BOSC
BOARD OF SCIENTIFIC COUNSELORS

August 25, 2020

Jennifer Orme-Zavaleta, Ph.D.
Principal Deputy Assistant Administrator for Science
Office of Research and Development
U.S. Environmental Protection Agency

Dear Dr. Orme-Zavaleta:

On behalf of the Board of Scientific Counselors (BOSC), I am pleased to provide you a review report addressing charge questions posed by two of the Office of Research and Development's (ORD) six National Research Programs.

The BOSC was reconstituted in 2017 with an Executive Committee and five subcommittees aligned with each of the National Research Programs (part of the Health and Environmental Risk Assessment program is reviewed in conjunction with the Chemical Safety for Sustainability program). Two of the subcommittees met in May–June 2020 culminating in an Executive Committee meeting in July 2020. This report represents the cumulative effort of the subcommittees and the Executive Committee.

We anticipate that this report will assist ORD in evaluating the strength and relevance of these two research programs and aid in guiding further course adjustments to each program. We will be happy to provide any additional information concerning the review or answers to any questions you may have, and we look forward to working with your in the future on these programs.

Sincerely,

Paul Gilman, Ph.D.
Chair, BOSC

Lucinda Johnson, Ph.D.
Vice Chair, BOSC

Cc: Bruce Rodan, Associate Director for Science

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REVIEW OF U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT'S RESEARCH PROGRAMS

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August 25, 2020

A Federal Advisory Committee for the U.S. Environmental Protection Agency's Office of Research and Development

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BOSC
BOARD OF SCIENTIFIC COUNSELORS

REVIEW OF U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT'S RESEARCH PROGRAM

BOSC Chemical Safety for Sustainability/ Health and Environmental Risk Assessment Subcommittee

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August 25, 2020

A Federal Advisory Committee for the U.S. Environmental Protection Agency's Office of Research and Development

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LIST OF ACRONYMS

A-E	Air and Energy
AOPs	Adverse Outcome Pathways
BOSC	Board of Scientific Counselors
CCTE	EPA's Center for Computational Toxicology and Exposure
CHEAR	Children's Health Exposure Analysis Resource
CPSC	The Consumer Product Safety Commission
CSS	Chemical Safety for Sustainability
EPA	U.S. Environmental Protection Agency
ECOS	The Environmental Council of the States
ERASC	Ecological Risk Assessment Support Center
ERIS	The Environmental Research of the States
FDA	Food and Drug Administration
HAWC	Health Assessment Workplace Collaborative
HHRA	Human Health Risk Assessment
HERA	Health and Environmental Risk Assessment
HERO	Health and Environmental Research Online
HHEAR	Human Health Exposure Assessment Resource
HSRP	Homeland Security Research Program
NAAQS	National Ambient Air Quality Standards
NAM	New Approach Methodologies
NCATS	NIH's National Center for Advancing Translational Sciences
NIEHS	NIH's National Institute of Environmental Health Sciences
NTP	NIEHS' National Toxicology Program
ORD	EPA's Office of Research and Development
OCSPP	EPA's Office of Chemical Safety and Pollution Prevention
OITA	EPA's Office of International and Tribal Affairs
OPP	EPA's Office of Pesticide Programs
OPPT	EPA's Office of Chemical Safety and Pollution Prevention
PAH	Polycyclic Aromatic Hydrocarbons
PBPK	Physiology-Based Pharmacokinetic
PFAS	Per- and Polyfluoroalkyl Substances
POD	Point of Departure
RA	Research Area
RACT	Research Area Coordination Team
SEM	Systematic Evidence Mapping
SHC	Sustainable and Healthy Communities
SSWR	Safe and Sustainable Water Resources
STAR	Science to Achieve Results
StRAP	Strategic Research Action Plan
STSC	Superfund Health Risk Technical Support Center

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INTRODUCTION

To protect human health and the environment, the U.S. Environmental Protection Agency (EPA) and its federal, state, and other government partners and stakeholders must make critical decisions about the risks of exposures to environmental stressors. The primary focus of EPA's Office of Research and Development (ORD) is to provide the strong scientific and technical foundation the Agency relies on to fulfill its statutory obligations and help Agency, state, and other partners address their most pressing environmental and related public health challenges. EPA designed the Health and Environmental Risk Assessment (HERA) program to develop and apply state-of-the-science research to characterize impacts on human and ecological systems – whether they result from exposure to single, complex, or multiple physical, chemical, or biological stressors – to support and improve EPA's risk assessment decisions. It is one of the Agency's six, highly integrated national research programs. The other five are Chemical Safety for Sustainability (CSS), Air and Energy (A-E), Homeland Security Research Program (HSRP), Safe and Sustainable Water Resources (SSWR), and Sustainable and Healthy Communities (SHC).

ORD prepares Strategic Research Action Plans (StRAPs) to guide its research planning over the ensuing 4 years, and beyond. The StRAPs are designed to guide an ambitious research agenda that delivers the science and engineering solutions the Agency needs to meet its goals now and into the future, while also cultivating an efficient, innovative, and responsive research enterprise. Currently, ORD is seeking input from the Board of Scientific Counselors (BOSC) on the draft 2019–2022 StRAP documents and proposed research strategies. The emphasis is on advancing ORD research that can successfully address the needs identified by EPA programs and regions, and states and tribes. This review by the BOSC CSS/HERA Subcommittee is focused on strategic directions and proposed research priorities described in the draft HERA StRAP. Future BOSC reviews will address research activities and outcomes over the course of the StRAP implementation.

BACKGROUND

To assist the Agency in meeting its goals and objectives, HERA developed a draft StRAP for fiscal years 2019–2022 (StRAP FY2019–2022). The StRAP outlines a four-year research strategy to advance the goals and cross-Agency priorities identified in the FY 2018–2022 EPA Strategic Plan. The StRAP builds upon prior StRAPs as outlined in the Human Health Risk Assessment (HHRA) StRAP, FY2012–2016 and FY2016–2019, and continues a practice of conducting innovative scientific research aimed at solving the problems encountered by the Agency. In 2019, as part of a reorganization of EPA's ORD, the name of the research program was changed from HHRA to HERA to better reflect the breadth of the program, which includes environmental assessments such as those presented in the Integrated Science Assessments for secondary National Ambient Air Quality Standards (NAAQS).

The overarching goal of the CSS national research program is to lead the development of innovative scientific methods and tools to reduce risks associated with exposure to chemicals in commerce, consumer products, food, and the environment. Because both the CSS and HERA research programs inform Agency activities related to chemical hazard and risk assessment, HERA-CSS integration is expected to be a key outcome of the generation of StRAPs, in order to advance the development and implementation of new methods and new data streams in risk assessment. The 2019–2022 CSS StRAP was reviewed in June 2019, so the subject of this review is restricted to the 2019–2022 HERA StRAP.

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STRAP RESEARCH OBJECTIVES

This HERA StRAP 2019–2022 outlines the structure of the overall HERA four-year research program design. HERA will provide priority assessment products, identify critical science issues as they arise, and develop or stimulate advances in approaches and solutions to address emerging challenges, incorporate innovations, and continuously refine applications. Ultimately, the goal of the HERA research program is to ensure that decisions by EPA are based on reliable, transparent, and high-quality risk assessment methods, models, and data.

The HERA research program is organized under two broad topics: (1) Science Assessments and Translation and (2) Advancing the Science and Practice of Risk Assessment. The implementation plan includes four research areas and 11 outputs.

- The Science Assessments and Translation topic provides scientific and technical support from development to application of assessment products, throughout the lifecycle of the Agency decision. Emphasis is placed on providing high quality, state-of-the-science, transparent, consistent, and scientifically defensible assessment products to meet EPA's diverse statutory and policy needs, and to address requests from EPA programs and regions, states, and tribes for technical support and consultation.
- The Advancing the Science and Practice of Risk Assessment topic focuses on scientific innovations to advance analytic approaches and applications for assessments to improve the accuracy, efficiency, flexibility, and utility of assessment activities served by the HERA program. Emphasis is placed on enhancing hazard characterization, expanding the repertoire of dose-response methods and models, and characterizing the utility of emerging data and new computational tools as applied to risk assessment. It also enhances and maintains critical assessment infrastructure, including databases, models, and software support.

CHARGE QUESTIONS AND CONTEXT

The CSS/HERA Subcommittee was charged with four questions as follows:

> Q.1a. Please comment on the extent to which the research outlined for the 2019-2022 timeframe supports the relevant Agency priorities as described in the EPA and ORD Strategic Plans?
>
> Q.1b. Each ORD research program undertook a rigorous engagement process to provide additional detail on specific EPA program and region, state, and tribal needs, the results of which are summarized in introductory sections, descriptions of specific research topics, and appendices. How well does the proposed foundational research program respond to these identified needs?
>
> Q.1c: Does the StRAP, including the topics, research areas, and proposed outputs, clearly describe the strategic vision of the program? Please comment on the extent to which the StRAP provides a coherent structure toward making progress on the strategic vision in the 2019-2022 timeframe.
>
> Q.1d: Recognizing ORD's focus on addressing identified Agency, state, and tribal research needs, are there any other critical emerging foundational research needs, or fields of expertise and/or new research methods, where this program should consider investing resources?

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SUBCOMMITTEE RESPONSES TO CHARGE QUESTIONS

The Subcommittee appreciates the efforts of the HERA program leadership and staff to develop and deliver a StRAP that builds on the prior HHRA program focused on advancing the scientific basis for risk assessments, including development of contemporary hazard identification and dose-response evaluations, and evaluation of new data and science for advancing risk assessment practice. The HERA StRAP explicitly identifies its role as supporting the needs of EPA program and regional offices, which is consistent with ORD's core mission as articulated in the ORD Strategic Plan. The research topics identified clearly support the goals of the EPA and ORD strategic plans. HERA research and translation efforts under the previous StRAP and those planned under the current StRAP are well positioned to significantly contribute to EPA's efforts to protect and enhance health and the environment. The technical support offered to EPA regions and states and the products to support decision-making are generally well connected with EPA's goals of a cleaner healthier environment and prioritizing robust science. Several overarching issues emerged during the review and are summarized below to help frame the specific responses to the charge questions.

The overall structure of the StRAP topics, research areas, and outputs necessary to achieve the strategic vision are appropriate and advance the science and practice of hazard and risk assessment. However, it was difficult to determine from the StRAP document how the goals will be accomplished through specific research projects and deliverables without more depth and detail on the implementation strategy. This can be accomplished without lengthening the document by providing appendix material with lists of specific projects, roles, and responsibilities.

A consistent theme throughout much of the Subcommittee discussion was the lack of metrics to define progress toward specific research outputs and a process for developing performance measurements and self-assessments. The ORD Strategic Plan clearly articulates categories of metrics ORD expects to use to link performance and progress with the Agency-wide strategy. The HERA StRAP would be improved by developing specific performance metrics commensurate with the guidance outlined in the ORD Strategic Plan.

An area of considerable discussion was the importance of integration between HERA and CSS regarding the development and usage of new methods and data types to support EPA's risk assessment decisions. While HERA has been active in research and training to advance the use of new data in hazard and risk characterization, little information was provided about the partnership with CSS and co-development efforts on tools or assays and how both groups integrate their efforts into the larger ORD strategy.

The Subcommittee also noted considerable confusion regarding the definition of exposure in the EPA risk assessment framework versus how HERA incorporates exposure science within the scope of the research activities covered in the StRAP. Exposure characterization is an essential part of any risk assessment. The BOSC believes that a statement of how HERA defines the exposure science component of risk assessment, and its role in advancing this aspect of the science, is critical for the HERA mission. Thus, the StRAP needs to be clear on how HERA incorporates exposure science to complement the hazard identification and dose-response characterization when providing support for a risk assessment and risk management plans.

Another missing feature of the StRAP was an approach to prioritizing and continuing research on chemical mixtures and cumulative risk assessment. This topic has come up in past BOSC meetings and reports, such that the absence of a plan was concerning. Mixtures research is critical to assessing real-world impacts and should be an explicit component of the HERA research program. For example, HERA should evaluate how new computational tools and new testing methods for mixtures of chemicals with co-exposure routes

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could be used to calculate cumulative risk, and not just for pre-formulated mixtures and mixtures of a class of chemicals (e.g., polycyclic aromatic hydrocarbons, or PAHs).

There was also little discussion in the StRAP regarding exposures to susceptible populations and risk factors for those populations including genetic variability, cumulative stressors, age, health status, pregnancy, and other population-level factors. Given the importance of susceptible populations for risk assessment, the Subcommittee felt that HERA should consider developing fit for purpose methods across the portfolio of projects that take into account both variability and sensitivity for factors contributing to increased susceptibility.

Detailed summaries and responses to each of the four charge questions follow below. The responses highlight strengths of the plan as identified by the Subcommittee, as well as suggestions for additions or clarifications to the plan that might reinforce priorities or enhance understanding of ongoing activities and initiatives. The responses also include specific recommendations for action by the HERA program leadership and staff for each charge question.

Charge Question 1a

> Q.1a. Please comment on the extent to which the research outlined for the 2019-2022 timeframe supports the relevant Agency priorities as described in the EPA and ORD Strategic Plans?

Narrative

The HERA StRAP aims to support the Agency priorities set out in the FY 2018–2022 EPA Strategic Plan, namely attaining (1) a cleaner healthier environment, (2) more effective partnerships, and (3) greater certainty, compliance, and effectiveness. The HERA StRAP likewise supports the corresponding goals identified in the ORD Strategic Plan 2018–2022, which include advancing environmental science and technology, facilitating cooperative federalism, and enhancing the ORD workforce and workplace. The HERA program is described as intended to "develop science assessment products that better meet the needs of EPA programs and regions, states, tribes, and external stakeholders." (HERA StRAP Draft April 2020). Interestingly, the StRAP frequently discusses the needs of the EPA programs and regions, states, tribes, but only has one brief mention of stakeholders. Given HERA's roles and responsibilities, it appears from the StRAP document that actions by HERA to directly address stakeholder needs are limited, and largely occur indirectly via use of HERA's work products by EPA programs and regions, states, tribes to address health and environmental issues faced by stakeholders.

The HERA StRAP identifies two main research topics: (1) Science Assessments and Translation and (2) Advancing the Science and Practice of Risk Assessment. The aim of translation focus is described as providing assessment products to meet EPA's statutory and policy needs, and to address requests from EPA clients. Work under the risk assessment focus addresses hazard characterization, expands the repertoire of dose-response methods and models, and supports/characterizes databases, models, and software for these elements of risk assessment. The StRAP lays out a program for evaluating and integrating information to characterize human and environmental hazards and evaluate qualitative and quantitative relationships.

Strengths:

- The HERA StRAP explicitly identifies its role as supporting the needs of EPA program and regional offices, which is consistent with ORD's core mission as articulated in the ORD Strategic Plan.

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Presentations by HERA scientists and managers, and from EPA program and regional representatives, reflected close, effective coordination between HERA and its EPA partners. As described in those presentations (and to a lesser degree in the HERA StRAP), outreach to the EPA program and regional offices is both formal and informal, creating a deep and adaptive network.

