Goal 2 begins with an assessment of unregulated pathogens, and then moves to methods, exposure, treatment, health risks, occurrence and risk characterization for five organisms (methods, occurrence and exposure must be better linked in the APG, prior to health risks) In Long-Term Goal 3, better monitoring of sources and distribution systems is needed as part of the Annual Performance Goals to meet the model development needs. The flow from one Annual Performance Goal to the next is not well described. The DWC believes that innovative tools, methods and techniques, and treatments are critical. An approach to verify the performance of watershed protection best management practices (BMPs), and treatment and protection of distribution systems is also needed in the LTG.

### **Six Year Review of Regulated Contaminants**

The Six Year Review concerns specific contaminants, lead/copper, fluoride, and chromium, with some specific requirements for distribution systems, particularly with the total coliform (TC) monitoring requirement. Overall, the research goals do represent logical progression of activities and intended outcomes. They should also provide useful information that can be used to aid the Six Year Review. However, the Annual Performance Goals for Distribution Systems and the associated Annual Performance Measures do not have the provisions necessary to re-evaluate the TC monitoring requirements. While a number of Annual Performance Measures for Distribution Systems are referred back to Annual Performance Goals for Long-Term Goal 1 and Long-Term Goal 2, it does not appear that any are related specifically to the Six Year Review in Long-Term Goal 1.

The Six-Year Review has variable target dates, based on the actual promulgation dates of the individual National Primary Drinking Water Regulations (NPDWRs; the last major review was completed in 2002). Data on the effects, occurrence, treatability, and risks of regulated chemicals specific to the Six Year Review are anticipated outcomes sufficiently in advance to be of use in the review process. The Six-Year Review under Long-Term Goal 1 (T-1.13) is somewhat limited in scope, with rather specific and attainable Annual Performance Measures for the 2005 Annual Performance Goals. However, it is less well-defined for the 2008 Annual Performance Goals. The progressional logic of the research plan is appropriately driven by statutory requirements of the rules.

### **Source Water Protection and Distribution Systems**

For Source Water Protection and Distribution Systems, the research goals do present logical progressions of activities and intended outcomes. They are rather broad, but this may be the best that can be done at this time in capturing the over-arching goals of this new program. As the Long-Term Goal 3 timeline continues into the future (in coordination with the rule schedules), it is expected that the next cycle of the DWMYP will identify more specific targets for this effort. Since specificity is achieved through the Annual Performance Measures, it is expected that the number of Annual Performance Measures will increase in these two areas in the future.

Some attention should be placed on the timing of ORD research efforts. EPA is currently engaged in discussions on distribution systems and water quality, and it may be appropriate to bring many of these work products up in the timeline. EPA has been working with stakeholders to develop rule options for the Stage 2 DBPR and the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR), both of which have distribution system components. As the Long-Term Goal 3 timeline extends out further into the future (i.e., 2008), it would be beneficial to move work efforts forward to accommodate the rule schedule.

Given the importance of Source Water Protection, it is not clear why the first Annual Performance Goal is delayed until FY06. For example, earlier Annual Performance Goals might involve the development of linkages with the Clean Water Act activities of ORD to facilitate integration of those activities with long-term drinking water goals. Another earlier Annual Performance Goal might be the identification of key contaminants of concern that need to be managed for the FY06 Annual Performance Goal. Another Annual Performance Goal for FY10 could be added to address performance of those tools, methods, models and data for improving source water protection developed in the FY09 Annual Performance Goal.

A similar comment applies to Distribution Systems regarding the delay of the first Annual Performance Goal until FY06 and the importance of this subject. Contaminants of concern need to be identified before they are characterized and managed in the FY06 Annual Performance Goal. Additionally, the hydraulic behavior of water and contaminants in Distribution Systems is a key component of public exposure to contaminants in tap water. Accordingly, an important Annual Performance Goal that could be added for FY05 or FY06 is the development and demonstration of network models for water quality in distribution systems. Such models would address the spatial and temporal variability of water in distribution systems.

## **CHARGE QUESTION 2**

On pages 6-10, the MYP identifies key scientific questions for each of the major components of the research program. These questions are intended to focus research on the highest priority issues (i.e., the areas of greatest scientific uncertainty and programmatic impact).

