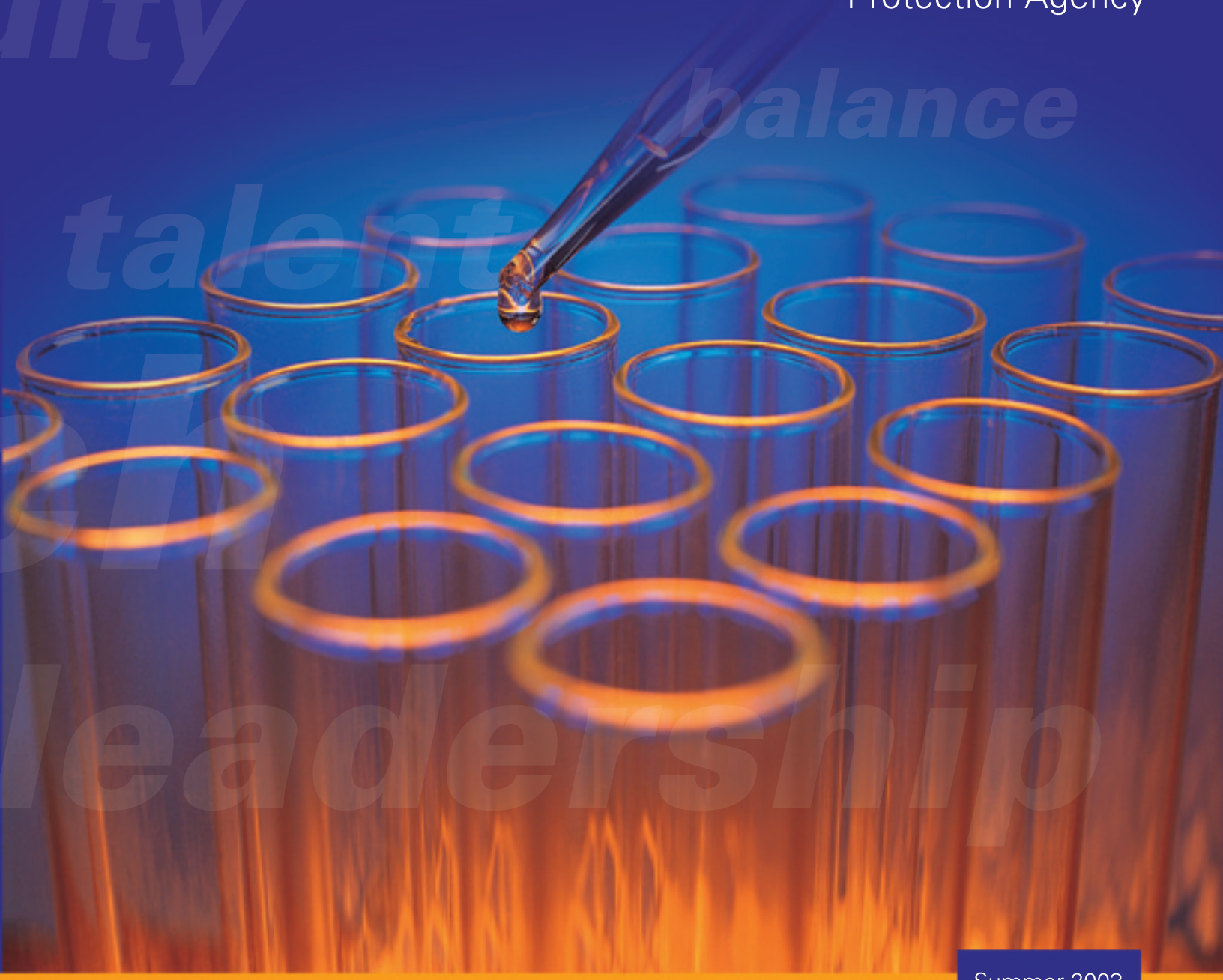
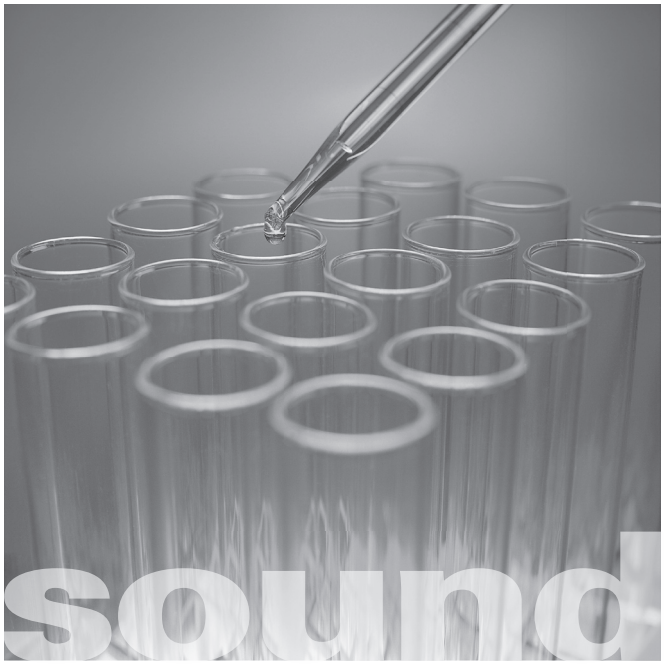
the**state**of **sound**science

at the U.S. Environmental Protection Agency



Summer 2003



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at the U.S. Environmental Protection Agency
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sound science

EPA's recent accomplishments in advancing its science program go beyond the recommendations in "Strengthening Science."