- From a substantive perspective, the technical support offered to EPA regions and states and the products to support decision-making are generally well connected with EPA's goals of a cleaner healthier environment and prioritizing robust science. HERA's continued work to translate and integrate products into the relevant decision contexts is important and impressive.
- HERA's focus on emerging and innovative assessment methodologies appears carefully aligned with the needs of EPA program and regional offices. The breadth of the outputs is appropriately broad, reflecting important advances in science and technology. Notable examples of significant progress include efforts towards integrating new approach methodologies (NAMs) into hazard identification and dose-response analysis and further developing the sophistication, speed, and utility of systematic review methods (including the use of machine learning for reviewing scientific literature).
- Overall, the research areas and outputs in the HERA StRAP clearly support the goals of the EPA and ORD strategic plans, and past and planned research and translation efforts and outputs by HERA are well positioned to significantly contribute to EPA's efforts to protect and enhance health and the environment.

Suggestions:

- While there are excellent efforts in outreach to EPA program office and regions, it is harder to see in the StRAP how outreach and interaction is occurring with state and tribal parties to support the ORD goal of cooperative federalism. The StRAP would be improved if additional details were included on HERA engagement with state and tribal parties to understand their priority needs and how these may be addressed by HERA through the areas of Science Assessment Translation, Emerging and Innovative Assessment Methodologies and Essential Assessment and Infrastructure Tools.
- Improving the organization and presentation of elements of the StRAP should be considered to highlight how it addresses EPA and ORD goals. In particular:
    - It would be helpful to specifically label and highlight HERA's mission and vision statements linked to the overall goals of EPA and ORD as call-out boxes in the StRAP document.
    - It would also be helpful to describe the outputs in more detail in Table 2, or as separate tables for each topic in the StRAP document.
- There is a pressing need for HERA workforce development and internal training programs. These are called out in the HERA StRAP, but the connection to HERA's research mission is not well articulated. In particular, while there is expertise in advanced/refinement of new risk assessment approaches (benchmark dose analysis, integration of physiology-based pharmacokinetic (PBPK) modeling into risk assessment), workforce development and training is needed in the integration of advanced and emerging bioactivity profiling methods (ToxCast, toxicogenomics, adverse outcome pathways (AOPs), in silico approaches, read-across, etc.) using weight of evidence assessment methodologies for hazard characterization and risk evaluation.
- The ORD StRAP does a good job of articulating and linking ORD performance metrics with the Agency-wide strategy. However, the HERA StRAP would be improved by developing more specific performance metrics and clearly linking them to ORD strategies and metrics.

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- There is a need to better describe research coordination and research management functions for activities that span HERA, CSS, and program offices (e.g., how the Research Area Coordination Teams, or RACTs, are organized and function).
- Given that HERA has an important role to play in implementing NAMs in risk assessment, it would be helpful if the StRAP included, as an illustrative example, the Agency's NAM strategy matrix management structure in a manner that shows HERA's roles, HERA's responsibilities, and HERA-specific science objectives (including leading or participating in the development of case studies) in relation to those of the other EPA programs that are involved in NAM implementation, such as the Center for Computational Toxicology and Exposure (CCTE), the Office of Pesticide Programs (OPP), and the Office of Pollution Prevention and Toxics (OPPT).
- HERA's StRAP rightfully focuses on the development, evaluation, and improvement of risk evaluation-relevant methods, and advancing these into practice. However, the StRAP does not address transparency and the role of public participation in these areas. The StRAP would be improved by including specific actions for enhancing opportunities for public participation and transparency (defined in Objective 2.2 from the ORD Strategic Plan), particularly in (1) the development, performance assessment, and proposed applications of new and improved methods, including NAMs, systematic review and evidence integration methodologies, AOPs, and biologically-based dose-response extrapolation models and (2) the development of HERA StRAPs.
- Within the HERA StRAP, efforts to include and evaluate uncertainty were not clearly stated. Although implied, explicit attention needs to be placed on (1) evaluating uncertainty and conducting sensitivity and predictive performance analyses; and (2) communicating these analysis outcomes since they are critical components for building the scientific confidence in new and improved methods for use in various hazard characterization decision contexts.

Recommendations

The Subcommittee offers these recommendations to support the relevant Agency priorities:

Recommendation 1a.1: The Subcommittee recommends including specific actions for enhancing opportunities for public participation and transparency (defined in Objective 2.2 from the ORD Strategic Plan), particularly in (1) the development, performance assessment, and proposed applications of new and improved methods, including NAMs, systematic review and evidence integration methodologies, AOPs, and biologically based dose-response extrapolation models and (2) the development of HERA StRAPs.

EPA Response:

ORD agrees with the BOSC subcommittee that it is important to be transparent and to provide opportunities for the public to participate in HERA program activities. At present, the majority of HERA assessment and research activities include public comment components, as conveyed through Federal Register and Internet notices of comment periods. Regarding strategic planning, ORD's primary input is from EPA programs and regions, along with increasing focus on state and tribal input, who as part of their direct public-contact relationships and experience convey various aspects of stakeholder and public priorities. Draft ORD strategic planning materials for the BOSC are also disseminated publicly prior to meetings, along with FACA-required meeting set-asides for public comment. Going forward, ORD will include this BOSC recommendation for increased public participation as we re-evaluate the

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strategic planning process ahead of StRAP4. Text has been incorporated into the revised StRAP to highlight public participation and transparency aspects where relevant.

Recommendation 1a.2: The Subcommittee recommends that a workforce development and training program strategy connected with research mission should be further articulated in the StRAP. Particular emphasis should describe the integration of advanced and emerging bioactivity profiling methods (ToxCast, toxicogenomics, AOPs, in silico approaches, read-across, etc.) using weight of evidence assessment methodologies for hazard characterization and risk evaluation. A similar strategy should be further developed in future StRAPs.

EPA Response:

ORD appreciates the BOSC recommendation and shares the importance of focusing on workforce development to stay abreast of advances in science, including in the human and environmental assessment space where the need is particularly evident regarding the capacity of our scientists to integrate across disciplines. ORD emphasized workforce development in ORD Strategic Plan Objective 3.3, and has implemented this recommendation through drafting an ORD-wide workforce plan and creating a Human Capital Strategy and Development Branch (HCSDB) in ORD's Office of Resource Management (ORM). HCSDB provides leadership and expertise on the development of ORD-wide policies, programs, and cross-cutting strategic planning on issues related to human capital management, including performing workforce gap analysis, organizational and employee development, and diversity and inclusion programs. Notably, these workforce planning activities are oriented more toward the ORD Center structure where the research is implemented under the ORD matrix-management system, rather than the strategic research planning aspect which is HERA's purview.

Recommendation 1a.3: Because research collaborations with CSS are integral to several of the research outputs of HERA, the Subcommittee recommends that HERA should update the Subcommittee at yearly review meetings on progress made in, and challenges arising from, these collaborations. For future StRAPs, the Subcommittee recommends that HERA more clearly delineate the roles and responsibilities within and outside HERA that are necessary to deliver projects.

EPA Response:

HERA continues to work together with all ORD National Research Programs to address areas where there are similar scientific challenges and program objectives. In particular, coordination and collaboration between HERA and CSS is valuable in meeting the objectives of both National Research Programs and the EPA partners and stakeholders for whom this research is being undertaken. CSS and HERA will outline these activities at future BOSC meetings, including examples where CSS directly supports EPA program/region and state activities, and where CSS and HERA collaborate directly. As noted in the revised StRAP, examples of CSS-HERA collaboration include enhanced data access through the interoperability with the CompTox Chemicals Dashboard, coordination and joint development of the RapidTox Dashboard including case study applications for HERA hazard-decision contexts, and collaborations to link CSS-supported high-throughput testing of numerous PFAS with HERA-supported systematic evidence mapping of the toxicology literature. The importance of these linkages will be further delineated in future StRAPs and in product development as ORD moves forward.

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Charge Question 1b

Q.1b. Each ORD research program undertook a rigorous engagement process to provide additional detail on specific EPA program and region, state, and tribal needs, the results of which are summarized in introductory sections, descriptions of specific research topics, and appendices. How well does the proposed foundational research program respond to these identified needs?

Narrative

StRAP Discussion of Partner and Stakeholder Engagement and Their Research Needs. The HERA StRAP briefly describes engagement with partners and stakeholders (pp. 6–7 of the StRAP), noting HERA's general approach to soliciting research needs from EPA programs and offices, states, and tribes. The approach, as described in this section, involves (1) receipt of research requests from EPA programs and offices and measurement of success through an annual survey, (2) engagement with states through the Environmental Council of the States (ECOS) and through state public health agencies regarding specific products, and (3) engagement with tribes through the Tribal Science Council, the National Tribal Toxics Council, and other tribal groups. The engagement with other stakeholders (presumably entities outside EPA other than states and tribes, although this is not clearly stated) is reportedly "built into" "public processes embedded in assessment product development." While the general approach may be reasonable, the lack of detail presents a challenge to answering the charge question.

In each section describing a HERA research area, the StRAP includes a paragraph summarizing the research needs of EPA programs and regional offices, states, and tribes. The discussion related to Research Area 2 (pp. 12–13 of the StRAP) refers to requests that HERA has received from partners. Otherwise, these paragraphs are brief, vague, and focus on what HERA provides rather than on what partners have requested.

Appendix 1 of the StRAP provides additional information about the research needs of states, with a table summarizing results mostly from a 2016 ECOS survey, with some mention of subsequent meetings and discussions with ORD in 2018. Most of the needs are expressed generically (e.g., "Water Quality/Surface Water Quality/Groundwater Quality"). It is difficult to understand what the specific state needs related to these broad categories really are. It is not clear to the Subcommittee if an ECOS survey is sufficient to identify all state needs. It is also not clear what mechanism HERA has used to identify tribal needs, since this effort is not described in either the StRAP or the appendices.

Partner and Stakeholder Presentations at the BOSC Subcommittee Meeting. Representatives of EPA offices and one region voiced strong support and confidence in HERA's work. The presentations highlighted the productive engagement between HERA and EPA program offices and regions.

General Observations. The StRAP appears to be primarily oriented toward the needs of the program offices, secondarily to the EPA regions, and less clearly toward the needs of the states and tribes. This impression was furthered by the fact that no state or tribal representatives were present at the meeting, making it appear as if their priorities might be viewed as less important.

The proposed research program responds to the very broadly characterized needs of EPA programs and regions, states, and tribes as they are summarized in the StRAP. What is less clear is (1) the process used to elicit opinions from these entities, (2) how complete the needs are that are reported in the StRAP, and (3) the relative priorities of these issues among the EPA partners.

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The "rigorous engagement process" cited in the charge question needs to be more fully described.

- Who was consulted and what questions were they asked? Did they define priorities among their list of needs?
- Is the survey specific to HERA, or is it generic to ORD?
- What is the procedure for continued engagement, including the specific use of the annual survey cited in the StRAP to assess success of the program? Did HERA scientists have input into the questions used in this survey so that results would be helpful in assessing the success of the HERA research program?

The Subcommittee made very similar comments previously on the CSS StRAP. Specifically, the Subcommittee said: "Several important aspects of the engagement process and its outcome remain opaque in the StRAP... For example, the StRAP lacks discussion of how regional partner needs were identified beyond the fact that meetings, workshops, and collaborations occurred. How were partner representatives identified and recruited to ensure that relevant voices were heard? Were research needs solicited from all EPA program offices and regions, states, and tribes? How exactly were research needs elicited?" The Subcommittee finds that these comments apply equally well to the HERA StRAP and may therefore represent a cross-cutting issue in ORD's approach to collecting input from partners.

Strengths

- The StRAP reflects an effort to assess the needs of partners – defined by HERA as EPA programs, regions, states, and tribes – and includes a paragraph generally describing how each research area responds to these needs.
- The proposed research program appears to be highly responsive to the needs of the EPA program offices, and quite responsive to the needs of EPA regional offices. The responsiveness is evident in the StRAP and in the presentations by representatives from both program and regional offices during the Subcommittee meeting.

Suggestions

- The methodology of the "rigorous engagement process" to gather details of EPA partner needs should be described more clearly in the StRAP, including the efforts to be inclusive and comprehensive about gathering and documenting needs from programs, regions, states, and tribes. The document refers to outreach to states in 2018 and 2019, but no references or information were provided about these more recent outreach efforts. There should also be information in the StRAP about outreach to tribes.
- The StRAP should discuss and reference, at a minimum, summaries of the ECOS surveys for ORD (e.g., The Environmental Research of the States, or ERIS, Results of 2018 Biennial Survey on State Environmental Research Needs, https://www.ecos.org/wp-content/uploads/2019/04/2018-ERIS-Survey-Summary.pdf), an ORD report summarizing outreach to states (U.S. EPA Office of Research and Development and Environmental Council of the States: Partners for Meeting State Research Needs, February 2019 Update; https://www.epa.gov/sites/production/files/2018-12/documents/state_stories_december_12_2018.pdf), and its website featuring EPA research that supports State needs (https://www.epa.gov/research-states).
- Appendix 1 should be expanded to provide more specific information about more recent outreach to states and tribes (since 2016), and the HERA products that respond to the identified needs. The current table focuses almost exclusively on the 2016 ECOS survey and describes needs in very general statements.

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- HERA should consider opportunities for outreach and consultation with the Office of International and Tribal Affairs (OITA).
- In future Subcommittee meetings, it would be helpful for the Subcommittee to hear from state and tribal representatives to understand their perspectives and to hear whether the HERA research program responds to their needs.
- Agreement from states and tribes on these priorities will be critical for them to be able to be prepared with the right capabilities during the implementation process.

Recommendations

The Subcommittee offers these recommendations to identify and respond to partner needs.

Recommendation 1b.1: The Subcommittee recommends developing a detailed partner and stakeholder engagement plan to identify needs, recognizing that priorities and needs may shift over time. For the current StRAP, the Subcommittee recommends soliciting feedback from partners to ensure that the implementation is meeting the identified needs and to enable mid-course corrections, if necessary. For future StRAPs, the plan should include (1) how EPA offices/programs, states, tribes will be engaged, (2) how input will be solicited, and (3) how identified needs will be prioritized for inclusion in the HERA StRAP. HERA should seek guidance from partners as to how they would like to be included in the research planning process and then tailor the plan as needed to specific partner and stakeholder groups.

EPA Response:

ORD agrees that partner and stakeholder engagement in order to recognize priorities and needs is an important step in the strategic research planning process. ORD has committed to continuous partner and stakeholder engagement throughout planning and implementation across all the National Research Programs. Partner and stakeholder engagement in planning and implementation of assessment products in Research Area 1 (Science Assessment Development) is formally structured throughout the assessment identification, development, and delivery workflows. Research Area 2 (Science Assessment Translation) is inherently a partner-engagement process. For Research Areas 3 (Emerging and Innovative Assessment Methodologies) and 4 (Essential Assessment and Infrastructure Tools), HERA has formed coordination teams comprising ORD and EPA program office staff to ensure regular partner engagement. These research area coordination teams (RACTs) have worked to define and prioritize specific products that will be needed to meet output objectives presented in the StRAP. The RACTs will maintain their role as a key contact point during research implementation for partner engagement, ensuring partner needs are being met and for receiving additional feedback on the implementation of the HERA research plan. ORD is also in the process of evaluating the overall StRAP3 partner-engagement process, with a view to further increasing responsiveness to partner needs while reducing the time and resources necessary to receive this input for StRAP4. ORD will also be building on the regional and state-scientists engagement and tribal consultation processes piloted under StRAP3.

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Charge Question 1c

Q.1c. Does the StRAP, including the topics, research areas, and proposed outputs, clearly describe the strategic vision of the program? Please comment on the extent to which the StRAP provides a coherent structure toward making progress on the strategic vision in the 2019-2022 timeframe.

