HUMAN HEALTH MID-CYCLE REVIEW SUBCOMMITTEE

Meeting Summary
Wednesday, January 24, 2007
Arlington, Virginia

Welcome and Purpose

Dr. Jim Clark, Exxon-Mobil Corporation, Subcommittee Chair

Dr. Jim Clark, Chair of the Human Health Mid-Cycle Review Subcommittee, welcomed the Subcommittee members to the face-to-face meeting to conduct the mid-cycle review of the Office of Research and Development's (ORD) Human Health Research Program (HHRP). He explained that the purpose of the meeting is to review the progress of the HHRP in responding to the Board of Scientific Counselors' (BOSC) program review that was conducted in 2005, as well as the program's accomplishments and any changes that have been implemented by the program since the 2005 review. Since the face-to-face program review meeting in early 2005, the BOSC prepared a report and submitted it to ORD, and the HHRP prepared a response to the BOSC report. Also since the program review, a Program Assessment Rating Tool (PART) review of the HHRP was conducted by the Office of Management and Budget (OMB).

Dr. Clark stated that the charge to the Subcommittee was provided in the meeting notebook (see Tab C), and the mid-cycle review is organized around the charge questions. He welcomed Dr. Hugh Tilson, who was recently named the National Program Director (NPD) for Human Health after acting in that position for a number of years. Dr. Clark then asked the Subcommittee members to introduce themselves for the benefit of those in attendance.

Dr. Clark commented that this is a BOSC review and the discussion is to be among the Subcommittee members. The U.S. Environmental Protection Agency (EPA) employees are here to make their presentations; they cannot participate in the discussion but can respond to questions of the Subcommittee that are directed to the EPA staff members by the Chair. He then introduced Virginia Houk, the Designated Federal Officer (DFO) for the Subcommittee, who reviewed administrative procedures, the Federal Advisory Committee (FACA) rules, and the Subcommittee's charge.

DFO Welcome and Charge

Ms. Virginia Houk, Designated Federal Officer, ORD, EPA

Ms. Houk thanked Dr. Clark and the Subcommittee members for assisting ORD with this mid-cycle review, stating that the insights and advice of the Subcommittee is appreciated. She also thanked the HHRP staff members for the work they did to assemble the background materials and the presentations.

Ms. Houk then reviewed some of the more important rules and administrative procedures that are required for federal advisory committee meetings.

Role of the DFO and FACA Requirements

As the DFO for this meeting, Ms. Houk serves as the liaison between the Subcommittee and EPA, and she is responsible for ensuring that these meetings comply with FACA. She summarized a few of the relevant FACA rules:

- All meetings involving substantive issues—whether in person, via phone, or by e-mail—must be open to the public. This applies to all group communications that include at least half of the Subcommittee. Issues that are solely administrative or preparatory in nature are exempt from this requirement.

- The Subcommittee Chair and DFO must be present at all meetings.

- A *Federal Register* notice must announce all meetings 15 calendar days in advance of any meeting.

- Meeting minutes must be prepared and certified by the Subcommittee Chair within 90 days of the meeting. The minutes must be made available to the public, along with any documents supplied to the Subcommittee. The notice and agenda for this meeting were entered in a public docket, which can be accessed on the Web at http://www.regulations.gov. The Docket Number for this Subcommittee meeting is EPA-HQ-ORD-2006-0978.

Today's Meeting and Public Comments

As Subcommittee Chair, Dr. Clark will preside over the meeting and mediate the deliberations of the Subcommittee. ORD staff members are not permitted to ask questions of the Subcommittee or provide opinions on the deliberations, and before responding to any questions raised by the Subcommittee, the ORD staff member must first be recognized by the Chair.

No member of the public requested time for comments prior to the meeting, but if there are requests that arise during the meeting, there is time on the agenda at 2:10 p.m. for any public comments. Each public comment will be limited to 3 minutes.

Ms. Houk stated that a contractor is taking detailed minutes of this meeting, and to improve the accuracy of these minutes, she requested that speakers please identify themselves prior to making a comment.

Conflicts of Interest

As DFO, Ms. Houk has assured that all appropriate ethics regulations related to FACA meetings have been satisfied; the Subcommittee members have completed their annual ethics training, and each member has filed a standard government financial disclosure report. She mentioned that Dr. Timothy Buckley, who is the lead for the Long-Term Goal (LTG) involving Susceptible Subpopulations, is a co-investigator on a grant application that recently was submitted to EPA's Science To Achieve Results (STAR) Program to investigate asthma effects associated with

ambient air particle exposure. Although the source of the funding for the grant is the Air Program and not the Human Health Program and the decision on funding has not been made, Ms. Houk has asked Dr. Buckley to recuse himself from any discussions specifically related to asthma, should they arise.

Function of the BOSC Subcommittee

EPA's research programs are reviewed by the BOSC every 4 to 5 years, with a mid-cycle evaluation held midway through the review process. The purpose of a mid-cycle review is to gauge the program's progress relative to the commitments it made following its last review and obtain advice on issues such as future directions and performance and accountability. The HHRP was last reviewed by the BOSC in 2005, and the Mid-Cycle Review Subcommittee represents a subset of the Subcommittee that conducted the program review in 2005.

The Mid-Cycle Review Subcommittee has been asked to respond to five charge questions. It is anticipated that a draft report addressing these charge questions will be produced by the Subcommittee following this meeting. The draft report will be submitted to the BOSC Executive Committee, which will review and approve the report prior to submission to ORD. Ms. Houk noted that the rights of decision making and program implementation remain with the Agency.

Today's face-to-face meeting was preceded by a conference call on January 9, and no additional meetings are planned. In the event that another meeting or conference call becomes necessary (for example to finalize the draft report), an announcement will be placed in the *Federal Register* at least 15 days prior to the meeting or call.

In closing, Ms. Houk thanked the Subcommittee members once again for their participation in this review. She asked them to submit their completed Time Sheets and Travel Voucher Forms, including receipts, by the end of the meeting.

Dr. Clark thanked Ms. Houk for her remarks and mentioned that there were a number of BOSC Executive Committee members in the audience. He explained that the members wanted to attend the meeting because this is the first mid-cycle review conducted by the BOSC. He then asked Dr. Tilson to make his presentation.

Review of Action Items: Response to Recommendations of 2005 Review
Dr. Hugh Tilson, NPD for Human Health, ORD, EPA

Dr. Tilson expressed his appreciation for the recommendations and observations made by the BOSC during the 2005 program review. The HHRP staff members worked hard to identify all of the comments and recommendations in that report and have done their best to address them. He noted that the document provided for this mid-cycle review included a number of items that had not been identified in the initial ORD response prepared in 2005. Also there were some redundancies in that initial document that have been eliminated in the response for this mid-cycle review. This document includes both comments and recommendations from the 2005 program review report and a description of what ORD has done in response to each one. In the mid-cycle review document, the responses have been organized by LTG (in the original ORD response they were ordered as they appeared in the BOSC report); some comments, however, were not associated with an LTG. Dr. Tilson then went through the action items and presented ORD's progress in addressing those items.

BOSC Issue: Program scientists should contribute more to international efforts (in overview and LTG 2).
ORD Response: HHRP scientists have numerous interactions with international groups. The scientists attended a European Union (EU) workshop in June 2005 and met with other investigators to identify ways to integrate ORD's human health research on toxic chemicals with ongoing and planned EU activities. ORD scientists participate in a number of international activities and Table 7 in the 2005 documentation package attempted to summarize these interactions. Specific research collaborations were not, however, clearly articulated. For the next review, the documentation package will include a new section documenting specific research interactions of HHRP scientists with international programs.

Dr. Clark commented that there was acknowledgement of informal interactions in the 2005 review documentation, but the BOSC had wanted there to be more formal international interactions. Dr. Timothy Buckley mentioned that the documentation could have acknowledged that there were significant regulatory developments in Europe and EPA scientists should identify ways to make a contribution to these. He mentioned, for example, involvement in generating testing guidelines for neuroendocrine studies of mechanisms of action. Dr. Joseph Landolph suggested including a table with color that makes the information stand out for the reviewers.

