Preliminary Comments from Members of the Chartered Science Advisory Board (SAB), SAB Liaisons, and Board of Scientific Counselors (BOSC) on Materials provided by the EPA Office of Research and Development for the July 10-11, 2012 SAB/BOSC Meeting

List of comments received

Comments from Dr. George Alexeeff..... 2
Comments from Dr. Joseph Arvai 7
Comments from Dr. Ingrid Burke 10
Comments from Dr. Ed Carney 13
Comments from Dr. Costel Denson..... 15
Comments from Dr. David Dzombak 16
Comments from Dr. Taylor Eighmy 21
Comments from Dr. Henry Falk 23
Comments from Dr. Barbara Harper..... 24
Comments from Dr. Nancy Kim..... 27
Comments from Dr. Cecil Lue-Hing..... 31
Comments from Dr. Judith Meyer..... 34
Comments from Dr. Amanda Rodewald 39
Comments from Dr. Jonathan Samet 43
Comments from Dr. Daniel Schlenk 45
Comments from Dr. Pamela Shubat 47
Comments from Dr. Gina Solomon..... 52
Comments from Dr. Daniel Stram 55
Comments from Dr. John Tharakan 58
Comments from Dr. Russell Thomas..... 64
Comments from Dr. Paige Tolbert..... 67
Comments from Dr. John Vena..... 70

Comments from Dr. George Alexeeff

Draft quality review comments on the strategic research plans 2012.

I. DRAFT SAB/BOSC CHARGE QUESTIONS FOR EACH BREAKOUT GROUP
1. FIRST YEAR PROGRESS
The Strategic Research Action Plans were developed during 2011, with the benefit of SAB and BOSC advice [*Office of Research and Development (ORD) New Strategic Research Directions: A Joint Report of the Science Advisory Board (SAB) and ORD Board of Scientific Councilors (BOSC)*. (EPA-SAB-12-001)].
Charge Question: How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

The Strategic plan provides a useful introduction to each of the strategic research areas. For example the Air, Climate and Energy Strategic Research Plan comprehensively describes the relationship and interplay between air pollution, climate change and energy policies. The Strategic plan for Chemical Safety for Sustainability comprehensively discusses the issues of chemical safety and sustainability. In one sense the descriptions of the research areas indicate that the Plans are focused in the right directions.

It is difficult to assess the question of whether the ORD research programs are sufficiently progressing in FY12 for several reasons. First, we are still in FY12 and it is not clear whether the work product committed to will be completed. Second, there isn't a clear update of what has been accomplished thus far in FY12.

The plans are organized by theme. For each theme there are science questions to be addressed within the theme. Then a key outcome is identified for each theme. Outputs to reach that outcome are then listed as specific results from current projects. The CSS Overview in Figure 1 is a helpful organizing visual. The example provided for nanoparticles is helpful in that it explains the specific topic regarding nanoparticles and the nanoparticle related topic outputs that will inform that science question. It would be helpful to have a header in the task tables that provides an indication on how the groups of outputs are organized in a manner that informs the science question.

CSS. Under Theme 2 Systems models, the example outputs are again helpful and first 5 match up easily with the table. But I was unable to find corresponding outputs for 6-9 on page 26. I would be helpful if all the outputs were organized under specific subheadings that provided an indication of how they were answering the science question.

In general, for the strategic plans, the examples are helpful when they guide the reader to understand how the outputs inform the science questions. The outputs described for research activities seem to be appropriate within the science question. If the outputs could be organized into topic subheadings that inform the science questions that would help to inform their value.

Looking at the output tables, several outputs are slated for FY 12 for each of the themes in each of the plans, but it is not clear how those outputs are progressing. The examples in the text help the reader to see how the outputs identified move the science closer to a more comprehensive/holistic

understanding of the answer to the question. However, it is not clear how the outputs were identified as the way to answer the science question. That is, each theme has a list of questions to be answered. However, the flow from the general science questions to the more specific ones, and then to the outputs could use a little more bridging information. When one considers the timelines for each output, it isn't clear if answering some questions one year will assist in answering questions in subsequent years. For example, the outputs are slated to be completed at various years but they are not in chronological order.

2. SUSTAINABILITY

The SAB and BOSC concluded in the October 21, 2011 report that "…ORD's research frameworks can advance EPA's adoption of sustainability as a core principle by more consistently and clearly describing where and how ORD research relates to sustainability."

Charge Question: How are ORD programs contributing to sustainability through their research plans and activities? What advice do the SAB and BOSC have for each research program about advancing sustainability in future research?

The strategic plan "science for a sustainable future" does a good job in integrating sustainability across research plans. This document was a big step in understanding the issue of sustainability across research areas. The discussion how major pollution issues have been addressed over the years and the progression to a systems approach is a good one. However, it is good that the plans continue to mention that focusing on the individual issues is important as well. Air pollution continues to be a major health issue and climate change has emerged as a major one as well. The sustainable future plan is a very good summary of the sustainable elements of the other strategic plans.

3. BALANCING IMMEDIATE PROGRAM NEEDS AND EMERGING ISSUES

Meeting program and regional needs is a primary objective of ORD research. The highest priority needs of the programs tend to be those that are most immediate. Another important role for ORD is to anticipate the future scientific needs of the programs and regions, areas of research that tend to get less support from the EPA partners. Anticipating emerging issues and investing in innovative approaches that could lead to more sustainable, less expensive or timely solutions often requires longer term and potentially higher risk research. The Strategic Research Action Plans strike a balance in addressing current priorities and future science needs; however, new emerging issues will likely arise that are not currently anticipated.

Charge Question: As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

The strategic plan clearly demonstrates knowledge of emerging issues. Many of these, such as movement toward nanomaterials and nitrification are discussed in the plan. Annual review of the plan with a specific question to reviewers regarding emerging issues could be used to help identify new emerging issues and determine the need to focus research in the area.

4. PROGRAM SPECIFIC QUESTIONS

Chemical Safety for Sustainability Charge Questions:
• Is the CSS program well positioned to support EPA needs in the three key areas of endocrine disrupting chemicals, nanotechnology, and computational toxicology research?

The CSS program is well positioned to support EPA needs in the three key areas of endocrine disrupting chemicals, nanotechnology, and computational toxicology research.
Nanotechnology is focused on in the theme of inherency.
Endocrine disrupting chemicals are focused on in the themes of systems models, biomarkers, extrapolation, and dashboards.
Computational toxicology is focused on in the themes of biomarkers, cumulative risk, extrapolation, dashboards, and evaluation.

II. DRAFT CHARGE QUESTIONS FOR GENERAL ORD/PLENARY SESSION

1. INTEGRATION ACROSS PROGRAMS

By their very nature, environmental issues are cross-disciplinary. Pollutants move and change across air, land, water and species. Energy, health, environmental justice and ecology are cross cutting topics. To organize research that is so intertwined requires a structure. By realigning its program from 16 distinct research topics to six related programs, ORD has made it a priority to eliminate stove-piped research and foster integrated, transdisciplinary research.

In the first year of implementation, the National Program Directors are in the early stages of managing each research program, while also taking steps to integrate across the six programs. This requires a balance of formally organizing and integrating research that relates to multiple programs, without creating additional, separate research programs.

While there are numerous topics that involve integration, ORD has selected five examples to present as case studies for the SAB and BOSC to consider. These five integrated topics reflect a range of dimensions including:

- topics that ORD has just begun to integrate and others that are further developed
- topics germane to every research program and others more narrowly focused among two or three
- topics that are more immediately client-driven and others that are longer-term

Integrated Topics:

- Nitrogen
- Global Climate Change
- Children's Health/Environmental Justice
- Applying new chemical assessment approaches in human health risk assessment
- Endocrine-mediated Dose-Response

Charge Question: Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

Regarding new chemical assessment approaches in human health risk assessment. Integration with the Sustainable and Health Communities should be considered. In general, incorporation of more social sciences information is needed in this area. Consideration of the social sciences will spark new lines of research and innovation. Currently our understanding of community vulnerabilities is in their infancy. By exploring more of the community health issues that have been associated with pollution, we will be able to expand much of our scientific inquiry. For example, how does current disease status or life-stage affect susceptibility to pollution?

2. INNOVATION

The Path Forward principles that guide ORD's realigned research program emphasize pursuing innovative, ground-breaking research. To address increasingly complex and expensive environmental problems, innovative solutions are needed.

Charge Question: How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

It would be useful to establish general environmental and community indicators of health with a clear baseline. Collaboration with other federal health agencies would be helpful in considering the full picture of human and environmental health.

Comments from Dr. Joseph Arvai

General Comments

I enjoyed reading the Strategic Research Action Plan for Sustainable and Healthy Communities and found the issues discussed to be both ambitious and important. Moreover, I am sensitive to how difficult it is to write a strategic plan that is as sweeping as this one and under, what seems to me, like extraordinary time pressure. For this reason, I commend ORD and EPA for their efforts thus far.

In the spirit of constructive criticism, however, I might offer the following: With respect to the Strategic Research Action Plan, I was left feeling a bit as though there was a mismatch between what were referred to as "Broad Science Questions" and Outputs (and the overarching objectives of the Strategic Action Plan). Not all of the outputs seemed to be tightly linked to the science questions, which led me to wonder: Were some outputs included because these projects were underway and "needed a home", so-to-speak, within the series of Strategic Action Plans prepared by EPA?

Put another way, it's not clear to me how some of the questions and outputs discussed are linked to the needs outlined in EPA-SAB-12-001 (New Strategic Research Directions).

CQ1.1 First Year Progress

I am in only my first year as a SAB Chartered Board member so I don't have the benefit of a complete understanding of the decisions that led to consolidation within ORD. Moreover, it's rather difficult for me to tell – and I acknowledge that I may be missing something – how much progress has been made, and how what *has / is being* done fits with the programmatic objectives outlined in the Strategic Research Action Plan.

CQ1.2 Sustainability

My read of the materials I reviewed is that this program is all about helping to inform tradeoffs, namely between environmental protection and social / economic development.

As I read through the Strategic Research Action Plan for Sustainable and Healthy Communities, I was confronted by a raft of information about what counts fundamentally as a *data* to inform decision-making (e.g., there is much written in the plan about indicators, forecasting, and the like). What seems to be missing, however, is a discussion about *what kinds* of decision making tools and methods will be developed, and *how* these can / will be used to inform the kinds of tradeoffs outlined above.

This omission is problematic because years of research in the social and behavioural sciences have shown that, in many contexts, better information and more education are largely disconnected from improved decision making (e.g., Sunstein and Zeckhauser 2011, Weber and Stern 2011). For example, people tend to ignore or discount key information when thinking about risks and, instead, utilize a variety of judgmental heuristics (Kahneman et al. 1982) when making the kinds of complex and unfamiliar decisions that are commonplace in many risk management contexts.

To fill this gap (in terms of examples of decision support that go beyond information), ORD and EPA may wish to look at a variety of recent research efforts neatly summarized in Gregory et al. (2012). There is also a decision support tool on display at the Marian Koshland Science Museum in Washington, DC that may be of interest to EPA ORD planners (as it is reminiscent, based on my read of the report, of some of the concepts discussed around the TRIO model).

CQ1.3 Balancing Programmatic Needs and Emerging Issues

This question asks, how – in the face of shrinking budgets –should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

My view on this is that "data" about the state of the environment (whether descriptive or forecasted) is relatively easy to come by. The bigger challenge, in my mind, lies in research focused on how to select and use this data for decision making.

Were it up to me, therefore, I would invest as heavily as possible in research on decision support tools and techniques (e.g., in the economic and decision sciences) with an eye toward creating mechanisms that can be moved across a broad range of EPA contexts.

CQ1.4 Program Specific Questions

See my responses to CQ1.1 – CQ1.3, above.
Some additional comments:

- As I note above, the bulk of the discussion in this report is devoted to collecting and presenting data as an input to decision making. The exception is the discussion of TRIO on page 26. I think the ideas behind TRIO are innovate and important; possibly game changing for EPA. I wish there had been more discussion of tools like this in the plan.
- Still with TRIO, one area of confusion for me was regarding where the "weights' discussed on page 28 would come from. In my experience, a decision support system like TRIO could be better used to help decision makers to *assign* weights to attributes (e.g., see Arvai et al. 2012, Gregory et al. 2012)
- I thought the focus on LCA was a useful idea.

CQ2.1 Integration Across Programs

My general comment here is that there seem to be a number of opportunities for integration across EPA programs. Based on the short integration reports, my concern is that what's being presented is more along the lines of a list of areas where integration *is possible.* What seems to be less developed are actual examples of integration (on the one hand), and a plan for more meaningful integration on the other. However, as I am new to the Chartered SAB, I would benefit from hearing and learning more about these examples of integration. So, please take my comment with a grain of salt.

CQ2.2 Innovation

What I read about innovation seems to make sense. I like the emphasis on programs that attempt to seed / spark innovative practices and methods. As a personal bias, I would have liked to read more about innovation in the area of decision support (beyond data collection and presentation). However, I thought what I read was a good start and I look forward to learning more.

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Comments from Dr. Ingrid Burke

1. FIRST YEAR PROGRESS
The Strategic Research Action Plans were developed during 2011, with the benefit of SAB and BOSC advice [*Office of Research and Development (ORD) New Strategic Research Directions: A Joint Report of the Science Advisory Board (SAB) and ORD Board of Scientific Councilors (BOSC)*. (EPA-SAB-12-001)].

Charge Question: How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

Indy: The strategic research plans are impressive in their depth as well as specificity. They are quite ambitious, and match the science questions in the Strategic Research Plan. The identification/hiring of the National Program Managers was fast! This represents a good deal of progress in one year.

2. SUSTAINABILITY
The SAB and BOSC concluded in the October 21, 2011 report that "…ORD's research frameworks can advance EPA's adoption of sustainability as a core principle by more consistently and clearly describing where and how ORD research relates to sustainability."

Charge Question: How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

Indy: We will benefit from Board discussion about this topic. My overall impressions are these:

1) The systems framework for Sustainability, linking the research programs, is tight and well-conceived;
2) There is a lot of use of the word "sustainability", but the actual linkage is not very clear in any but two of the programs, the Sustainable and Healthy Communities and the Safe and Sustainable Water Resources programs. The others seem sort of forced;
3) The agency could do a great deal to truly lead national agencies in walking the walk of *doing* sustainable science, and running a sustainable agency.

3. BALANCING IMMEDIATE PROGRAM NEEDS AND EMERGING ISSUES
Meeting program and regional needs is a primary objective of ORD research. The highest priority needs of the programs tend to be those that are most immediate. Another important role for ORD is to anticipate the future scientific needs of the programs and regions, areas of research that tend to get less support from the EPA partners. Anticipating emerging issues and investing in innovative approaches that could lead to more sustainable, less expensive or timely solutions often requires longer term and potentially higher risk research. The Strategic Research Action Plans strike a balance in addressing current priorities and future science needs; however, new emerging issues will likely arise that are not currently anticipated.

> **Charge Question: As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?**

Indy: The only way to do this is to set aside part of the budget for emerging issues. Any exercise like this makes it clear that being prepared for emerging issues diminishes the capability of the

agency to meet its current goals and priorities. Again, this is a great topic for Board discussion. I might be amenable to the idea that addressing emerging issues in a significant way should not be a key priority for EPA in terms of the science the agency does – that other national agencies have this more as their mandate. It is hard for any science board to support such a view, as we want our agencies to be on the cutting edge. Nonetheless, it is a possible way to think about this, or to embrace the idea that emerging issues should be best approached by multiple agencies, setting aside collective budgets to address these.

4. PROGRAM SPECIFIC QUESTIONS

Air, Climate and Energy Charge Question:

To create an integrated program, research in ACE is organized in three Themes: 1) Assess Impacts, 2) Prevent and Reduce Emissions, and 3) Respond to Changes in Climate and Air Quality. Research related to energy and environment is not a specific focus, but is most prevalent in Theme 2. Relevant topics include research on near-road air pollution, multi-pollutant research, and greenhouse gas impacts.