Narrative

The depth and breadth of the HERA expertise and research products was clear in the StRAP and especially in the presentations during the review. The presentations by staff highlighted the scope of the activities outlined in the StRAP. The many positive examples cited by the programs and offices supported by HERA speaks to the value of the research products and the broad impact on risk assessment and related activities of HERA partners.

The strategic/program vision for the HERA StRAP is, *"To innovate and advance the science and practice of health and environmental risk assessment by developing a portfolio of fit-for-purpose assessment products and assessment research that meet the needs and priorities of EPA programs and regions, states, tribes, and external stakeholders."* (Page 8) This is an appropriate and ambitious vision that captures the nature of the HERA activities including the ongoing need to provide hazard identification, hazard characterization (e.g., dose-response analyses and PODs), and key aspects of exposure characterization (e.g., EPA's Exposure Factors Handbook) for partners and stakeholders and the continuing need to transform the science and practice of risk assessment. Although details are lacking, the basic structure of strategic and tactical goals outlined in the StRAP are consistent with the vision.

The portfolio of outputs under the three main research areas under consideration for this report (Research Areas 2–4) span the two research topics and are appropriate. The goals are ambitious and have the potential to meet new challenges for the Agency in developing risk assessments (e.g., to increase the use of NAMs in a manner that ensures public health and environmental protection, and to integrate multiple lines of evidence in chemical hazard and risk characterization). There is an appropriate mixture of new science and methods and a focus on providing better tools to facilitate, streamline, and advance systematic review. At a high level, a major challenge for HERA may be to simultaneously support the ongoing risk assessment needs of their partners (flying the plane – Topic 1) while developing new science and tools that transmit/translate that science into risk assessment products (rebuilding the plane – Topic 2). Balanced resources allocated across all these activities will be critical.

The overall structure of the StRAP topics, research areas, and outputs necessary to achieve the strategic vision are appropriate and advance the science and practice of hazard and risk assessment. However, it was difficult to determine whether the StRAP "provides a coherent structure toward making progress on the strategic vision in the 2019-2022 timeframe." It is unclear how the goals will be accomplished with regard to specific research topics and deliverables and how HERA will track progress. The current StRAP is too general in some areas, touching on topics of interest and importance but without sufficient depth and detail. A chart that links research area outputs with specific projects would be a useful resource for the Subcommittee. Confidence that HERA is focused on the right areas was increased by the outstanding presentations by representatives from EPA regional and program offices during the meeting showing clear examples of high value and innovative tools.

The need to provide metrics across all the research areas and charge questions was discussed during the meeting. The inclusion of metrics in the StRAP would be consistent with the ORD Strategic Plan and can

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help inform the Subcommittee at its yearly meeting. For example, can HERA establish metrics on delivery of specific milestones for projects under research topics and outputs?

Another cross-cutting issue was how the HERA StRAP document and presentations caused confusion over the term "exposure" versus how exposure is defined in the EPA risk assessment framework to inform decision making. This led to confusion and considerable discussion and ultimately to a concern that there might be internal confusion over this critical component of risk assessment. The Subcommittee believes that HERA does in fact have a role in the exposure science area. This appears to be an overarching issue that pervades not only the HERA StRAP but may also cause confusion across EPA functions and partners. The StRAP is unclear on how HERA incorporates exposure characterization to complement the hazard identification and dose-response characterization it does when providing support for a risk assessment and risk management plan for its partners and stakeholders. The specific roles and responsibilities and activities of HERA in exposure science, including collaborations within ORD and with EPA program offices, regions, states, and tribes should be clarified in the next StRAP.

A major theme throughout the StRAP is the complementarity between HERA and CSS. This can be a strength of the plan through the coupling of early stage research on new methods in CSS with hazard identification and characterization by HERA. However, as pointed out in previous reviews, this interdependency also creates risk if the CSS and HERA objectives are not aligned both in concept (the science) and in practice (the resourcing and application). It remains unclear where roles and responsibilities cross the organizational boundaries and where the alignment happens.

How HERA efforts are integrated across ORD was also less clear. For example, there was considerable discussion regarding responsibility for NAM development, validation, and implementation. It is clear that HERA is not the primary party responsible for leading EPA's overarching NAM strategy and implementation; this is a much larger issue for EPA and ORD, but NAMs and the AOP framework are clearly represented within HERA's innovation goals and outputs. This raised concern that multiple challenges and constraints imposed by various objectives for NAM development, validation, and deployment at the Agency could impact HERA. The StRAP was not clear on roles and responsibilities associated with delivery and use of NAMs necessary for effect characterization and where the work will be done. Given ORD's renowned program on chemical hazard assessment, as well as the key technical resource to EPA programs, regions, states, tribes, and other entities, it is clear that HERA has a role to play in the application of NAMs and AOP development for chemical assessment. It would help if HERA could provide, at the next review meeting, additional information as to the role it plays in the Agency's efforts around NAMs and AOPs, including its associated research efforts and objectives, to assure that progress is being made, communication across EPA groups developing NAM approaches is clear, and the needs of partners relative to the use of NAMs in risk assessment are addressed.

TOPIC 1 – SCIENCE ASSESSMENTS AND TRANSLATION

RESEARCH AREA 2 – SCIENCE ASSESSMENT TRANSLATION

Output 2.1 – Technical support to EPA regions and states through the STSC and ERASC.

Strengths:

- A well-established mechanism for providing technical support for Superfund health risks is in place and praised by the partners.

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- The tools that HERA has developed for hazard characterization and dose response are appropriate for use in application for the Superfund Health Risk Technical Support Center (STSC) and Ecological Risk Assessment Support Center (ERASC).

Suggestions:

- Mixtures and cumulative exposures are an important component of the sites for which partners and stakeholders need to develop risk assessments. The StRAP should explicitly document what tools and expertise are available to support cumulative risk evaluation of chemical mixtures and other stressors.
- Many tribal lands have issues that can benefit from the technical advice that HERA can provide to develop risk assessments of contaminants on their lands, but there is little in the StRAP that specifically addresses tribal issues which might differ from other partners and stakeholders from the perspective of the extent and training needs.

Output 2.2 – Core translational research modules for expert technical support.

Strengths:

- The need for "help line" technical support for the partners is clear. Problems arise based on the needs of the moment. It is challenging to meet specific needs that come to HERA, often when they cannot be planned for in advance.

Suggestions:

- Outputs are not clear regarding the research/change agenda of the StRAP. A metric system to measure the effectiveness of the translation of information is not presented. Other than the identified project management approaches it was not clear if there are research/innovation objectives. Website development instances were outlined in the presentation but not incorporated into the StRAP.

TOPIC 2 – ADVANCING THE SCIENCE AND PRACTICE OF RISK ASSESSMENT

RESEARCH AREA 3 – EMERGING AND INNOVATIVE ASSESSMENT METHDOLOGIES

Output 3.1 – Advance, translate, and build confidence in the application of new approach methods (NAMs) and data in risk assessment.

Strengths:

- The AOP framework coupled to the availability of specific NAMs represents an exciting opportunity to advance risk assessment science and speed translation of new information into practice. HERA activities, carried out in conjunction with their CSS colleagues, represent the ideal opportunity to put this new framework and toolbox into practice over time.
- There is clear desire and need for HERA to involve itself and take a leading role in the *application* of NAMs in HERA work products as this focal area of science has become mainstream over the past five years. It is important that HERA maintain currency with the advancements in this sentinel area, both in knowledge of the breadth of tools/approaches and how they can be applied to partner and stakeholder needs in risk assessment. Additionally, since other EPA programs (e.g., the Office of Chemical Safety and Pollution Prevention, or OCSPP) and federal agencies (e.g., the National Institute of Environmental Health Sciences, or NIEHS, the National Toxicology Program, or NTP, and the National Center for Advancing Translational Sciences, or NCATS) have been active in the development

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and implementation of NAMs for chemical assessment, it will be important for HERA to coordinate with these entities on NAMs application.

- The StRAP highlights the collaborative nature of the relationship between HERA and CSS on NAMs development and applications. Advancing new technologies to advance HERA efforts in the areas of effect characterization (i.e., hazard identification and risk characterization) and to provide input for benchmark dose applications is an exciting area.

Suggestions:

- Although HERA and CSS have cooperative efforts, with respect to AOPs and NAMs, it is unclear how HERA and CSS interact to help prioritize AOP and NAM development against hazard identification and risk characterization needs. This area has been a major focus for ORD and will become even more important as the Agency works toward achieving the goals stated in EPA's recent directive to reduce animal testing.
- It is important for HERA to design a validation/proof of concept approach and system as they apply NAMs for real-world challenges and situations and implement retrospective program/approach for determining success rate in their implementation of NAM approaches in HERA work products for partners, states, and tribal needs.
- Since HERA has a direct role working with risk assessors, HERA should include a plan to educate and train them in evaluating the applicability and inherent uncertainty factors associated with NAMs in risk assessment relative to more traditional approaches to hazard characterization based on in-vivo animal data. This should include development of guidance for partners, as well as education and training of EPA program and regional, state, and tribal risk assessors in the strengths and limitations of NAMs approaches.
- As NAMs are used in HERA risk assessments, it will be important that as PODs are derived, the POD methods development and application are biologically based, not just statistically based. For example, considerations of homeostasis, species differences, biological variability, population versus individual thresholds, vulnerable/susceptible subpopulations, PBPK, and dose-dependent transitions should be addressed, as appropriate.
- It is not clear how HERA and CSS are interfacing with the NAM and toxicogenomic applications being developed in CSS and the partner NTP. At future meetings, examples of data usage in HERA research products will help the Subcommittee understand progress in this area. This is another area where the integration between CSS and HERA is critical, and new expertise is coordinated to meet their partners "in the middle" around specific case studies and examples.
- AOPs and AOP networks play a role in HERA's research efforts relating to the application of NAMs in chemical hazard identification and characterization, yet little focus and resources appear to be devoted to AOP/network development in the HERA StRAP. HERA should work with CSS to determine a strategy for prioritizing AOP/network development that would be more focused than crowdsourcing only efforts (e.g., AOPwiki). There is considerable promise for AOP/network development to take advantage of HERA systematic review tools (e.g., literature searching and screening tools), and to leverage Science to Achieve Results (STAR) grants and relevant expertise by other partners (e.g., NIEHS) as appropriate.

Output 3.2 – Conduct case study application of rapid assessment methodologies to inform parameters of interest to risk decision contexts.

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Strengths:

- Development and utilization of rapid assessment methodologies are an appropriate and important area for HERA. The Systematic Evidence Map approach presented during the meeting illustrated an excellent example on a high profile chemical class, per- and polyfluoroalkyl substances (PFAS). These applications have the potential to decrease time for key data needs and gap identification, and free up personnel to focus on high value assessment activities.

Suggestions:

- The StRAP document was devoid of specific project goals and deliverables making it very difficult to assess this part of the StRAP. Although the Systematic Evidence Map example was impressive, the scope of these activities and expected deliverables is unclear. Are products like the Systematic Evidence Map provided within Research Area 4, Output 4.1, or separately?
- A summary of the key tools, goals, and deliverables, and interdependencies with other StRAP research areas and outputs (e.g., Output 4.1) would make it clearer where support for the tool development resides.

Output 3.3 – Evaluate and develop improved methods for dose extrapolation and the related uncertainty characterization in human health risk assessment via classical methods and integration of pharmacokinetic models.

Strengths:

- The StRAP's description of HERA's broad approach to dose extrapolation through pharmacokinetic modeling is appropriate and clear. It recognized the complexity of using these models by the regional risk assessors and defines two approaches to assist them depending upon the needs and sophistication.
- Having products that increase the efficiency and accuracy related to model development and evaluation is worthy, particularly by focusing on well-defined input variables that are appropriate for predicting outcomes in humans.

Suggestions:

- The Subcommittee has previously recommended that HERA develop methods to evaluate mixtures that have common exposures. Research work on mixtures and cumulative risk assessment continues to be very important and should be a priority for HERA. While chemical class mixtures (e.g., PAHs) are one example with a common exposure route, methods to evaluate heterogenous mixtures with common exposure routes should also be addressed.
- While HERA stated that human exposure assessments are outside their purview, it is clear from Subcommittee discussions with HERA that certain components of exposure science fall within HERA's domain. The improved methods outlined under Output 3.3 (i.e., the application of PBPK, high-throughput toxicokinetics, and in vitro to in vivo extrapolation) are designed to define and/or predict concentrations/exposures (e.g. "internal dose") relevant to human risk assessment. Refinements in exposure assessment abound and are a strength and focus in ORD. HERA is encouraged to leverage opportunities to consider and, as appropriate, integrate these advances in robust exposure assessment characterization with their improved methods under Output 3.3 to improve HERA's

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response to its partners and expand HERA's contribution to 21st Century risk assessments. We request that the explicit ways HERA will coordinate with others in ORD on exposure characterization be included in future StRAPs. The StRAP would benefit from increased clarification on HERA's role in integrating the components of risk assessment: exposure, hazard assessment, and dose response. The current language suggest only hazard assessment and dose response is necessary for risk assessment. See suggestion for Output 3.5 below.

- As HERA continues to focus on applications of PBPK models, there is the opportunity when animal/human data are available to populate the model to consider the development and application of data-derived extrapolation factors (or chemical-specific assessment factors). This can have important implication for risk assessment (e.g., considering differential susceptibilities and refining uncertainty factors).
- The StRAP should clarify how concentrations are integrated with exposure estimates at a POD for risk assessments. The interplay between these two critical aspects of risk assessment was not clear. For exposure to be appropriately integrated in risk assessment, it is important that the activities be carefully coordinated even to the extent that terminology and clarification of the roles and responsibilities are clear.

Output 3.4 – Advance methods for systematic review, including evidence integration.

Strengths:

- HERA staff presented impressive advancements in the development of systematic review support tools (e.g., the Health Assessment Workspace Collaborative, or HAWC, and Health and Environmental Research Online, or HERO) that seek to substantially advance Agency efforts to transparently and efficiently identify, evaluate, and organize evidence that supports HERA chemical assessment products as well as assessment-related efforts of Agency partners within and outside ORD. The PFAS Systematic Evidence Mapping (SEM) support provided to CSS is a strong illustration of the advancements of such tools, including HERA's attention to ensuring that they are interoperable with other relevant platforms (e.g., CSS Chemistry Dashboard)
- The StRAP correctly identifies important areas of research and development for the systematic review in chemical assessments and related work at the Agency, including systematic evaluation of the wide breadth of mechanistic data that exist for animal and human studies as well as weight of evidence approaches to integrate data across lines of evidence (i.e., human, animal, and mechanistic). These are pressing areas in the evolution of systematic review for chemical assessment within and outside the Agency, and staff expertise and experience housed within HERA are well-positioned to help lead this broader effort. The systematic evaluation of mechanistic data is an area of ongoing research and validation at other agencies, notably NTP, but also globally (e.g., the International Agency for Research on Cancer) and in the academic arena.

Suggestions:

- The StRAP lacks specificity on the anticipated deliverables of Output 3.4. Case studies would provide particular value for exploring and assessing approaches for systematic evaluation of mechanistic data and consideration and integration of such data alongside animal and human evidence. HERA efforts in this realm should consider what has been developed by others within the systematic review field to leverage insights gained and lessons learned thus far, and to create cohesion where possible and appropriate.

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- Systematic review efforts within HERA have been largely focused on human health assessment. The StRAP recognizes this with an indication of a desire to advance methods for environmental/ecological assessment. However, the STRAP does not provide details on anticipated products, milestones, etc.

Output 3.5 – Advance methods in dose-response modeling with application to risk assessment.