BOSC Issue: Creation of the National Center for Computational Toxicology (NCCT) may pose challenges with regard to teamwork (in overview and LTG 1).
ORD Response: A number of productive HHRP scientists have been transferred to the NCCT Computational Toxicology Program. In response to the BOSC's concerns, the NPD for Human Health and the Director of NCCT meet on a quarterly basis to discuss coordination of the respective research programs. Several human health researchers have received funds from the NCCT for research relevant to the themes of the HHRP and their products are captured in the revised Multi-Year Plan (MYP) for Human Health. In addition, projects underway by some scientists transferred from the HHRP to NCCT continue, and products from their research program also are captured in the 2006 MYP for Human Health. Finally, as the NCCT has developed its mission and expertise, new projects (e.g., developing biologically based models of arsenic toxicity) related to current HHRP themes have evolved.

BOSC Issue: Greater interaction between extramural investigators in the university centers and intramural researchers could result in more significant research progress (overview and LTG 1).
ORD Response: ORD recognizes the need for better coordination between the intramural and extramural research programs. The NPD has had discussions with the Director of the National Center for Environmental Research (NCER) concerning this issue. Interaction between NCER and other ORD laboratories has increased through enhanced participation by NCER representatives on the Human Health Research Coordination Team (RCT), more inclusive review of new Requests for Applications (RFAs) for future extramural research, review of products coming from the grants program by ORD staff, and the hosting of scientist-to-scientist meetings involving intramural and extramural scientists. NCER routinely relies on scientists from ORD laboratories to sit on internal programmatic review teams to offer advice on final funding decisions on STAR grants. NCER also has started holding "initial investigators meetings," where newly funded grantees are brought together with EPA scientists to discuss their research plans; these types of meetings encourage communication between extramural and intramural researchers. Products arising from extramural

research also are more integrated into the 2006 Human Health MYP and the relationship of those products to the intramural program has been articulated more clearly.

BOSC Issue: It was difficult to determine the full extent of intergovernmental agency collaborations between the HHRP and its allied agencies (overview and LTG 1).
ORD Response: HHRP scientists collaborate extensively with scientists from other federal agencies. Although the documentation package provided for the 2005 program review attempted to capture these collaborations in the biosketches and posters, this approach greatly underestimated the extent of these interactions. For the next program review, the documentation package will include a section documenting the specific interactions of HHRP researchers with scientists from other federal agencies.

BOSC Issue: The public health benefits from doing good science need to be better articulated (overview and LTGs 2 and 3).
ORD Response: The public health benefits of the HHRP now are linked to performance measures developed in collaboration with OMB. In addition, the HHRP intends to place more emphasis on developing methods, models, and data to assist the Agency in evaluating the effectiveness of risk management decisions. In that respect, the development of biomarkers of effect or exposure to assess changes in human health will have public health benefits. ORD notes that the public health benefits for LTG 1 (Use of Mechanistic Information in Risk Assessment) were clearly articulated.

Dr. Buckley praised the ORD response for evaluating the public health benefits, but he did not see that in the revised MYP. Dr. Tilson responded that the MYP describes an extension of research and demonstration projects. Since June 2006, when the MYP was revised, the NPDs were asked to develop a vision for their programs. What Dr. Tilson just described as the ORD response was developed as part of that vision. Dr. Tilson added that the program is trying to identify issues identified in the *Report on the Environment* (ROE) that need to be addressed. The program seeks to identify valid indicators of exposure and then assess how these influence regulatory decisions. He mentioned that Dr. Rebecca Calderon will discuss this more during her presentation. It was not in the revised MYP because this is something that is just evolving. Dr. Elaine Symanski said there seems to be a piece missing with respect to how to track the indicators' impacts on decisions. Dr. Tilson replied that some regulatory decision making will deal with risk assessment and some with risk management. The program plans to collect more information on how its products are used through the Integrated Risk Information System (IRIS) and other means. He commented that EPA is trying to figure out ways to capture how the program's products are being used for risk management activities and litigation efforts. One means of gathering such information is through a client survey. This survey would not be specific to the HHRP, but would be for all of ORD. Dr. Buckley asked if Dr. Symanski's concerns were addressed by Dr. Tilson's comments. She confirmed that this new direction addresses her concerns. Dr. Buckley stated that what he wanted to see was more effective regulation that provides better protection for public health.

BOSC Issue: Reviewers would have benefited from a bibliometric analysis of publications.
ORD Response: A bibliometric analysis of peer-reviewed papers supported by the HHRP was completed on April 18, 2005, and provided to the BOSC for the program review. For the purposes of the mid-cycle review, the bibliography was updated (1,800 papers were identified) and another bibliometric analysis was completed. The results of this updated analysis were provided in the documentation for this meeting. Although the numbers were similar in the two reviews, the most current analysis is more illustrative of the program.

BOSC Issue: The conceptual framework of the HHRP needs to be better articulated (overview and LTG 3).
ORD Response: The revised Human Health MYP outlines the main objective of the program, which is to provide methods, models, and data that will reduce reliance on default assumptions and uncertainties in the risk assessment process. This will be accomplished by providing a greater understanding of the fundamental determinants of exposure and dose and the basic biological changes that follow exposure to environmental agents. The main research themes of the HHRP remain the same as those from the 2005 program review. In 2005, OMB reviewed the HHRP, supported its strategic direction, and agreed that the performance measures need to focus on reducing reliance on default assumptions in the risk assessment process.

BOSC Issue: The direction of the research is too heavily influenced by external advisory bodies.
ORD Response: The process by which broad research themes are transformed into a research program was not clearly articulated during the 2005 program review. Once broad research themes have been identified by external bodies such as the National Research Council (NRC) or Science Advisory Board (SAB) and recognized as high priority needs of the EPA, ORD relies on discussions with its clients (i.e., program and regional offices) and with the scientific community to determine what research needs to be addressed from both a programmatic and a scientific point of view. Meetings are held with the program and regional offices to understand their regulatory science priorities and confirm that the HHRP research is addressing these needs. Results of discussions with program and regional office clients were summarized in Attachment B of the 2006 Human Health MYP. Emerging HHRP science needs are compiled and prioritized based on science and resources. Scientist-to-scientist meetings are used to develop approaches to address these questions from a scientific viewpoint. Examples of scientist-to-scientist meetings related to the HHRP since June 2005 were provided in Table 2.

BOSC Issue: The program needs to plan for leadership succession.
ORD Response: ORD recognizes the reality of changing demographics in the near future. Individual laboratories and centers have developed their own approaches to dealing with this challenge. ORD also has institutionalized a postdoctoral training program with the goal of recruiting new scientists for future employment at ORD. Additionally, NCER manages the STAR Fellowship Program, which funds graduate level students who are studying environmental science. Although not directly linked to planning for leadership succession within EPA, the STAR Fellowship Program is providing funding for the training of the future generation of environmental scientists. Interactions between STAR fellows and EPA scientists are encouraged through annual fellowship conferences. Finally, NCER also manages the Association of Schools of Public Health (ASPH) Fellows Program, where recent graduates are placed in various fellowship assignments within EPA; the goal of the program is to provide professional training and employment for early-career public health professionals by enabling them to work in EPA on current and emerging environmental public health needs. Dr. Tilson also mentioned ORD's ability to attract excellent scientists using Title 42 authority.

Dr. Tilson then covered the BOSC issues associated with LTG 1, Use of Mechanistic Information in Risk Assessment.

BOSC Issue: The program needs to better address the Office of Water's (OW) need for information on the carcinogenicity of compounds containing hexavalent chromium when administered by the oral route.
ORD Response: This recommendation was discussed with OW members of the Human Health RCT and was not given a high priority relative to other water-related themes such as arsenic and noncarcinogenic disinfection byproducts.

