UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
RESEARCH AND DEVELOPMENT

SEP 11 2008

Gary S. Sayler, Ph.D.
Chair, Board of Scientific Counselors
Center for Environmental Biotechnology
The University of Tennessee
676 Dabney Hall
Knoxville, Tennessee 37996

Dear Dr. Sayler:

On November 14-16, 2007, the Human Health Risk Assessment Program Subcommittee of the Board of Scientific Counselors (BOSC) met in Bethesda, Maryland to evaluate the Office of Research and Development's (ORD) Human Health Risk Assessment (HHRA) Program. The Subcommittee presented a report of its findings and recommendations to the Executive Committee of the BOSC on March, 2008, and the Executive Committee, in turn, provided a final BOSC report to the ORD on May 27, 2008. With this letter, I am pleased to enclose the Agency's response to the final BOSC report of its review of the HHRA Program.

The HHRA Program greatly appreciates the insights, advice, and recommendations offered by the BOSC. The attached narrative presents an overview of specific recommendations made by the BOSC and provides a brief comment in response that indicates how the HHRA Program has taken the findings into consideration. A table that summarizes each recommendation, the action to be taken, and a schedule for completion of the action is also attached.

As you are aware, ORD conducts periodic evaluations of its research programs' progress at intervals of four-five years. The purpose of these reviews is to determine progress with regard to relevance, quality, performance and scientific leadership. The reviews also focus on identifying how the scientific community and programmatic clients utilize ORD's scientific outputs to protect human health and the environment. In addition to these formal reviews, ORD evaluates program progress midway through the review cycle. These mid-cycle reviews provide critical feedback to the program concerning its progress since the last review and the extent to which recommendations from that review are being met. The timing for the mid-cycle review of the HHRA Program will likely occur in 2010. In this context, we look forward to the possibility of working with you and other members of the Subcommittee again.

Sincerely,

for Kevin Y. Teichman, Ph.D.
Deputy Assistant Administrator for Science

Enclosure

Office of Research and Development's (ORD) Response to the Board of Scientific Counselors (BOSC) Report on Review of ORD's Human Health Risk Assessment (HHRA) Program **(final report received May 2008)**

September 2008

BOSC Human Health Risk Assessment Subcommittee
Dr. George Daston (Chair)
Mr. Bruce Allen
Dr. Henry Anderson
Dr. Richard Corley
Dr. John Evans
Dr. Mark Utell
Dr. Lauren Ziese

Submitted by:
Peter W. Preuss, PhD
Director, National Center for Environmental Assessment
Office of Research and Development

September 2008 Office of Research and Development's (ORD) Response to the Board of Scientific Counselors (BOSC) Report on Review of ORD's Human Health Risk Assessment (HHRA) Program (final report received May 2008)

The U.S. Environmental Protection Agency's (EPA) Office of Research and Development (ORD) relies on its Board of Scientific Counselors (BOSC) to conduct independent expert reviews of its environmental research programs every four to five years. The Human Health Risk Assessment (HHRA) Program Subcommittee of the BOSC met in Washington, DC on November 14-16, 2007 and the BOSC Executive Committee provided a final report in May, 2008. The principal charge to the BOSC reviewers was to evaluate ORD's HHRA Program from a program assessment framework relative to program relevance, structure, performance, quality, leadership, communication, and outcomes. A second priority was to provide a summary assessment and performance ranking for each of the three long-term goals identified with the HHRA Program. A set of specific charge questions was used to guide the Subcommittee through the review, producing a number of recommendations and observations with regard to the program.

The Subcommittee met by conference call twice in October 2007, and for a face-to-face meeting in November 2007, in Bethesda, Maryland. The face-to-face meeting consisted of an in-depth review of all aspects of the Program. NCEA Director Peter Preuss presented an overview of the HHRA Program. Each of the Program's long term goals (LTG) was introduced by a leader of the respective LTG, followed by poster sessions that highlighted some of the work being performed therein. The Subcommittee also heard from the key customers in the Agency's program offices and regions who rely on the information and scientific expertise provided by the HHRA Program, as well as external users of HHRA products. The Subcommittee began drafting its report at the face-to-face meeting. A draft report was reviewed by the Subcommittee in December 2007 and again in January 2008.