Strengths:

- Research into Bayesian model averaging, unified suite of models across dichotomous and continuous data, considerations of population incidence, and their application of trend testing in for dose response are appropriate.
- Incorporation of high throughput tools are important and necessary to meet the growing needs for immediate responses to emergencies and the expanding number of chemicals being introduced into the environment.

Suggestions:

- Providing some specific examples or a list of tools would be beneficial, perhaps in an Appendix.
- The StRAP specifies in Appendix 3 that a program need is exposure-dose-response modeling in risk assessments. While HERA stated that it will only address the dose-response portion, a mechanism stating how and with whom they will collaborate to characterize the appropriate exposure levels should be included. HERA should consider serving as a resource for its partners to identify methodologies and EPA personnel in other branches to support exposure characterization when conducting risk assessments. HERA should include exposure terminology in the StRAP consistent with that in EPA's Risk Assessment Guidance documents.
- Derivation of a POD can be a critical component of the dose-response modeling products developed by HERA. There was little discussion in the StRAP on "multivariate benchmark dose modeling" and how it is integrated with the overall dose-response modeling. It would help to provide a definition of this term and clarify whether this was referring to mixtures, endpoints, inputs, or other factors.
- Across HERA's research efforts, consideration of exposures to susceptible subpopulations is critical. Method development for dose-response modeling should include a focus on considerations relating to exposures to susceptible populations, including factors such as genetic variability, cumulative stressors, and variability related to age, health status, pregnancy, and other population-level factors.

RESEARCH AREA 4 – ESSENTIAL ASSESSMENT AND INFRASTRUCTURE TOOLS

Output 4.1 – Innovate, develop, and maintain a suite of essential software and support tools for risk assessment.

Strengths:

- The data collection and integration tools that automate accumulation of key data from literature sources is a critical objective to increase the speed, quality, and value of risk assessment research projects. The research outputs from 4.1 will have broad impact across the HERA mission and is an excellent example of advancing the process of risk assessment based on the best available science.

Suggestions:

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- Developing and maintaining a suite of essential software and support tools for risk assessment is a critical support function across many areas and needs to be appropriately resourced and integrated with partners and stakeholders. How this will be accomplished and focused was not clear.

Output 4.2 – Innovate, develop, and maintain a training program on the advances in risk assessment and systematic review.

Strengths:

- The HERA StRAP has an appropriate focus and appreciation for the need to train internal staff and stakeholders on both the new tools and the utility of new types of data in risk assessment. New technologies offer great potential to revolutionize risk assessment but if the end users do not have confidence in new methods and new types of data, new methods may not penetrate the process and become best practice. The StRAP points out that advancements in risk assessment is coupled to added reliance on new software tools – there is a learning curve with each new tool and training modules will need to be developed to improve dissemination.
- Training modules are a good approach to disseminating tools and new types of information. HERA is focused on training modules in close communication with their stakeholders internally and externally. New tool applications presented at the meeting for Systematic Evidence Maps and data extraction from literature (overlapping with Outputs 4.1 and 3.2–3.4) were impressive and should be encouraged.

Suggestions:

- The StRAP was not very specific on how much work with new (and potentially more complex for some users) tools will be done by HERA staff and how much effort is intended to transfer to the end user. Familiarity with new tools is bred by repeated use. If the end user does not use a particular tool on a regular basis, because their job function does not require a particular tool or data application, then it may be difficult for the end user to develop the necessary skill with the tool. Thus, HERA will need to think carefully about how many tools and research products (1) will be transferred to end users, (2) should be operated by "power users" who transfer output products to the end user, and (3) should be integrated into more standard risk assessment products familiar to the end user.
- Continued support for automation of report outputs and increasing electronic quality checks to reduce hands-on work will free up HERA staff to perform more high value work. HERA is moving in this direction. Understanding the resource needs and supporting efforts like these to increase case study examples within training module application is highly encouraged.
- The StRAP does not mention the EPA Exposure Factors Handbook which is a potential major resource for risk assessors formulating a human risk assessment. A short description of its applicability, how and when it is updated, and how potential users are informed about its applicability would be appropriate.

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Recommendations

The Subcommittee offers these recommendations to more clearly describe the program's strategic vision and provide a more coherent structure toward making progress on these objectives.

Recommendation 1c.1: The Subcommittee recommends significant improvements to the StRAP documents to provide additional clarity on the specific projects and deliverables associated with its various research outputs as well as metrics for benchmarking progress and success. Details are necessary to understand how HERA will deliver on research outputs and projects (i.e., coherent structure) in a well-integrated fashion. The Subcommittee recommends that for the current StRAP, (1) details which underpin the projects be addressed at the yearly reviews, (2) HERA should include an Appendix table listing the individual workstreams and/or projects and deliverables for each research output, and (3) HERA enumerate in the Appendix table for the individual projects under each research output an anticipated timeline for delivery. The Subcommittee recommends that future StRAPs include (1) the HERA groups responsible for delivery of various research products and (2) clear project timelines (for both intermediate goals and for project completion) and metrics for success. Finally, the Subcommittee recommends that under the current StRAP, HERA should develop specific performance metrics clearly linked to the format outlined in the ORD Strategic Plan and include those metrics in future StRAPs.

EPA Response:

The details requested regarding products (i.e., deliverables) and timelines are activities of the relevant Research Area Coordination Teams (RACTs), which take the outputs listed in the StRAPs and provide this additional detail. The RACTs were developed under StRAP3 to serve as a forum for this discussion, and include representatives from EPA programs and regions, NPDs and staff, and ORD laboratory scientists. Specifically for HERA, the products developed under Research Area 1 (and hence RA2, as support) are at the explicit request of senior Agency policy officials, and those developed under Research Areas 3 and 4 are requested or identified to the HERA Program as instrumental in advancing the work under Research Areas 1 and 2. Additional details on these products will be a central focus of future BOSC subcommittee meetings that focus on research implementation.

Both HERA and ORD measure success as – "increasing the percentage of products that meet customer needs." The ORD Strategic Metric is being implemented annually through surveys sent to EPA Partners/Regions –now to states, too, under an OMB-approved Information Collection Request—who are polled to numerically rate relevant research products on quality, usability, and timeliness. This approval to expand the strategic metric to include states increases its utility to HERA, as assessment products have broad applicability and use outside the Agency. In order to ensure on an ongoing basis that HERA products are meeting the needs of the customer(s), close engagement is maintained with partners from conception to completion, such that scoping and updating is built into our processes (weekly, monthly, bimonthly, annual engagements). ORD is also in the process of instituting LEAN management principles and processes across all its research portfolios to identify and resolve process delays and to ensure timely delivery of products.

Recommendation 1c.2: The Subcommittee has previously recommended that HERA develop methods to evaluate mixtures. Given the complexity of the topic, the Subcommittee recommends that during the current StRAP period, HERA develop a coherent strategy for evaluating co-exposures to chemical

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mixtures and nonchemical stressors for implementation in future StRAPs, specifically going beyond homogeneous mixtures (e.g. PAHs) and including cumulative risk assessment.

EPA Response:

ORD agrees that consideration of chemical mixtures, nonchemical stressors, and cumulative risk are important aspects of risk assessment. As noted in the StRAP, the HERA program was designed to develop and apply state-of-the-science research to characterize impacts on human and ecological systems – whether they result from exposure to single, complex, or multiple physical, chemical, or biological stressors – to support and improve EPA's risk assessment decisions. The HERA program will work with its partners, including the CSS national research program, to ensure consideration of these elements during prioritization of planned research for the next StRAP.

Recommendation 1c.3: The Subcommittee recommends that HERA consider implications relating to exposures to susceptible populations in its research activities, including factors such as genetic variability, cumulative stressors, and variability related to age, health status, pregnancy, and other population-level factors.

EPA Response:

All ORD National Research Programs recognize the importance of protecting susceptible populations. The Sustainable and Health Communities (SHC) National Research Program has a core focus on protecting susceptible subpopulations and highly exposed communities. Given the importance of susceptible populations for risk assessment, HERA must and does consider susceptible populations in research activities. These include advancements to tools that better estimate exposures to susceptible populations like children, such as the All Ages Lead Model, which estimates lead exposures from various media and lead concentrations in blood and other tissues from infancy through adulthood up to 90 years of age, and ExpoKids, which graphically illustrates estimates of relative exposure and aggregate exposure sources within and across lifestages. Further text describing the importance of susceptible populations, including these examples, was added to the revised StRAP where relevant. HERA will continue to consider how products could take into account both variability and sensitivity for factors contributing to increased susceptibility.

Recommendation 1c.4: The Subcommittee recommends that in the next StRAP HERA should define how exposure science will be incorporated into risk assessment and its role in advancing this aspect of exposure science, including specific HERA roles and responsibilities and collaborations within ORD and with EPA program offices, regions, states, and tribes.

EPA Response:

ORD agrees that clarity about the role that exposure science plays in the HERA program and risk assessment will be informative and beneficial in the next StRAP. The visual that illustrates HERA's contribution to risk assessment has been revised to more clearly delineate the HERA-related portions, and text has been added to the revised StRAP describing the HERA contributions to exposure science.

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Charge Question 1d

Q.1d. Recognizing ORD's focus on addressing identified Agency, state, and tribal research needs, are there any prioritization considerations, other critical emerging foundational research needs, or fields of expertise and/or new research methods, where this program should consider investing resources?

Narrative

The HERA program's mission is to "develop and apply state-of-the-science research to characterize impacts on human and ecological systems – whether they result from exposure to single, complex, or multiple physical, chemical, or biological stressors – to support and improve EPA's risk assessment decisions." To operationalize this mission, the program emphasizes the development and implementation of assessment products that meet EPA's statutory and policy needs and addresses requests for technical support from EPA programs, regions, states, and tribes. It is important for HERA to consider increased outreach and consultation with additional EPA programs, such as EPA's efforts focused on international environmental issues (EPA's OITA), EPA's efforts with plastic waste under the Trash Free Waters program (https://www.epa.gov/trash-free-waters), and EPA's Office of Land and Emergency Management efforts in addressing exposures and risks from natural disasters and accidental releases.

The reorganized divisions and centers within EPA provide an opportunity for new team science efforts among toxicologists and epidemiologists creating improved research synergies; these efforts should be encouraged. For example, epidemiologists and disease-oriented scientists should be involved in the development of AOPs, especially as it relates to integrating biomarkers. Melding the varied expertise in these groups may improve the development of AOPs – one set bringing more basic and chemo-centric research and the other a perspective on health and disease. The opportunity for team science to benefit important research areas also includes analysis of human and environmental monitoring data for both evidence of exposures and for analysis of links to human health and ecological effects. For example, an important emerging research technology is the use of high-resolution untargeted methods to detect exposures in biomonitoring samples. There is extensive work in annotating resulting data to metabolites of environmental chemicals – i.e., not just endogenous responses, but exogenous exposures. An advantage of these methods is that they provide evidence to relevant exposures. When these untargeted data are linked to human health and/or ecological effects, it provides a data source to perhaps change "unknown unknowns" to "known unknowns". Such data may be useful in more clearly characterizing the exposome and its impact on human health.

Focusing solely on tactical needs and requests from partners creates the potential to miss critical emerging foundational research needs. For example, there is an opportunity for the EPA to access publicly available human biomonitoring and health effects data for use in transparent risk assessments. The National Institutes of Health and, more specifically, the NIEHS supports the Human Health Exposure Assessment Resource (HHEAR) consortium of labs and a data center to evaluate biomonitoring samples and, now, environmental samples from human cohort and clinical studies. (In the initial realization it was focused on Children's exposures and was called CHEAR, or Children's Health Exposure Analysis Resource.) Once these data are peer reviewed and published, the epidemiologic and biomarker data will be publicly available through the HHEAR Data Center data repository. Many of these studies include untargeted metabolomics. These publicly available data provide an opportunity for HERA to use human data in their hazard identification and effect characterization of health effects. For example, the HERA program could consider establishing a pilot project to develop biomonitoring equivalent values from existing HERA toxicity values, and to compare biomonitoring equivalent values derived from targeted assays in HHEAR

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to biomonitoring equivalent values derived from endpoints from traditional lab animal studies. When a HHEAR study finds an association between exposures to single or mixtures of chemicals and a health effect (e.g., pregnancy outcome, asthma severity, incidence of autism, and obesity), such information should be evaluated along with other lines of evidence in HERA's characterization of potential hazards and dose-response relationships. Such an analysis and comparison would be useful to demonstrate transparency and establish scientific confidence in the approaches used for determining exposure guidance values. The STAR program could also potentially be used as a strategy to assist in identifying and addressing emerging research needs and integration with other funded research programs.

In short, we have identified both strengths and suggestions for the HERA program managers to consider for inclusion in the StRAP.

Strengths

- The HERA program scientists have developed and implemented innovative tools for risk assessment that can be utilized for partners and incorporated into decision-making, as evidenced by presentations in examples of outputs and products in Research Areas 2–4. This includes the continued development and use of in vitro, in silico, and genomic type data and models for improving risk assessment and establishing the ability to translate information from large sets of data to specific risk assessment requirements in a transparent form.
- The reorganization creates new opportunity for synergistic research activities across disciplines.
- The STAR program is a strength and may provide a strategy for conducting innovative new research.

Suggestions

- HERA should explore opportunities for using and developing new and improved approaches for evaluating exposures to mixtures of chemical and non-chemical stressors. These could use human and environmental monitoring data from high-resolution untargeted methods. For instance, HERA could consider deriving data-driven mixture assessment factors for use in its risk assessment of individual chemicals when there is knowledge of co-exposures.
- If HERA has constraints on internal research personnel and/or resources to address new research needs or methods, the Subcommittee suggests that HERA should consider other funding mechanisms, e.g., STAR grants, to be able to access the capabilities of collaborators.
- The Subcommittee applauds effort by HERA to automate data integration into risk assessment products. Recognizing the need to standardize data formats, models and lexicons as part of this effort, the Subcommittee encourages HERA to extend efforts into artificial intelligence and machine learning applications to leverage data repositories that currently exist and those that will be developed under the current StRAP.
- HERA should consider implementing a process for identifying emerging environmental issues, such as microplastics, where HERA's expertise in hazard evaluation and dose-response assessment could be integrated in a timely manner with the overall ORD issue identification strategy. Such a process should take into consideration lessons learned, for example, from experiences with PFAS.
- HERA's roles in pursuing inter-agency research strategies with agencies such as the Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC), and other organizations should be delineated.

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- The importance of the application of evidence integration should be identified in all programs, beyond just systematic reviews.
- For transparency, the language in the StRAP should be more specific with less jargon.

Recommendations

The Subcommittee offers these recommendations to address critical emerging environmental needs.

Recommendation 1d.1: The Subcommittee recommends that HERA increase training opportunities for the development and use of NAMs for partners in order to better understand the concerns in replacing current approaches with NAMs data and communicate their utility and uncertainties.

EPA Response:

HERA agrees that training for use of NAMs along with other models, methods, and applications relevant to HERA research should be incorporated into our training program.

Recommendation 1d.2: The Subcommittee recommends that HERA incorporate considerations relevant to chemical mixtures and other stressors consistently throughout their research and assessment activities, including a specific initiative to achieve this objective.

EPA Response:

Research relevant to chemical mixtures and other stressors will be discussed with HERA partners and stakeholders and considered as part of the research planning in the forthcoming StRAP cycle. This will be undertaken in conjunction with the other National Research Programs who share similar interests regarding improved understanding of cumulative risks and can prioritize applied research necessary to support application in risk assessment.