- *Do the science questions identified in the MYP address the most important research issues for each of the major research topic areas*

## **COMMITTEE RESPONSE TO CHARGE QUESTION 2**

### **General comments on Charge Question 2**

ORD has, for the most part, framed appropriate questions for targeting the important research efforts. We expect that questions will evolve (as will the APGs) with progress and rule development. The DWC has some concerns with research priorities. Elements of the research program may be continuing without any clear benefit. Drinking water issues progress from discovery, to data collection and regulation, followed by monitoring the effectiveness of the rule. The DWC believes that research resources dedicated to a specific issue should evolve in

accordance with this progression. In early stages, modest research allocations should be dedicated to reconnaissance and forward thinking research. As the agency approaches rulemaking, more resources should be allocated. After rulemaking, the budget should be decreased and focused on assessing the effect of the rule and the potential for future changes. Mature topics where research may need to be refocused include disinfection by-products and the effects of high levels of arsenic. Issues in early stages include CCLs, watershed protection and distribution systems.

Third party input to the development of the Long-Term Goals should be clearly stated, and a process should be articulated regarding how third party recommendations were handled. For example, were the recommendations adopted, not adopted, or are they under consideration (e.g., why were the Classification Methods described in the NAS report<sup>2</sup> not included in the Annual Performance Measures under Innovative Methods)?

The DWC recommends that the text and logical development of the Annual Performance Goals which form the Long-Term Goals should be reorganized with headings which include: a brief discussion of the issue; the current state of knowledge; and an indication of knowledge gaps. The key questions can then be derived from those gaps and ordered by regulatory priority or scientific need.

The MYP should distinguish between natural, accidental and intentional contamination (e.g., storm events or wastewater spills versus bioterrorism events). A context is also needed for each key question, so they can be more easily understood and relationships between Long-Term Goals, Annual Performance Goals, and Annual Performance Measures can be readily discerned. Further clarification was needed for some of the key scientific questions (section numbers in the pages that follow refer to those found in the MYP on pgs. 7-10).

## **Specific comments on Charge Question 2**

### *Section 3.1 Arsenic Rule*

- (1) What are the most cost-effective technologies for removing arsenic from drinking water and managing residual wastes, particularly for small systems? What is the significance of arsenic accumulation in the distribution system?*
- (2) How can the quantitative assessment of the relationship between exposure at low doses (in the 10 µg/liter range) and the risk of cancer or noncancer effects in susceptible populations be strengthened?*

These science questions are short, yet capture the debate over the treatment technology issues and health effects in the arsenic rule.

### *Section 3.2 M/DBP Rules--Waterborne Pathogens:*

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<sup>2</sup> National Academy Press, (2001) *Classifying Drinking Water Contaminants: for regulatory consideration*, National Research Council, Washington DC Error! Main Document Only.

*(1) How can analytical methods to detect Cryptosporidium in water matrices be improved?*

Before asking how to improve methods, ORD should define why they need to be improved (i.e., the rationale behind the question). Is the objective to improve Method 1623 so that it can be effective with a broader range of water matrices? Perhaps a bigger issue with the current detection method is the sample volume (10 liters) and its relationship with protozoa isolation in source waters. Reported results from Method 1623 are much lower than from the old Information Collection Rule (ICR) method and the reasons for this discrepancy should be determined. Is it due to misidentification by the old ICR method or is the sample volume the problem? or was the 18 month assessment a better representation of concentrations? The DWC suggests that new methods and monitoring schemes should focus on the infectivity and viability of pathogens.

*(2) What data and methods are needed for assessing the risks associated with exposure to protozoa and viruses in source water and ground water?*

It is difficult to understand what this question refers to. Is it a general risk question (i.e., are the current risk assessment tools the appropriate ones)? Or is it referring to new approaches to risk assessment or a question of whether there is a possible reduction in efficacy of disinfection from complying with the Stage 1 and 2 Disinfection By-Products (DBP) rules? The question that should be asked is: Has implementation of Stage 1 and 2 DBP rules at treatment plants effectively reduced or increased protection against pathogens, and what is a reasonable approach to determine the level of protection?