The purpose of the following narrative is to respond to the recommendations made in the *Review of the Office of Research and Development's Human Health Risk Assessment Program at the US Environmental Protection Agency, received May 27, 2008*.

RELEVANCE

The BOSC concluded that the Program's goals are fully consistent with the Agency's strategic mission and with the Program's multi-year plan (MYP). The products from LTG 1 and LTG 3 are critical to EPA's regulatory mission and form the foundation for regulatory decisions and policies in a variety of program offices and regions. The BOSC also found that: 1) Integrated Risk Information System (IRIS) assessments are critical to a number of goals and objectives listed in EPA's 2006-2011 Strategic Plan; 2) IRIS serves as the internationally recognized standard in chemical risk assessment for other federal, state, local and international regulatory bodies and the private sector; 3) LTG 3 is aligned with the requirements for assessment of criteria air pollutants as mandated by the Clean Air Act (CAA), and the importance of the HHRA Program in meeting CAA requirements could not be overstated; 4) the research conducted under LTG 2 focuses on critical needs and that good strategic choices have been made to concentrate

research in areas that are likely to result in marked improvements in risk assessment and 5) the HHRA Program has been highly responsive to the needs of the program offices and regions who strongly value the work and expertise of the HHRA, both in providing risk assessment products (IRIS assessments, provisional peer reviewed toxicity values-PPRTVs, and integrated science assessments- ISAs) and in supporting emergency responses to crises like the 9/11 terrorist attacks on the World Trade Center and Hurricane Katrina.

The BOSC, however, raised concerns regarding the rate of production of assessments, the 10-year life span of IRIS assessments, the review cycle of IRIS assessments and the potential effects of removing older IRIS assessments from the database. The BOSC's recommendations and HHRA Program's response are outlined below.

Recommendation 1: NCEA should assess what needs to be done to increase the Program's ability to produce more IRIS and PPRTV assessments per year, not only to meet their own stated objectives but also to satisfy the needs of their clients. This could either be in the form of a recommendation to the Agency for more resources, or the development of a more streamlined process.

Response: The HHRA program agrees that there is a need to provide more IRIS and PPRTV assessments per year and that there are both process requirements and resource limitations that affect productivity. For example, one prime limitation relates to the extensive reviews required for IRIS assessments and the additional demands on staffing and resources to conduct and respond to these reviews. On April 10, 2008, EPA Deputy Administrator, Marcus Peacock announced an update to the IRIS process for development of new assessments and reassessments and recommended the expeditious implementation of changes. The HHRA Program is implementing the revised process to meet current commitments and is revising the chemical prioritization and selection process to better reflect client office assessment priorities and associated resource requirements. For more information on the revised IRIS process and its implementation please refer to the websites below.

EPA's Integrated Risk Information System: Assessment Development Process (2008) (PDF) (9 pp, 65 KB, about PDF)
Implementation of Revised IRIS Process Memo: Marcus Peacock, EPA Deputy Administrator (PDF) (11 pp, 256 KB, about PDF)

In addition, an IRIS Update Process is being developed that will include an updated literature search and re-evaluation of the qualitative and quantitative determinations in IRIS assessments greater than ten years old. This new process is integrated with the current Literature Screening Project which has identified existing chemical assessments where either no new data are available or new data are available for updating values. Application of new analytical methods (e.g., benchmark dose, PBPK modeling) will also be taken into consideration where appropriate as part of the re-evaluation. In some cases, significant new data may warrant advancing assessments into the queue as a new IRIS assessment. The update process will include peer review by a Federal Standing Science Committee as well as a Standing External Peer Review Panel. This IRIS Update Process will process 8-12 chemicals at a time to maximize throughput of updated assessments.

The HHRA Program is addressing the concerns raised by the BOSC to assess what needs to be done to increase the Program's ability to produce more PPRTV assessments per year. The program has recently undertaken improvements in the standardization of document development and enhancements in the peer review and clearance processes. It is anticipated that these efforts will decrease the time required for the production of PPRTV assessments and increase the number of PPRTVs available to the program office.