• How do we bring together research on biofuels, oil and gas measurement methods, combustion related pollutant effects and modeling/decision support tools into a coherent whole to address the environmental effects of energy production and use?

Indy: I am not convinced that a "coherent whole" is possible with this rapidly changing field that is driven by economics and technological advances, and that is so incredibly spatially variable within the U.S. We might better articulate the goals here.

I am finding that this question in particular, is one is which terrestrial ecosystems *must* be considered, and thus far, are not. Some of the major impacts of energy production and use are related to many ecosystem services besides clean air. While EPA's focus is indeed human health, tradeoffs among energy sources involve more than life cycle assessments focusing on greenhouse gas or other air pollutants, including wildlife habitat, natural resources production (rangelands, croplands), indirect land use change, and many others. I realize that I am asking more questions than answering this one, but the key notion is that if a coherent whole is needed, we need to get something into this area that focuses on the land.

II. DRAFT CHARGE QUESTIONS FOR GENERAL ORD/PLENARY SESSION

1. INTEGRATION ACROSS PROGRAMS

Charge Question: Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

Indy: The first step toward integration is communication. Sharing ideas leads to shared challenges, shared questions, and then bottom-up, shared research.

There are two models for communication that achieve different things, and both are important. The first is low-level, detailed communication, that occurs on a frequent basis. For interdisciplinary, integrated work to occur, the participants have to know what each other is working on, so that they can see the linkages. Some organizations try to accomplish this by forums, conferences, poster sessions, etc, once a year or so. That's a good idea. Another way to do this is for fewer people to meet more frequently, without a goal of necessarily developing big-picture integration, but a more proximal goal of staying in touch. So I'd suggest that this "regular" communication be accomplished through *really* frequent communication among the national program leaders --- say, once a week for 1.5 hours of "tell me what's going on".

The other model for communicating to achieve integration is to truly focus on the strategic approach for integrating. This requires longer, more intensive, goal-oriented meetings. The effectiveness of these is very much dependent on the frequent communication above. I'd suggest that once a month or so, all the team leaders (national program leaders and their top scientists) meet to talk about strategies for integration. This could be done via video btw!

2. INNOVATION

The Path Forward principles that guide ORD's realigned research program emphasize pursuing innovative, ground-breaking research. To address increasingly complex and expensive environmental problems, innovative solutions are needed.

Charge Question: How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

Indy: I have frankly been very impressed with EPA's efforts at this to date and have few comments in this area. I think the ways EPA is going about this are great. I am not sure that metrics are appropriate for something we want to think of as "innovation". This is inherently risky, so proportions or numbers of products are not appropriate…we're trying to do something fundamentally different here. Maybe numbers of proposals that come in (because that means that you are stimulating that many new ideas) could be metrics. I really think that stories and case studies of successes work best…we know innovation when we see it, and we know it a decade or so later. Don't worry about metrics!

Comments from Dr. Ed Carney

1. First year Progress

   It appears that good progress is being made in the first year as evidenced by numerous research programs having been described in the provided pre-meeting reading materials. As best as can be ascertained, the planned activities appear to be on track as well. The desired integrative nature of the programs comes across loud and clear.

2. Sustainability

   The core principle of sustainability is clearly emphasized as a unifying theme across all of the research programs. While sustainability is a very broad term which has become something of a buzz word, the value this theme brings is the implicit shift in direction toward more real world problems facing us now and in the future. As the overview document points out, many of the early problems confronting EPA in its first few decades have been solved. Current problems are much more complex and sometimes insidious in nature, requiring an extremely multidisciplinary, highly integrated approach. An increased emphasis on developing tangible solutions to these real world problems is very much apparent in each of the program descriptions. The plan is on target. Realizing that plan is all about implementation. Therefore, mechanisms and metrics are critical to ensure that investigators keep their focus on these real world problems and embrace the value of such applied, team-oriented research.

3. Finding this balance is always important as some of the best laid plans cannot always predict the future. However, emerging issues generally take a number of years to mature to the point that they impact regulatory agencies, as the emerging science needs to be vetted in the basic science community first. Therefore, ORD should clearly focus the large majority of its resources on implementation of its research plan. Perhaps the most effective approach is to ensure that ORD scientists are adequately supported in terms of travel to scientific meetings, professional society service opportunities and continued education and training such that they fully understand these emerging issues and possess the cutting edge technologies and knowledge needed to evaluate their significance and implications for the agency.

4. Program-specific questions (My answer focuses on the CSS program as per my expertise area and assigned break out group).
   a. Is the program well positioned to support EPA needs in endocrine disrupting chemicals, nanotechnology and computational toxicology research?

   In general I found the CSS program description to be extremely exciting and bold - particularly the computational toxicology section which portends a new paradigm which is much more aligned to the needs of today than is the current system of toxicity testing. It is a highly ambitious program which is moving ahead quickly – perhaps too quickly? While this reviewer is highly supportive of such efforts, there does seem to be a great deal of emphasis on development of new tools, but less is said about evaluating their

predictive capability. The thorny nature of this issue is well appreciated by this reviewer, and some balance needs to be struck between the rush to deliver new tools and the time required to qualify them so that they will be accepted by stakeholders. Additional emphasis on proving the predictive value of these new methods would be helpful. In concept, the approach FDA uses to "qualify" biomarkers is something that EPA might want to leverage.

Another aspect of computational toxicology which should be considered is with respect to chemical categories of structurally-related molecules. The documents repeatedly cite a figure of 80,000 chemicals on the TSCA inventory and claim that a huge proportion have not been adequately evaluated, but this is rather misleading. The reality is that most of the current production volume has been evaluated, not necessarily by actual testing in animals, but by "read-across" to structurally similar molecules which have good data. Some mention of how these new computational approaches will integrate with read-across programs, such as those used in Europe (e.g, REACH) would be helpful.

With respect to endocrine disrupting chemicals, the desire to transition from the current EDSP to EDSP21 is a move in the right direction, provided of course, that the high throughput assays are proven to be predictive. While Endocrine Disrupters and EDSP signaled a shift from apical effects-based testing to mechanism-based testing, there are simply too many different mechanisms of toxicity to build an EDSP-like program for each of them. Therefore, a shift to EDSP21 is not only important for the evaluation of endocrine disrupters *per se*, but it also will establish a framework for evaluating the entire waterfront of potential toxic modes of action.

b. How well has the exposure component progressed?

First, EPA should be applauded for integrating exposure into the CSS (and other) programs. Keeping exposure in the forefront is one of the most important considerations in problem identification and prioritization, and the resultant allocation of limited research resources. It is difficult to assess the degree of progress based on the provided documents, although programs such as ExpoCast provide evidence that work is moving ahead.

Part 2. Innovation

This emphasis on innovation is highly commendable. Some of the programs should act as incentives to promote such a cultural shift. Again, much of this comes down to implementation. Hiring decisions should consider candidate's penchant for (educated) risk-taking and rewards systems should also align with the desired behavioral changes.

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Comments from Dr. Costel Denson

The (HSRP) program was advised in 2011 by the SAB and BOSC that "the program should consider expanding research and capabilities in relation to natural disasters…" The charge question is as follows: What advice (e.g., strategic, tactical, structural) can the SAB give to guide the program toward this broader role?
The HSRP in response has identified three research themes: Securing and Sustaining Water Systems; Characterizing Contamination and Determining Risk; Remediating Indoor and Outdoor Environments.
EPA's disaster-related responsibilities fall into three areas: water systems, indoors/outdoors, and laboratories.
EPA has unique responsibilities related to disasters, and so no duplication of work is judged to exist with other agencies. Notably, EPA has entered into Memorandum of Understanding with two other departments.
The HSRP program design is built on a systems-based approach and looks to identify strategic directions by identifying both current and emerging issues.
Priority science questions have been developed around each of the three research themes. Importantly, with each question, research products contributing to an output are listed, along with impacts.
A critically important feature of the Homeland Security STRAP is the summary tables of outputs and outcomes for each of the theme areas. These tables are unequivocal in the expected outcomes, output and the output year.

Comments from Dr. David Dzombak

Comments of David Dzombak on June 20, 2012 report by Dr. Peter Preuss on "ORD Innovation Moving Forward"

July 5, 2012

This is a well-organized and informative progress report. I commend Dr. Preuss and the Innovation Team on the progress to date, and the clear desire and plans for establishment of an innovation culture throughout the agency. I offer some thoughts in response to the charge questions that may help support some of the potential future directions identified by the Innovation Team.

1. How can ORD's initial innovation activities be improved to ensure continued and long-term benefits for the EPA?

   I have two general recommendations in response to this question: (a) keep the activities focused on real existing gaps and needs directly related to the EPA mission for which real solutions are needed today or will be needed in the near future; (b) establish a permanent framework for innovation at EPA ORD that recognizes the unique mission of the agency and that contains flexibility to evolve as the agency and environmental protection and restoration goals of the nation change. The Innovation Team already has both of these topics as priorities, which I support. I have some specific suggestions for moving forward on each.

   Innovation is best motivated by and supported by real problems clearly in need of new kinds of solutions. It is harder to engage teams, garner institutional and external support, and mobilize financial support for hypothetical problems that may occur in the future. As important as some of the problems may eventually be, it is hard for organizations to mobilize interest and support to address them. The EPA will always be an organization with an abundance of current challenges in need of new approaches, and the focus of innovation investments should be on these challenges, in my view.

   Innovation investments should be on the most important of those current problems identified as in need of innovative approaches. This will help engage the best people to work on the innovation challenge, and will help mobilize internal and external financial resources and other support to address the challenge. To this end, I recommend that a systematic process be established for bringing forward problems in need of innovative solutions from the EPA regions and offices. The process for soliciting ideas from regions and offices by the Innovation Team is unclear. In this regard, I recommend that the Innovation Team examine the organization and process established by the EPA Environmental Technology Action Council for requesting, compiling, and ranking problems faced by EPA regions and offices for which new technology development would make a big difference. Perhaps the efforts of the Innovation Team could even be merged with those of the Environmental Technology Action Council. There are similar goals, though the Innovation Team would be interested in a broader range of problems to be addressed.

Innovation investments should be directed to organizations best suited to address the particular problem identified. The Open Innovation challenges provide an excellent vehicle for accomplishing this, and I recommend that this challenge program be expanded and strengthened. Some of the projects funded internally do not appear optimally directed. For example, one of the EPA ORD Pathfinder Innovation Projects funded in January, 2011, was focused on "nanomaterials designed to facilitate decomposition at end of product life." Without knowing anything about this project, which I expect was performed with a high degree of competence, I have to wonder if EPA ORD was the best organization to conduct the work. Is design of nanomaterials a core competence of EPA ORD? Should it be? If design of degradable nanomaterials is really a priority problem for ORD and the Agency to address, organizations with focused expertise in design of nanomaterials should be engaged for optimal impact of innovation investment.

In regard establishing a permanent framework for innovation at EPA ORD, as noted in my recommendation I believe that it will be important to do so with recognition of the unique mission of the agency and with flexibility to evolve as the agency and environmental protection and restoration goals of the nation change. In the progress report, under the description of the Pathfinder Innovation Projects, it is noted that DOD, DOE, and DHS have offices that fund high-risk, high-reward research (DARPA, ARPA-E, and HS-ARPA). It is useful for EPA to examine such models, but none of these agencies have as extensive and unique a regulatory mission as does the EPA. The innovation program for EPA must be customized to the mission and particular needs of the agency.

2. Are there useful experiences and lessons from other research organizations about managing innovation?

   I think that the Innovation Team has identified the key elements for building innovation into the fabric of EPA ORD: provide incentives, accept the risk involved, authorize innovation across the organization and with strong approval of leadership, and provide guidance to members of the organization about what innovation is and how it can benefit them and the organization.

3. What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

   As noted above, I recommend that innovation investments be tied to specific existing problems. Metrics can then be developed around specific problems and how solutions were implemented and advanced. For example, an innovation developed through an Environmental Technology Council action team was the development of technology for on-site detection of lead paint in homes.
   http://www.epa.gov/epahome/sciencenb/action_teams/lead/index.html

Examples of some metrics that could be developed around this innovation would be sales of the improved spot test kits for lead in paint, and number of houses tested for lead in paint
per year in particular regions.

There could also be a number of metrics related to Open Innovation challenges, including number of proposals submitted, percentage of successful solutions identified, and metrics related to the particular problems addressed.

Comments of David Dzombak on June 2012 reports on "ORD Research Integration"

I have reviewed the five summary reports on ORD Research Integration efforts. They are organized in a consistent format and were very informative. I commend ORD for the significant progress made in integrating research efforts for five quite different and complex topics. I offer some general comments relevant to all five research topics.

Charge Question: Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

From my review of the summaries of progress made in integrating ORD research for each of the five broad topics, I conclude that ORD is making good progress in developing integrated research efforts across the major ORD research programs. The five areas are at different stages of integration, but common approaches to achieve integration are apparent.

I have two general comments that apply to all five research topics.

(1) I recommend that for each of the integration topics a "roadmap" be developed as is planned for the Nitrogen integration effort. As described on page 2 of the Nitrogen summary: "We have committed to developing a Nitrogen Roadmap that identifies how we will foster research, program implementation, and policy integration for nitrogen and co-pollutant issues across the Agency over time, and have initiated discussions with external stakeholders." The Nitrogen summary report includes presentation of plans for future integration efforts, in addition to descriptions of integration activities already in place. The current and planned activities provide the basis for the development of a "roadmap" plan that can set forth near-term and longer term goals, and outline paths for achieving those goals. Development of such a roadmap plan will benefit the Nitrogen integration effort and could benefit each integration area.
(2) The summaries of all five integration research topics show significant progress in integrating efforts across ORD research programs. Focusing on internal integration is certainly the right priority and the right place to start. However, there are important

opportunities, and critical needs in some cases, for integration with research efforts at other agencies. Coordination and partnerships with other agencies receives little discussion in the research integration summary reports. This is very important for the impact of EPA efforts and for leveraging EPA research investments. For example, in the integrated nitrogen research effort it will be important for ORD to engage with the USDA Mississippi River Basin Initiative to help guide and to benefit from the watershed-scale studies of nutrient control being funded and supervised by USDA NRCS.

With respect to the Nitrogen research integration summary, I appreciated very much the careful compilation of ORD research projects and expected outcomes corresponding to the various recommendations of the SAB Integrated Nitrogen Committee. This was very helpful to understand how ORD is responding to the INC report, and is a powerful tool for both internal planning and external communication regarding ORD integration of nitrogen research.

Comments from Dr. Taylor Eighmy

1. How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

Six areas of research and technical support have been identified for SSRW (nutrients, chemicals, pathogens, infrastructure, watersheds, climate change). These have been applied across two broad themes: theme 1: sustainable water resources and theme 2: sustainable water infrastructure systems.

There are three science questions associated with theme 1 and four science questions associated with theme 2. They are accompanied by many expected outputs. Most of the outputs for both themes have 100% deliverables by 2014-2017, however, there are no milestones offered between FY13 and their output years. Therefore, it is difficult to assess progress. More granularity would be helpful. This request was also made during the FY13 budget review. Nonetheless, the expected outputs for each theme appear quite reasonable. Based on the offered outputs and schedule, there is a lot to do between now and 2017.

It would be helpful to have a bit more granularity on each listed output, their interim milestones, and the personnel/groups/programs assigned so as to assess the likelihood of meeting the output year deliverable.

In particular, under theme 1, I believe that the recharge of subsurface water resources is a wise and important area of focus and learning more about this activity would be helpful.

In particular, under theme 2, the PIP program does have the ability to help with out-of-the-box innovation. I also think close collaboration with ASCE and WRF/WEF would be wise relative to infrastructure assessment and prioritization around critical rehabilitation.

2. How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

I believe that the consolidation of the many research programs into the four plus two construct will go a long way to making sure sustainability is embedded across the agency and within ORD.

I think there may be opportunities to conduct some very specific pilot projects that showcase sustainability in a way that the public can easily grasp. These can be done in close concert with the regions. Looking at the LEED process for new buildings as a model, I think there could be some very similar models brought forward in the water supply infrastructure environment/water reuse/aquifer storage arenas. Creating a LEED-equivalent might be helpful.