SUMMARY LIST OF RECOMMENDATIONS

Charge Question 1a: Please comment on the extent to which the research outlined for the 2019-2022 timeframe supports the relevant Agency priorities as described in the EPA and ORD Strategic Plans?

- **Recommendation 1a.1:** The Subcommittee recommends including specific actions for enhancing opportunities for public participation and transparency (defined in Objective 2.2 from the ORD Strategic Plan), particularly in (1) the development, performance assessment, and proposed applications of new and improved methods, including NAMs, systematic review and evidence integration methodologies, AOPs, and biologically based dose-response extrapolation models and (2) the development of HERA StRAPs.
- **Recommendation 1a.2:** The Subcommittee recommends that a workforce development and training program strategy connected with research mission should be further articulated in the StRAP. Particular emphasis should describe the integration of advanced and emerging bioactivity profiling methods (ToxCast, toxicogenomics, AOPs, in silico approaches, read-across, etc.) using weight of

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evidence assessment methodologies for hazard characterization and risk evaluation. A similar strategy should be further developed in future StRAPs.

- **Recommendation 1a.3:** Because research collaborations with CSS are integral to several of the research outputs of HERA, the Subcommittee recommends that HERA should update the Subcommittee at yearly review meetings on progress made in, and challenges arising from, these collaborations. For future StRAPs, the Subcommittee recommends that HERA more clearly delineate the roles and responsibilities within and outside HERA that are necessary to deliver projects.

Charge Question 1b: Each ORD research program undertook a rigorous engagement process to provide additional detail on specific EPA program and region, state, and tribal needs, the results of which are summarized in introductory sections, descriptions of specific research topics, and appendices. How well does the proposed foundational research program respond to these identified needs?

- **Recommendation 1b.1:** The Subcommittee recommends developing a detailed partner and stakeholder engagement plan to identify needs, recognizing that priorities and needs may shift over time. For the current StRAP, the Subcommittee recommends soliciting feedback from partners to ensure that the implementation is meeting the identified needs and to enable mid-course corrections, if necessary. For future StRAPs, the plan should include (1) how EPA offices/programs, states, tribes will be engaged, (2) how input will be solicited, and (3) how identified needs will be prioritized for inclusion in the HERA StRAP. HERA should seek guidance from partners as to how they would like to be included in the research planning process and then tailor the plan as needed to specific partner and stakeholder groups.

Charge Question 1c: Q.1c. Does the StRAP, including the topics, research areas, and proposed outputs, clearly describe the strategic vision of the program? Please comment on the extent to which the StRAP provides a coherent structure toward making progress on the strategic vision in the 2019-2022 timeframe.

- **Recommendation 1c.1:** The Subcommittee recommends significant improvements to the StRAP documents to provide additional clarity on the specific projects and deliverables associated with its various research outputs as well as metrics for benchmarking progress and success. Details are necessary to understand how HERA will deliver on research outputs and projects (i.e., coherent structure) in a well-integrated fashion. The Subcommittee recommends that for the current StRAP, (1) details which underpin the projects be addressed at the yearly reviews, (2) HERA should include an Appendix table listing the individual workstreams and/or projects and deliverables for each research output, and (3) HERA enumerate in the Appendix table for the individual projects under each research output an anticipated timeline for delivery. The Subcommittee recommends that future StRAPs include (1) the HERA groups responsible for delivery of various research products and (2) clear project timelines (for both intermediate goals and for project completion) and metrics for success. Finally, the Subcommittee recommends that under the current StRAP, HERA should develop specific performance metrics clearly linked to the format outlined in the ORD Strategic Plan and include those metrics in future StRAPs.

- **Recommendation 1c.2:** The Subcommittee has previously recommended that HERA develop methods to evaluate mixtures. Given the complexity of the topic, the Subcommittee recommends that during

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the current StRAP period, HERA develop a coherent strategy for evaluating co-exposures to chemical mixtures and nonchemical stressors for implementation in future StRAPs, specifically going beyond homogeneous mixtures (e.g. PAHs) and including cumulative risk assessment.

- **Recommendation 1c.3**: The Subcommittee recommends that HERA consider implications relating to exposures to susceptible populations in its research activities, including factors such as genetic variability, cumulative stressors, and variability related to age, health status, pregnancy, and other population-level factors.
- **Recommendation 1c.4:** The Subcommittee recommends that in the next StRAP HERA should define how exposure science will be incorporated into risk assessment and its role in advancing this aspect of exposure science, including specific HERA roles and responsibilities and collaborations within ORD and with EPA program offices, regions, states, and tribes.

Charge Question 1d: Recognizing ORD's focus on addressing identified Agency, state, and tribal research needs, are there any prioritization considerations, other critical emerging foundational research needs, or fields of expertise and/or new research methods, where this program should consider investing resources?

- **Recommendation 1d.1:** The Subcommittee recommends that HERA increase training opportunities for the development and use of NAMs for partners in order to better understand the concerns in replacing current approaches with NAMs data and communicate their utility and uncertainties.
- **Recommendation 1d.2**: The Subcommittee recommends that HERA incorporate considerations relevant to chemical mixtures and other stressors consistently throughout their research and assessment activities, including a specific initiative to achieve this objective.

CONCLUSIONS

In conclusion, the Subcommittee believes that the HERA StRAP articulates research areas and outputs that are appropriate and advance the science and practice of hazard and risk assessment. The technical support offered to EPA regions and states are well connected with EPA's goals of a cleaner healthier environment and prioritizing robust science. The Subcommittee looks forward to reviewing the implementation of the research outlined in this StRAP in future meetings and continuing to serve as a resource to the HERA and CSS programs on scientific and strategic topics related to its research programs.

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APPENDIX A: MEETING AGENDA

Day 1: Tuesday, May 12, 2020, Eastern Daylight Time

Time	Topic	Speaker
12:30–12:45 pm	Welcome and Opening Remarks	**Tom Tracy,** Designated Federal Officer (DFO) **Katrina Waters, PhD,** BOSC Chair
12:45–1:00 pm	Subcommittee Introductions	**Subcommittee**
1:00–1:15 pm	ORD Welcome	**Jennifer Orme-Zavaleta, PhD,** ORD Principal Deputy Assistant Administrator for Science
1:15–2:30 pm	HERA Strategic Research Action Plan • HERA Introductions • Program Structure and Approach • Comments/Responses to BOSC Review in 2019 • ORD Collaborations (e.g., CSS)	**Samantha Jones, PhD,** HERA National Program Director (NPD) **Beth Owens, PhD,** HERA Principle Associate NPD
2:30–2:40 pm	Break	
2:40–3:00 pm	Review of Charge Questions	**Katrina Waters, PhD,** BOSC Chair
3:00–3:15 pm	Public Comments	**Tom Tracy,** DFO
3:15–4:15 pm	Discussion with EPA Program/Regional Office Representatives – Perspectives on HERA StRAP	
	Office of Land and Emergency Management (OLEM)	**Kathleen Raffaele, PhD**
	Office of Water (OW)	**Betsy Behl**
	Office of Chemical Safety and Pollution Prevention (OCSPP)	**Stan Barone, PhD**
	Office of Air and Radiation (OAR)	**Bob Hetes, MSPH**
	Lead Regional Office – Region 5	**Carole Braverman, PhD**
4:15–4:25 pm	Break	
4:25–5:30 pm	BOSC Subcommittee Discussion and Deliberations	**Katrina Waters, PhD,** BOSC Chair

Day 2: Wednesday, May 13, 2020, Eastern Daylight Time

Time	Topic	Speaker
12:00–12:20 pm	BOSC Subcommittee Convenes: Questions and Clarifications	**Katrina Waters, PhD,** BOSC Chair
12:20–12:40 pm	HERA in ORD – Center for Public Health and Environmental Assessment (CPHEA) Perspective	**Wayne Cascio, MD,** CPHEA Director
12:40–2:30 pm	Looking Closer – Overview of the Research Areas in HERA StRAP	**Beth Owens, PhD,** HERA Principal Associate NPD
	Research Area 2 – Examples of Outputs/Products (Translation) and Questions	**Emma Lavoie, PhD**

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Time	Topic	Speaker
	Research Area 3 – Examples of Outputs/Products and Questions	**Lucina Lizarraga, PhD** **Kris Thayer, PhD** **Amanda Bernstein, PhD**
	Research Area 4 – Examples of Outputs/Products and Questions	**James Brown, PhD** **Jennifer Nichols, PhD**
	Looking Closer – Summary of the Research Areas in HERA StRAP and Discussion	**Samantha Jones, PhD,** HERA NPD
2:30–2:40 pm	Break	
2:40–3:00 pm	BOSC Subcommittee Discussion, Deliberations, Writing Assignments	**Katrina Waters, PhD,** BOSC Chair
3:00–5:00 pm	Subcommittee Breakouts by Charge Questions – Virtual Document Preparation; Comment Summary	**Subcommittee Breakout Groups by Charge Question**
5:00–6:00 pm	Reconvene for BOSC – Reporting Out and Next Steps to Completed Review Document	**Subcommittee**
6:00 pm	Meeting Adjourns	**Katrina Waters, PhD,** BOSC Chair **Tom Tracy,** DFO

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APPENDIX B: MATERIALS

Material Provided in Advance of the Meeting

Materials to Support the Charge Questions

- Agenda
- Charge questions
- HERA Draft StRAP FY 2019–2022
- Presentation: HERA Program Overview
- Presentation: HERA Looking Closer
- Presentation: CPHEA Overview

Informational Materials

- Virtual Participation Guide

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REVIEW OF U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT'S RESEARCH PROGRAM

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August 25, 2020

A Federal Advisory Committee for the U.S. Environmental Protection Agency's Office of Research and Development

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LIST OF ACRONYMS

AWWA	American Water Works Association
ATSDR	Agency for Toxic Substances and Disease Registry
BOSC	Board of Scientific Counselors
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease 2019
DASEES	Decision Analysis for a Sustainable Environment, Economy & Society
EPA	U.S. Environmental Protection Agency
FEMA	Federal Emergency Management Agency
HIA	Health Impact Assessments
NCEH	CDC's National Center for Environmental Health
NIEHS	National Institute of Environmental Health Sciences
MDH	Minnesota Department of Health
MPCA	Minnesota Pollution Control Agency
ORD	EPA's Office of Research and Development
PFAS	Per- and Polyfluoroalkyl Substances
R2R2R	Remediation to Restoration to Revitalization
RACT	Research Area Coordination Team
SD	School District
SHC	Sustainable and Healthy Communities
SJ	Sustainable Jersey
StRAP	Strategic Research Action Plan

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INTRODUCTION

The U.S. Environmental Protection Agency (EPA) Board of Scientific Counselors (BOSC) Sustainable and Healthy Communities (SHC) Subcommittee appreciates the opportunity to provide input on planned research products. We understand that the products are at an early stage. We recognize the need for time and flexibility to carry out research during the Coronavirus Disease 2019 (COVID-19) pandemic, and we appreciate the creative efforts to continue working to the extent possible from remote locations. We further acknowledge the planning and initiation of many of the Research Area 9, "Benefits from Remediation, Restoration, and Revitalization," or R2R2R, and Research Area 10, "Community-Driven Solutions" outputs and products occurred prior to the current pandemic. We included research area descriptions, outputs, and products in Appendix A.

CHARGE QUESTIONS AND CONTEXT

The SHC Subcommittee was charged with two questions as follows:

> Q.1: BOSC subcommittee members have been provided a summary of planned research products related to research areas 9 & 10 for review at this BOSC meeting. After reviewing these materials, combined with the presentations provided during the 2-day virtual meeting, are there any critical gaps that would preclude accomplishing the environmental science goals of RA 9 and 10? Please provide recommendations for addressing those.
>
> Q.2: The combined StRAP and Research Area Coordination Team (RACT) process was resource intensive for both ORD scientists and partner organizations. Yet, this engagement has clearly vested EPA programs and regions, states, and tribes in the research to be conducted, and heightened their interest in participation with ORD and in the outcomes of the work. ORD is seeking BOSC input on effective ways to maintain this mutual engagement and communication between researchers and our research partners as we go forward with implementation.

The responses of the SHC Subcommittee to the charge questions are contained in the following section.

SUBCOMMITTEE RESPONSES TO CHARGE QUESTIONS

Charge Question 1

> Q.1. BOSC subcommittee members have been provided a summary of planned research products related to research areas 9 & 10 for review at this BOSC meeting. After reviewing these materials, combined with the presentations provided during the 2-day virtual meeting, are there any critical gaps that would preclude accomplishing the environmental science goals of RA 9 and 10? Please provide recommendations for addressing those.

Narrative

Overall, we believe SHC is moving toward a more holistic approach to encompass a greater range of methods and tools, which do a better job of addressing the needs of communities. We further

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acknowledge the efforts to work closely with partners in planning and carrying out research. The holistic nature of EPA's Office of Research and Development (ORD) methods and expected outcomes were well summarized in the presentations. We appreciated SHC staff efforts to crosswalk BOSC recommendations from 2019 and SHC outputs and products in both the reports and oral presentations, which facilitated assessment of strengths and gaps.

We see only a few critical gaps in research at this time, although additional gaps might appear as output development proceeds and as more systematic research design unfolds. We expect development of research products will be an iterative process where input from SHC and others leads to product refinement. Particularly during the COVID-19 pandemic, it will be important for SHC to adapt products to changing circumstances.

In this report, we acknowledge strengths of the work to date and highlight a few gaps, offering suggestions and recommendations related to research generalizability, inference of causality, and other themes. Many of our observations and suggestions cut across Research Areas 9 and 10. Where we have specific comments within research areas, it is noted below.

Strengths

- **Complementarity**: Graphics such as the Resilient Community-Driven Solutions matrix show that considerable thought has been given to the complementarity of Research Areas 9 and 10 outputs across overarching question areas. This helps to avoid critical gaps in inquiry and recognizes the importance of systems-thinking in addressing community resilience related to contaminated sites.
- **Systems-Thinking:** We appreciate the broader complex systems approach SHC is taking in bringing together outputs and products to address Research Areas 9 and 10.
- **Community Applicability**: ORD's research has progressed significantly from that of twenty years ago, when research stopped at the site boundary and it was unclear whether and how research products would be used. The current SHC research extends into communities to serve more stakeholders through more beneficial tools. The Subcommittee appreciates how SHC is designing tools based on stakeholder need, with an emphasis on training and evaluating use. For example, Product 9.4.1 appears to identify stakeholders who could benefit from applying EnviroAtlas to brownfields assessments and offer training. Further, the research aims to better understand and relate the value of a restored environment to the health of a community (e.g., restoring a forest not just for its own sake, but for the benefit of a community that can now access this forest and its ecosystem services). This recognition of the direct and indirect health benefits of a healthy, restored environment are a classic example of the application of "health in all policies" – a key tenet of public health. This research direction brings SHC's mission more in line with how the general public sees EPA's mission – to consider all of the needs of a community. We appreciate the recognition of the stakeholders for SHC models and tools and the emphasis on user-driven research, the clarity on work with partners, and the idea of co-production. This is especially evident in partnerships with regional offices and local communities. New research downscaling data to a more local levels were highlights in 2020, e.g., products in Output 10.1 (aiming to further enhance EnviroAtlas and other geospatial tools), and Products 10.5.2, 10.5.3, and 10.5.5.
- **Vulnerability Disparities**: Many aspects of the current SHC research focus on disparities experienced by vulnerable populations. For example, Product 9.3.1 considers revitalization indicators of social equity, environmental justice, and public health, and Product 9.3.6 considers how revitalization benefits a marginalized community. We appreciate the support for research on social vulnerability

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and equity issues concerning human health and ecosystem services/ecological health across EPA research program areas. There is now an effort to focus on disparities in environmental exposures and adverse acute and/or chronic health outcomes—though more the former than the latter at present—between vulnerable sub-populations and others. Product 10.1.5 incorporates a Social Vulnerability Index and extensively incorporates features of the local built/physical environment, soil/sediment, and agricultural and farm animal operations; Output 10.2 addresses the vulnerability of particular community sub-groups, including children, to environmental stressors and incorporates the Environmental Quality Index and Eco-Health Relationship Browser; and, Product 10.4.3 considers flooding impacts on poor, minority communities. In addition, there is an enhanced focus on identifying and quantifying both chemical and non-chemical stressors, and mixtures of exposure agents present, in SHC research models/tools. This was evident within Output 10.2.