Action/Timeline: The HHRA Program is implementing changes addressing development of new IRIS assessments and reassessments, is revising the chemical prioritization and selection process to address client office needs, has initiated development of a process for updating older assessments on IRIS and begun efforts to enhance and streamline the PPRTV process. The next update of the HHRA MYP will reflect any significant changes in these programs and new metrics agreed upon with OMB. Progress regarding these efforts will be discussed at the mid-cycle review of the HHRA Program in Fall 2009.

Recommendation 2: Mechanisms should be considered for retaining IRIS assessments older than 10 years that have not been updated, rather than allowing these assessments to expire and be removed from the IRIS database and Web site. One option is to simply annotate them as such.

Response: The HHRA Program appreciates the support of the BOSC to retain IRIS assessments older than ten years that have not been updated on the Website. The program has considered this recommendation and discussed with the programs offices and other interested partners the issue of whether to retain IRIS assessments older than ten years that have not been updated or to remove them from the IRIS database and Web site Older assessments will remain in the IRIS database and Website and annotated as to the literature screening results until they undergo updating by the new IRIS update process or the traditional IRIS process.

Action/Timeline: Implementation of the IRIS update process is underway and progress regarding these efforts will be discussed at the mid-cycle review of the HHRA Program in Fall 2009.

The BOSC commented that the collaborative efforts between NCEA and NCCT scientists relating to the development and application of new tools for toxicity assessment should continue and that this collaboration should inform NCCT research that will be of value to HHRA.

Recommendation 3: The HHRA Program should continue to develop ties with NCCT, and should provide formal input to that Program on the aspects of its research that will be of value to HHRA.

Response: The HHRA Program agrees with the BOSC's recommendation and is continuing to enhance communication and collaboration with NCCT. A number of such activities are underway including: 1) NCEA management and staff involvement in the development of the ORD Strategy for Toxicity Testing for the 21st Century; 2) formation of an NCEA-lead cross-Agency workgroup on the analysis and application of PBPK models for perchlorate that includes

principal scientists from NCCT; and 3) NCEA scientists serving as internal Agency reviewers of DSSTox database. Examples of more informal collaborations are: 1) NCCT scientists' participation in NCEA sponsored workshops and conferences such as the State of the Science workshop on Issues and Approaches in Low Dose-Response Extrapolation for Environmental Health Risk Assessment and the annual Toxicology and Risk Assessment Conference; 2) cross program sharing of information and resources, e.g., access to NCCT models and databases for SAR/QSAR screening approaches; 3) use of NCEA ARRAYTrack database and server by NCCT staff; 4) NCEA consultations with NCCT staff on the exposure communities of practice workgroup and 5) consultation on BMD methods and models development and 6) cross-participation in program seminars (e.g., NCCT seminar on the virtual fetus held August 2008). In addition, efforts to enhance LTG1 assessment development include collaboration with NCCT on agenda-setting for the IRIS Program and sharing assessment needs and prioritization information provided by clients with NCCT for consideration in prioritization of testing and evaluation in ToxCast. Future collaborations on the use of mode of action information in the virtual liver modeling efforts are also being discussed between scientists in both programs.

NCEA is continuing to build and strengthen expertise in the area of computational toxicology with staff participation in the upcoming Computational Systems Biology and Dose Response Workshop sponsored by the Hamner Institutes for Health Sciences. Dr. Rory B. Conolly of EPA's NCCT is one of the course advisors and trainers.

Action/Timeline: HHRA Program has initiated and will continue to seek opportunities to further collaborate with NCCT to share data and information. In addition, NCEA is continuing to build and strengthen expertise in the area of computational toxicology. Further efforts will be discussed at the mid-cycle review of the HHRA Program in Fall 2009.

STRUCTURE

The BOSC believes that the HHRA Program has a comprehensive and logical framework for producing high-quality risk assessments and for managing internal and external review processes. The consolidation of staff from multiple groups into a single core program under the HHRA rubric has facilitated communication and the adoption of standard practices and continuously improving processes. The interaction and cooperation between the HHRA Program and other ORD Programs, program offices and regions is occurring at higher levels than previous interactions. However, the BOSC pointed out that while HHRA staff members have provided invaluable service to program offices, regions, states, etc. in responding to emergencies (e.g.. the 9/11 terrorist bombings, Hurricane Katrina) or assisting in difficult cleanup activities (e.g. asbestos cleanup in Libby, Montana), these high-value activities are not captured in the overall framework and HHRA MYP.

