

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institute of Environmental Health Sciences Superfund Hazardous Substance Research and Training Program Strategic Plan; Request for Comments**

ACTION: Notice.

SUMMARY: The National Institute of Environmental Health Sciences (NIEHS), a research institute of the National Institutes of Health (NIH) within the Department of Health and Human Services (DHHS), is seeking comments on this draft National Institute of Environmental Health Sciences Superfund Hazardous Substance Research and Training Program (SRP) Strategic Plan.

DATES: To assure consideration, comments must be received by 30 days following the date of publication of this notice.

ADDRESSES: Comments may be e-mailed to Srpinfo@neihs.nih.gov.

Introduction

The National Institute of Environmental Health Sciences (NIEHS) Superfund Hazardous Substance Research and Training Program (SRP) is a critical player in the national effort to protect human health and the environment from hazardous substances. The university-based research program was created under the Superfund Amendments and Reauthorization Act (SARA) of 1986 to meet the need for innovative strategies and technologies to provide solutions to the magnitude and complexity of Superfund assessment and remediation. The SARA legislation calls for a basic research and training program with four targeted mandate areas: Human health effects, assessment of risks, detection technologies, and remediation approaches relevant to hazardous substances. The SRP was created by the same legislative framework that created the Environmental Protection Agency's (EPA) Superfund hazardous waste remediation program and the Center for Disease Control and Prevention's Agency for Toxic Substances and Disease Registry (ATSDR). The SRP's role is to support science-based decision-making by elucidating the basic principles underlying hazardous substance toxicity, risk assessment, measurement, and remediation. Accordingly SRP, EPA, and ATSDR constitute a shared partnership to improve human health and the environment through reducing or

eliminating the negative impacts of hazardous waste sites.

In order to fulfill its mandates, the SRP has developed a research framework that integrates the many different disciplines required to address the complex, interdependent, yet fundamental issues related to hazardous substances. These disciplines include toxicology, molecular biology, engineering, geosciences, epidemiology, ecology, *etc.* SRP research achieves a fundamental understanding of biological, environmental and engineering processes (*i.e.*, basic science) and exploits this knowledge to contribute to solving hazardous waste-related issues (*i.e.*, applied science). In addition, the SRP seeks to train the next generation of researchers and professionals tasked with protecting human health and the environment from the risks of hazardous substances.

Objectives and Goals

The purposes of this Strategic Plan are to communicate objectives and goals identified by the Program staff and to present strategies to be implemented over the next five years. Three overarching objectives provide direction to the SRP:

1. Address issues of high relevance.
2. Maximize the impact of program investments.
3. Foster innovation.

Objective 1: Address Issues of High Relevance

Relevant research is defined in the SRP mandates presented in SARA Section 311(a). SARA describes the Program's primary objectives to be the development of: Advanced techniques for the detection, assessment, and evaluation of the effects on human health of hazardous substances; methods to assess the risks to human health presented by hazardous substances; methods and technologies to detect hazardous substances in the environment; and basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances.

Within the context of Program mandates, the SRP considers the diverse research and information needs of its stakeholders as important criteria for determining relevance. The SRP's primary stakeholders are its sister Superfund programs at EPA and ATSDR. Additional stakeholders include other Federal agencies, State, local, and Tribal entities responsible for the myriad sites impacted by hazardous substances, as well as the individuals and communities living near hazardous waste sites.

Goals To Achieve Relevance

- *Encourage problem-based, solution-oriented research.* The multi-disciplinary scope of mandates and the Program structure provide the potential for SRP research to address complex environmental problems, particularly related to sites impacted by hazardous substances. In addition to addressing complex problems, the SRP wants the research to continually achieve greater relevance. To promote relevance, the SRP challenges applicants to design problem-based, solution-oriented research proposals. This will create opportunities to solve issues relevant to the SRP stakeholders' needs. In consultation with stakeholders, Program staff seeks to improve the processes for identifying stakeholder research needs and to incorporate these needs into its research agenda.

- *Promote interaction between SRP and its stakeholders.* The SRP recognizes that ongoing interaction with stakeholders promotes research relevance. Therefore, investigators should seek input from stakeholders as they develop a proposal and should keep them apprised of progress throughout the life of the grant. This applies not only to research, but also community engagement activities. Program staff will assist in fostering these interactions by creating networking opportunities between stakeholders and grantees. Program staff will also investigate mechanisms to provide research opportunities between grantees and stakeholders.

- *Prioritize critical research areas.* Maximizing relevancy requires that SRP covers all mandate areas (health effects, risk, detection and remediation) and addresses the most critical current and emerging needs. To accomplish this, SRP will be proactive in achieving coverage across mandate areas, contaminants, and exposure scenarios placing emphasis on stakeholders' critical needs. This also means deemphasizing areas of duplication within Program research. Program staff will take steps to effectively communicate these priorities to applicants, grantees, and peer reviewers. When preparing applications, applicants should, in turn, assemble teams to address research challenges within a given mandate area, contaminant, or exposure scenario with the greatest potential to support SRP's goal to protect human health and the environment from hazardous substances.