- **Health Impact Assessments:** Health Impact Assessments (HIAs) are valuable tools for gathering community input to shape R2R2R objectives. The use of HIAs for Output 9.4.3 is a strength that will improve information and allow for partnerships with local agencies.
- **Longer-term Research Vision Opportunity**: Overall there seems to be greater potential opportunity to work with partners to establish longer-term data collection and analysis using a more purposeful research design framework to capitalize on opportunities for experiments to build on initial field and lab research. These opportunities could assess acute and chronic outcomes of interest.
- **Variety of Research Methods**: SHC recognizes that there are multiple ways to do research and is exploring relevant models and case studies and developing reasonable approaches in a variety of settings around the United States. Research Area 9, Output 9.3 captures this challenge well with emphasis on interdisciplinary and translational social-ecological systems research at remediation and restoration sites and leveraging understanding of human communities to improve remediation and restoration outcomes. The emphasis on place-based case studies (e.g., Product 9.1.2) helps to identify context-specific factors driving relationships between ecosystem services and wellbeing in the context of R2R2R. Comparison and synthesis across case studies helps identify what is generalizable and what is context specific.
- **Social Science**: ORD is taking into account the many factors that influence community health by integrating social scientists into the research (e.g., sociologists, communication specialists, geographers, anthropologists, and economists). They are contributing quantitative and qualitative expertise.

Suggestions

- **Balancing Partner-driven Research and Longer-term Systematic Research by Design**: We applaud the increased focus on partner-driven research that emerges in the course of addressing Agency priorities. It is responsive and takes advantage of research opportunities that arise among partners. As we have highlighted in previous BOSC reviews, we note a potential gap in the research portfolio as pertains to longer-term, systematic research by design (e.g., purposeful opportunities to examine longitudinal effects and processes across a diverse array of contexts). Place-based or "emergent" research driven by partner needs and willingness to partner is important, but can be focused on a limited scope of research questions. This can subsequently limit systematic understanding of how remediation (the treatment) affects environmental quality (air, surface water, groundwater, soil, sediment), ecological health, social, and economic outcomes, each of which have importance for community revitalization and resilience.

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We suggest incorporating additional focus on broader research design and site selection, which are important for long-term data collection and generalizability. Long-term data collection is essential to assess impacts over time that are chronic and aggregate (one pollutant) or cumulative (multiple/mixture of pollutants) and not immediate (acute) human and/or ecological health effects. Research design is important even if the goal is not a strict experimental design, as SHC must still draw implications from a comparison study. For example, in Output 9.1, ORD should be explicit about how control sites are defined. For site cleanups, it would be helpful to establish "parallel sites" as control sites.

Collecting a lot of data can lead to analyses and interpretations that may differ from those associated with research driven by a clear research question or questions. There is opportunity here to carefully formulate guiding research questions.

In partner-driven research, there might be self-selection in terms of who SHC scientists are partnering with. As discussed in response to Charge Question 2, a more systematic research design with a standardized process for soliciting partners may be worth exploring.

It is challenging to find a balance between place-based research that is often locally specific, and broader research guided by design in which variables are comparable and thought through purposefully, such that scientific questions can be answered at broader community level. SHC may want to more deeply consider how to synthesize and integrate across place-based research, and how to evaluate tradeoffs and relationships in this synthesis.

- **Synthesizing and Generalizing Information**: SHC research involves collecting a lot of data in many areas through case studies and other tools. Synthesis across different economic, social, and ecological situations and with different degrees of community revitalization will be challenging. If not selected carefully, it could be difficult to generalize from a set of case studies. We recommend wherever possible that case studies be selected from a range of contexts to consider biophysical, chemistry, sociocultural, and socioeconomic factors. Further, it is important to consider how to synthesize place-based research and case studies. Currently, SHC research relies heavily on EnviroAtlas, but there may be a need for additional frameworks and modeling tools to get at system-level processes. This is especially important regarding economic outcomes and job creation, for which a regional economic modeling framework is needed. Hedonic models are a good place to start to link remediation and restoration to a broader set of economic and social outcomes, but there is also a need for models that account for neighborhood change, education attainment, household, and firm location decisions.
- **Furthering Community Applicability:** It would be helpful to establish ways for states, territories, tribes, university researchers, and communities to pilot the tools created by SHC. While SHC has made progress on co-production, more effort is needed to ensure that each tool is meeting the community needs and building local-to-regional level capacity is warranted. This includes increasing the number of case studies to obtain the local information needed. Output 10.1 focuses on mapping of assets and vulnerabilities, but the way inor rural? which the types of assets and vulnerability components are identified is unclear. Communities might have different perspectives on what contributes to vulnerability, or which are key assets. In line with the focus on disparities between populations, local level data, and increasing case studies, developing mechanisms to engage communities early in the mapping processes may help identify hidden vulnerabilities. This will improve the development of planning tools and vulnerability assessments (e.g., Product 10.5.6 and Product 10.5.7).
- **Vulnerability Disparities**: Although many aspects of the current research focus on disparities experienced by vulnerable populations, there is some room for growth. SHC should ensure that it is focusing not just on children, certain ecosystems/species, and lower-income minority urban

neighborhoods, but also on older adults, indigenous populations, and other vulnerable populations including those in rural areas. The intersectionality of vulnerability across characteristics is important to investigate. Further, SHC should consider potential disparities between more vulnerable populations and less vulnerable populations throughout all research, not just in Product 9.3.1 and Product 9.3.6. The impact of COVID-19 on vulnerable populations could also be a consideration here.

- **Units and Levels of Analysis**: The data collected to date might not be at the unit the research question is looking for, particularly for research at the level of local communities. The efforts in Output 10.1 to build and integrate data layers should be mindful of the alignment between units of analysis and the level of inquiry related to community vulnerability and resilience in the context of contamination. Local partners might be able to help with more granular data. For example, there are statewide environmental sustainability, education, and public health-oriented programs with local (city/town municipal governments) and/or school district (SD) and individual schools' participation. The non-profit organizations and/or state agency partners coordinating such programs will likely have information on participants, including mini-grants awarded for specific supporting projects funded by other foundations, energy companies, public-private partnerships, etc. For example, in New Jersey, there is Sustainable Jersey (SJ) for municipalities and schools (https://www.sciencedirect.com/science/article/abs/pii/S0013935120302929?via%3Dihub). Connections with planners (local and regional) and local public health staff who have tools and capacity to quantify ecosystem services and local vulnerabilities may provide synergistic opportunities to facilitate SHC research.

- **Health Impact Assessments**: HIAs can be time- and resource-intensive. Thought and planning are needed to incorporate them into the R2R2R process. Partnering with local or state health departments on this work would be a beneficial way to bring them to the table and ensure they are involved in decision-making.

- **Causation**: For both Research Areas 9 and 10, there are times that causality is assumed, when the issue may really be about correlation or association (e.g., Output 9.3, Product 10.1.1, and Product 10.2.1). The potential causal connections between community health and environmental indicators need to be clearly described and supported by science.

  Geographical proximity to contaminated sites does not always equal exposure to contaminants. A source emits into the environment and exposure occurs by routes targeting human or other species. As such, creating an integrated database of brownfields, ecosystem goods and services, and health records implies connections that may or may not exist.

  There is a need to acknowledge the influence of a variety of factors related to spatially articulated data and be cautious in drawing implications of associations between chemical/environmental stressors and health impacts on people living in adjacent areas. For example, does greenspace cause better health, or are those living near greenspace healthier because they are more affluent? People sort into neighborhoods and are also constrained in their location by income, race, ethnicity, and other potential barriers, which are related to underlying conditions and health outcomes. Alternatively, some greenspaces may have negative attributes (e.g., crime or trash) that challenge assumptions of associated ecosystem goods and services in some locations. Causality cannot be inferred without addressing more complex questions of household location, sorting, and other constraints. Similarly, brownfield redevelopment can lead to improvements in public health unrelated to site contaminants or ecosystem damage. They can present opportunities for health improvement – which is hinted at when looking at diabetes data and availability of parks and greenspace that provides opportunities for healthy physical activity.

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Several metrics used for measuring impacts to human well-being are derived from U.S. Census data sets, which are often lagging indicators of community conditions. Recognizing the challenges in developing location-specific outcome evaluations, research projects should plan to revisit these metrics over the course of coming decades to gain a full picture of community transformations. This is also an area where local partners may have access to newer and more localized data.

The use of a more epidemiology and health science focus could help address this concern. Greater input from environmental epidemiologists at the Centers for Disease Control and Prevention (CDC), including their National Center for Environmental Health (NCEH) and the Agency for Toxic Substances and Disease Registry (ATSDR), and state health programs, could be beneficial.

- See the Minnesota Data Access Portal for examples of how environmental and population data can be layered in relevant ways: https://data.web.health.state.mn.us/web/mndata/.
- Also, see similar national CDC data: https://ephtracking.cdc.gov/DataExplorer/#/.

Note: Many states have received funding to do this work as well.

- **Learning and Resiliency**: The incorporation of workshops and co-production of knowledge through research emphasized particularly in Output 9.2 related to tools to support R2R2R offer opportunities to evaluate the role of learning in adaptive management of contamination in community contexts. Considerable extant research on the concept of multiple-loop learning [1] might be useful in operationalizing learning concepts for incorporation into SHC research. Expanding beyond single-loop learning focused on incremental adjustments to double- and triple-loop learning that challenges assumptions and reframes or even transforms how socio-ecological systems are understood may enhance the resilience of community-based restoration and revitalization efforts.
- **Scenario Planning**: One way to manage adaptively in the face of COVID-19 and other changes is to use scenario planning, where different scenarios are developed based on research questions, possible future conditions, and stakeholder concerns. Scenario planning is a good mechanism for co-production of research.
- **DASEES Integration**: We recommend that SHC explore opportunities to integrate the Decision Analysis For A Sustainable Environment, Economy & Society (DASEES) tool more broadly across Research Areas 9 and 10 to support better decisions through integrating local to global issues. The tool allows decision-makers to better account for ecosystem services. Expanding the array of partners to include the Federal Emergency Management Agency (FEMA) could be beneficial as DASEES could inform and enhance the benefit-cost analysis FEMA uses for hazard mitigation grants. There is already an agreement between FEMA and EPA for working on these kinds of issues (https://www.epa.gov/sites/production/files/2016-08/documents/moa-between-fema-and-epa-signed-8-9-16.pdf). It can also be noted this is an explicit interdependency in Product 10.3.3, where technical briefs will go to FEMA and the U.S. Army Corps of Engineers.
- **Per- and Polyfluoroalkyl Substances**: Other than Product 10.2.7, there seems to be limited consideration of the effects of per- and polyfluoroalkyl substances (PFAS). In its June 12, 2020 comment letter, American Water Works Association (AWWA) suggested that only drinking water can

[1] Pahl-Wostl C. 2009. A conceptual framework for analysing adaptive capacity and multi-level learning processes in resource governance regimes. Global Environmental Change 19: 354-365. https://doi.org/10.1016/j.gloenvcha.2009.06.001;
de Kraker, J. 2017. Social learning for resilience in social-ecological systems. Current Opinion in Environmental Sustainability. 28:100-107. http://dx.doi.org/10.1016/j.cosust.2017.09.002.

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be analyzed for PFAS with a validated method. AWWA suggested developing ways to monitor PFAS in non-drinking water (particularly wastewater) and other media. We concur with this comment and recognize that PFAS is covered in other research areas.

- **COVID-19**: Workplans for the products may need to be updated to consider COVID-19 precautions, particularly when engaging with stakeholders.
- **Built Environment and Vulnerable Infrastructure**: SHC should include the built environment and vulnerable infrastructure (e.g., high risk dams) in its geospatial model layers when considering vulnerability. In addition, SHC research should explore any available information on infrastructure maintenance and other major infrastructure integrity (e.g., bridges). Infrastructure failure could impact soil and water quality at adjacent or downstream contaminated sites or waste management sites. For example, an extreme weather event could completely overwhelm an aged, weathered and weakened infrastructure, thus aggravating an environmental disaster and affecting construction and demolition debris.

Recommendations

The Subcommittee offers these recommendations to address critical gaps:

Recommendation 1a: Maintain a balance across the research program to incorporate long-term systematic research – guided by research questions and design – with careful research site selection that will allow for inquiry across time and localities to better understand what findings can be generalized and what is context specific. This systemic research is fundamental to support the Agency's applied research goals.

EPA Response:

SHC agrees with this recommendation and we realize the importance of a portion of our portfolio being longer-term, systematic research. While the StRAP and associated products are planned and implemented in a 4 yr cycle, much of the research has been underway even before this current StRAP and will likely continue beyond FY 22. Example: The Great Lakes work in Areas of Concern and the importance of considering ecosystem services at contaminated sites are examples of work that is longer-term. ORD will work to sample a representative sample of localities over time to facilitate generalization of research results and lessons learned.

We agree that the research should be designed in a way that the findings can be generalized to all communities, not just those we're engaged with. We appreciate the suggestions (e.g., about site selection) to strengthen our ability to do this. We also agree with the caution you raise about drawing conclusions about causality and correlation related to ecosystem goods and services, health outcomes, and community revitalization from a limited sample of sites.

Recommendation 1b: Incorporate frameworks beyond EnviroAtlas to quantify a holistic range of environmental, economic, and social tradeoffs as relevant and needed to assess community resiliency.

EPA Response:

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SHC agrees with this recommendation. We continue to add layers to the EnviroAtlas that allow the Atlas to be used in a more holistic manner as well as looking at frameworks that integrate the natural, economic, and social aspects of community resilience.

Multi-sector indicator-based decision tools like ORD's Climate Resilience Screening Index (CRSI) and Multisector Evaluation Tool for identifying Resilience Opportunities – Community Environmental Resilience Index (METRO- CERI) provide qualitative and quantitative indicators of community resilience, including environmental, economic, and social domains for communities to assess their strengths and vulnerabilities. Future development of METRO-CERI will focus on application of resilience indicators relevant for Brownfields redevelopment. Lifecycle analysis tools included in Research Area 7: Life Cycle Inventories and Methodologies (not reviewed by the BOSC SC) will allow communities to consider broader supply chain impacts related to community resilience. Health Impact Assessment (HIA) is another model for integrating the holistic range of environmental, economic, and social outcomes relevant to community decision making and resilience. SHC scientists are also exploring building out tools developed elsewhere in the Agency, like OLEM's Cleanups in My Community and Office of Environmental Justice's EJ Screen, or the Global Change Explorer

In addition, SHC's ecosystem services research incorporates a framework for identification, quantification, and, eventually, valuation of ecosystem services, including those that contribute to resilience against a broad variety of environmental stressors. This framework is implemented through a suite of tools including the NESCS Plus ecosystem services classification tool, the draft Final Ecosystem Goods and Services Scoping Tool for community use, and the Ecoservices Model Library.