Recommendation 4: The BOSC considers the responsiveness of the staff members to national emergencies and the HHRA Program's contributions to particularly difficult cleanup sites as being of such high value that this should somehow be captured in the Annual Performance Goals (APGs).

Response: The HHRA Program appreciates the BOSC's recognition of the high value of the program's responsiveness and contributions to national emergencies or assisting in difficult cleanup activities. We agree with that recommendation that these contributions should be accounted for in a meaningful way within the overall framework of the HHRA Program. It is clear that HHRA staff expertise will continue to an integral part of such responses. The program also recognizes that one of the significant implications of responding to such events as national emergencies maybe the reallocation of staff from key assessments or projects within LTG1, 2, and/or 3. As noted by the BOSC, it may not be plausible due to the unplanned nature of such events to fully account for or plan the resources needed to respond to such events or requests within an APG. The current APM/APG structure of ORD's MYPs is that APGs are major outputs that represent significant and timely milestones along a critical path toward the accomplishment of a LTG and that are planned over several years (three-five years). The program will however, work more closely with EPA's Office of Emergency and Redial Response to be better prepared to respond to such events.

The HHRA Program has also started to implement procedures to better track these activities and the resources expended internally. Under its Regulatory and Program Support activities NCEA currently tracks monthly program office and regional requests for assistance and assignment of HHRA staff to cross-Agency regulatory workgroups. This system is being expanded to include emergency responses. In addition NCEA is working with ORD's Labs and Centers and the Office of Science Policy to develop measures for support activities across ORD.

Action/Timeline: The HHRA Program has started to better track these activities and the resources expended both internally and across ORD. The program will also work more closely with EPA's Office of Emergency and Redial Response to be better prepared to respond to such events. The next update of the HHRA MYP will include a section or description relating to these response efforts.

The BOSC stated that under LTG 1 there is potentially a greater challenge in meeting the needs of its customers given the sheer number of chemical assessments that are needed by both internal and external customers. They noted that while the processes for developing IRIS documents and PPRTVs under LTG 1 are clear, the LTGs call for a static number of assessments to occur each year rather than calling for stretch goals to increase the number of annual assessments.

Recommendation 5: The BOSC recommends that, in addition to the goals of 16 new IRIS and 50 new or revised PPRTV assessments per year, goals be established for increasing the number of assessments. The BOSC recognizes that it may not be possible to do more, given current staffing and budgetary limitations, but there is clearly a significant demand for these products.

Response: The HHRA program agrees that there is a need to establish goals for increasing the number of assessments beyond that of 16 new IRIS and 50 new or revised PPRTV assessments per year. However, as noted in response to Recommendation # 1, there are both process requirements and resources limitations that affect productivity. The HHRA Program is implementing the revised process to meet current commitments and is revising the chemical prioritization and selection process to better reflect client office assessment priorities and

associated resource requirements. Further, the HHRA Program is developing a process for the update of IRIS assessments ten years and older.

The HHRA Program is also addressing the concerns raised by the BOSC to increase the Program's ability to produce more PPRTV assessments per year and has initiated significant modifications to protocols for the development of draft documents. In addition, the HHRA Program has initiated a process for the evaluation of PPRTVs with sufficient data to develop into IRIS assessments. Two PPRTV assessments (vanadium pentoxide and cobalt) are being evaluated and modified for entry into the IRIS review process. PPRTV assessments are also being evaluated for use in the IRIS Update Process.

Action/Timeline: The HHRA Program has begun a number of efforts to streamline and increase the number of assessments produced per year such as: 1) the development of an IRIS Update Process; 2) significant modifications to the PPRTVs development process; 3) the modification of PPRTVs with sufficient data for entry into the IRIS process and 4) PPRTV assessments are being evaluated for use in IRIS Update Process. An assessment of the programs' effectiveness, productivity and resource needs will be made as part of the implementation of these efforts. Consultations are also ongoing with OMB on new measures and metrics for the program.