Better methods to detect and eliminate viruses are needed, given that groundwater and small systems are at risk. The second science question should be reframed. The data and methods needed to assess risk are known. The real question is how to more effectively monitor source waters given limited funding and laboratory capacity. The contamination is tied to land use and transport during environmental conditions (i.e., rain events) so spatial and temporal assessment is a challenge. The DWC recommends a greater emphasis be placed on viruses and groundwater, and measuring the effect of compliance with Stage 1 and Stage 2 DBP rules on pathogen inactivation.

*(3) How can treatment be optimized to remove/inactivate Cryptosporidium, particularly for small systems? How can these approaches be balanced to also control DBPs?*

Is this question about optimization of conventional treatment, or is it more general? The last question on small systems is particularly important. Monitoring small systems will be a challenge. There are issues associated with small systems that need to be considered:

- Small systems are more likely to be located in rural, agricultural environments;
- Small systems often rely on groundwater with an assumption that groundwater is safer without proper assessment; and
- Water supply degradation may go unnoticed due to inadequate microbial monitoring.

The DWC recommends including small systems using groundwater in research projects. Questions should be framed as follows: what conventional optimization procedures and alternative treatment technologies may be most effective for the reduction and inactivation of *Cryptosporidium* in small systems? How can treatment approaches for *Cryptosporidium* in (medium and) small systems be optimized in light of the new DBP rules?

*Section 3.2 M/DBP Rules--Disinfection Byproducts:*

- (1) *How can the health effects (especially adverse reproductive outcomes) of the highest priority byproducts and DBP mixtures be better characterized?*
- (2) *What is the risk posed by exposure to the byproducts that are formed:*
  - (a) *from the use of alternative disinfectants (i.e., other than chlorine alone), and*
  - (b) *as a consequence of differences in source water quality (e.g., sources with high versus low bromide concentrations)?*
- (3) *What analytical methods, occurrence data and methods for estimating DBP formation are needed for determining exposures to byproducts of concern?*

For Disinfection By-Products, the DWC concurs that the three questions posed are important. The question regarding how health effects can be better characterized is too qualitative. There are many ways to define “better” and each would lead to different research programs. *Better* can mean less expensive, more rapid, or in a system that extrapolates to humans, more reliable or more detailed versions of the characterizations that have already been done (e.g., more doses to better define the shape of the dose-response curve in the region of likely human exposure or where there is concern for non-linearity). Therefore, the DWC recommends that the phrase “better characterized” be more clearly defined.

The MYP needs to address the future of disinfection, chlorination, ozonation, UV disinfection, plasma disinfection, etc. EPA should take a leadership role in defining the future of disinfection (and its by-products). For example, EPA could commission the NRC to analyze the future of disinfection. Such an analysis would include the costs and benefit to society vs. cost of research. The DBP research program may be locked into institutional momentum. In other words, is research continuing without clear benefit?

*Section 3.3 Six-Year Review of NPDWRs*

The science questions identified in the MYP do address important research issues for each of the major research topic areas identified in the Six-Year Review. However, specific science/research questions for this topical area of the MYP are not developed. Future National Primary Drinking Water Regulation (NPDWR) reviews may identify heretofore unrecognized data requirements and issues. Therefore, a matrix of NPDWRs, review cycles, and current data requirements may help to guide the development of additional science issues. A matrix of priorities for the DW Research Program would be useful.

*Section 3.4 Unregulated Contaminants (CCL) and Future Rules*

- (1) *What contaminant-specific research is needed to address key data gaps for high priority waterborne pathogens and chemicals that are or could be listed on the CCL?*

For unregulated contaminants (CCL), EPA needs to develop research programs for understanding and mitigating predictable hazards that will affect drinking water. These arise from changes in agricultural practices that will impact drinking water, by affecting source water quality (both pathogens and the types of agricultural chemicals that enter water) and seawater desalination and potable water reuse.

For CCL pathogens on page 9, the DWC supports the broad scientific question as stated. For pathogens that might be added to the CCL in the future, new approaches are needed. For current CCL pathogens, the questions should focus on developing a risk assessment that addresses:

- Where do microbes of most serious concern enter the system (at the source or in the distribution system)?
- What new methods can be used to address potential for exposure (occurrence, survival and transport)?
- How can gaps in treatment be filled (conventional vs. future technology)?
- Where is the uncertainty in the health risk (dose, health outcomes, sensitive populations)?