Dr. Landolph commented that the program may want to coordinate with the National Toxicology Program's (NTP) efforts to study the carcinogenicity of hexavalent chromium exposure through drinking water. With respect to OW's low interest in hexavalent chromium, Dr. Buckley asked Dr. Tilson what would be done if ORD scientists thought this was an important issue. Do the program offices define the research agenda or do the ORD scientists? Dr. Tilson responded that the agenda is established in a two-step process. The first step is to identify issues that are of high priority to EPA and the second step is to identify the science needed to address these issues. Given the budget constraints, it is impossible to conduct all the research needed, so the program focuses on research that meets high priority goals and is of high scientific merit. He acknowledged the need for the program to conduct more basic research as well as research that meets the high priority needs of the program and regional offices, but the basic research has to be approved by ORD managers for it to go forward.

BOSC Issue: The extramural grants program needs to be better advertised.
ORD Response: NCER, which is responsible for the STAR Program, has redesigned its Web site to provide greater access to information concerning the grants program. EPA also has provided better links to the grants program on its Web site. The newly developed Web site for the HHRP includes a major link called "Funding Opportunities." NCER also has increased the frequency of workshops to bring together extramurally funded researchers and increased its efforts to advertise upcoming RFAs. NCER has started conducting "initial investigator meetings," where a set of newly funded grantees is brought together with EPA scientists to discuss their research plans. NCER personnel also travel to major scientific conferences (such as the Society of Toxicology meeting and the American Public Health Association Meeting), where they staff an exhibit booth to provide conference attendees with information about NCER, including upcoming RFAs and fellowship opportunities.

BOSC Issue: The HHRP MYP needs to be revised.
ORD Response: A revised Human Health MYP was accepted by the ORD Science Council in June 2006. The 2006 MYP now serves as the road map for the HHRP for the period 2006 to 2013. Products (Annual Performance Measures [APMs]) in the MYP will be updated annually and the plan will be revised in 2009. Recent scientist-to-scientist meetings provide the opportunity for refinement of research approaches relevant to HHRP research themes and dealing with emerging issues. Dr. Tilson commented that Dr. Andrew Geller will describe in more detail the revisions to the MYP.

Dr. Tilson then presented the BOSC issues associated with LTG 2, Aggregate/Cumulative Risk.

BOSC Issue: The overall criteria and framework for decisions regarding why specific elements are vital and have been included in the research program were not clear.
ORD Response: ORD receives broad strategic direction from the Agency, which is influenced by external advisory bodies and public health concerns, and generates strategic approaches to address those broad goals. ORD scientists generate the research needed to address those concerns in

collaboration with input from program and regional office stakeholders. Articulation of annual products is derived from discussions by the RCT, which includes ORD scientists and Agency stakeholders. Dr. Tilson stated that research planning is complicated, and it involves the program and regional offices, primarily through the RCT.

BOSC Issue: A broadening of the list of stakeholders was suggested (also LTG 3).
ORD Response: ORD agrees that many of the research projects described at the 2005 program review were highly relevant to needs raised by the Food Quality Protection Act (FQPA) of 1996. Until recently, issues raised by the FQPA have been a significant driver for research in the HHRP. As a result, much of the research described at the 2005 program review involved pesticides; research related to other stakeholders did not appear to have as high a priority. This impression may have been misleading because the HHRP is intended to address cross-cutting research needs of multiple stakeholders. Significant progress has been made since the 2005 program review to ensure that the HHRP is a more balanced program. In preparation for this mid-cycle review, ORD prepared a table (Table 3), which cross-walks ongoing ORD research by stakeholder for each of the program's research themes. This table provides a much more inclusive picture of the current research portfolio as it relates to stakeholders other than the Office of Prevention, Pesticides and Toxic Substances (OPPTS).

BOSC Issue: Exposure research should include a wider range of chemicals.
ORD Response: As stated earlier, issues related to the FQPA have served as a driver for much of the work in the HHRP, including its exposure research program. Exposure research does to some extent use pesticides as a class of chemicals to facilitate development and validation of models. Exposure research in the revised MYP focuses on developing more generic models that can be applied to any class of chemicals. Emerging issues related to community/cumulative risk and evaluation of risk management decisions, as well as obtaining observational data on susceptible subpopulations, will be pertinent to all classes of chemicals.

BOSC Issue: Broad strategies need to be developed to manage exposure and risks from thousands of new chemicals.
ORD Response: ORD's NCCT is dedicated to developing computational approaches to identify and manage risks for larger numbers of new chemicals. One of the research themes in the HHRP is linked to that effort by developing emerging methods and models that can be used for computational models. Other MYPs (Safe Pesticides/Safe Products, Drinking Water, and Endocrine Disruptors) also support research to develop approaches for prioritization of chemicals for screening and testing relative to their specific problem-driven areas. A new research area in LTG 2 is designed to develop and evaluate tools for identifying communities at risk from real-world cumulative exposures to chemical (mixtures) and non-chemical stressors.

BOSC Issue: Better integration is needed between exposure and effects research.
ORD Response: Some of the fundamental research in the HHRP is laboratory- or center-specific. Research on toxicity pathways or modes of action clearly falls into that category. Multidisciplinary research projects are emphasized to a greater degree in the 2006 MYP. For example, areas such as pharmacodynamic/pharmacokinetic (PD/PK) model development, development of biomarkers, community risk, susceptible populations, and evaluation of risk management decisions depend on multidisciplinary integration.

Dr. Tilson addressed the BOSC issues associated with LTG 3, Susceptible Subpopulations.

BOSC Issue: Peer review will be enhanced by providing critiques from previous reviews.
ORD Response: The ORD *Human Health Research Strategy* document was externally reviewed in 2003 by a panel of the SAB. The HHRP, however, had not been reviewed prior to 2005. At the next review of the HHRP, projected for fall of 2008, comments from the 2005 review, ORD's response to the review, and the results from the 2007 mid-cycle review will be included in the documentation. ORD laboratories/centers supporting the HHRP also have periodic scientific reviews at the division and/or program level. The results of those reviews can be provided to the BOSC Subcommittee upon request.

BOSC Issue: The asthma research program should have regular group meetings.
ORD Response: A coordinator for asthma research, Dr. Hillel Koren, has been appointed and an asthma research team has been formed. This group now sponsors a seminar series for which senior asthma researchers are invited to ORD to share the latest in their research activities.

BOSC Issue: Researchers working on aging issues should meet with those working on children's issues.
ORD Response: ORD views research on children and aging from a life-stage perspective. Most of the scientists working on children's issues are either actively involved with research being planned and implemented to address issues for the maturing populations or they interact directly with those more specifically involved with the aging end of the life-stage spectrum.

BOSC Issue: Source-to-effect research should progress to include pharmacodynamic issues.
ORD Response: Table 3 in the documentation indicates that biomarker research in LTG 2 is developing state-of-the-science mathematical and statistical modeling techniques to estimate target tissue dose and individual exposure, and apportion these results to sources. Once such models have been evaluated, they will be linked to studies that focus on pharmacodynamic issues. Research on developing linkages between PK and PD models also is covered in LTG 1 where PK/PD models for pyrethroid pesticides and arsenic are being developed. NCCT is providing leadership for the development of systems biological approaches to investigate the differences in tissue response.

BOSC Issue: Expand program expertise to include community-based participatory research.
ORD Response: Much of the research supported by the STAR Program includes community-based participatory research. Specifically, the Children's Environmental Health Research Center RFAs required community-based participatory research (CBPR) from the program's inception. The Children's Center investigators are considered experts in the use of CBPR in environmental health research; they have published on the subject and have organized scientific sessions at meetings on the subject of CBPR in environmental health research. Additionally, the newly developing intramural research program related to community risk will require CBPR. The initial steps of the intramural program include: (1) inventorying available tools, (2) establishing collaborations with groups conducting community-based research to gain expertise and to test these tools, and (3) revising the tools for addressing future needs.

Dr. Tilson identified the BOSC issues associated with LTG 4, Evaluation of Public Health Outcomes:

✍ LTG 4 needs to be better focused.

- Goals and a process for decision-making need to be established.
- Criteria for demonstration projects need to be explicit.
- Research needs to be reviewed externally on a periodic basis.
- Additional resources may be required.

He stated that Dr. Calderon will address the ORD response to these issues during her presentation.

Questions and Discussion

Dr. Clark thanked Dr. Tilson for his presentation and asked the Subcommittee members if they had any questions or comments.