Recommendation 6: The BOSC recommends that well-developed PPRTVs be considered as a source of prioritization in the development of full IRIS documents. This should assist the HHRA Program in meeting its goal of producing 16 IRIS assessments per year, but also should facilitate the accomplishment of stretch goals for completing additional assessments.

Response: The HHRA Program fully agrees with the BOSC recommendation that well-developed PPRTVs be considered as a source for the possible development of IRIS assessments. As noted in the response to Recommendation # 5 above, the HHRA Program has initiated this effort and currently PPRTVs for vanadium pentoxide and cobalt have been selected for modification and entry into the IRIS process.

Action/Timeline: HHRA Management is routinely evaluating new and renewed PPRTVs for potential development of new IRIS assessments or updating existing IRIS assessments. Thus far PPRTVs for vanadium pentoxide and cobalt have been selected for modification into IRIS assessments.

PROGRAM PERFORMANCE

The BOSC summarized HHRA's performance as making substantial and satisfactory progress on each LTG based both on the clearly defined milestones (APGs and APMs) and on providing the support requested in response to unscheduled emergency needs. The BOSC did note, however, that with respect to LTG 1, the APGs for every year include the completion of 16 high priority health hazard assessments and 50 new or renewed PPRTVs. This rate of completion will not satisfy the stated goal to have no IRIS entries over ten years old because there are now over 540 IRIS chemicals, and a renewal rate alone of 54 per year would be needed to achieve that goal.

Therefore, the BOSC re-iterated their recommendation that NCEA should assess what needs to be done to increase the rate of assessment completion.

Recommendation: NCEA should assess what needs to be done to increase the Program's ability to produce more IRIS and PPRTV assessments per year, not only to meet their own stated objectives but also to satisfy the needs of their clients. This could either be in the form of a recommendation to the Agency for more resources, or the development of a more streamlined process.

Response: See Response to Recommendations #1, #2, #5 and #6 above.

Action/Timeline: See Response to Recommendations #1, #2, #5 and #6 above.

PROGRAM QUALITY

The quality of the products of the HHRA Program was judged primarily on the basis of the global acceptance and use of the health assessments and the presentation of the research efforts completed and currently being pursued by staff scientists. The BOSC stated, on both counts, the very high quality of those products was evident. They also stated that IRIS assessments are considered internationally to be of the highest quality and reliability. The research efforts presented to the BOSC had a high degree of scientific relevance and merit. The review of criteria air pollutants has an excellent record of past performance.

Recommendation 7: In order to maintain the high level of quality that is evident in the HHRA work products, the BOSC strongly recommends that steps be taken to ensure the transparency of decisions made in the process of performing IRIS and PPRTV assessments and ISAs

Response: ORD appreciates the BOSC's recognition of the "very high quality" of its products and noting of the international status of IRIS assessments as being "considered to be of the highest quality and reliability" and agrees with the recommendation that steps be taken to ensure the transparency of decisions. As part of the new IRIS process announced on April 10, 2008 by EPA Deputy Administrator, Marcus Peacock, the Program has begun chemical specific "listening sessions". Since the April announcement, the HHRA Program has conducted listening sessions for the carbon tetrachloride, cerium, beryllium, and tetrachloroethylene IRIS assessments. Protocols and standard operating procedures for the selection, prioritization and development of IRIS assessments are available on the IRIS website and the program is currently revising the chemical prioritization and selection process to better reflect client office assessment priorities and associated resource requirements. All external peer review meetings are announced in the Federal Registered and are open to the public.

The IRIS Update Process is currently under development. In developing the draft process, the HHRA Program has met with EPA's Regional and Program Offices, the EPA Science Policy Council and the Toxic and Risk Subcommittee of the Committee on the Environment and Natural Resources (CENR) for their input into the process. Agreements have been established to involve all interested parties and agencies in the prioritization and peer-review of updated

chemicals assessments. The draft process includes both public notices through the Federal Register announcing chemicals under consideration and a request for available data and announcement of external peer review meetings. All external peer review meetings for the IRIS Update Program will be conducted through a FACA process and will be open to all interested parties.