It should be noted that there is a separate research plan for Homeland Security and there should be exchange between the EPA Drinking Water MYP and the Water Protection Division's research plan. Separate research for intentional and natural/accidental contamination events should be developed with a different set of key questions for each.

- (2) *What innovative approaches can be developed for identifying and prioritizing contaminants for listing on the CCL, as well as for assessing and managing risks?*

This question is an example of water-related research activity that is outside of ORD and therefore not included in the MYP. This question is addressed in the 2001 NRC report *Classifying Drinking Water Contaminants for Regulatory Consideration* with modified recommendations adopted by the National Drinking Water Advisory Committee (NDWAC) in May, 2004. This is a broad science question; it includes innovative models, predictive tools, methods, and exemplary experimental approaches, such as assay systems and microarray technology. In terms of innovative approaches, the Annual Performance Goals and Annual Performance Measures under Innovative Approaches address this science question well for the CCL list.

The DWC recommends expanding the scientific questions to include the following:

- Where innovative technology exists in allied science and engineering fields, what environmentally unique drinking water and source water issues exist that inhibit exploitation of these technologies for ORD problem solving?

- What is the most effective way to integrate across ORD's pre-existing development or use of innovative technology to achieve the greatest benefits for GW/DW, Source, and Distribution in meeting the SDWA requirements?
- Can innovative approaches be effectively transmitted to State and municipal governments to avoid basing future rules on outdated technology, such as total coliform analysis?

If ORD is seeking a compilation of the development, use and implementation of innovative technology, this could be accomplished by an internal Annual Performance Measure, a cooperative agreement, or an international workshop.

### *Section 3.5 Source Water Protection*

The Agency has, for the most part, framed appropriate questions for targeting the important research efforts. However it is not clear how each Annual Performance Measure specifically addresses the science needed to answer these questions. The Annual Performance Goals do not seem to address each of the science questions in Table 3, particularly the first question about the adequacy of Ambient Water Quality Criteria in protecting public health.

- (1) *How adequately do the Ambient Water Quality Criteria (AWQC) that address the major drinking water contaminants protect public health?*

It does not appear that significant effort is directed at answering this question based on the work products which are associated with Long-Term Goal 3. It is an important question which will frame how the CWA and the SDWA efforts can be coordinated. Coordination of these two programs is critical to appropriately directing EPA's resources and efforts. It might be helpful to develop a series of white papers that review AWQC parameters, SDWA expectations and treatment. This would provide a framework for developing targeted research projects.

- (2) *What improved techniques are needed to better define source water characteristics and sources of contamination?*

A significant effort is aimed towards developing methods for assessing microbial contamination and new emerging chemical contaminants. Defining source water characteristics is addressed to a lesser extent. It will be important to not only identify what contaminants are in source waters but also the variability in space and time of these constituents. This will be critical information needed to answer Question #5 below.

- (3) *What are the fate and transport characteristics of certain types of contaminants in surface water and ground water?*

Based on the work products identified for Long-Term Goal 3, it appears that limited effort is targeted at this issue. Fate and transport is an important consideration for both the CWA and the SDWA. The occurrence and persistence of known and emerging chemical and microbial contaminants will drive treatment for both wastewater and drinking water utilities.

- (4) *How effective are candidate protection measures (i.e., Best Management Practices) on improving the quality of the source water?*

This is an important area of research because pollution prevention is one of the most important things that can be done to ensure public health and safety. For the most part, however, BMP's are not inexpensive and historically, regulatory agencies have been reluctant to identify reliable benefits to a utility. This is understandable because of the paucity of demonstrations. To encourage utilities to participate, clear, measurable benefits need to be demonstrated. A small number of work products address this question for specific contaminants. More effort could be directed towards this question as it is another important link between the CWA and the SDWA. BMP's also are a critical element of the proposed LT2 "Toolbox" which currently has too few viable tools in it. These BMP's (their characterization and value to avoiding treatment at a plant) are necessary for inclusion in the rule to meet the stated expectations of the FACA agreement for that negotiated rule package.