3. As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

I believe a little bit of seed funding can go a long way to achieving the balance needed between scarce resource allocation to planned versus emerging needs. I think the PIP process will be crucial for bringing forward responsive R&D to new issues. Assuring that a sufficient portion of resources is always made available for PIP will be key. Allowing agency researchers to tackle critical R&D questions around emerging issues is likely the fastest way to articulate new R&D needs around the issue and then best frame the magnitude of the response. Once these needs are identified, then a better-informed strategic/tactical evaluation process can be conducted so as to allow reallocation of resources.

4. ORD has integrated programmatic research, with EPA Program Office input, to begin developing a strategic nutrient management plan for the nation with the intent of accomplishing SAB's recommended goal to reduce reactive nitrogen by 25 percent. Are there research gaps that would impede accomplishing this goal?

5. To better accomplish our goal of using a variety of approaches to address storm water issues, should EPA also consider incorporating natural infrastructure into research on constructed green and gray infrastructure?

I think this is essential, especially aquifer recharge.

Comments from Dr. Henry Falk

I don't feel comfortable posting my impressions at this point, because they are very preliminary and I suspect will evolve, particularly over the course of the discussions next week.

1. First Year Progress. I think the action plans are clearly done, but I would be hesitant to characterize the FY 13 activities just yet without more detailed discussion at the meeting. The summary tables at the end of the action plans showing research projects by FY are very helpful in understanding the plans for implementation. I also liked the layout of the Action Plans, with the summary, overview, problem statement, distinct themes, etc, and in general the research efforts seem appropriate to the themes, but would feel more comfortable being more explicit after the discussions at the meeting.
2. Sustainability was highlighted throughout, and that is very positive. I think there is some variability in being able to articulate the themes in terms of sustainability; I think the Safe and Sustainable Water Resources action plan was actually the best at describing their plan in terms of sustainability.
3. Balancing immediate program needs and emerging issues. I feel that for any Agency to be responsive in the public mind, it must address emerging issues; those are the moments when the public's attention is riveted and focused. Shrinking budgets to me require more streamlined and efficient ways to accomplish program needs and goals.
4. The program specific questions, particularly for the HHRA group that I am assigned to, are really important and challenging questions, and I would like to defer on these till after the discussion with the group.

Comments from Dr. Barbara Harper

Charge Question: How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

- I believe so. It was a bit unclear how the 5 or 6 programs (5 programs in some docs and 6 programs in other docs), 6 integrating programs (inconsistent between documents), and EPA's 7 priorities all fit together. The integrating themes seem to be continually evolving; for instance endocrine-mediated dose response is a new integrating theme but is not included in some figures, and while it crosscuts a couple programs it does not integrate across them. It was not clear which were the most current visions.

Key Areas of Program Integration	ACE	CSS	SHC	SSWR	HHRA	HS
Children's Health			■			
Climate Change	■					
Emergency Response						■
Energy	■					
Environmental Justice			■			
Nitrogen				■		

■ Lead Program
□ Contributing Program

EPA's Seven Priorities
Taking action on climate change and improving air quality
Protecting America's water
Cleaning up our communities and advancing sustainable development
Ensuring the safety of chemicals and preventing pollution
EPA's cross-cutting strategies
Expanding the conversation on environmentalism and working for environmental justice and children's health
Strengthening state, tribal, and international partnerships

Charge Question: How are ORD programs contributing to sustainability through their research plans and activities? What advice do the SAB and BOSC have for each research program about advancing sustainability in future research?

- Programs are very focused on sustainability overall. I can't tell if each study or grant includes sustainability as an evaluation criterion.
- Dashboards and portals are good, but tend to get buried in various web pages (hard to find), and may not be actively updated. Attention needs to be paid to the user interfaces.
- Previous efforts, in particular Comparative Risk tools, were very useful, but the new generation of EPA employees seems to have forgotten them (and do not cite them).
- I agree that a model community like Durham is good. Portland Oregon might be another example; it has an office that focuses on sustainability but appears to have only one part-time person staffing it. I recommend having a good web page and progress reports, listserv, and other ways for communities to track progress.

Charge Question: As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

- There are many statements about methods that will be developed. This is good, but perhaps there could be a DQO step where EPA identifies specific needs and prioritizes in case funding is limited internally or extramurally. I believe the SHC is inherently balanced between existing commitments and emerging issues. However, flexibility to incorporate or respond to emerging issues and identifying efficiencies if funds have to be shifted could be added. There might be a draft appendix on how the SHC plan could be implemented, like a work plan.
- It would also be interesting to explain how EPA identifies emerging issues such as fracking – could EPA have identified it as an emerging issue before it suddenly resulted in community emergencies? Five years ago we never heard of it; now we are scrambling to collect trend data, geophysical data, develop reporting criteria on the compounds used, and develop regulations. In the interim, community complaints were ignored by the regions. Does EPA have a future-casting think tank, or a way for communities to report early signals of emerging problems?

Sustainable and Healthy Communities Charge Questions:

• The Sustainable and Healthy Communities Research Program incorporated a number of diverse research elements (e.g., ecosystem goods and services, human health outcomes, waste and contaminant remediation, environmental indicators) in building a research program focused on supporting community decision-making. The SHC Strategic Research Action Plan aims to provide science-based research and tools to assist communities in evaluating their decisions from a sustainability perspective. What advice can the SAB/BOSC provide to help ensure this research and these tools will most effectively support communities in doing so?

- Once a tool is developed and national data are collected to populate the tool, the community may be locked into using it without flexibility. Will tools like TRIO or the sustainability index be modifiable for local circumstances or different community values?
- The decision science tools could address not only behavior of individuals and data & planning tools for communities, but could also include some perspective on governmental structures and overcoming impediments to making changes in order to move toward sustainability. For example, how do lifecycle costs and benefits relate to short-term hurdles for implementing front-loaded costs such as smart grid re-wiring or costs of parks maintenance when benefits are non-monetary. The way that individuals make decisions may be different from the way that institutions (agencies, government) make decisions.

• The SHC's fourth theme investigates sustainability practices within four high-priority decision sectors identified during SHC community listening sessions. These sectors are: transportation, land use, buildings and infrastructure, and waste and materials management. There are three primary goals: to assess opportunities for communities to achieve greater synergies from practices within a given sector and across multiple sectors; to provide methods to more comprehensively account for these practices in terms of their social, economic, and environmental outcomes; and to collaboratively apply and refine these findings in partnership with specific communities (e.g., Durham, NC). Does the Committee agree that this fourth theme provides a useful way to integrate research within SHC? If so, what are the most important implementation questions that ORD must address?

- I generally agree with the 3 pillars of sustainability (economy, environment, and society). The University of Oregon (Bob Doppelt) uses 4 systems (built systems, economic systems, natural systems, and human systems) in their sustainability analysis. There is some merit in separating out economic systems for

special consideration. Descriptions of the elements of economy, environment, and society might be useful as an appendix (like the Millenium Ecosystem Assessment materials do).

• Does the Committee feel that SHC has the appropriate balance of breadth and depth in its design? If out year budgets continue to shrink, what areas should SHC maintain as the primary areas of focus? Can the committee recommend areas that SHC should invest in if budgets increase?

- EPA could dig out its Comparative Risk methods as an example of how to prioritize community needs across health, environment, and socio-cultural categories.
- Getting data is always a problem for communities, from community exposures to energy audits and community-level energy use. GIS-based integration and decision tools are another challenge. Ways to get data cheaply should be maintained; again, a DQO-based implementation plan would help prioritize.

Comments from Dr. Nancy Kim

Homeland Security

1. How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

   Homeland Security has research in three different themes: Theme A – securing and sustaining water systems, Theme B – characterizing contamination and determining risk, and Theme C –remediating indoor and outdoor environments.

   The information provided in the Strategic Research Action Plan 2012-2016 includes an eight page summary of the three research themes and tables containing a title of the output, the output year(s) and the relevance to other science questions and the research questions. With this limited information, the research activities appear to appropriate for answering the science questions. The research programs appear to be progressing well in the first year of implementation, but information on progress is limited. The SAB/BOSC may want to consider what information is needed to answer this question if we decide to answer it in any detail in future years. The question of sufficient progress may be one that should be directed to program managers.

2. How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

   For HRSP, this question is related and similar to question 4 and the response to question 4 will be included here.

   In the EPA Research Program Overview 2012-2016 and in its Strategic Research Action Plan 2012-2016, the HRSP program includes contributing to sustainability. A good addition to the description is the concept of community resilience (the capacity to successfully prepare for, respond to, and recover from disasters). Community resilience along with sustainability provides a great concept for this particular program to use in its research planning and activities.

   Sustainability and responding to natural disasters (see question 4) have been included in HRSP's planning and research activities; however, the addition of these concepts to the research plan is not seamless (e.g. planning the research for homeland security, sustainability and natural disasters tends to be addressed in separate paragraphs rather than uniting them). For example, page 12, third paragraph of its research plan mentions CBR agents in the first sentence while the first two paragraphs discusses contamination events (I read this as including such possibilities as VOC or pesticide contamination, etc., unrelated to terrorism). The rest of the third paragraph is broader than CBR. This is a

relatively minor example of focusing on CBR in one specific place, but illustrates both the progress that has been made and the type of wording that could be expanded.

More importantly, additional examples of how its research can also apply to sustainability, resilience and natural disasters should be added in all three areas.

Other concepts could be added in addition to sustainability and natural disasters. For example, the HRSP's research could also apply to the preparation, response and recovery from other contamination incidents (accidental releases, spills, explosions, etc.). One recommendation would be to specifically include these concepts in its research planning/benefits when synergistic results could be achieved.

The research in water systems is more developed than research in the other areas, probably because of EPA's lead role in water. In addition, the integration of sustainability and natural disasters occurs to a greater extent in water systems than in Themes B and C.

The description of Theme B states, "Following a chemical, biological, or radiological attack…" Natural disasters and other contamination should be integrated into the description of Theme B and the subsequent write-up to a much greater extent. This same statement applies to Theme C: remediating indoor and outdoor environments.

Theme B focuses primarily on CBR agents and collection and analyses of samples. These results could also be applied to natural disasters or other contamination events. For example, a number of pesticides are similar to some of the chemical agents and cause similar, acute effects. Some of the collection procedures may be useful for routine sample collections. The updates to analytical methods may also be useful for investigating contamination not related to terrorism events. The write-up for remediating indoor and outdoor environments could also be expanded to natural disasters or accidental releases/spills, etc. HRSP may be thinking in these directions, but the description should demonstrate the intent to a greater degree.

The concept of research into prevention should be added to Theme C for indoor environments. What can be done to make buildings less vulnerable to terrorism, natural disasters, or incidental contamination? This question is being addressed in the water security area and can be studied for buildings and other indoor environments (subways, etc.). Even if HRSP does not have the resources to answer these questions, other partners may be able to assist in answering them.

3. As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

   No simple answer exists for this question. In some cases, an emerging issue will have to be addressed immediately and ORD will have to respond. In other cases, an emerging issue can be included in an on-going research initiative. If ORD is flexible and resilient,

it may be able to accommodate high priority needs and will have to make lower priority projects take longer or eliminate them as appropriate.

4. The HRSP has conducted research primary to support EPA's homeland security mission, i.e. response to acts of terrorism. In 2011, the SAB and BOSC stated that "the program should consider expanding research and capabilities in relation to natural disasters…." What advice (e.g. strategic, tactical, structural) can the SAB give to guide the program toward this broader role?

Integration

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

The five write-ups for the integrated topics are a good first step in ensuring that ORD's research across its programs and beyond ORD are in fact integrated. Climate change and nitrogen seem to be further along than the other three.

Nitrogen appears to be the most integrated. That may be because the research questions were the focus of the integration chart. For climate and children's health and environmental justice, it seems as though the research that was started in each program area listed under a research issue heading. These are logical first steps. As ORD proceeds with integration, if the first step is to have the programs and other partners identify an important research question in an area and then develop the agenda to answer the question, integration will occur seamlessly. This appears to be happening with the non-monotonic dose response curve integration.

Having HHRA be the lead for applying new chemical assessment approaches in human health risk assessment seems like a good strategic approach. The HHRA program may benefit more than other programs if the integration across ORD programs and other partners succeeds. Choosing a lead program for integration that has much to gain from successful integration is another tactic that ORD can continue to use.

One area that appears to need additional consideration in integration is the social and behavioral sciences. The success of implementing the research in many areas depends on people or organizations taking action. ORD should evaluate the need to add research in this area to the 5 topics and other integrated topics as they are developed.

Innovation

How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

Evaluating ORD's innovation activities should help to provide an understanding of these activities benefit EPA and whether or not to continue these activities. The evaluations could be about the scientific project and about the impact on the workplace (employee morale, impacts on co-workers who did not participate and supervisors, etc.). Possible metrics to use are the number of peer reviewed papers or the number of products developed. Another method that might work is to obtain an evaluation of the project from people who participated in the activities and/or from their coworkers and supervisors about how they view the benefits and down sides of participating in these activities. The information could come from a required report/summary written by the participants, co-workers and supervisors or from interviews. All those who participated in PIPS, Open Innovation, Apps and Sensor projects, and the Culture and Collaboration projects could be involved.

Comments from Dr. Cecil Lue-Hing

Homeland Security Charge Question
The HSRP has conducted research primary to support EPA's homeland security mission, i.e., response to acts of terrorism. In 2011, the SAB and BOSC stated that "the program should consider expanding research and capabilities in relation to natural disasters …" What advice (e.g., strategic, tactical, structural) can the SAB give to guide the program toward this broader role?

Response
The Charge Question for HSRP identifies two categories of disasters, acts of terrorism, and natural disasters. However, there is another category of disasters, accidental disasters, which, while anthropogenic, are not due to acts of terrorism. This category also deserves to be recognized, since they do occur, and history has shown that the consequences of these disasters can have far reaching detrimental environmental and human health effects comparable to those caused by acts of terrorism. Examples of these include the recent BP Gulf of Mexico oil spill, and the more distant Exxon Valdez oil spill in Alaska. It is important to include this category also because of the following:

- It is possible that the Exxon Valdez type spill (an accident/human error event) could have been the result of a severe storm, or act of terrorism, with a comparable degree of environmental and public health damage
- The BP type spill (an accident/human error event) could be the result of an act of terrorism, with a comparable degree of environmental and public health damage
- The 1993 City of Milwaukee type experience with cryptosporidium contamination of its drinking water supply (an accident or human error event) could have been caused by an act of terrorism

Thus, one can argue that acts of terrorism, natural disasters, or human error could result in disasters with similar characteristics and comparable consequences, and would require similar mitigation measures.

From the above discussion, it appears that the EPA has developed a strong background of experiences dealing with disasters of natural or anthropogenic origin, and associated with the following environmental issues:

- Chemical related indoor air contamination – 9/11 at the World Trade Center
- Biological/pathogenic contamination of indoor air – the recent anthrax incident in Washington DC
- Biological/pathogenic contamination of the drinking water supply of a major US city – the City of Milwaukee's cryptosporidium contamination incident
- Chemical contamination of a recreational water-body – the pesticide contamination of Pond Lick Lake, Ohio
- The Recent BP Gulf Oil Spill in the marine environment

Natural disasters – Natural disasters in which the EPA is more likely to be involved include hurricanes, non-hurricane-related flooding events, earthquakes which may cause damage to water distribution infrastructure, e.g., the 1993 Kobe City, Japan earthquake, and tornadoes, all of which currently receive significant attention and support collectively from the 6 ORD programs, more so from particular programs than others. Notable examples of attention and support from the US.EPA include for Hurricane Katrina, and recent Mississippi Basin flooding events.

Acts of terrorism – Recent EPA experiences with acts of terrorism include the events of 911 where iconic buildings were heavily damaged e.g., the Pentagon building, or totally destroyed e.g., the World Trade Center in NYC, both resulting in indoor air quality contamination problems. Acts of terrorism can also include air space contamination by chemical or biological agents e.g., the recent anthrax contamination of indoor air in public buildings in Washington DC.