For PPRTVs, OSWER works with the HHRA program to identify and prioritize chemicals for development. New contaminants s are selected based on their frequency and level of contamination at Superfund sites and whether or not other toxicity values are available e.g. Cal EPA or ATSDR values. Existing PPRTVs are re-evaluated every five years and updated as appropriate.

As noted in the BOSC report and discussed during the face-to-face meeting, the Agency has developed a new NAAQS review process which includes the development of Integrated Science Assessments (ISAs) by the HHRA Program. The new process was developed by an internal EPA workgroup in consultation with the Clean Air Scientific Advisory Committee (CASAC), Congressional staff and interested stakeholders. The new process also includes extensive collaboration and consultation between ORD and OAR throughout the entire review. It incorporates additional steps for peer-consultation with outside experts and stakeholders and includes an integrated planning step that guides the entire review. This integrated planning is achieved through workshops jointly sponsored by ORD and OAR to receive input from experts including members of CASAC who discuss key issues. The transition to the new process began in 2007 with the NOx and SOx reviews.

Action/Timeline: The HHRA program is developing and implementing a new IRIS development process which includes extensive intra- and interagency and public involvement, revised approaches to chemical prioritization and accountability, and a new Update Process Also, as noted above, ISAs are being developed as part of the new NAAQS process which includes extensive collaboration and consultation between ORD and OAR and public involvement throughout the entire review. An update on the development of IRIS assessments, PPRTVs, and ISAs will be provided at the mid-cycle review in Fall 2009.

SCIENTIFIC LEADERSHIP

The BOSC found that: 1) there are important areas in which HHRA Program scientists have played leadership roles at both the national and international levels; 2) the HHRA Program is clearly recognized as an international leader in risk assessment in both methods development and implementation; and 3) the areas of impressive leadership are related to IRIS and Air Quality Health and Environmental Assessments. Also the report states that taken as a whole, the evidence speaks to a community of highly trained and productive scientists, many of whom are leaders in their field, who are providing leadership to the United States and international governments as well as scientific communities and are engaged in risk assessment science and in solving important risk assessment problems.

Recommendation 8: The HHRA Program should consider using available resources to recruit one or two additional senior scientists, especially into the LTG 2 Program where efforts are underway to integrate emerging technologies into the risk assessment processes.

Response: The HHRA Program appreciates the feedback and recognition by the BOSC of the quality and extent of its leadership both nationally and internationally. The HHRA Program agrees with the recommendation to enhance that quality by recruiting senior scientists throughout its program and will look for opportunities to fill positions with senior leaders from both within the Agency and outside experts.

Action/Timeline: Recently, the HHRA program recruited a senior scientist from NHEERL, Dr. Linda Birnbaum. In addition, ORD has obtained authority to hire experts and senior scientists under Title 42. The HHRA Program has initiated one recruitment action under this program and will announce an additional recruitment in 2009.

COORDINATION AND COMMUNICATION

The BOSC stated that communication and coordination activities have been effectively institutionalized within HHRA. These activities are well established and occur vertically and horizontally within NCEA and with other relevant EPA programs and regional offices. Well-documented systems are in place and have operated for many years to provide a systematic, structured prioritization and communication strategy to assure that EPA program and regional office scientists and managers are effectively involved in setting priorities for assessment development and that HHRA activities such as IRIS and PPRTV assessments reflect the client's needs. The BOSC noted that with the exception of PPRTVs, HHRA products including assessments (such as IRIS and ISAs), methods, guidelines, and reference documents such as the Exposure Factors Handbooks, are all available to the public on the Internet and provide information not available from any other source.

Recommendation 9: PPRTVs far outnumber IRIS assessments and are being developed at four to five times the rate of IRIS assessments. They have been developed specifically to address the site specific needs of EPA's Superfund Program. Currently, PPRTVs and their supporting documentation are only available on a Web site restricted to use by EPA staff or to those who obtain special permission from EPA. The BOSC encourages EPA to make the PPRTVs publicly available for use in hazardous waste site risk assessment and promote their use where appropriate.