- (5) *What is the impact of sudden increases in source water contaminant concentrations on drinking water treatment performance?*

It is not clear that this question is appropriate as a part of Long-Term Goal 3 and source water protection. This question speaks to water treatment plant operations, performance and reliability. It also may be geared towards security considerations. As stated, this question would be best evaluated through pilot plant work and assessment of full scale plants under stress conditions. This question can be re-worded to ask *how robust are treatment facilities in their ability to respond to sudden increases in source water contaminant concentrations and to changes in the source water contaminants themselves in the event of an intentional or unintentional spill/challenge?*

A more logical connection to source water protection would be to characterize variability (space, time and concentration) of various contaminants across water sources and then using those levels challenge a pilot plant or document full scale plant performance. No Long-Term Goal 3 work products are clearly related to this aspect of the question.

- (6) *What early warning and monitoring systems should be developed to alert utility operators of contaminant excursions at the source so that corrective actions might be employed?*

Coordination with security efforts will enhance the resources which can be allocated to this important issue. The type of contaminant, the extent of the excursion and the frequency of events all must be identified *a priori* to the selection of "sensors". The nature of the excursion (intentional or natural) will also be a determining factor. Once these factors are established, then warning systems can be logically developed. A key item not identified in the question (or any work products associated with this Long-Term Goal) is characterization of the appropriate corrective actions that utility operators could employ once "warned". If the excursion is "natural" then it would be logical to follow "good operating practices" at the Water Treatment Plant; if the event is an intentional contamination, then security Standard Operating Procedures should be employed. These security Standard Operating Procedures are yet rather ill-defined for



the drinking water industry. The question should be expanded to address corrective actions utilities might take when they are alerted to contaminant excursions at the source, and to identify when an excursion is significant enough to require corrective action.

An additional science question that should be added to this section is, *what new developments in the arena of cyber-infrastructure and information technology are appropriate for incorporation and use in source water protection monitoring programs?* Lastly, the subject of water reuse is not mentioned at all in any of these questions, yet it is a growing practice, and its potential impact on health is of considerable concern to the public.

### *Section 3.6 Distribution Systems*

- (1) *What are the public health risks associated with contamination of the distribution system?*

This is the most important question to ask regarding distribution systems. It frames the entire cost benefit discussion inherent in rule-making. In order to address this extremely important question we need to improve our understanding of what diseases are related to distribution systems. The synthesis documents should provide some of this information, but the timing of their completion does not appear to be well coordinated with other research efforts. It may be useful to identify coordination with other agencies such as the CDC so that all the work underway or planned is identified. As reported in the MYP, however, that effort is not sufficient.

- (2) *How can the structural and operational failure modes that reduce water quality in the distribution system be characterized?*

This question is not worded very clearly. Does “failure mode” refer to infrastructure failure, or to degradation in distribution system water quality? Further, questions should not be restricted to failure modes. An additional question would be, *what operational practices help avoid degradation of distribution system water quality?*

The work products which focus on the formation and behavior of biofilms and scales, and the impact of treatment changes on the same appear to be the major work efforts designed to address the distribution system-water quality issue. Beyond that there is a need to understand the integrity of our distribution systems, opportunities for backflow and cross connections, the significance of transient pressure changes and how water ages in a distribution system. The latter (water age) is addressed in some of the work products, but should be more thoroughly investigated. Coordinating microbial methods development and ensuring that occurrence data from distribution systems is collected will also provide valuable information.

- (3) *What new or improved methods are needed to prevent, detect, locate, repair, and rehabilitate contaminant intrusion points in water distribution systems?*

Enhancement of hydraulic models coupled with water quality layers would be a valuable tool for locating intrusion points. Improvements in construction and repair guidance and strengthening backflow prevention and cross connection control programs are also necessary.

Some work products are designed to address hydraulic modeling but do not appear to be sufficient to address this significant need.

- (4) *What new or improved methods are needed to monitor and control internal distribution system conditions that may result in the deterioration of water quality?*

First it is necessary to understand the changes in water quality that occur in distribution systems. Some work is designed to address this portion of the question. In order to control distribution conditions, the processes in the system which affect water quality need to be adequately assessed. The work products identified to do this are a good beginning but do not adequately address the breadth or immediacy of the needs. The word “model” might be added to Question #4 (i.e. *...needed to monitor, model, and control...*). Perhaps another related question here deals with a better understanding of the dynamic nature of the distribution system as it influences spatial and temporal variations in water quality, which directly affects exposure of the consumers to these contaminants.