EPA Responds to National Research Council Report

In the three years since the National Research Council's (NRC) June 2000 report, "Strengthening Science at the U.S. Environmental Protection Agency: Research Management and Peer Review Practices," significant progress has been made to achieve relevant, peer-reviewed, sound science at EPA. The report, prepared in response to a request from Congress for an independent assessment of the overall structure and management of EPA's research and peer review programs, has been a very useful guide for enhancing EPA's already strong science program. EPA's recent accomplishments in advancing its science program go beyond the recommendations in "Strengthening Science."

Strengthening Science

The NRC made recommendations for strengthening EPA science in five areas:

- scientific leadership and talent
- research continuity and balance
- research partnerships and outreach
- research accountability
- scientific peer review

In the past two years, the Agency has made significant progress in all five areas, each of which we deem to be of high priority for the Agency. EPA has not rejected any of the NRC's recommendations, although in some cases it has adapted implementation of a recommendation's intent to accommodate jurisdictional realities and administration priorities.

leadership

Scientific Leadership and Talent

The NRC recommended establishing a new position of Deputy Administrator for Science and Technology, as well as converting the position of Assistant Administrator for Research and Development into a six-year statutory term appointment. The Administrator addressed the NRC's concerns for coordinated agency-wide scientific leadership by naming Dr. Paul Gilman, Assistant Administrator for Research and Development, as the EPA Science Advisor. As the Science Advisor, Dr. Gilman is positioned to ensure that EPA has the best science to support Agency policies and decisions, and to advise the Administrator on science and technology issues and their relationship to EPA's policies, procedures, and decisions.

A key recommendation in "Strengthening Science" was that EPA continue to place a high priority on its graduate fellowship and postdoctoral programs. In FY 1999, EPA deployed a long-range program of hiring postdoctoral scientists and engineers for three-year term appointments. Our post-docs provide a dynamic infusion of intellectual energy and state-of-the science expertise to ensure that EPA continues to produce outstanding scientists and engineers in the field of environmental protection. Examples of post-doctoral research contributions include: participation as members of the ground zero monitoring team at the World Trade Center site, development of a method to identify Hepatitis E in watersheds, and the development of a population model to predict children's exposure and dose resulting from contact with pesticides applied in homes and on lawns.

balance

Research Continuity and Balance

The NRC's principal recommendations for research continuity and balance were that EPA continue and expand its multi-year research planning effort, and maintain a balance between core and problem-driven research. EPA has done both. The Agency has initiated a multi-year planning effort to set the direction of its research program in selected topic areas over five or more years. This approach will promote EPA's focus on the highest-priority issues and will provide a coordinated means of achieving its long-term research goals. To date, EPA has completed 16 multi-year plans, and is coordinating external review of the plans by the Science Advisory Board (SAB), and other external bodies. EPA's allocation between problem-driven and core research is approximately 60 and 40 percent, respectively. This distribution has remained constant in recent years, and the Administrator believes this is an appropriate allocation for a research program designed to support EPA's mission.

Research Partnerships and Outreach

The focus of the NRC's recommendations for research partnerships and outreach was two-fold: greater EPA awareness of research being conducted outside the Agency, and better communication of EPA research to outside parties. The Agency is achieving significant success in partnering with others in research activities. For example, EPA and the American Chemistry Council have signed an agreement to coordinate on two multi-year Cooperative Research and Development Agreements to understand better the potential effects of chemicals on fetal and childhood immune system development, and the potential impacts of endocrine-active chemicals on wildlife populations. EPA also is active in many interagency task forces and workgroups in such areas as safe food and trans-boundary pollution.

EPA's Science to Achieve Results, or STAR program, funds research grants and graduate fellowships in numerous environmental science and engineering disciplines through a competitive solicitation process and independent peer review. The program engages the nation's best scientists and engineers in targeted research that complements EPA's own outstanding intramural research program and those of our partners in other federal agencies. In addition, through this same competitive process, EPA periodically establishes large research centers in specific areas of national concern. At present, these centers focus on children's health, hazardous substances, particulate matter, and estuarine and coastal monitoring.

"The U.S. Environmental Protection Agency's competitive research grants program has yielded significant new findings and knowledge critical for EPA's decision-making process," says a new report, released in May, from the National Academies' National Research Council. Established in 1995, STAR gives about $100 million a year in grants and fellowships to independent investigators, multi disciplinary teams, and graduate students at universities and nonprofit institutions.