Dr. Landolph suggested that ORD consider making LTG 4 a pilot; if it is considered a major theme of the HHRP, the program will have to obtain additional expertise. Dr. Tilson agreed that epidemiological expertise is needed; the program is positioning itself to identify valuable indicators of exposure and effects linkage. He added that the program has some current projects in its portfolio that are relevant and the HHRP has some strengths in this area that will not require additional resources. Dr. Landolph asked how many full-time equivalents (FTEs) are working on the program, and Dr. Tilson replied that there are 2 FTEs. Dr. Tilson stated that researchers working on LTG 3 will have a connection to those working on LTG 4. The planned approach is to focus on LTGs 1, 2, and 3, and identify where the efforts are relevant to bioindicators (LTG 4). This will allow the research to be conducted without assigning too many FTEs to LTG 4.

Review of Revisions to the Human Health MYP

Dr. Andrew Geller, Assistant Laboratory Director, National Health and Environmental Effects Research Laboratory (NHEERL), ORD, EPA

Dr. Andrew Geller, Assistant Laboratory Director of the National Health and Environmental Effects Research Laboratory (NHEERL), presented the revisions that were made to the Human Health MYP when it was updated in 2006. The revised MYP includes:

- A clear statement of the overarching theme of the HHRP.
- A clear process for obtaining and recording stakeholder and scientists' input to the MYP.
- Outcome-oriented LTGs.
- A concrete listing of regulatory decisions, tools, and methods that directly benefited from HHPR research.
- Explicit linkages made across LTGs within the MYP and between the HHRP and other MYPs.

The revised MYP is the product of a process that began with the 2003 plan. The BOSC review in 2005 and the subsequent PART review of the program provided some insightful comments on revising the MYP. The rewriting of the LTGs to make them more outcomes-oriented was largely in response to the PART review. In addition to the comments from the 2005 BOSC review and the OMB PART review, input for the revised MYP was obtained from: (1) ORD management, (2) stakeholder input (priorities and research needs of the regional and program offices), (3) ORD

researchers and writing teams, (4) RCTs, and (5) changes in the budget from FY2006 to FY2008 (e.g., there is no funding for the National Children's Study in the FY2007 budget).

Dr. Geller commented that input also was provided by the broader scientific and regulatory communities through meetings and conferences. He stated that the research needs of the program and regional offices are captured in Attachment B of the MYP. The revised MYP includes a table that cross-walks the research tracks in the MYP with the program offices' high priority needs. The team leads and writing teams for the research tracks are listed in Attachment E of the MYP. Details of the research to achieve the APMs or milestones of the program are provided in Attachment F. Dr. Geller explained that the prioritization process is not driven solely by top management. The scientists often meet with program office representatives and brief them on methods, models, and issues that would be of interest or new tools that could assist them in doing their jobs.

The revised MYP focused on addressing extrapolation issues in risk assessment. It deemphasizes aggregate risk, increases emphasis on biomarkers, and includes community risk as a new theme. The susceptible subpopulation LTG now focuses on life-stage, the National Children's Study is deemphasized, and an evolving theme to evaluate risk management decisions is included. The revised MYP also identifies cross-linkages to stakeholder needs and cross-linkages to other MYPs. Dr. Geller explained that the decreased emphasis on the National Children's Study is because of the lack of funding in FY2007.

Dr. Geller mentioned that the revised MYP contains a section entitled Progress to Date/Changes from Previous Version (page 14). It identifies the major program accomplishments by LTG and includes a list of the significant changes in the current version of the MYP.

Questions and Discussion

Dr. Clark thanked Dr. Geller for describing the changes in the Human Health MYP. He stated that the changes are responsive to the BOSC's program review and the cross-linkages are very helpful. Dr. Clark liked the additional detail that provides better insight into how ORD does its business at the 20,000-feet level. It is clear that the HHRP obtains input from the program offices and there are interactions with the regulatory community. Dr. Clark asked if input is sought from nongovernmental organizations (NGOs). Dr. Geller could think of a number of examples where the program sought input from NGOs; for instance, a series of public meetings were held around the country in areas where the percentage of older adults was higher to obtain input for developing the research focused on the aging subpopulation; input was obtained from a broad group of stakeholders with respect to the child health protection research, particularly those interested in autism; and there was a 3-day symposium in West Virginia focused on arsenic research.

Dr. Clark asked how ORD decided what research to pursue and what to deemphasize or eliminate. Is that negotiated between the NPDs and the program offices? Dr. Tilson responded that the NPD is responsible for developing a framework document to identify who is doing what research within ORD's matrix management system. The role of the NPD is strategic, and the role of the Laboratory/Center Directors is operational. Therefore, it is the responsibility of the NPDs to communicate the program office priorities and negotiate with the laboratories and centers regarding the research they can do to address these priorities. Dr. Geller added that, once the strategic direction is decided based on input from the Agency, the priorities can be determined. Dr. Buckley commented that the MYP reads like the research agenda is being defined by many others outside

ORD, but these comments indicate that the agenda is determined through a dialogue. It is critical that there is scientific input in determining the strategic direction of the program. He would prefer to see formal input from ORD scientists in defining the Agency's research agenda. Dr. Geller replied that obtaining input for strategic directions is one of the major responsibilities of the NPD in the research planning process. Dr. Buckley mentioned an article in *Environmental Health Perspectives* on how biomarkers play into the risk assessment process. The work was good and the article was prominently cited. Referring to the issue of arsenic, Dr. Landolph said that, although this issue was driven by regulation, it was the scientists at EPA who established a research agenda and pursued it because they thought this was an important topic.

Referring to the program design diagram and the cross-walk in the MYP, Dr. Clark commented that these are very helpful in identifying how the laboratories and centers will interact to achieve the identified outcomes. Dr. Geller was pleased that Dr. Clark found this information to be useful because it is the road map for the program. Dr. Tilson explained that the paradigmatic shift he described earlier is not defined clearly in the revised MYP because it was developed in December in response to a request from the ORD Executive Council. The Executive Council advised Dr. Tilson to present the concept to the BOSC Subcommittee during the mid-cycle review and seek an opinion on whether this is a reasonable direction for the program. If the Subcommittee finds that it is reasonable, a framework will be developed, a scientist-to-scientist meeting will be held, and a plan will be prepared.

Dr. Tilson noted that there is a multitude of audiences for the MYP within ORD and outside of ORD. The MYP has become a way of measuring progress, and this binds the program to some extent because it contains metrics for the program. He noted, however, that the MYP is a living document that will be updated annually and revised every 3 years. The plan developed in 2009 will be different from the 2006 plan.

Dr. Clark commented that the MYP is the "play book," which makes the review of the program easier. He acknowledged that it is difficult to keep such a document current and to define outcomes years before the results are expected. With respect to Dr. Clark's earlier question about input from NGOs, Dr. Geller stated that the program has been visiting the regional offices to obtain input on the program. He noted that the regions seek input from NGOs. Dr. Clark said that the challenge is for the program to generate data that meet the public's needs, which are translated through the regional representatives. The ORD scientists have to understand the problems and needs at the grass-roots level. He mentioned that much of the public's concern about an issue is not necessarily allayed when the scientists' response is that they have a technology to measure or address it. Dr. Geller replied that ORD's challenge is to obtain input from those responsible for strategic regulatory drivers as well as those engaged with the public health community.

Dr. Landolph asked if ORD has considered preparing a short white paper on its relevant efforts over the last 10 years when a scientific issue comes to closure. He mentioned that summation papers are becoming more important for communicating science more effectively. There are some superb review articles prepared by EPA scientists on arsenic, dioxins, etc. It would be beneficial to the program to communicate its successes in addressing these issues.

Dr. Clark mentioned that the BOSC Executive Committee received a briefing yesterday on communications and the work that is being done for communicating the HHRP. In response to Dr. Landolph's suggestion about summary papers, Dr. Tilson commented that ORD management used to

encourage the program to generate summary documents, the form of which was at the discretion of the program. Now, the program prepares a summary document on the research that supported an Annual Performance Goal (APG). How well this is being done is not clear; however, it is not designed to inform the public and consumers how the program's research has addressed the problem. The scientists currently are not preparing such a document but he will make it clear to ORD management that this needs to be done.