Objective 2: Maximize the Impact of Program Investments

The SRP anticipates that Program-generated scientific knowledge will be used by stakeholders in making science-based decisions ranging from selecting innovative remediation strategies, to reducing exposures, to improving risk reduction policy and practice. In the Program's more than 20 year history, SRP-funded researchers have made significant advances in each of the Program's mandated research areas. SRP sees tremendous potential to enhance research translation, dissemination, collaboration, and training in order to maximize the impact of its research investment.

Goals To Achieve Impact

- *Encourage investigator-initiated research translation.* Research translation fosters the movement of fundamental science toward a useable end-product. It is critical that researchers assume the responsibility for developing the connections that allow for the application of their research advances. This is an iterative process that will require a proactive effort from the grantee and coordination by Program staff. SRP seeks investigators who share an interest in effectively translating discoveries to stakeholders.

- *Disseminate Program successes and research findings.* Disseminating research findings to multiple audiences is critical to maximizing Program investments. Program staff, in coordination with grantees, will develop and/or facilitate use of tools to support enhanced distribution of Program advances. In addition to the traditional peer-reviewed publications expected by the SRP, the Program encourages grantees to develop position pieces, reviews, and non-traditional communication methods to make the significance and applicability of SRP-funded research discoveries more accessible to the Program's broad range of stakeholders.

- *Enhance coordination and collaboration between grantees.* By sharing knowledge and working together, grantees leverage resources, maximize productivity, and accelerate scientific advancement, ultimately benefiting those engaged in the policy and practice of Superfund-related work. Grantees should seek opportunities to coordinate with each other and, when appropriate, pursue collaborative projects. Program staff will, in turn, identify appropriate mechanisms to facilitate coordination and support for such collaborations.

- *Enhance impact of training activities.* SRP will continue to emphasize training of graduate and post-doctoral students in cross-disciplinary research. However, the objectives proposed within this strategic plan provide an opportunity to broaden the impact of SRP training. Grantees should identify ways to involve trainees in stakeholder interactions or community engagement, in projects that promote coordination or collaboration among grantees, and in research translation. To broaden cross-disciplinary opportunities, Program staff will foster networking among trainees, and between trainees and stakeholders.

Objective 3: Foster Innovation

The SRP was created to address the need for innovative strategies and technologies to provide solutions to Superfund-related issues. As such, SRP is uniquely positioned to develop new methods and approaches to tackle complex problems for which there is no easy solution. While achieving the relevance and impact, the Program strives to push the boundaries of science using the newest technologies and challenging current paradigms. SRP will provide the structure to allow grantees to pursue novel ideas and untested approaches. When successful, such high risk research results in significant scientific advances.

Goals To Foster Innovation

- *Promote transdisciplinary science.* SRP firmly supports transdisciplinary research—the synthesis and extension of disciplinary boundaries—as a mechanism for introducing innovative solutions to problems. Applicants are encouraged to create novel solutions to existing, relevant problems by adapting technologies and approaches from one field and applying them to other fields. SRP has and will continue to foster opportunities for this kind of research.

- *Encourage new technologies and challenge existing paradigms.* While a portion of SRP grants advance current risk paradigms or improve established clean-up remedies, forward-looking or “anticipatory” research is also critical to identify and address future stakeholder needs. This may include utilizing cutting-edge research tools, developing new risk frameworks, or devising more sustainable solutions to address Superfund issues. As these new approaches may be considered “risky” research, Program staff will ensure appropriate review of applications proposing high-risk, high payoff research.

Guiding Principles

The SRP recognizes that the successful implementation of the goals and objectives of the Strategic Plan must be accomplished in a manner that is accountable, coordinated, and transparent.

Accountable—SRP will meet and exceed the directives of the Program mandates while adhering to the policies of NIH. This Strategic Plan is designed to allow the Program to enhance its accountability to stakeholders and taxpayers by directing research towards highly relevant, impact-driven, and innovative solutions to our nation's Superfund-related issues.

Coordinated—As the SRP has limited resources, it is imperative to coordinate its research efforts with other research, training, community engagement, and technology development programs being administered through various academic, private-sector, and governmental entities. Where possible, the SRP, in partnership with other programs, will seek to leverage its finite research dollars, such that the benefits of its research advances are maximized and fully utilized.

SRP staff will coordinate interactions at multiple levels:

- Among the SRP grantee community which includes multi-project grants, individual investigator grants, and small business innovative research/small business technology transfer grants.

- Within the National Institutes of Health (NIH):

- With other research programs within NIEHS, such as the Worker Training Program and the National Toxicology Program.