Recommendation 1c: Include the built environment, including high risk dams and other major infrastructure maintenance and integrity, in geospatial model layers when considering vulnerability.

EPA Response:

The SHC updated program considers risks due to the combination of extreme events, potential for failure of community infrastructure elements, and the presence of waste and hazardous materials management facilities. We appreciate the recommendation to include additional high-risk infrastructure elements such as dams and levees that can fail and cause floods that can carry and distribute contaminants to communities, in addition to the direct risks extreme events pose themselves.

Charge Question 2

Q.2. The combined StRAP and Research Area Coordination Team (RACT) process was resource intensive for both ORD scientists and partner organizations. Yet, this engagement has clearly vested EPA programs and regions, states, and tribes in the research to be conducted, and heightened their interest in participation with ORD and in the outcomes of the work. ORD is seeking BOSC input on effective ways to maintain this mutual engagement and communication between researchers and our research partners as we go forward with implementation.

Narrative

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Overall, we find that SHC research responds to the needs of existing partners. This section offers observations of strengths and suggestions to effectively maintain mutual engagement and communication among researchers and partners to adequately represent ORD stakeholders, which is particularly important for the more applied and place-based research.

We recognize the challenge of adjusting research engagement in the face of the COVID-19 pandemic. For example, in Product 10.5.4, the initial problem formulation workshop with nearly five dozen EPA and partner organization participants was conducted in-person in February 2020. While it will be relatively easy to continue projects that require computer-based modeling and analysis and paper writing, projects that require laboratory work, field-intensive work, and engagement with stakeholders will be challenging. We hope that the remote learning experience during the pandemic can support maintaining and expanding remote engagement mechanisms with SHC partners.

Strengths

- **Responsive to Partner Needs**: Based on materials reviewed, presentations by SHC researchers, and the panel of program and regional partners, it is clear to us that SHC researchers are working to interact with a diverse array of partners and are responsive to their current needs. Examples of this responsiveness are particularly clear in work focused on brownfields in Research Area 9, Output 9.4 and Research Area 10, Outputs 10.1 and 10.4. The problem formulation and translational bridge workshops in Product 10.5.4 are a great example of appreciating the importance of partnerships and engagement throughout the research process.
- **Attention to Translational Deliverables**: Although there is a strong emphasis on journal articles as research outcomes as appropriate for research enterprises, there is considerable attention in the research outputs and products to deliverables that are more translational, going beyond standard peer-reviewed publications and technical reports. This attention to providing innovative research deliverables to meet the needs of a diverse array of partners is headed in a positive direction and will certainly help to maintain mutual engagement and communication between researchers and research partners.
- **Regional Representation**: There is significant representation across most regions and climate zones of the United States in the research highlighted in Research Areas 9 and 10.
- **Needs-based Tool Development and Sharing**: Development of tools is incorporating greater focus on addressing expressed needs of SHC partners and customers with instances of adopting human-centered design and agile methodologies that will improve usability and use of SHC tools. This needs-based tool development focus moves beyond a "build it and they will come" mentality (e.g., Output 10.3). There is recognition that no one tool can meet all partner needs (e.g., Product 9.2.3). The development of dashboards and interface tools (e.g., Product 9.4.1) is useful in facilitating the transfer of information. ORD has made a good effort to publicize the availability of new tools across EPA Centers and Offices and there has been progress since 2018–2019 in sharing tools with communities.
- **Recognition of Variable Local Capacity to Engage**: The recognition of variable local capacity to engage with various decision-support tools and information, as well as with research processes, is important and deepens appreciation that one-size-does-not-fit-all (e.g., Product 10.1.7).

Suggestions

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- **Diversify Partner Selection**: It appears that most of the SHC research partnerships are within EPA rather than with external stakeholders (e.g., Output 10.1). There appear to be few municipal partners (other than Daphne, Alabama for Product 9.1) or non-profit groups (other than RiverKeepers for Product 10.1.6) and no small local groups involved from what we can observe. SHC should consider having more community partners identified for Outputs 10.3 and 10.5 and finding ways to incentivize participation for those from communities with low engagement capacity who might otherwise find it challenging to participate. Reaching out to non-profit groups at local, regional, and national scales can tap into both their strengths in translational products as well as their networks and research capacities. Consider adopting a standard process to ensure that there is a diversity of research partners, including state, tribal, and local partners and marginalized communities such as Sun Valley (the subject of research in Product 9.3.6 but not listed as a partner). The process could involve an online solicitation form like that of Thriving Earth Exchange (an American Geophysical Union program that partners scientists with communities) as well as active outreach to communities by regional liaisons. A wide net should be cast to reach out to those who might not be highly connected. Additionally, many of the research products, particularly those for Output 10.2, are highly relevant for public health practitioners and increased partnerships are warranted. Coordination is suggested with existing networks, (e.g., Urban Sustainability Directors Network and Partner Networks in the Great Lakes, New England, Southeast, Cascadia) and consultants providing resilience support to communities. SHC could provide draft language for funding opportunity announcements/request for proposals recognizing SHC tools for local-level use demonstrations to inform case studies and research translation products.
- **State and Local Partner Perspectives**: At the state level, the Minnesota Department of Health (MDH) partners with the state's environmental agency (Minnesota Pollution Control Agency, or MPCA) on most contaminated site issues that involve direct human exposure to contaminants. Some of the funding for this work comes from ATSDR, and some from MPCA using state remediation funds. Such arrangements are valuable for supporting this work and bringing a public health perspective to the conversation that includes the affected communities. SHC should consider adopting a similar model for relevant outputs and products in Research Area 9 and perhaps broadening it ever further to include environmental science experts at state departments of natural resources or from local organizations that can provide an ecological or other useful perspective.
- **Document Regional Representation**: While ORD project presentations include significant representation across most regions and climate zones of the United States, some regions (Regions 7, 8, and 9) are not well represented in the materials presented to the BOSC SHC Subcommittee. For example, Regions 1 and 7 are highlighted in Research Area 10, but not in Research Area 9. Most examples provided to the Subcommittee were located in Regions 1–5 with a significant focus on particular parts of regions (such as the Great Lakes within Region 5), but less attention to other parts. It will be helpful in future presentations to help the Subcommittee better understand how the 10 regions are well represented across partner products. If there are real gaps in regional partner participation, these can be addressed through standardizing the partner selection process as described above.
- **Broaden Outreach Opportunities and Output Alternatives**: Peer-reviewed journal articles and technical reports might not be read by some partners or external stakeholders. Diversifying outputs is essential to reaching a diverse array of partners. Asking what type of outputs will be most useful to partners early in research relationships can help facilitate meeting these needs as work proceeds.
    - An awareness gap may exist due to a lack of translational research and limited external partners. This could be the case for health organizations (professional societies and non-profits) and local

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(city/town, county, or state) health departments and environmental groups. This is consistent with the stated purposes of Products 10.3.1, 10.3.2, 10.4.2, 10.5.1, 10.5.3, and 10.5.4. SHC should explore the capacity to further translate science for partners working within regions, states, and local communities. Research translation activities (with publicly available materials) beyond planned workshop proceedings or reports might be needed. Requiring research translation plans could facilitate this effort. An example is the National Institute of Environmental Health Sciences (NIEHS') accepted federal model for research translation (Translational Research Framework), which is implemented through community outreach and education cores of funded Centers (see https://www.niehs.nih.gov/research/programs/translational/framework-details/index.cfm).

- Additional forms of outreach and engagement may include citizen science such as developing apps for members of the public to share observations on extreme weather events, park use, or other parameters SHC is trying to measure. An example of a non-profit developing such an app is "I See Change" (see https://www.iseechange.org/observations).
- For every project and model/web-based tool developed by ORD, an output product should be identified beyond peer-review journal paper(s), technical reports, and/or a workshop proceedings document. These might include factsheets, briefs, Q&As posted to a webpage on the SHC website, webinars, user guides, etc. We do appreciate that community partners might want videos and social media and they are useful; however, we acknowledge the fact these types of products are rarely realistic in an affordable or timely manner.
- Look for opportunities to collect data on the effects of tools in terms of who is using these tools, so that tool marketing can be better tailored. Consult with partners as to whether conservation non-governmental organizations and health professionals are aware and/or contributing data, in particular with respect to certain health outcomes of interest and certain susceptible, vulnerable sub-groups. Health care providers, at least to date per EPA, have less exposure to these tools. It is notable that Product 10.3.1 assumes use of tools is a function of user capacity; an expanded focus on the utility and impact of tools will strengthen this work.
- SHC staff should continue to share and market these tools directly with the communities as it has started to do.

- **Utilization Metrics Tracking**: Several instances were noted where utilization metrics for online tools and resources have been difficult to develop and monitoring simple web traffic provides little insight into how ORD tools are used. While it might only provide anecdotal evidence, use of creative commons licensing, especially under Share-Alike terms, could prompt public users of SHC products to cite and acknowledge SHC researchers' role in their own work and create the "digital breadcrumbs" needed to find instances application of these tools and resources in the field. Customers could be encouraged to also share when they have relied on SHC resources while highlighting their own work in informal channels where academic citations are not the norm. Promotion of social media hashtags (e.g., #BuiltWithEPA) could be a way to alert ORD of resource utilization examples and promote the resources to broader audiences. We support tracking tool utilization and feedback on value to users.
- **Opportunity Mapping**: Many communities are going through their own processes of vulnerability assessments, either through voluntary initiatives such as the Global Covenant of Mayors or working within a growing list of state level guidelines and compliance requirements with funding opportunities (Massachusetts, California, New York, and Pennsylvania). These are good potential customers for many of the resources being developed and delivered through EnviroAtlas and other media. Curation

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of collections of resources applicable to the activities many communities are already taking part in could help deliver more value to communities.

- **Technical Capacity, Language, and Goal Alignment**: Exploring the alignment of technical capacities among SHC researchers and partners (e.g., geospatial and data management capacities) is an important aspect of maintaining strong research engagement and relationships. Similarly, it is important to take time periodically to ensure foundations of common language and understanding of research goals are aligned between researchers and research partners as these are frequently cited key challenges in interdisciplinary and transdisciplinary research.
- **COVID-19**: The wide-ranging impacts of the COVID-19 pandemic should be accounted for in research plans. Workplans for the products might need to be updated to consider COVID-19 precautions, particularly when engaging with stakeholders. Virtual engagement options should be explored. Once the pandemic has been contained, there will be a need to clearly recognize capacity building (to use ORD tools) in local communities as a research outcome. The availability of experts to share themselves at the local level should be considered and advertised via regional offices as applicable to local concerns and needs.

Recommendations

The Subcommittee offers these recommendations to enhance engagement and communication with the program's research partners:

Recommendation 2a: SHC should partner with regions to explore an intentional and measurable process to identify state and local expertise and local data sets to inform tool development, testing, local capacity, training needs, and tool use metrics across partners.

EPA Response:

SHC agrees with this recommendation. The Subcommittee's recognition that this will require Regional partnership is key. SHC's indicator and index development has sought to identify and incorporate data sets that exist at various scales such as census tract and even finer scales. SHC is particularly interested in reaching out to state, tribal and local expertise and relevant data sets that integrate ecosystem services with the numerous human health metrics that have been developed in the SHC program.

EPA's Regions are the holders of much info and knowledge on local conditions and partnerships. SHC and regional offices have piloted or participated campus community partnership programs (Region 3-Sustainability Partners Incorporating Research in Academia and Localities (SPIRAL); Region 9 – Educational Partnerships for Innovation in Communities – Network (EPIC-N)) to disseminate ORD research). METRO-CERI is taking this approach through its Discovery Workshops with local resilience/sustainability/emergency response personnel and its ideation workshops to develop-out this combined tool. Brownfields products follow similar regional and local engagement processes (HIAs, gas station project, indicator approach to extreme events impacts on revitalization decisions, etc.). SHC's Regional Sustainability and Environmental Sciences (RESES) program provides resources for ORD-Regional collaborations and has piloted some projects that incorporate the elements recommended by the Subcommittee (e.g., DISC – Decision Integration for Strong Communities) and will continue to seek similar opportunities. SHC is regularly engaged with EPA's regions through the Office of Community Resilience/Regional Disaster Resilience calls, EPA recovery and mitigation coordinators, regular ORD/OBLR (Brownfields) calls, the Great Lakes Network, and EPA's Environmental Justice (EJ)

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coordinators. We appreciate the suggestions above for possible models identifying/partnering with various groups of stakeholders and better tracking utilization of SHC tools and resources.

Recommendation 2b: SHC should establish a process with the regions to represent the heterogeneity within and across communities and expand the diversity and inclusion of stakeholders who become partners. This should include more equitable opportunities for states, territories, tribes, and communities (including marginalized or environmental justice communities) across all regions.

EPA Response:

SHC concurs with this recommendation. SHC's research program has long recognized that environmental risks and benefits are not evenly distributed across lifestages and communities and continues to include research on lifestage vulnerabilities and other environmental disparities. EPA's Regions are engaged with ORD through the continuing Children's Environmental Health Partner Alliance Coordination Team. SHC is also engaged with EPA's Offices of Children's Health Protection, Environmental Justice, and Community Revitalization and cross-federal Agency groups like the President's Task Force on Environmental Health and Safety Risks to Children and the Children's Health Protection Advisory Committee. This recommendation also speaks to SHC's continuing engagement with ORD in engaging state partners through ECOS (Environmental Council of the States) and ERIS (Environmental Research Institute of the States), ASTHO (Association of State and Territorial Health Officials), and NEHA (National Environmental Health Association), and with partners like SOPHIA (Society of Practitioners of HIA). SHC has also established links with the American Planning Association, Urban Sustainability Directors' Network, and ITRC (Interstate Technology and Regulatory Council Sustainable Remediation team, part of ERIS) sustainability efforts.

SHC appreciates the many helpful suggestions above related to partnering with various groups of external stakeholders and approaches for doing so. We will consider these suggestions as we continue to enhance our translational science capabilities and outreach efforts.

Recommendation 2c: SHC should explore requiring research translation plans (e.g., NIEHS model) for SHC products (ideally co-created with regions and partners) to support regional staff capacity to share SHC products with a broader set of partners.

EPA Response:

SHC agrees with this recommendation. Early on, SHC and other parts of ORD heard the call to translate ORD science and took that as a charge to build software tools that animated and applied environmental science. We now understand that research translation is a much more comprehensive process. The National Institute of Environmental Health Sciences (NIEHS) model was actually the topic of an SHC staff retreat, with discussion led by social scientists in ORD. SHC charged the Centers' research teams to consider this more sophisticated approach to research translation into their implementation plans and they responded well. SHC made the translational science framework a component of our evaluation for proposed products in RA10, i.e., is a proposed product a one-off or does it build on or lead to other stages of the translation process that enables it to ultimately be used. The Output teams for the Resilience research, for example, included problem formulation workshops in their plan, and the Remediation to Restoration to Revitalization (R2R2R) team has taken a similar approach. We will continue to work with SHC's product and output teams on developing translation plans, ranging from simple communications

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materials for technical publications to more staged research translation processes, as per the NIEHS framework.