Other acts of terrorism not well known can also include the deliberate contamination of recreational water bodies and potential water supply – See Pesticide Poisoning of Pond Lick Lake, Ohio, Investigation and Resolution, June 2- July 5, 1971,Oil and Hazardous Materials Program Series; OHM 71 06 002 also (NTIS PB229763). This reference is included for the following reasons a) it was an act of terrorism involving chemical contamination of a recreational fresh water body and potential drinking water resource, b) the act occurred before terrorism was a household word, c) the scope was much smaller than that of the Milwaukee incident (no one is known to have died), and d) the writer was directly involved as a member of the US EPA contract clean-up consultant team.

In the above case, the clean-up contract was managed by the then Chief of the US.EPA Hazardous Materials Branch which gives the EPA a history of managing this type of disaster, be it somewhat dated.

Accidental disasters – One of the more celebrated accidental/human/error category of disasters of interest here was the contamination of the City of Milwaukee's drinking water supply by cryptosporidium in 1993.

Advice

From the above review, it is clear that the EPA has a history of providing assistance and support in disaster events including natural disasters and acts of terrorism. Because of its history, research contributions, and management practices expertise, the agency is well positioned to readily enhance its research portfolio and field/practices capabilities to more effectively expand its disaster response assets relative to more extensive covering of natural disaster events. The response capabilities likely to be in greatest demand for most natural disasters appear to be water and air in that order. With respect to these capabilities, both ORD programs are sufficiently mature, such that this suggested enhancement could be accomplished by simple growth within these two programs, or through collaborative initiatives within and outside of EPA, or both.

Enhancement of EPA's capabilities should also include, a). - beefing up its Risk Assessment Management and Analysis portfolio to include natural disasters, and b). - include natural disasters in its emerging issues program. It is believed that these enhancements can be

accomplished through collaborative initiatives between HSRP and the respective existing ORD programs.

Tactical – In the short term, and with the realignment being implemented and refined, HSRP should develop a rapid inventory of the various Agency assets including research outcomes, and how-to management practices which are available within HSRP and across programs, and are generally utilized in, or compatible for disaster mitigation and relief activities for the disaster issues described above. HSRP should carefully examine these assets to determine, e.g., through gap analysis the type and extent of additional assets that are needed to improve HSRP's disaster response capabilities to bring them closer to perfection. Develop a similar inventory of desired assets which reside in other Departments outside the Agency, and pursue access to these assets.

Strategic – Develop long-term collaborative agreements to obtain additional disaster mitigation assets which may reside in other EPA programs and departments outside the Agency. If these collaborative agreements do not fill the asset pool, the HSRP should seek additional resources to complete the asset pool. The HSRP should seek access to resources related to natural disaster response capabilities in Risk Assessment Management and Analysis, and Emerging Issues programs through collaborative initiatives or new resources acquisition or both.

Structural – HS is already linked legally to EPA, and by extension to the ORD programs by a set of laws, Homeland Security Presidential Directives and Executive Orders, and national strategies, as outlined in the document, *Refining EPA's Strategic Approach to Homeland Security* (US.EPA, 2011), which further describes the Agency responsibilities.
These linkages put in place critical organizational structural components between Homeland Security, ORD's Homeland Security Research Program and the other ORD research programs.

According to the HS Strategic Research Action Plan 2012- 2016, "Within EPA's ORD, HSRP coordinates its efforts with EPA's other five national research programs." --- also "Ongoing communication between the program's leadership, laboratory and center management, and research staff ensures that HSRP's work: (1) is informed by synergistic projects and tasks in other programs and (2) does not duplicate other research within ORD" ------. This suggests that a working coordination and communication framework already exists in HSRP.

HSRP should exploit this built in asset by using it to strengthen the collaborative agreements made relative to natural disaster response capabilities.

Finally, a quick assessment of the move to enhance the HSRP's capabilities to better respond to natural disasters suggest that, given the existing structural and other assets, the enhancement can be accomplished to a large extent through collaborative and integrative initiatives with some minimal addition of new resources. The important missing step is the decision to proceed. Once the decision to proceed is made, most of the building blocks are in place, and implementation should not be too challenging.

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Comments from Dr. Judith Meyer

These responses are based on rereading the SAB/BOSC's earlier report and the agency's response and reading *Science for a Sustainable Future*, the various documents describing integration efforts (e.g., climate, nitrogen, human health, human health risk assessment, children's health and dose-response), the Innovation Overview, and the Strategic Research Action Plan for Sustainable and Healthy Communities (the group to which I have been assigned).

1. How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

Innovation: The Pathfinder Innovation Projects appear to be stimulating innovative research. I have one concern, which is the number of proposals submitted versus the number funded. The concern is that the low percentage of proposals funded means that considerable time was spent writing proposals that led to nothing. At some point that is going to lead to discouraged researchers and researcher time wasted. Can the proposal process be modified so that each proposal represents less preparation time? The Open Innovation program appears promising and should lead to new collaborators for the agency. It is not clear how those challenges were developed and what prioritization process was used; knowing that would enable one to assess whether the process will result in proposing the challenges most likely to improve human health and the environment. The Apps and Sensors program also looks promising; something like that for water would be beneficial.

Integration:
a) Forming the integrated nitrogen workgroup represents a step in the right direction. However, it is difficult to evaluate whether there has been significant progress until the Nitrogen Roadmap is completed in November 2012.
b) Formation of the Climate Integration Team is another step in the right direction, but it is not possible to assess their progress until the Climate Research Roadmap is complete; no date for completion was provided. The table of climate research activities across the six programs is useful, but that is not the same as integration, which should be the focus of the planned Roadmap.
c) Integration between Human Health Risk Assessment and Chemical Safety for Sustainability is straightforward. However, a more comprehensive, productive, and innovative integration would include working with the Sustainable and Healthy Communities program; the absence of that program makes this effort at integration incomplete.
d) Integration of Children's Health and Environmental Justice is led by the Sustainable and Healthy Communities program, which has established two workgroups to enhance collaboration on these issues across the agency and with other federal agencies. The fact that these are on parallel paths implies that although there are significant efforts on-going in different ORD programs, the two research areas are not really integrated. The workgroups should consider developing a single integrative roadmap as the other efforts are doing.
e) The non-monotonic dose-response curve (NMDRC) workgroup has established clear

objectives and is engaging several ORD research programs to achieve those fairly specific objectives. One strong point of this effort at integration is the involvement of both scientific and regulatory communities. Engaging both of those communities in other efforts at integration should be encouraged.
e) Cross program collaboration in the "One environment" model is mentioned briefly in the ACE program description in *Science for a Sustainable Future*. I see this as a more important integration effort than some of the ones described in the integration documents we were given.

2. How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

There is still no common definition of sustainability across programs. SHC has defined it based on 1969 NEPA legislation, but SSWR doesn't provide any definition (it should be in the summary). Surely a clearer definition of sustainability is available than what was proposed in 1969 legislation (perhaps in *Sustainability and the U.S. EPA* [National Research Council 2011]). To be most useful, there should be a general definition of sustainability with each program indicating how that broad definition is translated into the specifics of a program. The term sustainable is used frequently in program descriptions, but it is not always clear what the term means in that specific context as is clear from some of the questions posed in the following paragraphs.

Although SSWR uses the term often, sustainability is not mentioned in its vision statement. In the two bullets describing the challenges the program is targeting, the term "environmentally sustainable water resource management" is used. What does that mean? Why only environmentally sustainable – that is only one of the three pillars. The term "sustainable solution" is also used. What makes a solution sustainable?

It is not clear that CSS is designed around issues of sustainability; what does sustainability mean for chemicals? Does it mean the chemical fulfills its function but isn't toxic? Does it mean the supply of that chemical will be available for future generations? CSS needs to provide a relevant definition of sustainability.

I see little mention of sustainability in Human Health Risk Assessment. What does sustainability mean to this program?

In the context of Homeland Security, sustainability probably means that a community can withstand or rebound from natural or anthropogenic disasters. Again, some sense of what sustainability means for that program is needed.

The three pillars of sustainability – environment, economy and society – are clearly the foundation for SHC. Those three pillars are less evident in the other programs.

3. As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

Highest priority topics in each program should be identified. One criterion for that choice could be how essential that information is to completion of other topics in that program. For example, research around ecosystem services (e.g., production functions) in SHC is fundamental to all the other parts of that program. One approach to funding would be to sustain funding for those highest priority topics; then as each year's budget is determined, the funds remaining after those highest priority topics were supported would be allocated among the other topics and emerging issues. There has to be a core program with sustained funding while still having some flexibility to respond to emerging issues. Each year the program could evaluate the tradeoffs between research on emerging issues and furthering research in the Plans.

4. With reference to the Sustainable and Healthy Communities Research Action Plan
A. The Sustainable and Healthy Communities Research Program incorporated a number of diverse research elements (e.g., ecosystem goods and services, human health outcomes, waste and contaminant remediation, environmental indicators) in building a research program focused on supporting community decision-making. The SHC Strategic Research Action Plan aims to provide science-based research and tools to assist communities in evaluating their decisions from a sustainability perspective.
What advice can the SAB/BOSC provide to help ensure this research and these tools will most effectively support communities in doing so?

The listening sessions that were used in the development of this program are a useful way to increase the likelihood that the tools will be used by communities. Engagement with the decision sciences community will be essential for the success of this program. To more effectively answer this question, one would need to see the Communication and Community Engagement Plan that is being developed.

I see a danger in that by focusing on local communities, SHC has lost a national perspective. There is little discussion in the plan about how one takes a tool developed with one community and makes it useful to other communities. How many communities will the program work with? How are those communities chosen? Of what are they representative? The community typology effort will be essential for this; the relationship between the number of community types identified and the number of versions of tools that will be developed is not clear.

The listing of outputs and outcomes needs to be on the Table of Contents! I almost missed it. Also, it was difficult to see the correspondence between what was in the text (and example outputs) with what was in that listing.

One set of outputs is community-based EGS research for representative communities, but there has been no discussion of what representative means (representative of what?) nor how many communities will be included.

There is nothing under ReServe Regional EGS in the list of outcomes and outputs.

The outputs under Enhancing Community Public Health need to be done collaboratively with

Human Health Risk Assessment. Otherwise it sounds as though this program is reinventing the wheel.

B. The SHC's fourth theme investigates sustainability practices within four high priority decision sectors identified during SHC community listening sessions. These sectors are: transportation, land use, buildings and infrastructure, and waste and materials management. There are three primary goals: to assess opportunities for communities to achieve greater synergies from practices within a given sector and across multiple sectors; to provide methods to more comprehensively account for these practices in terms of their social, economic, and environmental outcomes; and to collaboratively apply and refine these findings in partnership with specific communities (e.g., Durham, NC).

Does the Committee agree that this fourth theme provides a useful way to integrate research within SHC? If so, what are the most important implementation questions that ORD must address?

I am shocked that water supply was not identified as a priority sector; or is the problem that this is the silo for SSWR. This is a topic where integration across programs is needed. This is an opportunity for the two programs to collaborate, using the approaches of SHC (e.g., ecosystem services) to tackle the water supply sector. Similar comments could be made about air quality. Little is said about integration across programs in the research plan. These four decision sectors strike me as what is left over once one has dealt with issues around air and water.

It seems that this theme is so far into the weeds that I don't see how this integrates SHC research.

As mentioned in an earlier comment, I am concerned that a national perspective is lost with the focus on individual communities. In the plan inadequate attention is being paid to how one takes the insights developed from working with one community and applies them to another community. That is the most important implementation question. It is not clear how many communities the program expects to be able to work with. Durham is the only one mentioned.

C. Does the Committee feel that SHC has the appropriate balance of breadth and depth in its design? If out year budgets continue to shrink, what areas should SHC maintain as the primary areas of focus? Can the committee recommend areas that SHC should invest in if budgets increase?

The highest priority theme in SHC is theme 2 (especially topic 2.1 as listed in the outcomes and outputs). That theme cannot be lost because it is fundamental to everything else. The focus on tradeoffs is appropriate and at the heart of the environmental decisions faced by communities. The ability to assess tradeoffs is fundamentally grounded in an understanding of ecosystem goods and services; the importance of developing this understanding is in Theme 2 but not adequately conveyed in the introductory section of this research plan. Classification of US communities is a critical component of theme 1 because it makes it more likely that tools developed for one community could be applied to other similar communities. Development of

the National Atlas of Sustainability is also a priority in theme 1 because it should provide a useful synthesis of information at a national scale that is fundamental for assessing tradeoffs. Peer review of that product is essential. Development of that atlas requires the assessment of ecosystem services described in theme 2. The highest priority actions in theme 2 are development of the National Ecosystem Goods and Services Classification System (NEGSCS) and the Ecosystem Goods and Services Production Function Library. I don't even see those listed in the table of outcomes and outputs! Or if they are there, those names are not used. Topic 3.3 (integrated nitrogen) is of highest priority in Theme 3.

The process by which this research plan was developed engaged a diverse group of stakeholders, which appears to have resulted in a plan that responds to the most pressing tradeoffs facing communities. However, a fairly limited number of communities and five of ten EPA regions were represented in the various sessions (Appendix B). Clearly the program needs to begin somewhere, but there are so many communities and they are so diverse in their environmental settings, capacities (economic and social), and willingness to use new approaches that I have difficulty accepting that approaches that work in a relatively progressive town like Durham will have broad application nationally. Therefore if additional funding were to become available, additional case studies of the application of TRIO in a greater number and diversity of communities should be done.

Comments from Dr. Amanda Rodewald

1. FIRST YEAR PROGRESS
Charge Question: How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

In terms of revising the Strategic Research Action Plans, the Agency did a fine job responding to comments from SAB/BOSC last year. Among the major accomplishments were the:

- more explicitly linking the research framework and the vision to sustainability.

- community listening sessions, which have helped to identify priority areas within the program. Engaging communities early in the process will undoubtedly serve the programs as they mature.

- addressing cross-cutting issues, as has been done with the research integration examples

-identifying key partnerships needed to support the research

I would have liked to see a more developed plan for building capacity in the core expertise areas needed for programs as well as a stronger role for behavioral and social sciences.

2. SUSTAINABILITY
Charge Question: How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

Research is needed to elucidate interactions among anthropogenic stressors and services, as well as to identify thresholds or tipping points that when exceeded ecological and human health rapidly decline.

Across all programs, there still needs to be a stronger and more explicit social and behavioral science element with a plan for developing in-house expertise in those areas or a mechanism for stable/reliable partnerships.

3. BALANCING IMMEDIATE PROGRAM NEEDS AND EMERGING ISSUES
Charge Question: As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

Ensuring that there is within-Agency expertise and capacity on certain foundational topics would seem to be the best strategy to promote responsiveness.

4. PROGRAM SPECIFIC QUESTIONS
Sustainable and Healthy Communities Charge Questions:

The Sustainable and Healthy Communities Research Program incorporated a number of diverse research elements (e.g., ecosystem goods and services, human health outcomes, waste and contaminant remediation, environmental indicators) in building a research program focused on supporting community decision-making. The SHC Strategic Research Action Plan aims to provide science-based research and tools to assist communities in evaluating their decisions from a sustainability perspective. What advice can the SAB/BOSC provide to help ensure this research and these tools will most effectively support communities in doing so?

I applaud the SHC's efforts to conduct actionable science and develop decision-support tools to help communities as they make choices related to sustainability. One concern that I have about the development of the tools is that the Strategic Research Action Plan emphasizes <u>information</u> as the key piece of the decision-making process that limits the ability of communities to make more sustainable choices. While information is certainly important, the literature is rich with studies and examples indicating that the decision-making process is often more limited by behaviors, judgment errors, different value systems, or perspectives about the appropriate spatiotemporal scales for the decision (e.g., the time horizon over which to consider costs/benefits). This point was discussed at length last year and was indicated in the letter to the Administrator.