- With other NIH Institutes, programs or offices, such as the Office of Behavioral and Social Sciences Research, and National Institute of Biomedical Imaging and Bioengineering.

- With trans-NIH programs, such as the Genes, Environment and Health Initiative, and *Countermeasures Against Chemical Threats* (CounterACT) Research Network.

- Between sister Superfund agencies, that is the EPA Office of Superfund Remediation and Technology Innovation and ATSDR.

- Between agencies with similar missions for research, training, and technology development such as the EPA Office of Research and Development and the National Science Foundation.

These coordination activities are necessary to fully advance SRP science into the hands of stakeholders.

Transparent—SRP anticipates an evolving process in implementing the

objectives of the Strategic Plan. Program staff will communicate anticipated actions to grantees, reviewers, and stakeholders. The staff will be open for suggestions to improve transparency or identify areas where clarification is needed.

Conclusion

There remains a need for fundamental research to address SRP's original mandates. The Program's sister agencies tasked with developing and implementing policies to protect health rely upon the best science. Likewise, communities living near sites impacted by hazardous substances need accessible science to fully participate in decisions made about site management. The stated objectives of the Strategic Plan (addressing relevant issues, maximizing impact, and fostering innovation) have been designed to better address stakeholders' needs. This Strategic Plan, as a living document, will guide the Program over the next five years. Program staff look forward to embracing this future with grantees, stakeholders, and others who share the greater vision of improving human health and the environment through reducing or eliminating the negative impacts of exposure to hazardous substances from hazardous waste sites.

Program staff thank the many contributors who have provided constructive comments during the strategic planning process and thereby assisted in the development of this draft strategic plan. We are now seeking comments on the draft strategic plan. Comments will be accepted for 30 days following the publication of this notice. Please e-mail comments to Srpinfo@neihs.nih.gov.

Dated: June 24, 2010.

William A. Suk,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "National Hospital Adverse Event Reporting System: Questionnaire Redesign and Testing." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on May 3rd 2010 and allowed 60 days for public comment. One comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by August 2, 2010.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (*attention:* AHRQ's desk officer) or by e-mail at OIRA_submission@omb.eop.gov (*attention:* AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at doris.lefkowitz@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

National Hospital Adverse Event Reporting System: Questionnaire Redesign and Testing

As provider of operational support to the chair of the Quality Interagency Task Force (QuIC), AHRQ coordinated the Federal response to the Institute of Medicine's (IOM) 1999 report on medical errors and outlined specific initiatives the QuIC agencies will take. The Errors Workgroup within the QuIC identified the need for measures to evaluate the use of adverse medical event reporting for managing and improving patient safety within healthcare institutions. In response, AHRQ created the Hospital Adverse Event Reporting Survey to provide national estimates. This survey has been fielded twice, first in 2005 and again in 2008.

Revisions to the questionnaire and sample selection are now necessary in response to the Patient Safety and Quality Improvement Rule (Patient Safety Rule), 42 CFR Part 3, issued by

the United States Department of Health and Human Services, which implements the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), 42 U.S.C. 299b-21 through 299b-26. The Patient Safety Rule and Patient Safety Act authorize the creation of Patient Safety Organizations (PSO) to enhance quality and safety by collecting patient safety reports of adverse events. AHRQ started listing PSOs in late 2008 pursuant to the Patient Safety Act. These organizations have begun working with hospitals and other providers to monitor patient safety events according to common reporting formats, and to improve patient safety. This revised survey will be used for the third round of data collection in 2011, under a separate OMB clearance, to assess the impact of the PSOs and the Patient Safety Act on the use of adverse event reporting systems and will incorporate questions about reporting using the AHRQ Common Formats, and reporting information to a Patient Safety Organization.

This project is being conducted by AHRQ's contractor, Westat, pursuant to AHRQ's statutory mandates to (1) promote health care quality improvement by conducting and supporting research that develops and presents scientific evidence regarding all aspects of health care, including methods for measuring quality and strategies for improving quality (42 U.S.C. 299(b)(1)(F)) and (2) conduct and support research on health care and on systems for the delivery of such care, including activities with respect to quality measurement and improvement (42 U.S.C. 299a(a)(2)).

Method of Collection

This project will include the following data collections:

(1) Semi-structured interviews will be conducted with one risk manager or other representative responsible for adverse event reporting from 7 participating hospitals and with one person from the two participating PSOs. These interviews will be conducted to learn more about the current hospital adverse event reporting environment and to understand how adverse event reporting may have changed in response to the Patient Safety Act. Survey developers will use the information from these interviews to develop questions for the revised questionnaire.

(2) Cognitive interviews will be conducted with one risk manager or other representative responsible for adverse event reporting in 30 participating hospitals. The purpose of these cognitive interviews is to test and refine the revised questionnaire. The