### **CHARGE QUESTION 3**

Research outputs (APMs) in the MYP represent new data, tools, technologies, databases, models, or assessments that are considered necessary for accomplishing a particular goal (APGs). Outputs listed under an APG are either interim or final products that are typically specific to one ORD Laboratory or Center. The MYP also identifies several synthesis documents, which integrate and summarize new research findings on a particular topic.

The MYP does not, by design, provide detailed information on specific research activities and products represented by Annual Performance Measures. Nevertheless, a general evaluation of the research program outputs can be based on a review of the Annual Performance Measures titles and the supplementary information on near-term Annual Performance Measures provided through linkages to the drinking water research tracking system.

- *Do the research products identified in the MYP focus on the highest priority research for each major topic area?*
- *Do the sets of Annual Performance Measures (APM) under the Annual Performance Goals appear both necessary and sufficient for accomplishing the intended goals?*

### **COMMITTEE RESPONSE TO CHARGE QUESTION 3**

The research products, also referred to as Annual Performance Measures (APMs), under each Annual Performance Goal identified in the MYP do focus on high priority research for each major topic area. The MYP does not, however, include the research required to support the conduct of a cost benefit analysis which must consider a variety of health benefits, ranging from lives saved to minor illnesses avoided. Annual Performance Measures should be framed in the context of the relative risk posed by target drinking water contaminants. This approach would

probably lead to an emphasis in microbial contaminants and chemical mixtures, and de-emphasis of individual trihalomethanes (THMs) and haloacetic acids (HAAs). For Distribution Systems, the opening paragraph in Section 3.6 (page 10) makes no mention of corrosion or formation of new DBPs (e.g. NDMA) in distribution systems. These items are important and should be added.

***Arsenic Rule:***

The Committee considers this to be another area where some research is driven more by institutional momentum rather than by need to support regulation. The information available to the Committee indicates that the studies in the Chinese population address high-dose exposure and actually classifies exposure of 10 ug/L or less as control. Because the low-dose exposure of interest is put in the control group, it is hard to envision how this study could strengthen the quantitative dose-response assessment in the low dose range. The Annual Performance Measures appear to be weighted towards cancer rather than non-cancer effects. There also appears to be a lack of effort in identifying human subpopulations that may be more sensitive to the non-cancer effects following exposure to arsenic. The 2000 Arsenic Rule included a discussion of important non-cancer health effects; however these could not be included in the cost-benefit analysis because the value of these benefits could not be estimated. This research need is not addressed in the MYP. If such research is being conducted as part of another MYP, then cross-references may be appropriate.

***Disinfection Byproducts***

The research emphasis given to THMs and HAAs should reflect the balance of evidence of their health effects. This committee has previously expressed the concern that the practice of using the THMs and HAAs as surrogates for whatever DBP causes cancer may lead to treatment strategies that increase exposure to the actual carcinogen while decreasing exposure to the surrogates.

The committee is uncertain as to whether or not there is enough effort on analytical methods, on occurrence and on methods for estimating formation of other potentially harmful DBPs. Are the data obtained from the Information Collection Rule sufficient for determining the nature and magnitude of exposures?

***Unregulated Contaminants (CCL)- Chemicals***

The list of substances making up CCL2 seems to consist largely of those agents retained from CCL1. It would be appropriate to revisit previously identified research needs for them, and verify that the research needs are covered in the 2005 and 2010 Annual Performance Goals; or that there is scientific justification for not filling them. The four Annual Performance Goals and their Annual Performance Measures collectively do cover all four categories of the risk assessment/risk management spectrum<sup>3</sup>.