Dr. Buckley asked if ORD had considered including the performance metrics from the PART review in the MYP; for example, will bibliometric analysis be incorporated into the plan? Dr. Geller responded that performance metrics are mentioned in the MYP. Dr. Tilson pointed out that the presentation includes only a few of the metrics used to measure program performance. He added that although the metrics are not included in the 2006 MYP, they could be included in the next one.

Review of Development of Performance Measures: Connecting Progress with LTGs
Alva Daniels, Assistant Laboratory Director–Multimedia, National Risk Management Research Laboratory (NRMRL), ORD, EPA

Ms. Alva Daniels, Assistant Laboratory Director–Multimedia for the National Risk Management Research Laboratory (NRMRL), stated that the HHRP underwent a PART review by OMB in 2005. The program received a rating of "adequate." The OMB examiner indicated that the program has an unambiguous, focused design and there was no evidence of any major flaws. The examiner also found that the program has meaningful annual and long-term performance measures, and the results are being used to reduce uncertainty in risk assessment.

The program was asked by OMB to develop performance metrics to assess progress in achieving long-term outcomes and annual outputs. The performance metrics for long-term outcomes are external expert review (such as the BOSC reviews), and documentation of the use of products. Ms. Daniels explained that a workgroup was formed, which included representatives from the BOSC Executive Committee, OMB, and ORD, to develop a tool that could be used as part of the external expert review to evaluate performance in achieving LTGs. The workgroup developed a tool that uses consistently defined terms along with a narrative statement to assess program performance. The three performance metrics approved by OMB for annual output measures are bibliometric analysis (for overall program), efficiency measure (time to process grants), and a client survey to determine how the program's products are being used.

Ms. Daniels provided a status update for each of the performance measures. For long-term outcomes measures, external expert review is ongoing, as is the documentation of the use of products (i.e., use of data to support risk assessments). For annual output measures, an updated bibliometric analysis was completed in December 2006, data on the time to process grants are being collected for the efficiency measure, and the client survey is being developed. Ms. Daniels stated that the efficiency measure will focus on the time to process grants under the STAR Program (the time from RFA release to the time of award). She informed the Subcommittee that a list of clients has been developed to facilitate distribution of the survey, but ORD is still working on the survey questions to ensure that the instrument captures the data needed to determine whether the programs are meeting their goals.

Dr. Landolph asked if information on collaborations could be mined from the bibliometric database or would it be necessary to go back to the investigators to obtain that information. Dr. Tilson replied

that the publications are identified as intramural or extramural but the database currently is not designed to capture data on collaborations. Dr. Buckley suggested that such information may be useful for future reviews to demonstrate interactions with other agencies and organizations. Dr. Symanski noted that the bibliometric analysis did not provide separate data for intramural and extramural publications. Dr. Tilson replied that the analysis provided in the materials was just an interim analysis because the one conducted in 2005 did not include the complete list of publications. The bibliometric analysis performed for the 2007 program review could provide separate data for intramural and extramural publications. He commented that this may be complicated because a number of the papers include both EPA scientists and extramural investigators as authors. Dr. Tilson said that the program would make that separation if the Subcommittee thought it would be useful. Dr. Symanski responded that she would find that helpful. She then asked if future versions of the MYP will include APMs that relate to productivity (e.g., peer reviewed publications). Dr. Tilson answered that it would be easy to add a section to the next MYP on performance metrics.

Dr. Buckley commented that there were some concepts in the presentation that were not in the revised MYP. Will the next MYP be moving in the new direction? Ms. Daniels responded that the MYP is moving in that direction. Dr. Buckley thought the new direction was very appropriate, stating that although the current version of the MYP clearly shows links between LTGs and milestones, laboratories/centers, and projects, there was a piece missing. This new direction is that piece. Dr. Buckley also liked the idea of using peer reviewed publications to compare year-to-year productivity and quality of research. It is a gold standard that everyone in the science community understands. He noted that there is more to be done with bibliometric analysis. What are the program's benchmarks? How many publications should a federal agency with a budget the size of EPA's produce each year? In academia, there are benchmarks against which to compare a program (publications/year or publications/FTE or publications/resource allocation).

Dr. Landolph thought the Agency should emphasize its success with arsenic in drinking water. ORD scientists have written a number of review articles on this topic that describe what ORD has done to address this problem. He thought this might be a better approach than focusing on the number of papers prepared by program scientists. Dr. Tilson responded that the performance measures were negotiated with OMB, so regardless of the changes made to the MYP, these measures are the ones that will be used to assess the program's progress in its next PART review (to be conducted in 2008). Prior to the 2005 PART review, there were no baselines for most measures. Now, baselines and measures have been established and are part of the official record. These metrics will be used as long as OMB thinks they are appropriate. Dr. Tilson commented that the program can look for better ways to use these measures for the BOSC reviews so that ORD can provide the information needed to review the program. With respect to efficiency measures, there are three measures that have been accepted by OMB, but they are not the same for all programs. The grant processing time measure is unique to the HHRP. ORD currently is talking to OMB about some generic efficiency measures for all ORD programs, but those have not yet been negotiated.

Dr. Buckley praised the example in the materials that informed the Subcommittee that HHRP publications have been cited in 17 risk assessments. This gives strong evidence that the program's research is being used exactly as it was intended—to reduce uncertainty in risk assessments for better protection of human health. It is unclear how such information is represented in the MYP. Dr. Tilson responded that revising the format of the MYP may be an issue for discussion by ORD. For the Human Health MYP, it would not be difficult to add a section on performance metrics but ORD

would have to approve such a change. Dr. Clark asked if there is another venue for such information.

Dr. Tilson asked if the Subcommittee members think the metrics negotiated with OMB for the program are appropriate. Are there other metrics that ORD could provide to the BOSC or OMB for the program and PART reviews? Most agreed that there were additional metrics that would be helpful. Dr. Landolph thought it would be useful for the BOSC Subcommittee to receive a bulleted list of the program's successes. Dr. Tilson replied that, for this review, he tried to list the program's accomplishments by LTG. He noted that the PART reviews are basically quantitative assessments. If the program claimed that its research solved the problem of arsenic risk assessment, this would be considered in only one item of the PART review. OMB is interested in the universe of the HHRP work and the metrics used to measure progress in this universe of work are different than a bulleted list of successes.

Dr. Symanski suggested including a section in the client survey that asks about the use of HHRP research in risk assessments. Dr. Buckley asked about the status of the client survey and Dr. Tilson responded that it is in the early development stage. He added that there have been some surveys developed for some of the more problem-driven research programs. There is some concern about the usefulness of the survey results. More thought must be given to identifying the audience and the appropriate questions to include. There also are issues about who within the program offices should receive the survey. Dr. Tilson commented that, for a multimedia program, it is difficult to generate a single survey instrument that will address all potential stakeholders. Ms. Daniels noted that if the questions are too different depending on the audience, this calls into question the objectivity of the survey. Dr. Tilson stated that the Office of Resources Management Administration (ORMA) is helping to develop the survey. Perhaps Dr. Dale Pahl from ORMA could provide more information about the timeline for developing the survey. Dr. Pahl indicated that during the past year, ORMA has been looking at the application of surveys, particularly client surveys. An ORMA staff member with evaluation expertise has been working with the NPDs to obtain feedback from client offices regarding the use of research in decision-making. ORD is trying to obtain information on documented use of the research and more thought is being given to how the information from the survey will be used in the reviews. A second design effort is planned in 2007. Dr. Buckley asked if the survey will actually be conducted or will ORD decide it is not appropriate. Dr. Pahl responded that, based on discussions with OMB, the BOSC, and other groups, ORD plans to move ahead with the development of a client survey instrument.

Dr. Clark thanked Ms. Daniels for her presentation and stated that Dr. Calderon would be making her presentation on LTG 4 immediately following the lunch break. He asked Dr. Symanski to facilitate that session because she was assigned to take the lead for LTG 4.