Thus, there remains the tacit assumption that if community decision-makers and stakeholders are provided with both technical information and a decision-support tool, they will choose courses of actions that are more sustainable and/or healthy for the community (i.e., relatively consistent with what EPA might consider to be a positive outcome) than they otherwise would. However, local stakeholders are motivated by a number of factors that likely operate over smaller spatial and shorter temporal scales than the Agency. This means that a successful/useful decision-support tool from the community's perspective might not actually lead to positive changes in the human health/environmental attributes that the EPA protects and regulates.

If the ultimate goal of the EPA is to positively affect the environment and community health, providing even the best information may not result in improved sustainability if the decision-makers' goals or values do not align with those of the EPA. Even in cases where values do align, structuring the decision-support tool in ways that ensure full consideration of a wider range of environmental & social values/goals would promote better decisions. Identifying the most effective language/framing and presentation of data (e.g., absolute numbers vs. proportions vs. ratios) related to framing also is also needed. It is imperative that the SHC program build more capacity in social sciences.

The Strategic Research Action Plan emphasized measuring and quantifying ecosystem goods and services, environmental indicators, human health outcomes, etc., but understanding the interrelationships among them is equally critical, as there are likely to be synergies and feedbacks. The interrelationships were probably best addressed in Theme 4, but research that aims to elucidate interactions and identify thresholds of anthropogenic stressors or tipping points is important to maintain throughout the entire program.

The SHC's fourth theme investigates sustainability practices within four high-priority decision sectors identified during SHC community listening sessions. These sectors are: transportation, land use, buildings and infrastructure, and waste and materials management. There are three primary goals: to assess opportunities for communities to achieve greater synergies from practices within a given sector and across multiple sectors; to provide methods to more comprehensively account for these practices in terms of their social, economic, and environmental outcomes; and to collaboratively apply and refine these findings in partnership with specific communities (e.g., Durham, NC). Does the Committee agree that this fourth theme provides a useful way to integrate research within SHC? If so, what are the most important implementation questions that ORD must address?

I agree that the program has correctly identified the most pressing decision sectors for communities. I especially liked how the fourth theme explicitly aimed to account for unintended impacts of actions and linkages among issues.

Does the Committee feel that SHC has the appropriate balance of breadth and depth in its design? If out year budgets continue to shrink, what areas should SHC maintain as the primary areas of focus? Can the committee recommend areas that SHC should invest in if budgets increase?

The breadth seemed appropriate to me, but the depth seemed inadequate in some places. As explained above, the emphasis seemed to be on developing metrics and indicators rather than developing an understanding of the interrelationships among environmental/ecological and human/social factors. In addition, the example outputs didn't seem linked to EPA research and original science. Rather, I questioned if the role of EPA was more to compile existing data rather than to produce new science – even through synthesis or metaanalysis.
If the program had to focus on a priority area initially, I would choose Theme 2 (Forecasting and Assessing Ecological and Community Health) because it is the most tightly linked to actionable science and research that the EPA is prepared to conduct now. The science in Theme 2 also is the foundation for all other themes. In a period of declining budgets, I would deemphasize the decision support tool, given that its success requires additional investment of resources, therefore this would not be my choice of a focal area were budgets reduced.
Investments are needed in behavioral sciences, as explained above.

5. INTEGRATION ACROSS PROGRAMS
Charge Question: Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

The focal topics selected for integration across programs represented some of the most important and complex issues facing the Agency and communities alike. The approach to integration was well-conceived and clearly presented.

6. INNOVATION

Charge Question: How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

The Innovation activities are creative and exciting and seem likely to support Agency science. I don’t have any new ideas to add currently.

Comments from Dr. Jonathan Samet

Initial Review Comments: Human Health Risk Assessment

General Comments

These overview comments relate to the general topic of human health risk assessment, as typically defined and not as constrained by the Agency's four themes in the *Human Health Risk Assessment* Strategic Research Action Plan, 2012-2016. In the 2011 joint report to Administrator Jackson, a recommendation was made to make human health risk assessment (HHRA) one of the six major themes. This recommendation has now been followed. In part, this approach reflects the programmatic nature of several of the themes of HHRA, including the IRIS Program and the development of ISAs in support of the assessment of the NAAQS. The methodology of risk assessment is an element of Themes 3 and 4 and it is also prominent in the themes of *Chemical Safety for Sustainability* (CSS). Thus, the methods of risk assessment are mingled with the problems to which they are being applied. This mingling seems to have been problematic previously as the positioning of HHRA was considered; the current integrative diagram (Figure 4 in *EPA Research Program Overview 2012-2016* reflects this difficulty. Risk assessment itself (whether for human or environmental health) is a foundation for application and problem scoping and management and not a set that only overlaps with components of other sets as portrayed.

This positioning of risk assessment may have real implications, given the imperative for EPA to continually refine and enhance its risk assessment methodologies. Various reports, from the Agency, the National Research Council (NRC), and others, have urged refinements and even major changes to Agency approaches, as with the 2011 NRC report on the draft IRIS formaldehyde assessment. Across the six programs, risk assessment figures to varying degrees. Within CSS and HHRA, risk assessment methods are mentioned extensively. While cross-program integration is proposed, the relevant agendas within these two programs are largely separated and the basis for selecting outputs and giving them priority is not clear. Even within HHRA, there is not adequate connection and synergy. For example, transparent evidence synthesis is integral to both the IRIS Program and the development of the ISAs, but this connection is not made.

Additionally, HHRA, as for other programs, would benefit from the integration of social, behavioral, and decision scientists into the activities related to risk assessment methodology in support of decision-making. This recommendation from the prior review remains relevant.

Human Health Risk Assessment Charge Questions:

• *The HHRA research program is committed to modernizing methods to evaluate the health effects of pollutants, consistent with advice of the SAB/BOSC and National Academy of Sciences. What aspects of the hazard and dose-response assessments produced by the HHRA research program are most likely to benefit from the application of state-of-the-art data streams and methods (e.g., in vitro toxicity testing results, gene expression profiling data, bioinformatics and QSAR modeling)? Additionally, what approaches can be envisioned to enhance risk managers' understanding, use and acceptance of these new methods?*

This charge question is quite broad in its reach and not readily answered with specificity. It points to the many new sources of data that are relevant to risk and the complexities of integrating them into practice. The many options call for strategic planning to take advantage of

ever-richer data sets. The Agency will need enhanced capacity in bioinformatics and in integrative modeling. As to which data stream should receive emphasis, there is no ready answer. Here, cross-talk across programs is needed.

The second component of this question, related to risk managers, also has no straightforward answer. Clearly, risk managers need to have information presented in ways that demarcate what is known from what is not known and that portray uncertainty in a useful way. This obvious statement applies, regardless of the underlying data used to characterize risk both qualitatively and quantitatively. Here, there is a topic for Agency research; how should evidence from these new lines of investigation be combined with evidence from "traditional" sources? The question is mis-phrased and efforts should be directed at the utility of these new data sources for decision-making and not at "risk managers' understanding, use, and acceptance." Isn't this an appropriate topic for investigation by decision-scientists?

• *In the 2010 mid-cycle progress review of the HHRA program the Board of Scientific Counselors noted that "IRIS assessments and ISAs are among the most heavily peer reviewed documents provided by scientists anywhere." How can the HHRA research program efficiently obtain robust peer reviews that contribute to the scientific integrity of assessments without impacting the timely provision of documents with public health value? Additionally, can the SAB/BOSC provide advice on the appropriate overall balance of peer review of individual products versus other recommended scientific capacity building activities?*

The Agency should have the overall goal of providing its assessments in a timely way. This goal has not always been met, particularly for the IRIS assessment and the past Criteria Documents. More recently, the Agency has been completing the peer review of the ISAs in a timely fashion, in part because of court-ordered deadlines. Additionally, the switch from the Criteria Document to the ISA format has led to more synthetic and transparent documents that can be more readily reviewed. Some of the IRIS assessments that have been tardy in being completed have been overly long and found to be deficient in various ways. The plans to change the process used to carry out the IRIS assessments should enhance peer review.

As to the specific mechanism of peer review, I do not have specific guidance at this point. Various approaches have been used and various entities have been involved. A tiered, screening strategy might be useful that is reflective of the underlying complexity of the assessment being reviewed. Regardless, "rigorous peer review" cannot be sacrificed to expediency. The suggestion that there is a trade-off between peer review and scientific capacity buildings seems artificial, lacking further explanation.

Comments from Dr. Daniel Schlenk

1.Charge Question: How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

Only 3 tasks of the CSS program had FY13 deadlines. Most of the tasks were vague and would be difficult to quantify whether objectives were accomplished. How is "success" to be measured? Nearly all of the tasks had FY16 deadlines. Since the funding cycle is 2012-2016, it will be impossible to address progress until the cycle is over. A sequential plan of specific objectives and annual or even semi-annual deadlines needs to be utilized to quantify success.

2.Charge Question: How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

The SAB/BOSC recommended that social, behavioral, and decision science be implemented into research strategies to move ORD's focus toward sustainability. Areas of focus included risk communication, evaluating aspects of uncertainty analysis and incorporation of policy regulators/stakeholder input from regional program offices into the strategic vision of ORD. While these aspects are central in the problem formulation aspects of risk assessment paradigm (i.e. stakeholder input), it would appear the Agency is actually pursuing linkages with Risk Management strategies which incorporate the social, behavioral and decision sciences (economics) subsequent to risk assessments.

The provision of Dashboards will likely help policy makers and regulators incorporate the information generated through the tools that are constructed by CSS. This should be a priority for all of the Themes.

The two areas of Green Chemistry and Chemical Life Cycle Assessments are logical areas to incorporate sustainability into ORD's research program. However, it was unclear how specific interactions between engineers, synthetic chemists and social scientists (economists?) would be linked together. How will these individuals communicate with one another? What are the specific mechanisms that will allow social and natural scientists to blend? Perhaps some specific examples of how these groups have collaborated or will communicate could be provided with specific goals and objectives that can be measured.

3.Charge Question: As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

ORD should use risk-based strategies to prioritize research efforts. Efforts should be focused on issues where data gaps exist. Emphasis on computational tools and in silico predictive strategies should be highlighted to enhance the speed and efficiency of risk assessments. Inter and Intra-agency collaborations should continue to be a focus for research.

4.Chemical Safety for Sustainability Charge Questions:

• Is the CSS program well positioned to support EPA needs in the three key areas of endocrine disrupting chemicals, nanotechnology, and computational toxicology research?

The strengths of the CSS are associated with the provision of computational tools for more efficient and rapid risk assessments for legacy as well as emerging compounds (EDCs and Nanomaterials). Of particular concern in both human health and ecological risk is the phenomena of non-monotonic concentration-responses (particularly with EDCs), and mixtures in cumulative risk assessment paradigms. While mixtures were discussed in the ORD overview, threshold derivations with non-monotonic responses were not discussed and should be a focus in the development of a Cumulative Risk Paradigm.

• How well has the exposure component of the CSS research program progressed since its inception?

Based upon the documentation provided, it is unclear how well the exposure component has progressed as a time-line was not obvious. The models proposed (ExpoCast and SHEDs) seem appropriate and should provide accurate exposure assessments which will enhance risk characterization.

ORD (in collaboration with other federal entities (NIH, NSF) have rightly tried to determine metrics of exposure for nanomaterials. Nanomaterials elicit effects based on physico-chemical properties that do not always correspond to mass-based normalization. This is an excellent example of using common resources and collaboration among federal agencies to address a common concern.

Comments from Dr. Pamela Shubat

I. DRAFT SAB/BOSC CHARGE QUESTIONS FOR EACH BREAKOUT GROUP

1. FIRST YEAR PROGRESS

Charge Question: How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

My comments are limited to the HHRA SRAP (my assigned breakout group). Overall, the research activities described in the HHRA SRAP are ambitious.

Theme 1 (IRIS program): The IRIS program has been highly productive in the last few years, and has been under great scrutiny of late as the program responds to input from the SAB, BOSC, and NRC. The projected number of chemicals to be completed in the IRIS program in FY13 (15 chemicals) is impressive. Since many of the substances (e.g., benzo(a)pyrene; PAH mixtures. Libby asbestos, phthalate) will be closely watched due to the impact of changes in values, it is possible that challenges to the results will slow down progress. Additional metrics could be added to the program outputs as there are many improvements (e.g., enhanced documentation and materials from additional peer review) that might be used to gauge improvements in utility of the program's reviews (e.g. easier to use documentation may mean that values are used more readily or appropriately); quality (e.g., additional review perhaps yielding or confirming higher quality work); and the efficiency of the reviews (is continuous quality improvement in the efficiency of completing reviews now built into the program?).

Theme 4 (Modernizing risk assessment methods): One of the most impressive program achievements has been in moving the science forward on high- and medium-throughput studies and the computational toxicology that is needed to use the results. The FY13 program outputs in this theme (HHRA SRAP page 33) are very important to all of the new research programs, non-ORD programs throughout EPA, and clients outside of EPA that will use the results. While the outputs that are described for the coming year are timely and appropriately support the question for the theme, an additional output of annual training (beyond the RATE program described in the text as a basic course in risk assessment) is achievable and necessary to do more than place these new tools in the hands of users. ORD will need to provide comprehensive (multi-disciplinary, multi-program) education and training throughout EPA programs in order to promote the adoption of ToxCast, ExpoCast, and NextGen tools for toxicologists and exposure scientists, and to promote the acceptance of the results of these tools to risk assessors, risk managers, and science advisors to the communities affected by risk management decisions. Education efforts are needed immediately and frequently so that the capacity of potential end users (e.g., risk assessors and managers) grows along with the emerging work products. EPA has an excellent, excellent information-sharing tool in the web-based communities of practice (http://epa.gov/ncct/communities_of_practice.html). However, additional education (scaled appropriately to the background and application needs of the end users) will be needed to ensure

that those who are not positioned to develop data, but will need to understand and use the results, are learning about the utility of these data as the products evolve. The adoption of new human health risk assessment tools has languished in the past (for example, the very slow adoption of BMDLs among various EPA programs, regional offices, and state programs) due to a lack of early training, lack of 'official' guidance, and a lack of relevant policy that is needed to utilize risk assessment methods (e.g., consensus on the interpretation of adverse effects). Such policy tends to develop (or at least honed) through the trial and error of application.

3. BALANCING IMMEDIATE PROGRAM NEEDS AND EMERGING ISSUES

Charge Question: As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

As described above, one way to achieve some efficiency is to use emerging tools to respond to emerging problems as a way to improve the utility, efficacy, and acceptance of new tools. EPA has already suggested that new activities will be taking place in certain communities. However, there are obvious drawbacks to this approach (a community preferring a better understood and established scientific approach; lack of transfer of results to other communities or broader problems; too many site specific projects may spread staff too thinly) which must be carefully weighed before investing resources in one location or emerging issue.

4. PROGRAM SPECIFIC QUESTIONS

Sustainable and Healthy Communities Charge Questions:
… The SHC Strategic Research Action Plan aims to provide science-based research and tools to assist communities in evaluating their decisions from a sustainability perspective. What advice can the SAB/BOSC provide to help ensure this research and these tools will most effectively support communities in doing so?

SHC has already engaged stakeholders in a needs assessment that was directed at communities, and the SHC SRAP describes the action plan as a response to supporting the needs of communities. The SHC program staff are to be congratulated for their work in understanding the needs of the communities that EPA aims to serve.

The SRAP describes output on methods to enhance children's health (Theme 2, Topic 2). Many of these lack the level of detail necessary to use the outputs as a metric of success (it will be difficult for a stakeholder to understand how progress is being made in the SRAP).

Human Health Risk Assessment Charge Questions:

The HHRA research program is committed to modernizing methods to evaluate the health effects of pollutants, consistent with advice of the SAB/BOSC and National Academy of Sciences. What aspects of the hazard and dose-response assessments produced by the HHRA research program are most likely to benefit from the application of state-of-the-art

data streams and methods (e.g., in vitro toxicity testing results, gene expression profiling data, bioinformatics and QSAR modeling)?

In the short-term, a very productive use of these methods will be to set priorities for developing additional dose-response data and subsequent guidance such as reference doses developed through the IRIS program. There is also an immediate need for comparative risk evaluations for substances that have little toxicity data for use in alternatives assessments for such applications as green chemistry. It appears from the HHRA SRAP that ORD is already working on such applications. A high priority should be placed on developing science policy around the question of what is an adverse effect in relationship to interpreting the results of high- and medium throughput testing.