***Unregulated Contaminants (CCL)- Pathogens***

Research projects on pathogens are divided into several categories. Twenty three (23) projects focus on new methods (including modeling), 18 on survival (mostly surrogates and

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<sup>3</sup> National Academy Press, (1983). *Risk Assessment in the Federal Government: Managing the Process*. National Research Council, Washington DC **Error! Main Document Only.**

models), 17 on control treatment (bank filtration, UV) and 24 on health risks (primarily epidemiological data). The epidemiological data does not provide new tools; however, there are some new data (spatially and temporally limited) and new controls (there are a few intervention type studies). With respect to defining health risks, the broad outcomes are not often assessed very specifically to dose-response or defining toxic algal outcomes. There are 13 projects focused on *Cryptosporidium*, 10 on *Cyanobacteria*, 15 on other CCL microbes, 6 on biofilms and approximately 24 on generic topics related to health and new methods. The generic projects may not provide as much information as needed. In the Source Water section, the combined sewer overflows (CSO) assessment will be of great interest. It seems there should be more on "Source Tracking," parasites and other pathogens in sewage discharges besides the Method for *E.coli* 0157.

The Annual Performance Measures as described while necessary, have deficiencies in the development of a clear application for method and technology transfer, and the development of occurrence data. Research on new innovative monitoring designs and statistical evaluation appear to be addressed in much of the modeling projects and efforts.

### ***Six-Year Review***

Under the Six-Year Review in general, the Annual Performance Measures within the Annual Performance Goals are necessary and appropriate for accomplishing the intended goals. The Annual Performance Measures for chromium, arsenic, lead, copper, and antimony are also very appropriate and will help provide a basic database on the health effects that these metals/metalloids exert.

### ***Innovative Approaches***

Under Innovative Approaches, for Annual Performance Goal 1, all the Annual Performance Measures appear necessary and appropriate for accomplishing the intended goals. When completed, Annual Performance Measures should be reevaluated to determine whether other research will need to be conducted. The use of QSAR models to predict cancer potency for CCL chemicals is necessary for determining the carcinogenicity of Drinking Water Contaminants. The development of DNA micro-arrays to detect multiple pathogens in a single water sample is a novel and potentially very powerful approach to achieve a practical end in the Drinking Water Program.

Four Annual Performance Measures are identified under Annual Performance Goal 2 which deals with developing new data and tools to determine cost, feasibility, and performance of technologies to support management decisions. These Annual Performance Measures will develop cost models for selected separation and disinfection technologies, maintain and update the treatability data base, evaluate costs and feasibility of small slow sand filtration technology for indirect drinking water reuse, and evaluate the cost and performance of new filtration and destruction technologies for indirect drinking water reuse. The Annual Performance Measures under Annual Performance Goal 2 all appear practical, and are necessary and appropriate for accomplishing the intended goals.

Under Annual Performance Goal 3, ORD proposes to develop new approaches for estimating risks and prioritizing contaminants of potential concern for the development of future

Contaminant Candidate Lists and making other management decisions. There are thirteen Annual Performance Measures to support this Annual Performance Goal. All of these Annual Performance Measures are necessary for accomplishing Annual Performance Goal 3. Microbial dynamic transmission, physiologically-based pharmacokinetic (PBPK) modeling, statistical models to assess cancer risk for children, proteomics approaches to detect drinking water pathogens, QSAR approaches to extrapolate data for CCL development, microarray approaches, methods to screen large numbers of contaminants, biomarkers of exposure to CCL chemicals, computational toxicology approaches, and animal models of human genetic polymorphisms to assess potential susceptibility to CCL chemicals, are all useful approaches. Many are novel and should increase the efficiency of accomplishing Annual Performance Goal 3.

The desired research outcomes under Long-Term Goal 2 are intended to address the issue related to classification of the waterborne contaminants on the CCL. The Annual Performance Goals and their associated Annual Performance Measures for Innovative Approaches which are listed under Long-Term Goal 2 are laudable but not complete. A number of the recommendations presented in the previously cited NRC report are not addressed in the MYP. The DWC notes that this is an OW activity not captured in the ORD MYP, and that modifications to the NRC report recommendations have been made by NDWAC. It seems likely that ORD will have research activities in support of innovative approaches for classifying drinking water contaminants. The DWC recommends that these be included in future plans.

All of the Annual Performance Measures are important. A clarification of the priorities among Annual Performance Measures and an explanation of the ways in which project results will contribute to refining and directing future research would be helpful. In some cases, only a little more explanation is needed; however, there are certainly areas that need further attention as well. The integration of results is addressed to some extent.