Response: The HHRA program agrees that PPRTVs are extremely important to the Superfund program and these assessments are important for assessing hazards at waste sites. PPRTVs are available to the states and other partners involved in waste site assessments and they are provided updates on a quarterly basis. PPRTVs are also being made available to other program offices within EPA for screening and prioritization of research needs, e.g. Use by Office of Water to prioritize research needs for CCL3 decisions. PPRTVs are also being modified where appropriate to support the development of IRIS assessments and new PPRTVs evaluated for use in IRIS Update Process.

Please note there currently are over 547 chemical assessments on IRIS. PPRTVs have been developed for 381 chemicals.

Action/Timeline: PPRTVs are available to the states and other partners involved in waste site assessments and they are provided updates on a quarterly basis. Within EPA PPRTVs are being made available to other program offices for screening and prioritization of research needs.

OUTCOMES

The BOSC concluded that outcome measures are extremely well defined for each LTG and that annual measures are well described. The procedures for IRIS and PPRTVs appear to be well considered and to work well, but how decisions are made is not immediately transparent. The BOSC was particularly interested to know whether chemicals that had not reached a high enough priority level to be reviewed in a given year were carried over for consideration in ensuing years, and whether they were accorded a higher priority status by virtue of having been on the list for a period of time. The BOSC also re-iterated its recommendation (See Recommendation #4) to consider capturing in the APGs the program's responsiveness to national emergencies and high profile site clean-ups.

Recommendation 10: The HHRA Program needs to consider information on the potential public health concern of various chemicals as it prioritizes them for IRIS or PPRTV review. It appears that some of this information is being provided by the program and regional offices, but it would be of value for the Program to make transparent the basis for its prioritization decisions for IRIS and PPRTVs.

Response: The HHRA program agrees with the BOSC's recommendation to consider information on the potential public health concern of various chemicals as it prioritizes them for IRIS or PPRTV review and the need for transparency within the program. Criteria for the selection and prioritization of chemicals for new IRIS assessments and reassessments have been established and are available on the IRIS website (www.epa.gov/iris). The IRIS process provides both opportunities for public comment as well as providing available data. Currently NCEA is meeting with the program offices and regions to provide more explicit information on the IRIS process and setting priorities. For the IRIS Update Process a draft process has been developed which includes a detailed selection and prioritization process as well as public notification. The selection of chemicals for development of new PPRTVs or updating assessments is determined by OSWER in consultation with ORD. The selection criteria are based on frequency and extent of contamination at Superfund sites, the availability of toxicity values from other sources and the availability of qualitative and quantitative information.

Action/Timeline: NCEA is meeting with the program offices and regions to provide more explicit information on the IRIS process and setting priorities. Progress regarding these efforts will be discussed at the mid-cycle review of the HHRA Program in Fall 2009.

Human Health Risk Assessment Program
Summary of Recommendations and Proposed ORD Actions and Timelines

Recommendation	Action	Timeline for Action
Recommendation 1: NCEA should assess what needs to be done to increase the Program's ability to produce more IRIS and PPRTV assessments per year, not only to meet their own stated objectives but also to satisfy the needs of their clients. This could either be in the form of a recommendation to the Agency for more resources, or the development of a more streamlined process.	The HHRA Program is implementing changes addressing development of new IRIS assessments and reassessments, is revising the chemical prioritization and selection process to address client office needs, has initiated development of a process for updating older assessments on IRIS and begun efforts to enhance and streamline the PPRTV process.	The next update of the HHRA MYP will reflect any significant changes in these programs and new metrics agreed upon with OMB. Progress regarding these efforts will also be discussed at the mid-cycle review of the HHRA Program in Fall 2009.
Recommendation 2: Mechanisms should be considered for retaining IRIS assessments older than 10 years that have not been updated, rather than allowing these assessments to expire and be removed from the IRIS database and Web site. One option is to simply annotate them as such.	Implementation of the IRIS update process is underway.	Progress regarding these efforts will be discussed at the mid-cycle review of the HHRA Program in Fall 2009.
Recommendation 3: The HHRA Program should continue to develop ties with NCCT, and should provide formal input to that Program on the aspects of its research that will be of value to HHRA.	HHRA Program has initiated and will continue to seek opportunities to further collaborations with NCCT and to share data and information. In addition, NCEA is continuing to build and strengthen expertise in the area of computational toxicology.	Further efforts will be presented at the mid-cycle review of the HHRA Program in Fall 2009.
Recommendation 4: The Subcommittee considers the responsiveness of the staff members to national emergencies and the HHRA Program's contributions to particularly difficult cleanup sites as being of such high value that this should somehow be captured in the APGs.	The HHRA Program has started to better track these activities and the resources expended both internally and across ORD. The program will also work more closely with EPA's Office of Emergency and Redial Response to be better prepared to respond to such events.	The next update of the HHRA MYP will include a section or description relating to these response efforts.
Recommendation 5: The Subcommittee recommends that, in addition to the goals of 16 new IRIS and 50 new or revised PPRTV assessments per year, goals be established for increasing the number of IRIS assessments. The Subcommittee recognizes that it may not be possible to do more, given current staffing and budgetary limitations.	Given current limitations, the HHRA Program has begun a number of efforts to streamline and increase the number of assessments produced per year such as: 1) the development of an IRIS Update Process; 2) significant modifications to the PPRTVs development process; 3) the modification of PPRTVs with sufficient data for entry into the IRIS process and 4) PPRTV	Ongoing. Progress regarding these efforts will be discussed at the mid-cycle review of the HHRA Program in Fall 2009.