Review of Accountability and LTG 4: Evaluating Public Health Outcomes
Dr. Rebecca Calderon, Director Human Studies Division, NHEERL, ORD, EPA

Dr. Calderon, Director of the Human Studies Division of NHEERL, stated that, in response to BOSC recommendations, a Steering Committee consisting of representatives from all ORD laboratories/centers as well as the Office of Environmental Information was formed for the purpose of developing a framework document that provides a definition, overall objective, and research needs for a research program to evaluate the effectiveness of risk management decisions. In October 2006, the Steering Committee charged a working group with developing an outline for the document

by February 1, 2007. Dr. Calderon chairs the working group that developed the outline for *A Framework for an Environmental Accountability Research Program.* The outline and several of the key diagrams for the draft framework document were provided in the meeting materials.

It is anticipated that a completed framework document will be ready for review by program and regional offices as well as external peer review by spring 2007. The framework document then would serve as the basis for working with external and internal scientists to develop an implementation plan. At the October 2006 Steering Committee meeting, it was noted that the ROE is being used with greater frequency to develop strategic planning within the Agency and for budgeting and prioritization of research within ORD. Many of the research needs articulated in the ROE are themes contained in the HHRP. It is likely that the framework document and the ROE will have a significant influence on planning human health research in the future. The ROE currently includes a separate health chapter, but it is expected that health outcomes will eventually be reported in the air, land, and water chapters.

Dr. Calderon said that the proof of concept pilot program was launched in 2005. Two studies of the pilot are underway and they are progressing well. Both of these projects reside in her group, they are multidisciplinary, and involve a number of ORD laboratories/centers as well as the regions.

Dr. Calderon identified the following challenges to the program:

- Defining the program, including cost, benefit assessment, ROE indicator, intramural expertise, and extramural expertise.
- Developing prioritization criteria.
- Identifying national indicators when the effects are seen locally.
- Determining new health/exposure metrics.

The next steps outlined by Dr. Calderon included: (1) review of the framework document by a broader group; (2) external peer review of the framework document; (3) conduct of a workshop of internal and external scientists, and possibly other federal partners, to provide input for the implementation phase; (4) development of an implementation plan; and (5) possible future initiative.

Dr. Calderon closed her presentation by asking the Subcommittee members for any recommendations regarding the proposed next steps.

Dr. Symanski thanked Dr. Calderon for her presentation and asked if there were any questions.

Questions and Discussion

Dr. Symanski said she had two questions—one related to the tracking of health trends in the United States and the other to evaluation. With respect to the first research track, there were 10 key questions listed (page 60 of the MYP). How were these questions identified? Are these questions related to activities under LTGs 1, 2, or 3? Some of them were not linked to APMs so what are the expected outputs? Dr. Calderon responded that the list of questions comes from historical documents; they were originally conceived in 1999. Dr. Symanski commented that it would be

helpful for the MYP to articulate how these questions relate to LTGs 1, 2, or 3. Not all of the APMs for LTG 4 link back to likely outputs. Dr. Calderon replied that this is probably a result of the infancy of the program. The APMs relate to ongoing work. For further clarification, Dr. Symanski asked if the 10 historic questions relate to what the program should be rather than what it currently is. Dr. Calderon confirmed that statement. Dr. Symanski then asked about the two demonstration projects and the RFA. Dr. Calderon commented that the two demonstration projects are intramural but the goal is to have a balance between intramural and extramural research. The challenge is in constructing the RFAs for the extramural research because the grants cannot result in direct benefit to the Agency.

Dr. Clark stated that the 2005 program review recommended that more be done with regard to LTG 4. He thought more would have been accomplished in the 2 years since that review, rather than just describing what is planned for the future. He did not think this plan reflected a sense of urgency and he expected the program to have made more progress in this area. Dr. Calderon agreed that until last year when the ROE became a driver, there was no sense of urgency for this research. Until last year, only ORD thought this program was worth pursuing. Now, there are plans to move forward aggressively. Dr. Clark asked about who is setting the pace. Dr. Calderon responded that the demonstration projects opened a dialogue with program scientists, and OW and the Office of Air and Radiation (OAR) have established committees focused on outcome measures and the program is in discussions with these committees. The regions also have developed some sense of urgency and the dialogue with them has accelerated since the pilots were initiated.

Dr. Clark endorsed the idea of linking this research theme to the ROE. Dr. Tilson commented that up until now, the program offices have had no interest in this program. Because EPA's strategic plan will include performance metrics for the Agency, there is a greater sense of urgency. He also noted that it had been very difficult to identify the research questions to be addressed by ORD until the questions were raised in the ROE. ORD can look at the issues in the ROE and decide how to build a program that is consistent with the resources available.

Dr. Symanski noted that the ORD response to the 2005 BOSC program review indicated that there were four to six projects funded. Why are there only two pilots? Will additional ones be funded in the future? Dr. Calderon replied that the program initially planned to fund four to six projects over a 2-year period; however, with the budget cuts, the resources were reduced and only two projects could be funded. Dr. Clark noted that EPA is not the only agency on which the public relies for protection of human health. It is clear that EPA will have to leverage with other agencies, such as the Centers for Disease Control and Prevention (CDC) to overcome its budget limitations. Dr. Calderon stated that EPA is heavily engaged in working with CDC on the environmental health tracking program. The Agency is advising and working closely with CDC in a successful interagency partnership.

Dr. Buckley said that in the 2005 program review, LTG 4 was a research initiative program; now it seems to have morphed into a means of evaluating the HHRP. Dr. Tilson responded that this LTG will help the program establish methods to determine how research is used in regulatory decisions. It has a parallel to the other three LTGs in determining who is using the information to do their jobs.

Dr. Symanski asked the second of her initial two questions regarding evaluating the use of program outputs. Do you need a before and after analysis of exposure to assess the impact on public health? Dr. Calderon responded that the key to this question lies in the other parts of the MYP—identifying

the right indicators and understanding the dynamics of exposure. If enough is known about the link between exposure and effect, before and after studies probably are not needed. It may be necessary, however, to collect data to look at time trends. The idea is to identify what to use to measure effect and she was not sure that "one size fits all" for regulations.

Dr. Buckley stated that ORD is exercising powerful leadership in a way that is redefining the way the Agency does business. Dr. Tilson commented that the program will have to be creative, innovative, and opportunistic to identify projects where there is a chance of determining where a decision has had a specific consequence or effect. There are a few examples he could recall, one of which was where a smelter ceased operations and there were before and after data that allowed the Agency to determine what was changing. He noted that the program has not engaged the regions in this problem yet, but Dr. Tilson thinks the regions could help with the development of this program.

Dr. Symanski stated that once the program obtains information from the regional offices, it seems there would need to be a rationale in place to determine which risk management decisions to evaluate. Are there any criteria in place? Dr. Calderon responded that the criteria include cost, the benefits anticipated as a result of the regulation, the ROE, and the expertise available.

Dr. Symanski noted that the materials for the review did not include an assessment of the human or financial resources needed for the program. Will that information be in the framework document? Dr. Calderon answered that the usual approach is to identify different scenarios; for example, for $0.02 you get "x," for $2 you get "y," and for $200 you get "z." The question then becomes what you want it to look like and how much do you want to pay. Dr. Symanski asked what will be viewed as effective in measurable terms in a reasonable time period. Dr. Calderon replied that this will be determined by what is being evaluated. They will not be looking for longer term effects such as cancer, but perhaps they would look at a precursor to cancer. Exposure and health sit together equally at the table; the program is comfortable not making a distinction between the two. She noted that there must be a specific health outcome of some kind.

Dr. Symanski mentioned the new RFA to be issued by NCER concerning the development of environmental health indicators. This is a new RFA, which opens in June 2007, on research for outcomes and accountability; it seems that this research will support LTG 4. How is this new RFA (Research for Outcomes and Accountability: Development of Novel Environmental Health Outcome Indicators) different from the first one (Development of Environmental Health Outcome Indicators)? Dr. Calderon replied that the first RFA was based on the use of existing databases. She asked Kacee Deener from NCER if she had any additional information on the RFA. Ms. Deener stated that the second RFA is on the same topic and concerns developing outcome-related indictors. She did not have any additional details on the RFA at this time.