In the long-term, assurances must be provided that these new scientific methods result in new research that explores and explains the links between environment and health for our most susceptible populations. Early life stage and exposure and sensitivity (including early life origins of late-in-life disease); the relationship between socio-economics, environment, and health; and cumulative exposure leading to cumulative risk throughout life require much more research. The benefits of state-of-the-art data streams and methods will ultimately be judged by the extent to which the use of these new methods result in faster and more definitive information that is successfully used to protect health through public health programs and environmental health protections.

Additionally, what approaches can be envisioned to enhance risk managers' understanding, use and acceptance of these new methods?

As mentioned in my response to charge question 1, ORD will need to provide comprehensive education and training throughout EPA programs, offices, states, and communities in order to promote the acceptance and adoption of Tox21 among risk assessors, risk managers, academia, and science advisors to the communities affected by risk management decisions. Also as mentioned, policy needs to be developed that make application of the results of the work possible. Such policy may best evolve at the community and state level through application.

Education efforts are needed immediately and frequently. One option may be to offer a next generation of risk assessment community of practice that is targeted to risk assessment and management application rather than ToxCast and ExpoCast development and validation. It will be important to grow the capacity of potential end users (e.g., risk assessors and managers) along with the tools so that the results are optimized for application and policy for use can evolve rapidly. EPA will need to identify innovators and influencers in various sectors (e.g., regional offices, state risk assessment programs, academia, science advisors from the non-profit sector, community leaders) and optimize training to match the background, experiences, and needs of these change leaders. Developing coursework and ensuring it is taught in influential toxicology and exposure science academic training programs; developing public health policy training through public health institutes; and similar tailored outreach will be helpful. In-laboratory rotations and visits will enhance understanding of testing techniques that are unfamiliar to most risk assessment practitioners. Providing education and training is a resource intensive activity

that requires specialized staffing and the support of management, and HHRA should be adding annual output goals in this area.

ORD staff already have a great influence on peer scientists through participation in professional meetings. ORD must continue to support scientists in offering symposia, workshops, and continuing education options focused on human health risk assessment at professional meeting. ORD scientists should continue to influence the content of scientific meetings by taking active roles in these societies. ORD is making excellent use of the newest technology by hosting webinars, and can extend this to training at the community, University, state, or regional level using videoconferencing, virtual meetings, or other remote access tools.

In the 2010 mid-cycle progress review of the HHRA program the Board of Scientific Counselors noted that "IRIS assessments and ISAs are among the most heavily peer reviewed documents provided by scientists anywhere." How can the HHRA research program efficiently obtain robust peer reviews that contribute to the scientific integrity of assessments without impacting the timely provision of documents with public health value? Additionally, can the SAB/BOSC provide advice on the appropriate overall balance of peer review of individual products versus other recommended scientific capacity-building activities?

ORD appreciates that the intensity of peer review is proportional to the importance of the product. Toxicology reviews, reference doses, and cancer slope factors are extremely important in programs across EPA and in environmental and public health actions carried out across the country. It is likely that the reforms already being implemented in the IRIS program, and that lead to greater transparency and stakeholder involvement early in the review process, will result in less onerous peer reviews. EPA will be able to address more concerns more directly during the review and stakeholders can target their comments more effectively in a peer review. The results of peer reviews could become more acceptable and the reviews more efficient if EPA management can more openly discuss the implementation policies or interpretations that could ensue from various aspects of a review (e.g., policy and remediation options that state or EPA risk managers might adopt or might need to adopt based on outcomes), so that the scientific findings can be evaluated with less prejudice concerning the application of the finding. This is in keeping with some of the ideas within the NAS report, Science and Decisions, that advocates for greater understanding (disclosure?) of the risk management options and how risk assessments will assist in evaluating options.

II. DRAFT CHARGE QUESTIONS FOR GENERAL ORD/PLENARY SESSION
1. INTEGRATION ACROSS PROGRAMS

Charge Question:

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs?

The Children's Health and Environmental Justice integration goal is built on a solid foundation of directives and planning regarding both children's environmental health and environmental justice. Early life stage exposure and sensitivity to hazards are well integrated into chemical evaluation, but ORD can take a stronger leadership role in ensuring that more options are available to programs that have not had an adequate focus on early life or disparities. HHRA can provide multiple reference doses, specifically including short-term duration periods suitable for evaluating windows of vulnerability to high exposures. Similarly, HHRA can explicitly describe populations that may face a greater risk due to genetics or other sensitivities and quantitatively describe this disparate risk. SHC can provide quantitative and qualitative guidance for estimating disparate exposures, cumulative chemical exposures (e.g., which chemicals should be grouped), non-chemical stressors (e.g., which stressors will have the greatest effect on health outcomes related to the exposures), and special sensitivities (e.g., pre-existing disease states) that should be evaluated in a risk assessment. All of these are long-known contributors to risk, but ORD has not offered specific and quantitative information on the contribution to risk.

The need for this work is described in the research integration document, but these are not simple problems and no simple solutions have yet emerged for complex issues such as using information about social determinants of health in developing health risk assessments. The two workgroups led by SHC that are charged with coordinating research are a hopeful indicator of longer-term success. However, transmitting this ORD work to programs throughout EPA may be difficult, and ORD should consider including influential program representatives from outside of ORD in the workgroup in order to facilitate the transfer of findings to end users.

Comments from Dr. Gina Solomon

Overall comments on the Human Health Risk Assessment Strategic Research Action Plan:

The document is very impressive, clearly-organized, and well-written. It outlines an ambitious plan that would take ORD in a very positive direction. This plan would help significantly to address criticisms that have been directed at the programs, and to move toward incorporating the new scientific advances in toxicology, exposure science, and risk assessment. Overall, the document is weakest in describing ORD's planned direction on exposure science, and this should be remedied, especially in light of the pending NAS report on this topic. The four themes are all presented as clear and distinct, and each is important for the future of HHRA. I did not identify any significant deficiencies in the plan, except the paucity of attention to exposure science as mentioned above.

1) What aspects of the hazard and dose-response assessments produced by the HHRA research program are most likely to benefit from the application of state-of-the-art data streams and methods?

It seems obvious that the IRIS assessments will benefit substantially from new data and new risk assessment methods. The IRIS program is at a point where it is under some pressure to 'reinvent' itself, because of criticisms the program has endured (some fair, and some unfair) over the past year. There are great opportunities to 'reinvent' the IRIS program by doing three main things: (1) substantially shortening and streamlining the documents to make them easier to use and to review, (2) incorporating Tox21 data, initially in qualitative discussions, then in parallel with traditional toxicology data, and ultimately as part of critical pathway-based extrapolations, and (3) incorporating the key recent recommendations from the NAS on reforming risk assessment, with a particular focus on grappling with cumulative risk, making implicit defaults explicit, better characterizing uncertainty, and exploring the unified dose-response. These points are all reflected in the Strategic Research Action Plan, although perhaps not as clearly as they could be.

It was also great to see that EPA is developing an approach to multipollutant standards in the ISAs -- this is a great context in which to develop approaches to cumulative risk assessment, since air pollutants are known to have interactive and cumulative effects, and there is a rich literature to draw on in order to develop a sound approach.

It is important not to lose sight of exposure science in all of these programs. The upcoming NAS Exposure21 report will increase attention to this area, and it was unfortunate to really only see discussions of exposure in the CRT section, when in fact it belongs in multiple sections. In particular, the Strategic Research Action Plan only mentions Expo-Box in the table on p. 30, and has no discussion of it in the text on pp. 20-22. This should be remedied, and at a minimum, the discussion of exposure science should be expanded in the text. All of the HHRA assessments will benefit substantially from state-of-the-art data and methods in exposure science.

Rapid turn-around risk assessments and crisis-level technical support may need to rely almost exclusively on some of the new data streams and methods in the near future. This is well-illustrated by the rapid assessment of dispersant mixtures during the Gulf oil disaster, where new

toxicology methods were used to rapidly screen various dispersants, and quick risk calculations formed the basis of risk management decisions. This approach is not ideal, since some of these tools may not yet be ready for that kind of 'prime time', but it may be the best we can do in a crisis. This example also provides significant incentive to improve EPA's approach to rapid screening and to the incorporation of the new data, since these will be what the Agency will need to turn to in a crisis; improvements in the process now will substantially improve ORD's readiness for the next emergency.

With regard to the section on "Modernizing Risk Assessment Methods", in the Strategic Research Action Plan, which seems to be responding directly to this question, there are numerous laudable efforts described. The efforts to educate risk assessors on the newer methods (the RATE program) is a much-needed approach toward improving the consistency of risk assessment across EPA and at other agencies. The HERO system is intriguing, and I am interested in learning more about it; such a system could be an extremely useful tool, if it is well-designed and thorough, and doesn't encourage 'dumbing-down' of the process. The goals articulated by ORD for this program (three bullets at the top of page 24) are an excellent starting place for this work.

2) What approaches can be envisioned to enhance risk managers' understanding, use and acceptance of these new methods?

It seems important to begin - as soon as possible - implementing and integrating some of these new methods into risk assessments. For some of the new toxicology approaches, the risk assessment calculations may need to be done in parallel, using both a traditional and a non-traditional approach, to see how the results vary for well-studied chemicals. For some of the new approaches to risk assessment, these can be incorporated qualitatively or quantitatively as part of an uncertainty analysis in the near-term (ie. using a unified dose-response, or incorporating improved assessments of variability and vulnerability). In some cases, specific chemicals in the 'pipeline' for risk assessment may offer opportunities to explore the use of newer approaches. Any of the upcoming assessments for which the chemical has undergone testing under the Tox21 regime should - at a bare minimum - present the data and incorporate it into a qualitative discussion. Upcoming assessments beyond the phthalates that could adopt a cumulative approach should do so, at least in stages.

3) How can the HHRA research program efficiently obtain robust peer reviews that contribute to the scientific integrity of assessments without impacting the timely provision of documents with public health value?

This is a critical question at the current time. The Formaldehyde review by the NAS has put significant pressure on the IRIS assessments, and has created an opening for the scientific integrity of these assessments to be questioned -- unfairly, in my opinion. The key recommendations of the Formaldehyde review included a focus on the cumbersome and confusing nature of the formaldehyde assessment, which was a fair criticism. Responding to that criticism by creating streamlined documents that are well-edited and easier to read will have several benefits, including improvement of the quality and usability of the IRIS assessments, and also a much easier job for peer reviewers. I was pleased to see this commitment in EPA's July

2011 announcement reprinted on p. 15 (ironically, the three bullets in the announcement are redundant - they all say essentially the same thing - so they could have benefited from editing too). Some models of risk assessments that are shorter, well-organized and easier to read can be found in documents issued by California's Office of Environmental Health Hazard Assessment, so perhaps these could be a model for future IRIS assessments.

This reviewer is also very concerned about proposals to bring large numbers of IRIS assessments for review to the NAS. NAS reviews are extremely time- and resource-intensive, and they provide no added benefit over an SAB review. The plan to create an SAB committee to review IRIS assessments is a reasonable approach to moving forward at the present time. It is of major public health importance that IRIS assessments are done in a timely and efficient manner, and multiple rounds of redundant peer reviews are a waste of federal funds without providing any significant added scientific benefit.

4) Can the SAB/BOSC provide advice on the appropriate overall balance of peer review of individual products versus other recommended scientific capacity-building activities?

The release of the three groundbreaking NAS reports (Tox 21, Science & Decisions, and Phthalates) has created enormous scientific pressure on EPA to modernize their overall scientific approach to risk assessment. This modernization needs to occur in parallel with the ongoing production of individual risk assessment products, since there is an ongoing need to provide the best possible current risk numbers for decisionmakers. However, in my opinion, the balance of effort should shift toward building EPA capacity to incorporate the new toxicology data into a new risk assessment approach. Perhaps the PPRTV approach could be a model in some ways, since the need is really for new IRIS assessments that will incorporate what we have now in a more streamlined way (more detailed than a PPRTV, but less-detailed than the current IRIS assessments), while also piloting new approaches. If EPA does not put significant effort into building the scientific capacity to integrate new toxicology data, and to figure out how to implement the recommendations to make defaults more explicit, employ a unified dose-response, and perform cumulative risk assessments, then these important reforms will not happen and EPA will be utilizing outdated science. EPA cannot allow itself to be left behind as the science of toxicology and risk assessment moves forward, so a significant shift of effort is needed.

Comments from Dr. Daniel Stram

Charge: provide additional advice on

- Plans to implement its six research programs
- Efforts to strengthen program integration
- Efforts to strengthen and measure innovation
    1. How can ORD's initial innovation activities be improved to ensure continued and long-term benefits for EPA?
    2. Are there useful experiences and lessons from other research organizations about managing innovation?
    3. What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

Preliminary written comments
My comments are in the following parts
1) specific comments relating to the response of the agency to the advice (October 2011) given by the SAB/BOSC in the document "*ORD New Strategic Directions: A Joint Report of the SAB and BOSC"*
2) more general comments mainly focused on the HHRA plans as outlined in the HHRA's *Strategic Action Research Plan*
3) comments on integration (forthcoming)
4) comments on innovation (forthcoming)

The October 21, 2011 SAB/BOSC report to Administrator Jackson emphasized a number of themes in its advice on the strategic plan(s) under review

- That sustainability should be included as a part of the research vision for each of the six programs and that a consistent definition of sustainability be described and applied
- That clear metrics for assessing progress towards sustainability be indentified
- The need to enhance the role of social behavioral and decision science research with ORD
- Need to strengthen research on natural ecosystems
- Further collaboration within EPA, with other agencies, extramural researchers (visitors, post-docs, etc) and international organizations to promote integration
- Increasing EPA's capacity to explore computational analysis and modeling of complex environmental data
- Early assessment of the progress of EPA's innovation initiatives

Specific advice was provided to all six programs however the strongest criticism seemed to be reserved for the plan for *Sustainable and Healthy Communities.* This program was criticized of a lack of clarity concerning the ORD's role in providing assistance to communities, related criticisms were of the vagueness of definition of the decision-makers/stakeholders needing decision support and lack of plans and metrics for evaluating the program; Lack of linkage with regional offices and the potential for misalignment between local and regional policies was

noted; under-funding of ecologic studies was also noted. Criticism of the remaining research programs was relatively mild; for ACE, CSS, HHRA and HS the committee suggested that stronger reference to a (properly defined) concept of sustainability was required. A suggestion was made that activities related to green chemistry and computational toxicology (CSS, HHRA) and how these could be applied in HHRA products should be highlighted. The HHRA document was criticized for not indicating how the program would meet the demand for increased number of values in the IRIS system.

The core criticism above of the SHC research program (i.e. lack of clarity about what kinds of community decisions and stakeholders will benefit from SHC research and how SHC would operationalize its goals of providing this advice) seems to be only partially addressed by indicating some of the kinds of community decisions that the SHC program is to be designed to deal with, such as zoning decisions, other land use planning, infrastructure needs, options for solid waste and disposal, transportation, etc. Implementation of the plans to offer assistance with these needs remains quite vague other than to indicate that this aspect of the SHC plan would build upon EPAs existing community-based programs and a list of these programs is provided. However at a more basic level the science questions proposed in the research plan seem very open-ended and difficult to assess success or failure for. I do like general ideas of developing a National Atlas for Sustainability, but I suspect that putting together such an atlas could be both scientifically challenging; because of the many inputs required (and uncertainties about their values) and politically controversial (no one wants their district declared unsustainable by the EPA).

It is not clear that there have been major changes to link each program research area to a unified vision of sustainability, the word "sustainability" is used a lot but rarely defined in any of the documents. While there are words to the effect (in some documents) that metrics will be developed or explored none are described.

The role of social, behavioral, or decision research within ORD is now mentioned (a few times) in the documents, and the SHC document specifically mentions (in a footnote) the goal of including either external experts or internal new hires in expanding either extramural or intramural research in behavior studies.