We have also taken actions in SHC's Regional Sustainability and Environmental Sciences (RESES) program to encourage research translation. The last two years we have mapped projects along the NIEHS Translational Research Framework and encouraged teams to use that framework to guide development of their project management plans (PMPs), which are co-created by Regional and ORD team members. We have shared types of products that may be associated with the different rings in their framework and provided examples of potential audiences, venues, and key messages at each stage. We have expanded the communications section in the PMPs to ask teams to describe communication and dissemination of project progress and results to collaborators and stakeholders and also to other communities, states, and Regions beyond their specific project location. We also ask teams to identify target audiences and key messages for each audience, building on the information we present to teams in our kickoff webinar.

SUMMARY LIST OF RECOMMENDATIONS

Charge Question 1: BOSC subcommittee members have been provided a summary of planned research products related to research areas 9 & 10 for review at this BOSC meeting. After reviewing these materials, combined with the presentations provided during the 2-day virtual meeting, are there any critical gaps that would preclude accomplishing the environmental science goals of RA 9 and 10? Please provide recommendations for addressing those.

- **Recommendation 1a:** Maintain a balance across the research program to incorporate long-term systematic research – guided by research questions and design – with careful research site selection that will allow for inquiry across time and localities to better understand what findings can be generalized and what is context specific. This systemic research is fundamental to support the Agency's applied research goals.
- **Recommendation 1b:** Incorporate frameworks beyond EnviroAtlas to quantify a holistic range of environmental, economic, and social tradeoffs as relevant and needed to assess community resiliency.
- **Recommendation 1c:** Include the built environment, including high risk dams and other major infrastructure maintenance and integrity, in geospatial model layers when considering vulnerability.

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Charge Question 2: The combined StRAP and Research Area Coordination Team (RACT) process was resource intensive for both ORD scientists and partner organizations. Yet, this engagement has clearly vested EPA programs and regions, states, and tribes in the research to be conducted, and heightened their interest in participation with ORD and in the outcomes of the work. ORD is seeking BOSC input on effective ways to maintain this mutual engagement and communication between researchers and our research partners as we go forward with implementation.

- **Recommendation 2a:** SHC should partner with regions to explore an intentional and measurable process to identify state and local expertise and local data sets to inform tool development, testing, local capacity, training needs, and tool use metrics across partners.
- **Recommendation 2b:** SHC should establish a process with the regions to represent the heterogeneity within and across communities and expand the diversity and inclusion of stakeholders who become partners. This should include more equitable opportunities for states, territories, tribes, and communities (including marginalized or environmental justice communities) across all regions.
- **Recommendation 2c:** SHC should explore requiring research translation plans (e.g., NIEHS model) for SHC products (ideally co-created with regions and partners) to support regional staff capacity to share SHC products with a broader set of partners.

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APPENDIX A: RESEARCH AREA DESCRIPTIONS, OUTPUTS, AND PRODUCTS

Research Area 9: Benefits from Remediation, Restoration, and Revitalization

Description: Research Area 9 develops methods and metrics to characterize and forecast the potential benefits from remediation and restoration that improve ecological and human health and well-being. Research Area 9 builds on the research in Topic 1 by using the Remediation to Restoration to Revitalization (R2R2R) framework developed by GLNPO to link site-specific environmental improvements to community revitalization after natural disasters and contaminant cleanup and restoration efforts. Research will be focused on: 1) understanding the causal links between ecosystem goods and services and their effects on human health and well-being; 2) developing weight of evidence approaches to evaluate environmental restoration and the contribution of ecosystem services to community revitalization and health promotion; 3) and provide EPA, states, and communities with metrics to evaluate environmental conditions and environmental public health and well-being.

Outputs and Products:

- *Output 9.1: Methods and Measures for Characterizing Restoration Effectiveness*
  - Product 9.1.1: Approaches to evaluate restoration effectiveness and to quantify levels of restored ecological condition needed to ensure production and resilience of beneficial uses and other ecosystem services
  - Product 9.1.2: Demonstrations and lessons learned from place-based studies evaluating the effectiveness of restoration to produce beneficial uses and other ecosystem services
- *Output 9.2: Ecosystem Services Tools and Approaches to Support Remediation to Restoration to Revitalization*
  - Product 9.2.1: Comparison of a framework for incorporating ecosystem services into decision making across five U.S. case studies: Governance, engagement, tools, assessment, and benefits
  - Product 9.2.2: Consideration of ecosystem services at cleanup sites – A retrospective analysis and synthesis of existing ORD research
  - Product 9.2.3: Translating ORD's ecosystem services tools and approaches to support contaminated site cleanup activities
- *Output 9.3: Contribution of Site Remediation and Restoration to Revitalizing Communities and Improving Well-being*
  - Product 9.3.1: Assessing ecosystem services and human well-being indicators for Great Lakes Areas of Concern, Superfund cleanup, brownfields remediation, and waterfront revitalization
  - Product 9.3.2: Risks of extreme events to Superfund, community waste management and remediation activities and verification of the climate resilience screening index
  - Product 9.3.3: Assessing how human health and wellbeing is affected by site remediation and restoration
  - Product 9.3.4: Economic evaluation of contaminated site and brownfields remediation using non-market and market valuation methods

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- Product 9.3.5: Where to work? Development of remediation and restoration strategies to revitalize community health and well-being in contrasting urban-estuarine ecosystems
- Product 9.3.6: Documenting and baselining the benefits of community revitalization at Sun Valley Colorado

- *Output 9.4: Case Studies to Apply and Analyze Use of Tools at Brownfield Sites*
  - Product 9.4.1: Applying EnviroAtlas to Brownfields assessments and redevelopment
  - Product 9.4.2: Demonstration of effectiveness of revitalization of a prevalent type of brownfields site
  - Product 9.4.3: Health impact assessment (HIA) applications to brownfields reuse and redevelopment to support community resiliency and revitalization

Research Area 10: Community-Driven Solutions

Description: Research Area 10 addresses community resilience, with a focus on vulnerable groups, and examines potential impacts of hazards with the objective of speeding community recovery and sustaining public benefits. Communities are complex environments where the interrelationships among geography, people, land use, policies, and the built, natural, and social environments help determine a community's health and well-being. Adverse impacts from natural hazards such as extreme climate events are magnified when a community's or individual's resilience is low, meaning they lack access to fundamental resources such as healthy food, health care, and robust infrastructure. Vulnerable groups, such as children, the elderly, people with low-income, and minorities, warrant special consideration because these groups often face greater adverse impacts due to disproportionate exposures, more susceptible physiology, or other social or built environment factors.

Many communities responding to, or preparing for, natural hazards struggle with understanding the best way to make their community more resilient to chronic and acute stressors. To become resilient, programs and communities need information on the intended and unintended consequences that often result from environmental changes. EPA's mission includes consideration of vulnerable groups in its actions, in addition to ensuring that its regulations do not have a differential impact on communities or cause an increase in health disparities. Taking actions that minimize adverse impacts and disparities while maximizing benefits requires understanding the linkages between changes in the biophysical environment and the resulting consequences on health, economy, and well-being.

Outputs and Products:

- *Output 10.1: Data and Approaches for Identifying and Mapping Assets and Vulnerabilities*
  - Product 10.1.1: Quantifying ecosystem services and identifying beneficiaries for parks, public/protected lands and community greenspaces
  - Product 10.1.2: Assessment of multidimensional community vulnerability and resilience
  - Product 10.1.3: Building an approach and tool to estimate human health-related outcomes from community built and natural features
  - Product 10.1.4: Enhanced EnviroAtlas functionality and new tools for asset and vulnerability mapping

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  - Product 10.1.5: New EnviroAtlas national geospatial data layers for mapping assets and vulnerabilities
  - Product 10.1.6: Developing novel, collaborative methods to create EnviroAtlas featured community data
  - Product 10.1.7: Decision integration for strong communities (DISC)
- *Output 10.2: Characterize Select Interrelationships Between Environmental Stressors to Address Cumulative Impacts on Community Health*
  - Product 10.2.1: The role of environmental and public health factors in children's long-term health and social development
  - Product 10.2.2: Translating the wealth of publicly available children's environmental health information
  - Product 10.2.3: Selected chemical and non-chemical stressors measured in licensed child care centers in Portland Area Indian Country
  - Product 10.2.4: Evaluating non-chemical stressors for children's environmental health protection
  - Product 10.2.5: Understanding environmental asthma triggers and ways to manage it in community settings through research, education, and outreach
  - Product 10.2.6: Novel and improved biomarker-based health metrics to evaluate cumulative health impacts of contaminated sites and blighted communities
  - Product 10.2.7: Bioaccessibility model for organic compounds sorbed to ingested soils and house dusts
  - Product 10.2.8: Advancing translation of eco-health science through EnviroAtlas and the Eco-Health Relationship Browser
  - Product 10.2.9: Environmental Quality Index (EQI) – Development of census tract, community, rural, tribal and examine cumulative health impacts for vulnerable groups
  - Product 10.2.10: Cumulative health effects of exposure to contaminated sites and non-chemical stressors: Causal interactions and biomarkers of effect
- *Output 10.3: Pathways to Revitalization and Resilience that Build Community Capacity*
  - Product 10.3.1: An examination of EPA tools through a capacity lens
  - Product 10.3.2: Building community capacity in revitalization and resilience planning through partner training
  - Product 10.3.3: Social acceptance of disaster waste and debris
- *Output 10.4: Impacts from Environmental and Natural Disasters*
  - Product 10.4.1: Models and simulations for community vulnerability and climate resiliency to flood impacts on contaminated sites in partnership with regions and states
  - Product 10.4.2: Best practices for assessing community and contaminated site vulnerability to extreme events
  - Product 10.4.3: Community health effects of hurricane-related flooding

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  - Product 10.4.4: Vulnerability of waste infrastructure to extreme events
- *Output 10.5: Guidance for Effective Resiliency Actions*
  - Product 10.5.1: Protecting coastal communities and contaminated sites with resilient coastal wetlands
  - Product 10.5.2: An ecosystem services and ecological integrity decision support system: Strengthening resiliency in coastal watersheds
  - Product 10.5.3: Ecosystem service assessment as a tool for building community resilience to flood risk
  - Product 10.5.4: ORD contaminated sites problem formulation and translational bridge workshops
  - Product 10.5.5: Analysis and story mapping of community plans and projects for resilience
  - Product 10.5.6: Resilient community planning module on contaminated sites, waste, and vulnerable populations
  - Product 10.5.7: Modeling urban dynamics in a global change context to improve community resilience

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APPENDIX B: MEETING AGENDA

Day 1: Tuesday, June 16, 2020, Eastern Daylight Time

Research Area 9: Benefits from Remediation, Restoration, and Revitalization

Time	Topic	Speaker
10:45–11:00 am	Sign on and Technology Check	
11:00–11:05 am	Welcome and Opening Remarks	**Tom Tracy,** Designated Federal Officer (DFO) **Courtney Flint,** BOSC SHC Chair **Matthew Naud,** BOSC SHC Vice Chair
11:05–11:15 am	ORD Welcome	**Jennifer Orme-Zavaleta,** ORD Principal Deputy Assistant Administrator for Science
11:15 am–12:00 pm	ORD Overview Presentations • SHC Overview • Center Capabilities: Implementing the Portfolio	**Michael Slimak,** SHC National Program Director (NPD) **Andrew Geller,** SHC Principal Associate NPD **Wayne Cascio,** Director, Center for Public Health and Environmental Assessment (CPHEA) **Rusty Thomas,** Director, Center for Computational Toxicology and Exposure (CCTE) **Tim Watkins,** Director, Center for Environmental Measurement and Modeling (CEMM) **Greg Sayles,** Director, Center for Environmental Solutions and Emergency Response (CESER)
12:00–12:10 pm	Break	
12:10–1:05 pm	Research Area 9 Presentations (Part 1)	
	Research Area 9 Overview	**Marc Russell,** Assistance Center Director, CCTE
	Output 9.1	**Susan Yee,** CEMM
	Output 9.2	**Matt Harwell,** CEMM
1:05–1:15 pm	BOSC Clarification Questions on Research Area 9, Part 1	**Courtney Flint and Matthew Naud,** BOSC Chairs
1:15–1:25 pm	Break	
1:25–2:05 pm	Research Area 9 Presentations (Part 2)	
	Output 9.3	**Joel Hoffman,** CCTE
	Output 9.4	**Britta Bierwagen,** CPHEA

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Time	Topic	Speaker
2:05–2:20 pm	BOSC Clarification Questions on Research Area 9, Part 2	**Courtney Flint and Matthew Naud,** BOSC Chairs
2:20–2:30 pm	Break	
2:30–3:00 pm	BOSC Discussion	**Courtney Flint and Matthew Naud,** BOSC Chairs

Day 2: Wednesday, June 17, 2020, Eastern Daylight Time

Research Area 10: Community-Driven Solutions

Time	Topic	Speaker
10:45–11:00 am	Sign on and Technology Check	
11:00–11:05 am	Welcome – Day 2	**Courtney Flint,** BOSC SHC Chair **Matthew Naud,** BOSC SHC Vice Chair
11:05 am–12:00 pm	Research Area 10 Presentations (Part 1)	
	Research Area 10 Overview	**Susan Julius,** Assistance Center Director, CPHEA
	Output 10.1	**Anne Neale,** CPHEA
	Output 10.2	**Nicolle Tulve,** CPHEA
12:00–12:10 pm	BOSC Clarification Questions on Research Area 10, Part 1	**Courtney Flint and Matthew Naud,** BOSC Chairs
12:10–12:20 pm	Break	
12:20–1:25 pm	Research Area 10 Presentations (Part 2)	
	Output 10.3	**Emily Eisenhauer,** CPHEA
	Output 10.4	**Thomas Johnson,** CPHEA
	Output 10.5	**Michael Nye,** CPHEA
1:25–1:40 pm	BOSC Clarification Questions on Research Area 10, Part 2	**Courtney Flint and Matthew Naud,** BOSC Chairs
1:40–1:50 pm	Break	
1:50–2:20 pm	Program/Regional Partner Panel	**Sarah Mazur,** *Moderator,* SHC Associate Director **Ann Carroll,** *Panelist,* Office of Land and Emergency Management **Lisa Chang,** *Panelist,* EPA Region 10

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Time	Topic	Speaker
		Jonathan Essoka, *Panelist,* ORD Superfund and Technology Liaison for EPA Region 3 **Jeanine Finley,** *Panelist,* Office of Water **Amy Pelka,** *Panelist,* Great Lakes National Program Office **Alexis Rourk,** *Panelist,* Office of Community Revitalization
2:20–2:30 pm	Public Comments	**Tom Tracy,** DFO
2:30–3:00 pm	BOSC Discussion	**Courtney Flint and Matthew Naud,** BOSC Chairs

Day 3: Thursday, June 18, 2020, Eastern Daylight Time

Time	Topic	Speaker
3:00–5:00 pm	BOSC Discussion and Deliberations	**Courtney Flint and Matthew Naud,** BOSC Chairs

Day 4: Tuesday, June 30, 2020, Eastern Daylight Time

Time	Topic	Speaker
1:00–4:00 pm	BOSC Discussion, Deliberations, and Report-Out	**Courtney Flint and Matthew Naud,** BOSC Chairs

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APPENDIX C: MATERIALS

Material Provided in Advance of the Meeting

Materials to Support the Charge Questions

- Agenda
- Charge questions
- Descriptions for SHC Research Areas 9 and 10
- SHC FY19 Research Compendium
- SHC Final StRAP FY2019–2022
- 2020 ORD Response BOSC EC Report
- Presentations

Informational Materials

- EPA Presenter Bios BOSC SHC 2020
- Center Director Bios BOSC SHC June 2020
- Panelist Bios BOSC SHC June 2020
- BOSC SHC Subcommittee Roster
- Virtual Participation Guide

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