Dr. Symanski asked about collaborative activities, citing the example in the materials of the Memorandum of Understanding with CDC that led to the PHASE project. Are there any other collaborations established that would support this LTG? Dr. Calderon responded that there are no additional collaborations yet; once the program takes shape, ORD will approach CDC and other potential partners.

Dr. Symanski asked if the client survey will be used to support LTG 4—identifying the use of research in risk assessments. Dr. Tilson said the survey will be used to find out how the program's products are being used regardless of the LTG. The program needs input on all uses of its products

and their effectiveness. He added that more is known about use in risk assessments; mitigation aspects are more diffuse and many of them are at the regional level. The program needs data on what portion of mitigation projects was based on research done by ORD. This is a question that will be asked by OMB, so the program will need to address it.

Dr. Clark thanked Dr. Tilson for his insights on where the program is going. Given this information and the materials provided to the Subcommittee, he asked the members to think about what recommendations can be made for the program. He suggested that the Subcommittee give some thought to how the report should be framed.

Dr. Tilson stated that the purpose of the mid-cycle review is to assess the progress that has been made with respect to the recommendations from the 2005 program review, to learn of changes that have taken place since the review, and to provide input on future directions and emerging issues. The framework document was provided to give the Subcommittee an idea of where the HHRP wants to go with LTG 4. This is a paradigm shift. In the Subcommittee's estimation, knowing the HHRP's research and resources, is this a viable direction for the program? There currently is no program to address LTG 4 for the Subcommittee to evaluate, but ORD would like feedback on whether this is the right direction for the program.

Discussion of Program Rating
Dr. Jim Clark, Exxon-Mobil Corporation, Subcommittee Chair

Dr. Clark announced that it was now time for the Subcommittee to begin discussing the responses to the charge questions and preparing a draft report. He stated that the discussion will be among the Subcommittee members, but if additional information or clarification is needed, Dr. Clark will ask Dr. Tilson or another EPA staff member to address the request.

Dr. Buckley thought the charge appeared to be a moving target. If the target was the revised MYP then his response would be different than it would be based on the information presented today. It would be helpful if Dr. Clark could clarify the target. Dr. Clark said the review should focus entirely on the information received from ORD, the changes implemented since the 2005 program review, and the plans for the program (particularly LTG 4). The Subcommittee members should consider all of the information from the conference call, meeting materials, and the presentations today. It will be more useful to ORD if the members provide advice on the planned directions of the program. He asked the Subcommittee members to consider the revised MYP to be a template but recognize that it is only one of the informational inputs for the review.

The last charge question is for the members to consider with respect to the progress that the HHRP has made since the 2005 program review. There are four rating terms that will be used in responding to this question—exceptional, exceeds expectations, satisfactory, and unsatisfactory. These terms are from the new rating tool that was developed by the BOSC/ORD/OMB workgroup. The tool makes specific reference to goals. The goals have been rewritten in the revised MYP to be more outcomes-oriented. Are the changes identified in the ORD response to the program review being implemented by the program? Are the planned directions appropriate? Dr. Clark emphasized the need to come to consensus on the rating term used to characterize the program.

Dr. Buckley said he thought the LTGs were solid and on target. The difficulty with the LTGs in the 2005 program review concerned how the goals were conceptualized and justified in the broader

perspective. There certainly has been progress on addressing this problem. He thought the program should have made more progress on LTG 4. There was a lot of information on the program's plans for LTG 4, but he thought that there would be some accomplishments 2 years following the program review. He noted that some of the activities could have been achieved rather easily, so he was somewhat disappointed in the response. Dr. Buckley noted that it also would have been helpful to directly link the changes in the MYP with the comments/recommendations of the program review. Dr. Symanski thought that, in some respects, those changes were reflected in the MYP. The program identified the changes that they thought should be made and those changes were incorporated into the revised MYP. She had some difficulty following the chronology; she did not initially understand that the revised MYP was prepared about 6 months before the mid-cycle review document. The program could have done a better job in communicating what changes had been made and why they were made.

Dr. Landolph thought the program did a good job of trying to address all of the comments and recommendations in the 2005 program review. There were a few areas that could be improved, such as the leadership transition plan. He would like to see ORD adopt some type of policy that assigns senior leaders the responsibility of training junior staff to become leaders. There also should be a somewhat formal mechanism for recruiting experts from outside EPA. He also thought there should be more emphasis on the nanoparticle issue. EPA should be determining if these particles pose a serious health problem. Are studies needed to address key issues? He mentioned that more thinking is needed on the pesticides issue. He acknowledged that the HHRP probably did not have the resources to address all of these issues, but the program could partner with CDC or the National Institutes of Health (NIH) to determine if such research is worth pursuit. Dr. Landolph thanked the HHRP staff for the materials—it is clear that a great deal of effort went into the response.

Dr. Clark commented that the revised MYP and various supporting documents were very helpful in reviewing the changes since the program review. He was favorably impressed with the revised MYP; his only negative comment was that he expected that the program would have achieved more under LTG 4 since the program review. He also mentioned that implementation and prioritization were not clear to him.

Dr. Symanski stated that the MYP was revised in response to the 2005 program review; however, charge question 4 suggests that LTG 4 may be a unifying unit to link LTGs 1, 2, and 3. This reflects a paradigm shift that is not clearly articulated in the revised MYP.

Public Comment

Ms. Virginia Houk, Designated Federal Officer, EPA, ORD

At 2:10 p.m. the discussion was paused so that Ms. Houk could call for public comments. She asked that anyone wishing to make a comment please identify themselves prior to commenting. No comments were offered so the discussion resumed.

Discussion of Program Rating (Continued)

Dr. Jim Clark, Exxon-Mobil Corporation, Subcommittee Chair

Dr. Clark asked if any of the Subcommittee members thought the progress made since the 2005 program review was unsatisfactory. None of the members supported an unsatisfactory rating. Dr. Clark said he could not justify an exceptional rating, particularly because of the lack of

progress on LTG 4. Dr. Landolph thought LTG 4 should be considered a pilot. He thought this would make the review more balanced. Dr. Clark asked if the program is asking the right questions with regard to emerging issues. Perfluorooctanoic acid (PFOA), pesticides, and nanoparticles are some of the areas that may need more attention; he pointed out, however, that the program seeks input from the program and regional offices concerning their priorities and these issues may not be important to them. Dr. Landolph commented that Dr. Tilson will have to downsize certain areas in order to shift priorities as new issues arise. Dr. Buckley said he was not overly concerned about the exclusion of a particular issue, such as nanoparticles, as long as the program has a framework in which such issues can fit. Issues that do not make the cut in terms of priorities would not be addressed.

Dr. Clark asked the members to focus on the points they want to make in the report. Drafts of responses to the charge questions will be distributed through Ms. Houk and a public conference call will be held in the future to approve the report.

Dr. Clark asked the members if the program is meeting its goals. Dr. Buckley responded that this question was not part of the charge. Dr. Clark answered that the last charge question involves rating the program's progress. Is the program on the right track to achieve the goals? Is the program working fast enough to meet the goals? The Subcommittee needs to provide feedback to ORD on these questions. Dr. Buckley suggested that the members rate each charge question.

Dr. Clark then asked the members to rate the HHRP's responsiveness to the program review recommendations. Dr. Landolph assigned an exceeds expectations rating; the program tried to address each comment and recommendation and he was pleasantly surprised with the response. Dr. Buckley stated that if the revised MYP is ORD's response to the program review, he had some difficulty with the transparency of the response with respect to how the comments were incorporated into the plan. He agreed with Dr. Landolph, however, that the program tried to respond to all the comments and recommendations to the extent possible. Dr. Symanski said she was not sure how to interpret responsive. If there is a plan for action, should that be viewed as responsive? Dr. Buckley commented that he thought a plan would be an appropriate response if the program is somewhat difficult to implement; if it is relatively easy to implement, he would expect more than a plan.