Discussion of the key role of ecologic research at the EPA is provided in both the ACE and SHC documents, no clear commitment to increase funding of ecological research is described however.

The overall strategic plan mentions joint work with other agencies (highlighting the "Net Zero" work with the Army) ; and the SHC plan is specifically responsive to the call by the SAB to collaborate with other federal and international agencies (and also highlights the Net Zero work). Regarding computational analysis and modeling of complex environmental data, the ORD overall research plan as well as the CSS and ACE plan describes using or evaluating computational methods in research on nutrients, climate change, and aerosols, and is mentioned also under methods development in the HHRA plan.

The assessment (for success or failure) of specific research topics is described in the SHC plan.

Regarding the progress on the plan for the HHRA. I found the related document (HHRA Strategic Research Action Plan) to be very readable overall. The research plan is quite clearly structured around a series of core tasks. Several of these (IRIS, ISAs) are important "legacy" programs that continue to need significant resources based on congressional mandates and agency needs. The Community Risk and Technical Support (CRTS) program is evidently new although I assume that EPA is already familiar with performing such assessments. The overall description of the program is much more task oriented than the remainder of the research plans. This is partly a reflection of the large "service" role that is played by IRIS, the ISAs, Provisional Peer Reviewed Toxicity Values (PPRTV), etc. However innovation is also stressed in the document, and perhaps more clearly than in much of the other material. The approach described to speeding up assessments (IRIS, PPRTV) by using innovative computer technology for literature review etc seems valid. The development of the HERO system seems both innovative and well motivated. This is in contrast to other parts of the review material (e.g. for SHC) where "tools" are alluded to but not defined or motivated.

Comments from Dr. John Tharakan

1. FIRST YEAR PROGRESS
The Strategic Research Action Plans were developed during 2011, with the benefit of SAB and BOSC advice [*Office of Research and Development (ORD) New Strategic Research Directions: A Joint Report of the Science Advisory Board (SAB) and ORD Board of Scientific Councilors (BOSC).* (EPA-SAB-12-001)].
Charge Question: How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

2. SUSTAINABILITY
The SAB and BOSC concluded in the October 21, 2011 report that "…ORD's research frameworks can advance EPA's adoption of sustainability as a core principle by more consistently and clearly describing where and how ORD research relates to sustainability."
Charge Question: How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

In general, research programs appear to be developing well with the appropriate (and commendable) focus on science based questions. Programs appear for the most part to be collaboratively developed with appropriate and adequate stakeholder input. Nevertheless, there are some gaps and omissions which are detailed in the specific comments below.

Some general comments:
There needs to be a clear and consistent definition of sustainability that is applied across programs and efforts. Not clear why EPA sees a need to (re)define sustainability per the NEPA (1969) instead of using the more globally accepted UN Brundtland Commission definition.

Research plans appear to have taken into account the SAB/BOSC recommendation to include sustainability explicitly in its research vision.

Specific Research Programs:
Homeland Security:
- Research program and plans are developing and progressing.
- Commend dedication to science based approach and framing of science questions.
- Some Gaps exist.
- Why does Homeland Security have no focus on linkage with Air quality?
- Lip service is paid to linkage to Natural Disasters – this is wholly inadequate given that more of the threats to homeland security will come from natural disasters brought on by global climate change. Hence it is unclear why there are no linkages between HSRP and NOAA, Coast Guard etc.
- Collaboration across Research Program – appears to integrate with other programs but needs to be placed under the umbrella of Safe, Healthy and Sustainable Communities. In my view, the Sustainable and Healthy Communities Research program should be renamed and refocused to be the Healthy Communities Research program and the six programs should be placed in the Universe (Venn Diagram) of or under the umbrella of Safe and Sustainable Communities which appears to be the theme that ORD is looking to develop and be.

- HSRP program design does not include Air. Why? Airborne contaminant release as a "terrorist" attack is as or more likely than water contamination.
- How about responding to a "drone attack"? It won't be long before our new favorite weapon of war will be smartly turned against us by some violent fundamentalist with a model airplane!
- Communication plans to public need to be better developed.

Sustainable and Healthy Communities:

- Commend the research plans collaborative development.
- Definition of sustainability – stick to one.
- Broad and inclusive overall program design
- Appropriate emphasis on community based and driven programs and projects.
- Need more emphasis on the primacy of the community in the research program. EPA is not an anthropology department.
- How has EPA sought community input and integrated that into workshops being conducted? Not clear if this is EPA (HQ) → EPA (State/Local) or EPA (HQ/State/Local) working with Community to develop, plan and deliver these workshops?
- One Science Question that doesn't appear to have been asked is in Theme 1:
- How to structure community engagement so that it is inclusive and broadly representative? ***EPA/ORD should be developing a model for such engagement.***
- Another science question that appears to be missing in Theme 2: Where is the community self-assessment brought into these programs and models? How is the need for that input communicated and how is it sought/obtained?
- In theme 3: A science question that needs asking is: How can communities that are most at risk be provided the tools and capabilities to assess and evaluate their environments and to monitor them on an on-going basis? What validity is given to community input through self-assessment?
- Theme 4 – Well developed, integrated and directed science questions.

Safe and Sustainable Water Resources:

- Strategic research action plan has been collaboratively developed and focuses research resources on protecting and safeguarding water resources and infrastructure.
- Challenges that have been identified are integral to developing the technologies, methodologies, processes and practices that will move our water resources towards sustainability and will keep them safe.
- Not clear how the best science will be "gotten out in front of tomorrow's problems" if there is not more partnership with scientists and engineers addressing similar problems in other places – want to see more international collaboration.
- Program design in commendable for level of integration and emphasis on developing partnerships from the start.
- Two themes focused on resources and infrastructure appears broad and inclusive enough.
- Priority science questions have adequate and appropriate focus on sustainability.
- Theme on water infrastructure needs to have an adequate balance on water management, technology and use/re-use design, community input appears missing.

3. BALANCING IMMEDIATE PROGRAM NEEDS AND EMERGING ISSUES

Meeting program and regional needs is a primary objective of ORD research. The highest priority needs of the programs tend to be those that are most immediate. Another important role for ORD is

to anticipate the future scientific needs of the programs and regions, areas of research that tend to get less support from the EPA partners. Anticipating emerging issues and investing in innovative approaches that could lead to more sustainable, less expensive or timely solutions often requires longer term and potentially higher risk research. The Strategic Research Action Plans strike a balance in addressing current priorities and future science needs; however, new emerging issues will likely arise that are not currently anticipated.

Charge Question: As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

- An ***ethics based*** approach needs to be developed at ORD. With the emphasis on safe and sustainable communities as the umbrella or Venn universe for the six different programs, an ethics-based approach may prove valuable. Are ethicists a part of the teams? When we talk about sustainability and environmental inequities, an ethics based approach can provide the rationale and justification for navigation of program priorities.

4. PROGRAM SPECIFIC QUESTIONS

Air, Climate and Energy Charge Question:

To create an integrated program, research in ACE is organized in three Themes: 1) Assess Impacts, 2) Prevent and Reduce Emissions, and 3) Respond to Changes in Climate and Air Quality. Research related to energy and environment is not a specific focus, but is most prevalent in Theme 2. Relevant topics include research on near-road air pollution, multi-pollutant research, and greenhouse gas impacts.

• How do we bring together research on biofuels, oil and gas measurement methods, combustion related pollutant effects and modeling/decision support tools into a coherent whole to address the environmental effects of energy production and use?

- EPA/ORD needs to take an integrated and systems-wide view (perspective) and approach. The approach needs to be broad, comprehensive, integrated across programs and community based and focused.

Safe and Sustainabile Water Resources Charge Questions:

• ORD has integrated programmatic research, with EPA Program Office input, to begin developing a strategic nutrient management plan for the nation with the intent of accomplishing the SAB's recommended goal to reduce reactive nitrogen by 25 percent. Are there research gaps that would impede accomplishing this goal? *(for example, should we be looking at green infrastructure for removing nutrients as well as for controlling storm water?)*

- Absolutely. An integrated approach should be employed at all levels and from all perspectives so that these multipronged problems are addressed holistically and with complementarity to achieve goals.

- To better accomplish our goal of using a variety of approaches to address stormwater issues, should EPA also consider incorporating natural infrastructure into research on constructed green and gray infrastructure?
    - Why not?

Sustainable and Healthy Communities Charge Questions:

• The Sustainable and Healthy Communities Research Program incorporated a number of diverse research elements (e.g., ecosystem goods and services, human health outcomes, waste and contaminant remediation, environmental indicators) in building a research program focused on supporting community decision-making. The SHC Strategic Research Action Plan aims to provide science-based research and tools to assist communities in evaluating their decisions from a sustainability perspective. What advice can the SAB/BOSC provide to help ensure this research and these tools will most effectively support communities in doing so?

- The approach at all times has to be community inclusive, community based and attempt as much as possible to be bottom-up given institutional and governmental constraints. To most effectively support communities, all community stakeholders need to be part of the problem identification and development of an approach for solution.

• The SHC's fourth theme investigates sustainability practices within four high-priority decision sectors identified during SHC community listening sessions. These sectors are: transportation, land use, buildings and infrastructure, and waste and materials management. There are three primary goals: to assess opportunities for communities to achieve greater synergies from practices within a given sector and across multiple sectors; to provide methods to more comprehensively account for these practices in terms of their social, economic, and environmental outcomes; and to collaboratively apply and refine these findings in partnership with specific communities (e.g., Durham, NC). Does the Committee agree that this fourth theme provides a useful way to integrate research within SHC? If so, what are the most important implementation questions that ORD must address?

- Four identified sectors do appear to essentially cover all community needs. Question that needs to be answered all the time and kept at the forefront is whether the community is on board, whether EPA actions are consistent and align with community priorities.
- EPA/ORD should have, as a component of Safe and Sustainable Communities theme, an effort to assist communities in making self-evaluations and assessments, so providing knowledge transfer to make this possible or enhance it should be a priority and goal.

II. DRAFT CHARGE QUESTIONS FOR GENERAL ORD/PLENARY SESSION

1. INTEGRATION ACROSS PROGRAMS

By their very nature, environmental issues are cross-disciplinary. Pollutants move and change across air, land, water and species. Energy, health, environmental justice and ecology are cross cutting topics. To organize research that is so intertwined requires a structure. By realigning its program from 16 distinct research topics to six related programs, ORD has made it a priority to eliminate stove-piped research and foster integrated, transdisciplinary research.

In the first year of implementation, the National Program Directors are in the early stages of managing each research program, while also taking steps to integrate across the six programs. This requires a balance of formally organizing and integrating research that relates to multiple programs, without creating additional, separate research programs.

While there are numerous topics that involve integration, ORD has selected five examples to present as case studies for the SAB and BOSC to consider. These five integrated topics reflect a range of dimensions including:

- topics that ORD has just begun to integrate and others that are further developed
- topics germane to every research program and others more narrowly focused among two or three
- topics that are more immediately client-driven and others that are longer-term

Comments on Integrated Topics:

- Nitrogen

Integrate nitrogen across all research programs.
Conduct broad research on Nitrogen mitigation techniques?

- Global Climate Change

No integration with NOAA etc?

- Children's Health/Environmental Justice

How are determinations made of vulnerable groups?
Increase focus on these vulnerable populations
How is EPA ensuring that all possible impacted vulnerable groups and their concerns are addressed?
How is EPA research being communicated to communities that might not be part of the workshop culture?
Need to ensure community representation and involvement at all levels.
How much community input into Plan EJ 2014?
Good level of integration in plans.

- Applying new chemical assessment approaches in human health risk assessment

Unclear how Communities are engaged in this and supported.

- Endocrine-mediated Dose-Response

Charge Question: Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

Use ethics based assessments.
Continue and expand integration across programs.

2. INNOVATION

The Path Forward principles that guide ORD's realigned research program emphasize pursuing innovative, ground-breaking research. To address increasingly complex and expensive environmental problems, innovative solutions are needed.

Charge Question: How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

- Need to be able to estimate the impact on the ground of the "innovation"
- Develop mechanisms/models to estimate probability of positive impact.
- Impact must be assessed in terms of the benefit to the community, the cost to the community, any issues of differential environmental benefits and burdens across the community demographic.
- Impact of innovation must also be addressed in terms of benefit to the communities that are stakeholders and party to environmental interventions whether the actions Is remedial or simply ameliorative.
- Bottom line is the quality of life improved? At what cost? And to Whom? Taking innovation into the community.
- Seek innovation from the community – they are best informed and aware of their problems.
- PIP projects an excellent way to proceed. Need to expand and support successes.
- What continuing support is provided to sustain innovation?
- Need to develop standardized methods to track outputs, outcomes and successes.
-

Comments from Dr. Russell Thomas

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

No response.

How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

In last year's SAB/BOSC response to a similar question, the joint committees recommend that: 1) ORD revise each research framework to include sustainability explicitly in its research vision, invoke a definition of sustainability shared across ORD, and demonstrate clearly how planned research relates to the key components of sustainability (the environment, the economy, and society); and 2) sustainability metrics for each research program will be needed to gauge whether research helps attain sustainability goals, even if such metrics only provide early markers of these long-term goals. Although it appears that the CSS Strategic Research Action Plan (the only one I reviewed) includes sustainability in its research vision and its use of the term is consistent with that used in the general overview, no clear metrics were proposed for measuring whether the research helps attain sustainability goals.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

Decisions relating to the balance between the Strategic Research Action Plan and the need to advance science on emerging issues should be made in close partnership with EPA program offices.

Is the CSS program well positioned to support EPA needs in the three key areas of endocrine disrupting chemicals, nanotechnology, and computational toxicology research?

In general, the CSS program is positioning itself appropriately to meet the needs of the agency. However, in my opinion, there are several areas that need to receive additional attention.

1. Assay validation, use of proprietary assays, and peer-review of assay interpretation. There is continuing discussion in the toxicology community regarding the appropriate level of validation, transparency, and peer-review associated with the ToxCast assays, signatures, and interpretation of the results. The NCCT has begun to take a position on these subjects as outlined in a presentation by Richard Judson at the Evidence-Based Toxicology Collaboration. Since these assays and the overall approach appear to be an important part of the CSS Strategic Research Action Plan, the validation topic should also be included in the plan together with a discussion on how external stakeholders will be

engaged. The plan for validation, transparency, and peer review should be reviewed by the BOSC/SAB.

2. Integrated experimental and computational effort to understand what is normal range of variation in the *in vitro* test systems and the context to which the assays are activated. It is well known that cellular pathways and processes can have significant normal intra-individual variability. For example, TP53 protein levels can differ over 20-fold during the course of a normal circadian cycle (Xu *et al*., Can J Cardiol 25:473, 2009) and exercise and diet can also activate TP53 (Hoene *et al*., Diabetologia 53:1131, 2010; Soliman *et al*., Evid Based Complement Alternat Med 2009). Further, the NFkB pathway can be pro-apoptotic or anti-apoptotic depending on the context in which it is activated (Lin *et al.*, Cell Death Differ. 6:570, 1999). Given the importance of linking perturbations in these pathways to adverse effects, there needs to be greater emphasis and a dedicated effort described in the CSS Strategic Research Action Plan for understanding the normal range of variability associated with the *in vitro* high-throughput screening assays and the context in which they are being assayed.
3. Targeted testing. Both the CSS Strategic Research Action Plan and the NRC report on Toxicity Testing in the 21st Century include targeted testing as part of its strategic vision for how we need to perform toxicity testing in the future. In fact, 'Targeted Testing' is one of four primary levels of 'Data Generation and Interpretation Tools' in Figure 1. However, other than the box represented in Figure 1, there is no mention of 'Targeted Testing' in the CSS Strategic Research Action Plan and it is not clear what research activities or interpretation tools are in development related to 'Targeted Testing ' in the different themes. The remaining levels - 'Inherent Properties' , 'Screening Assays', and 'Systems Models' – are all prominently discussed, but not 'Targeted Testing'. *In vitro* assays, QSAR, and computational modeling cannot meet all of our testing needs, especially in the near-term.
4. Higher throughput ADME beyond parent compound metabolism and protein binding. Toxicity depends on dose and, specifically, on the target tissue dose of the toxic moiety. There is a paucity of published pharmacokinetic and physiologically-based pharmacokinetic models relative to the number of chemicals being used in commerce or in the environment. A greater emphasis needs to be placed on higher throughput development of these models and measurement of the associated pharmacokinetic parameters. Some effort has been made by the NCCT towards measuring parent chemical metabolic clearance and plasma protein binding, but additional effort (both experimental and computational) need to be made towards estimating volume of distribution/partition coefficients, renal excretion, bioavailability, and what metabolites are generated.
5. Near-field exposure model development and validation. See response below.