#### **CHARGE QUESTION 4**

The total budget for the drinking water research program in FY 2003 was approximately \$50 M and 232 full-time equivalent (FTE) personnel. The MYP was developed based on an assumption of level resources over the period covered by the plan.

- *Is the relative allocation of resources across the major components of the drinking water research program appropriate, based on a consideration of scientific and programmatic needs?*
- *Is the overall resource level generally sufficient to address the most important research questions and achieve the intended outcomes of the research program?*

#### **COMMITTEE RESPONSE TO CHARGE QUESTION 4**

Given the materials provided to the DWC, this question was difficult to answer critically. Overall, the DWC believes that \$44.1 million is too little for the entire Drinking Water Program.

Long-Term Goal 2 has been allocated more than half of the total budget (64%), and the Innovative Approaches category (i.e., \$15.1 million or 34.2% of the total DWMYP budget for FY 2004, including 23 FTEs) within Long-Term Goal 2 is twice as large as any other category. In contrast, Long-Term Goal 3, which covers two very broad topics, is due to be addressed a year earlier and yet comprises only 5.6% of the total budget.

Innovative approaches will be important for answering many of the important scientific questions posed in the MYP, both from a scientific and practical point of view. Some of the scientific questions asked and the goals enumerated cannot be accomplished without use of novel technologies such as micro-arrays and proteomic approaches. These technologies will be expensive. After the first round of Annual Performance Measures has been accomplished, this issue should be revisited.

For Distribution Systems, the overall allocation of resources and timing appear to be insufficient and lag behind the drinking water program timeline. A shift of funds to Distribution Systems may be needed given the current issues that have arisen (i.e. use of chloramines, meeting lead and bacterial concentration limits and goals) . The needs of the drinking water program will certainly increase over time and the MYP timelines will need to evolve.

The effort in the Source Water Protection research is less than needed, especially with regards to drinking water research. Many of the projects connected to Source Water Protection are identified with other efforts (i.e., other MYP's). If one includes the work in those research projects which address Source Water Protection needs, then the relative allocation is improved. Long-Term Goal 3 is further out on the time line and based on the MYP, it would be expected that more resources and efforts will shift in the future. The paucity of work aimed at the source water protection goals identified as part of the proposed Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) is of some concern.

In conclusion, the drinking water program in general is under-funded. The safety of drinking water is still a high priority for the public. The Walkerton tragedy is a reminder of what happens with complacency, inadequate development of rules and inadequate implementation.

A few general observations and some additional specific recommendations are listed below:

- Exploratory and open-ended research has special value to EPA's mission, especially with respect to new issues and new technologies. The DWC believes that this research has significance because it provides support for drinking water issues of interest to EPA that is not always available elsewhere. In addition, this research stimulates activities within EPA, brings new expertise to EPA and transfers technology through EPA conferences and workshops.
- EPA is to be complimented for its cooperation in the Global Water Research Coalition and yet resources could also be better leveraged by strengthening formal research relationships with other governmental agencies (e.g. NIEHS, NSF, USGS, CDC, NCBI (bioinformatics), state agencies, etc.)
- In view of the growing research needs to support the CCL, the movement toward alternative disinfectants, competing drinking water regulations, increasing concern with

respect to source water protection and distribution systems, and increasing movement toward water reuse and desalination, the DWC believes that a level budget for drinking water research will not be adequate to accomplish what must be done to address these needs.

The DWC would also like to encourage ORD research staff to take some risks and follow some research which is not clearly regulation-driven. This will help EPA to further improve its research reputation and make EPA a more attractive home for top quality research professionals. With the emergence of new challenges and methodologies, the DWC sees the need for program staff to engage in professional development, as it is difficult for them to stay abreast with their scientific disciplines. Perhaps having some Annual Performance Goals and associated Annual Performance Measures within the program offices might be one way this could be approached. This would require EPA to invest in its human capital, and explicitly recognize it.

## **REFERENCES**

National Academy Press, (2001) *Classifying Drinking Water Contaminants: for regulatory consideration*, National Research Council, Washington, DC

National Academy Press, (1983). *Risk Assessment in the Federal Government: Managing the Process*. National Research Council, Washington, DC