With regard to charge question 2 concerning the clarity of the rationale for the revised MYP and its consistency with the BOSC's advice, Dr. Buckley did not think the program exceeded his expectations. Dr. Clark said that many of the revisions to the MYP were consistent with the recommendations in the program review; however, the response did not exceed his expectations. He assigned a rating of satisfactory with regard to this charge question. Dr. Symanski commented that the program was asked to put the rationale in context of the risk assessment framework. In that respect the program's rationale is clear; however, she did not see how this rationale incorporated LTG 4 as an equal partner with LTGs 1, 2, and 3. Dr. Landolph said that he could agree with a rating of satisfactory.

With regard to charge question 3, Dr. Buckley initially had some difficulty with it because of the way the revised MYP was written. The program has made significant progress toward establishing accountability but it is not clear how the quality and impact of the research will be evaluated. Today's presentation, however, satisfied his concerns. Peer reviewed publications,

the client survey, and other metrics will provide data for effectively evaluating the quality and impact of the program. Although he was not completely satisfied with the revised MYP, Dr. Buckley was extremely pleased with the updated plan for LTG 4 that was presented at today's meeting. He assigned it a rating of exceeds expectations. Dr. Landolph agreed, stating that the program's papers are published in good journals. He had some concern, however, about too much focus on numbers. The metrics are good but it is more important to address the scientific questions. Dr. Symanski was pleased with the plans for a client survey and the care that is being taken in its development. She agreed that for this question, the program exceeds expectations.

Dr. Buckley asked Dr. Symanski if she understood why he asked Dr. Tilson about the two purposes of LTG 4. Two years ago it was not used to evaluate the research program. Dr. Symanski responded that this was the intension 2 years ago but it was not explicit that it would be used to evaluate the Agency's actions. It is much clearer now. Dr. Buckley asked if she thought this was clearly stated in the MYP. Dr. Symanski responded that this is the major reason she asked about the 10 questions. It is not clear that the program will have sufficient resources to address LTG 4. Dr. Buckley said that it would be very powerful if the Agency could build health outcomes into the evaluation process and the program should get a lot of credit for that. Dr. Symanski said that she could not get a handle on what the intramural program would look like for LTG 4. Are there additional research questions that would allow the Agency to make better linkages between the impact of management decisions on exposure and health?

Dr. Clark moved to charge question 4, regarding the emerging research area to evaluate risk management decisions. Is the program on the right track? Is the program moving forward at the right pace? Have appropriate partners been identified? Dr. Symanski said that her difficulty in answering this charge question is related to the resources that are committed to LTG 4. With only 2 FTEs, they have been making considerable progress toward the goal, but without considering the limited number of FTEs, it would appear that more progress should have been made. Dr. Clark commented that the Subcommittee could recommend that the pace be accelerated because of the potential of this goal. Dr. Buckley said that he would support such a recommendation.

Dr. Clark asked for the members' ratings for charge question 4. Dr. Buckley said he wanted to send a very positive signal to EPA regarding the Subcommittee's enthusiasm for this LTG. The progress made, given the resources, is good and more progress could be made with additional resources. Dr. Landolph referred to Dr. Tilson's comment regarding the use of staff members supporting other LTGs to contribute to LTG 4. It is difficult to make this work. Dr. Symanski stated that one of two overall objectives was to track health trends in the United States. Dr. Calderon commented that this will change as the ROE becomes a major driver. It is more than just tracking health information—it involves developing biomarkers and tracking the status of trends. Dr. Symanski commented that even after biomarkers are developed, the data probably will come from the National Health and Nutrition Examination Survey (NHANES). Dr. Calderon responded that there are several initiatives at the local level to implement an NHANES-type data collection effort, giving the program some additional options. Dr. Tilson added that there are knowledge gaps identified in the ROE, such as identifying and applying bioindicators on a national scale when the impacts are observed on a local scale. The program could invest resources to try to understand the relationship between exposure and health outcomes. Dr. Landolph asked the following question: If the program decides it is appropriate to look at pesticides and neurodegenerative diseases, would the research fall under LTG 4? Dr. Tilson said

it is not clear how this would be done. Moving FTEs into LTG 4 would not be the most efficient way to address that issue. The coordination and oversight for the research might fall under LTG 4 but the orientation and products of the other goals would be modified to address the issue. This requires a paradigm shift in how the program is constructed.

To wrap up this discussion, Dr. Clark went through the charge questions and asked the members to reach consensus on a rating. The following ratings were agreed upon by the Subcommittee members:

Charge Question 1 — Exceeds Expectations
Charge Question 2 — Satisfactory
Charge Question 3 — Exceeds Expectations

Dr. Clark asked the members to revise their responses to each of the charge questions based on the information presented today and these discussions. Those revised responses should be submitted to Ms. Houk, who then will distribute them to the Subcommittee members. Dr. Clark reminded the Subcommittee members who had been assigned to lead the response for each charge question:

Charge Question 1 — Dr. Landolph
Charge Question 2 — Dr. Clark
Charge Question 3 — Dr. Buckley
Charge Question 4 — Dr. Symanski
Charge Question 5 — Dr. Clark

Once the revised responses have been distributed by Ms. Houk, a conference call will be scheduled to discuss and approve the report. He thanked the Subcommittee members for their willingness to participate in the mid-cycle review, noting that their experience with the 2005 program review was invaluable to this process. Dr. Clark also thanked Dr. Tilson and members of his team for preparing the materials and responding to the Subcommittee's questions. He asked if Dr. Tilson had any closing comments.

On behalf of his team, Dr. Tilson thanked the Subcommittee members for conducting the review, noting that the comments from the 2005 program review were very helpful. He said he was looking forward to receiving the report.

Dr. Clark then thanked Ms. Houk for her efforts to support the Subcommittee and adjourned the meeting at 2:55 p.m.

Action Items

- ✍ Each Subcommittee member should revise their responses to each of the charge questions based on the information presented at the meeting today and the discussions. Those revised responses should be submitted to Ms. Houk.

- ✍ Ms. Houk will distribute the revised responses to the charge questions to the Subcommittee members.

✍ Once the revised responses have been distributed, Ms. Houk will schedule a conference call to discuss and approve the report.

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APPENDIX A: Meeting Agenda

HUMAN HEALTH (HH) MID-CYCLE FACE-TO-FACE MEETING AGENDA

January 24, 2007

Crowne Plaza Washington National Airport
1480 Crystal Drive
Arlington, VA 22202
Phone.: 703-416-1600

Wednesday, January 24, 2007

9:30 – 10:00 a.m.	Registration	
10:00-10:10 a.m.	Welcome and Outline of Purpose	Dr. Jim Clark Chair, HH Mid-Cycle Subcommittee
10:10-10:15 a.m.	DFO Welcome and Charge - Administrative Procedures/FACA Rules - Objective of Subcommittee/Charge	Virginia Houk (EPA) DFO, HH Mid-Cycle Subcommittee
10:15-10:55 a.m.	Review of Action Items: Response to Recommendations of 2005 Review - Discussion and Q&A	Dr. Hugh Tilson (EPA) HH Mid-Cycle Subcommittee
10:55-11:35 a.m.	Review of Revisions to the Human Health Multi-Year Plan (MYP) - Discussion and Q&A	Dr. Andrew Geller (EPA) HH Mid-Cycle Subcommittee
11:35-12:15 p.m.	Review of Development of Performance Measures: Connecting Progress with LTGs - Discussion and Q&A	Alva Daniels (EPA) HH Mid-Cycle Subcommittee
12:15-1:00 p.m.	Lunch	
1:00-1:40 p.m.	Review of Accountability and LTG 4: Evaluating Public Health Outcomes - Discussion and Q&A	Dr. Rebecca Calderon (EPA) HH Mid-Cycle Subcommittee
1:40-2:10 p.m.	Discussion of Program Rating	HH Mid-Cycle Subcommittee
2:10-2:25 p.m.	Public Comments	Virginia Houk (EPA), DFO
2:25-3:00 p.m.	Wrap-up and Report Out	HH Mid-Cycle Subcommittee
3:00 p.m.	Adjourn	