How well has the exposure component of the CSS research program progressed since its inception?

Using only the documents provided, it is difficult to fully evaluate the extent to which the exposure component has progressed since its inception. This is understandable since there is limited space in the strategic plan and exposure is only one of many efforts that need to be

briefly summarized. Since last year, there appears to be a greater recognition on the importance of exposure since it is mentioned frequently in the document and there is an example on using integrated exposure and effects information (Example 3 under systems modeling). However, there are other important exposure efforts in ORD that are not mentioned (e.g., the mining of the Walmart MSDS data and ingredient lists). From my limited knowledge of the exposure component in CSS, I believe it is progressing well, but may be underfunded or underemphasized relative to other efforts within CSS. In my view, additional effort and resources should be put towards the refinement and validation of higher-throughput near-field exposure models. These models will be extremely important in putting the results from the *in vitro* high-throughput screening studies into appropriate context and will be absolutely essential for relevant prioritization. One way to begin to provide that emphasis would be to make exposure a theme in the CSS Strategic Research Action Plan. In my view, exposure could replace the biomarker theme (which seems pretty scant compared with the other themes) and the activities under the biomarker theme could be moved to the other themes (e.g., the biomarkers of exposure could be subsumed under the exposure theme and the biomarkers of effect could be moved to the systems modeling theme). Although making exposure a theme does not guarantee additional resources and the related activities may ultimately be the same, at least it would provide appropriate visibility to the effort.

How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

Although it is true that innovative ideas can come from anyone and ORD's innovation activities should continue to encourage the development and submission of these ideas from across ORD, my experience is that a select few individuals are more consistently innovative than others. I believe that the results from the two PIP competitions also bear this out since some of the finalists in the second PIP submission were awarded PIPs in the first round. I would suggest that the ORD identify these individuals within their organization and dedicate them towards specifically innovating on these difficult problems. The small multi-disciplinary team of individuals could be co-located to feed off each other. The team could be charged with interacting with other federal agencies to learn how they deal with related problems (e.g., DARPA, DOE), entertain visiting academic scientists with expertise in the problems, and have a direct line to communicate their findings to each of the National Program Directors. They also need to have some degree of freedom from the normal bureaucracy which can suppress innovation. In my view, this would create a true 'Skunkworks' team within EPA.

Comments from Dr. Paige Tolbert

I. SAB/BOSC CHARGE QUESTIONS FOR EACH BREAKOUT GROUP – AIR, CLIMATE, and ENERGY BREAKOUT

1. FIRST YEAR PROGRESS
Charge Question: How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

Responding to the question regarding how the Air, Climate and Energy (ACE) program is progressing in the first year of implementation must await the material on accomplishments which ORD will be distributing later this week, although the development of the Strategic Research Action Plan (STRAP) is clearly a major accomplishment, providing a well-articulated roadmap for the newly created program. Regarding the future activities planned for FY 13 and beyond, these plans appear appropriate and the various activities appear to be well-positioned to advance the agenda described in the ACE STRAP. Each of the three primary research themes – assessing impacts of air pollution and climate change, preventing and reducing emissions, and responding to changes in climate and air quality – is supported by a multitude of activities that will provide information critical to these themes. Since the Summary Tables of Outputs and Outcomes only provides the year the specified output is expected to be produced, it is difficult to have a sense of the overall timeline and relative emphasis on and investment in each of the activities; for instance, some may entail major, multi-year efforts and others may be minimal. In future rounds of updating the strategic plan, it would be helpful to give more information in this table – e.g., start- and end-date, effort committed or funding level, collaborators outside ACE. Related questions: will the STRAP be a living document? How often will the plan be updated? What are plans for assessing accomplishments relative to the stated plans? Is there flexibility to revise plans as information emerges and priorities evolve?

2. SUSTAINABILITY
Charge Question: How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

The combination of air, climate, and energy lends itself very naturally to the sustainability paradigm. By considering these three arenas jointly it is possible to create a more holistic view of how these inter-related areas impact one another and to consider co-benefits and unintended consequences of actions in one area on another. While the ACE STRAP does a nice job describing these interactions and the interest in studying co-benefits and unintended consequences, the ACE program seems to be a long way from implementing the kind of systems approaches that will be needed to fully understand and describe these interactions and predict the full impacts of potential actions and interventions. To accelerate the development of systems approaches, it may be helpful to have people with this expertise brought into the program, and to encourage extramural research in this area through RFAs and intramural systems-focused research and science through the innovations initiative and other avenues.

3. BALANCING IMMEDIATE PROGRAM NEEDS AND EMERGING ISSUES
Charge Question: As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

Of course, it is paramount to consider any efficiencies that can be achieved over the current status quo so that more can be accomplished with the shrinking budgets. Clearly integration is a way to achieve this end – reducing redundancies across programs and identifying synergies. Advancing the science on the topics described in the STRAP will (as the STRAP points out) lead to development of expertise that will be position EPA to respond to new issues that arise in the coming years. As pointed out in response to Charge Question 1 above, it will be important to have flexibility to drop certain planned activities if other activities are needed in response to emerging information and issues. Collaboration with NIEHS will be key to identifying scientific issues on the horizon that need attention.

4. PROGRAM-SPECIFIC QUESTIONS
Charge Question for Air, Climate and Energy: How do we bring together research on biofuels, oil and gas measurement methods, combustion related pollutant effects and modeling/decision support tools into a coherent whole to address the environmental effects of energy production and use?

This is a prime example of where systems approaches will be key – see response to Charge Question 2 above. Developing a full understanding of the entire spectrum of human health and ecosystem impacts of each of the energy options (using full life-cycle analysis and taking account of externalities) will be critical to providing effective decision support tools and laying the foundation for sound policy decisions regarding optimal and sustainable ways of meeting energy needs on multiple scales (community, regional, national, global). Currently, EPA scientists are for the most part working on separate aspects of energy questions, and there seems to be minimal effort devoted to making the connections between these different aspects. Understanding the various pieces does require focusing on them individually but integration will be the next step and this will require systems approaches which do not yet appear to be in place or under development. As has been done in the case of climate change, perhaps a Deputy NPD for Energy would help with developing a cohesive framework and vision for the overall research and science needs related to energy environmental concerns. Such a person could ensure that the connections between these very much inter-connected facets of energy research are drawn and made explicit and that expertise in the systems approaches is developed. In addition, an energy workgroup of staff from across ORD who are working on energy-related issues could convene periodically to review work and identify connections and possibilities for integration and collaboration.

II. CHARGE QUESTIONS FOR GENERAL ORD/PLENARY SESSION

1. INTEGRATION ACROSS PROGRAMS
Charge Question: Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

Tables of the activities for the illustrative examples of research integration show various separate activities and projects listed by program. It would be helpful to present the activities in a format that shows the linkages between the activities – e.g., how the output of one activity feeds into another or how the multiple pieces come together into a larger vision. Are there incentives in place to encourage collaboration on issues across programs? Are there mechanisms to ensure that turf battles and competition between programs are minimized and that collaboration, cooperation and coordination are rewarded? Several of the integration examples mention that securing steady support for the cross-cutting activity is a challenge – a commitment of multi-year funding and dedicated staff will be needed to ensure that the important cross-cutting issues have stable support.

2. INNOVATION
Charge Question: How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

The Innovation Team has been highly creative and energetic in its promotion of innovation at EPA, and has nice examples of specific successes it has engendered. As the program matures, it may be beneficial to shift the focus from support of individual innovation projects to identifying systemic ways to incorporate innovative thinking into the EPA culture in order to have a broad and sustained impact.

Comments from Dr. John Vena

Charge Questions for the Joint Meeting of the SAB/BOSC
Response from John Vena, July4, 2012

I. DRAFT SAB/BOSC CHARGE QUESTIONS FOR EACH BREAKOUT GROUP
1. FIRST YEAR PROGRESS
Charge Question: How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

As noted in the SAB/BOSC report consolidation should bring efficiencies and promote a systems approach to sustainability as an overarching framework for ORD research. The overview of the strategic plan effectively illustrated the new organization of the research programs and how the goals of each program relate to sustainability. The figures in the overview are well done and the definition of sustainability is well articulated. Each program description in the overview had a problem and vision statement, noted research themes, highlighted challenges, and described cross-program collaborations. From the examples of cross-program collaborations, there appears to have been a continued increase in transdisciplinary collaboration as well as coordination across ORD programs over the past year.

We recommended that ORD strengthen its research planning in several ways. ORD modified the plan and described all of its research as six integrated, cross-cutting research programs, rather than as four major programs plus two cross-cutting areas. To be successful, all six ORD programs should look for opportunities for broad problem formulation and science integration. We stated that as EPA develops a common definition of sustainability, the resulting definition should be used consistently across ORD. Figure 4 and narrative throughout the overview indicates that ORD addressed the concerns of SAB/BOSC. To advance sustainability as a goal, the research frameworks for each program should include sustainability as part of the research vision (this has been improved) and identify clear metrics for assessing progress toward sustainability goals (It is not clear to me that this was accomplished).

Ideally, each research framework would include sustainability explicitly in its research vision; invoke a common definition of sustainability; demonstrate clearly how planned research relates to the key components of sustainability (the environment, the economy, and society); and show how regional and program office science needs will be met. The overview narrative suggests that this was accomplished in each of the strategic plans. I read the Human Health Risk assessment Plan and believe that the framework is improved and addresses the concerns.

Interdisciplinary collaboration and research coordination across all areas could be strengthened by development of community of practice “core” teams in areas such as communication, decision tools and modeling, important to all six ORD research programs. Has this happened??

We stated that it may also be helpful for ORD to form an internal committee of cross-program futurists, with representatives from each research program to identify emerging issues and to consult regularly with the SAB, BOSC and other EPA groups and external stakeholders. Is this

the Research Coordination Team (RCT) described on page 13 of the HHRA Strategic Research Action Plan? Could the integration teams outlined in the five integration examples inform this effort?
Conclusion in Overview: "In alignment with EPA's mission of protecting human health and the environment, the Agency's Office of Research and Development has built this concept—science for a sustainable future—into the very foundation of all its research activities and scientific work." I agree with this conclusion. You are on the path to accomplish this.

2. SUSTAINABILITY

Charge Question: How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

In my view the key to sustainability is the integration of the science, communication across all program areas and implementation of the science to address community concerns and problems. The key to accomplish this is the continued training of EPA scientists and staff in methods to undertake the steps to meet the goals of the plan. It seems to me that more details are needed to outline the specific aims to ensure sustainability.

3. BALANCING IMMEDIATE PROGRAM NEEDS AND EMERGING ISSUES Meeting program and regional needs is a primary objective of ORD research. The highest priority needs of the programs tend to be those that are most immediate. Another important role for ORD is to anticipate the future scientific needs of the programs and regions, areas of research that tend to get less support from the EPA partners. Anticipating emerging issues and investing in innovative approaches that could lead to more sustainable, less expensive or timely solutions often requires longer term and potentially higher risk research. The Strategic Research Action Plans strike a balance in addressing current priorities and future science needs; however, new emerging issues will likely arise that are not currently anticipated.
Charge Question: As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?
The specific tables of outputs and timelines in each plan appear to have outlined priorities. Specific criteria should be developed on how to prioritize each of the tasks in the event of shrinking resources and/or emerging issues. Also how should and can emerging issues be rated in importance relative to the huge needs and backlog of work that needs to be done?
Human Health Risk Assessment Charge Questions:
• The HHRA research program is committed to modernizing methods to evaluate the health effects of pollutants, consistent with advice of the SAB/BOSC and National Academy of Sciences. What aspects of the hazard and dose-response assessments produced by the HHRA research program are most likely to benefit from the application of state-of-the-art data streams and methods (e.g., in vitro toxicity testing results, gene expression profiling data, bioinformatics and QSAR modeling)? Additionally, what approaches can be envisioned to enhance risk managers' understanding, use and acceptance of these new methods?

• In the 2010 mid-cycle progress review of the HHRA program the Board of Scientific Counselors noted that "IRIS assessments and ISAs are among the most heavily peer reviewed documents provided by scientists anywhere." How can the HHRA research program efficiently obtain robust peer reviews that contribute to the scientific integrity of assessments without impacting the timely provision of documents with public health value? Additionally, can the SAB/BOSC provide advice on the appropriate overall balance of peer review of individual products versus other recommended scientific capacity-building activities?

The vision articulated in the framework is:
The Agency will generate timely, credible human health risk assessments to Support all priority Agency risk management decisions, thereby enabling the Agency to better predict and prevent risk.

The four primary themes of the Human Health Risk Assessment program are:
• Integrated Risk Information System (IRIS) health hazard and dose-response assessments;
• Integrated Science Assessments (ISA) of Criteria Air Pollutants;
• Community Risk and Technical Support for exposure and health assessments; and
• Methods, models, and approaches to modernize risk assessment for the 21st Century
I believe the themes in bullets one and three are most likely to benefit from the application of state-of-the-art data streams and methods (e.g., in vitro toxicity testing results, gene expression profiling data, bioinformatics and QSAR modeling)?

SAB and BOSC recommended that ORD revise the documents so they more clearly communicate the intended research and its strategic science priorities. The Human Health Risk Assessment framework is improved and now highlights how the program will meet high priority program and regional needs, including the demand for an increased number of values in the Integrated Risk Information System. Regarding prioritizing programs for increased or decreased emphasis, the SAB and BOSC recommended that ORD conduct analyses to help develop criteria for prioritization. It is mentioned that HHRA has a goal of effective capturing, sharing, discussing and debate of knowledge across the program….. but how??

I was pleased to see in the plan the Risk assessment Training and Experience (RATE) program. It seems like a perfect mechanism to enhance risk managers' understanding, use and acceptance of these new methods. However, details were lacking. What is the course content, who will develop it, who are the target audiences, what are the focus areas?

The theme of this program "Methods, models, and approaches to modernize risk assessment for the 21st Century" has the potential to streamline the risk assessment methods and provide timely information for emerging issues with reduced uncertainty.

II. DRAFT CHARGE QUESTIONS FOR GENERAL ORD/PLENARY SESSION
1. INTEGRATION ACROSS PROGRAMS

Charge Question: Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

I agree that transdisciplinary and integrated, innovative research requires a balance of formally organizing and integrating research that relates to multiple programs, without creating additional, separate research programs.
The examples were helpful to see how integration is being formalized. The integration teams or workgroups (some with a dedicated team leader) focused on specific topics is an effective approach. The tables in Climate change and children's health examples were helpful in seeing how activities on specific topics cut across program areas. How many such topical areas are needed to facilitate integration across the programs?
A few of the integration plans are better developed than others. Management plans are stated but are inconsistent in details and approaches and timelines.

2. INNOVATION
The Path Forward principles that guide ORD's realigned research program emphasize pursuing innovative, ground-breaking research. To address increasingly complex and expensive environmental problems, innovative solutions are needed.
Charge Question: How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

In my view a much clearer articulation of the dimensions of innovation is needed. How are the research proposals and individuals ranked on innovation? What are the explicit criteria?
The PIPs program is a great idea and has spawned several great projects. However the number of proposals vastly outweighed the available resources and in year 2 only 5% of the proposals were funded. This seems to me to stifle the potential for innovation. Can all those great ideas be harnessed in some other way? Specific metrics should be applied to those projects that are similar to all the other research projects in ORD, such as publications, reports, communication of findings, specific aims were met, etc. In addition metrics on new methods, technologies, applications, etc could be developed.