	assessments are being evaluated for use in IRIS Update Process Consultations are also ongoing with OMB on new measures and metrics for the program.	
Recommendation 6: The Subcommittee recommends that well-developed PRTVs be considered as a source of prioritization in the development of full IRIS documents	HHRA Management is routinely evaluating new and renewed PPRTVs for potential development of new IRIS assessments or updating existing IRIS assessments. Thus far PPRTVs for vanadium pentoxide and cobalt have been selected for modification into IRIS assessments.	Progress regarding these efforts will be discussed at the mid-cycle review of the HHRA Program in Fall 2009.
Recommendation 7: In order to maintain the high level of quality that is evident in the HHRA work products, the Subcommittee strongly recommends that steps be taken to ensure the transparency of decisions made in the process of performing IRIS and PPRTV assessments and ISA assessments	The HHRA program is developing and implementing a new IRIS development process which includes extensive intra- and interagency and public involvement, revised approaches to chemical prioritization and accountability, and a new Update Process. ISAs are being developed as part of the new NAAQS process which includes extensive collaboration and consultation between ORD and OAR and public involvement throughout the entire review.	An update on the development of IRIS assessments, PPRTVs, and ISAs will be provided at the mid-cycle review in Fall of 2009.
Recommendation 8: The HRRA Program should consider using available resources to recruit one or two additional senior scientists, especially into the LTG 2 Program where efforts are underway to integrate emerging technologies into the risk assessment processes.	Recently, HHRA program recruited a senior scientist from NHEERL Dr. Linda Birnbaum. In addition, ORD has obtained authority to hire experts and senior scientists under Title 42. The HHRA Program has initiated one recruitment action under this program and will announce an additional recruitment in 2009.	Ongoing.
Recommendation 9: PRTVs have been developed specifically to address the site specific needs of EPA's Superfund Program. Currently, PRTVs and their supporting documentation are only available on a Web site restricted to use by EPA staff or to those who obtain special permission from EPA. The Subcommittee encourages EPA to make the PPRTVs publicly available for use in hazardous waste site risk assessment and promote their use where appropriate.	PPRTVs are available to the states and other partners involved in waste site assessments. Updates are provided on a quarterly basis. Within EPA, PPRTVs are being made available to other program offices for screening and prioritization of research needs.	Further efforts will be discussed at the mid-cycle review of the HHRA Program in Fall 2009.
Recommendation 10:	NCEA is meeting with the program	Progress regarding these efforts will be

The HHRA Program needs to consider information on the potential public health concern of various chemicals as it prioritizes them for IRIS or PPRTV review. It appears that some of this information is being provided by the program and regional offices, but it would be of value for the Program to make transparent the basis for its prioritization decisions for IRIS and PPRTVs.	offices and regions to provide more explicit information on the IRIS process and setting priorities.	discussed at the mid-cycle review of the HHRA Program in Fall 2009.