Because of its strong contributions to EPA scientific efforts, the grants program should remain an important part of the Agency's overall research program, the report says. For example, STAR research has resulted in a better understanding of the effects of particulate-matter air pollution on public health, new insights on the impact of pesticides and industrial chemicals on human and wildlife reproduction, and the development of new indicators for waterborne pathogens.

"The STAR program has established and maintained a high degree of scientific excellence," said Harold Mooney, chair of the committee that wrote the report and Paul S. Achilles, Professor of Environmental Biology at Stanford University in California. "It has provided EPA with independent analysis and perspective that has improved the Agency's scientific foundation. By attracting young researchers, this program has also expanded the nation's environmental science infrastructure."

"The STAR program has established a rigorous, independent peer-reviewed process for selecting grant awardees and funds scientists with impressive track records, who frequently are leaders in their fields," the report says. The NAS committee encouraged EPA to continue to attract the "best and brightest" to compete for STAR funding.

partnerships

The Agency has made great strides in its outreach efforts. In May 2003, EPA held its second annual Science Forum, a two-day public event with more than 1,100 attendees that showcased Agency science across the spectrum of environmental science activities. EPA has also enhanced communication of its extramural research program by providing public access, via the Internet and news releases, to its extensive database of STAR grants. The Office of Research and Development also holds several public workshops each year to highlight the research being conducted by STAR grantees and its intramural program.

Research Accountability

Under accountability, the NRC emphasized two areas: enhanced transparency in setting EPA's research agenda, and expanding EPA's new inventory of science activities. EPA has had success in both areas. EPA's multi-year research plans provide a transparent and forward-looking view of the Agency's research agenda for the next several years, by identifying long-term goals and presenting annual performance goals and associated annual performance measures for a planning window of approximately 5-10 years. The multi-year plans also foster the integration of strategic, risk-based environmental protection and anticipation of future environmental issues by communicating our research approach and timing for responding to environmental issues. The multi-year plans are living documents and are updated regularly to reflect changes in Agency strategic thinking, the realities of available resources, and the current state of the science.

EPA is also experiencing great success in expanding its inventory of science activities. In 2002, offices from across EPA provided more than 4,500 submissions of current science activities and recently completed scientific/technical work products. The inventory is currently being updated for 2003. This year, the Science Inventory is being made available across EPA via an Intranet portal. Experience with Agency staff using the inventory will prove valuable in determining the most useful and usable format for making the science inventory available to the public via the Internet.

Scientific Peer Review

Consistent agency-wide application of peer review has been an EPA priority for many years. Since issuing its peer review policy in 1993, EPA has taken several major steps to support and strengthen the policy. But proof of a policy's value lies in its implementation, and here also EPA has been very active to ensure that its peer review policy is not only understood across the Agency, but is *applied* rigorously across EPA's program and regional offices.

One example is the external peer review of EPA's research strategies and plans by the SAB and others. These reviews provide critical, early input to the Agency at the planning stage as it establishes its research priorities. A second example is the external peer review of EPA's research efforts by the National Research Council, the EPA Office of Research and Development's Board of Scientific Counselors and others. In March 2003, the Human Studies Division of EPA's National Health and Environmental Effects Research Laboratory (NHEERL) underwent a three-day peer review of its epidemiological and clinical research. Each of NHEERL's nine divisions conducts such a detailed review every four years, with a mid-cycle review after two years. Also, all the grants awarded by the

STAR program are selected through a rigorous peer review process, whereby panels of independent researchers review all the proposals for their scientific quality.

In response to the 2001 General Accounting Office (GAO) report entitled *EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance*, the SAB has taken several steps to address potential conflict-of-interest concerns. These include internal procedural actions within EPA's SAB Staff Office, as well as the new conflict-of-interest form developed by the SAB (and approved by the Office of Government Ethics) that is required to be submitted by all prospective panel members; this same, new conflict-of-interest form is now being used by EPA's other review bodies that utilize Special Government Employees, such as the SAP. These new conflict-of-interest procedures complement existing procedures used for all extramural peer reviews managed by contracts.

Internal conflict of interest – making sure that those EPA employees who manage the peer review process are not inappropriately influenced by Agency decision makers who will determine how the work product informs the decision – is also an issue EPA has considered and addressed. In its December 2000 2nd edition of the *Peer Review Handbook,* EPA included supplemental guidance to address this issue. The revised handbook, among other things, clarifies the importance of strictly separating the management of scientific work products from the management of the peer review of those work products.

Beyond "Strengthening Science"

While the above activities have gone a long way toward improving science at EPA, the Agency has pursued going beyond the recommendations of "Strengthening Science." This includes making sure that EPA is not only doing the science right and doing the right science, but that EPA's scientific and technical information is appropriately *applied* to the Agency's policies and regulatory decisions.

regulations

Enhancing Science in Regulations

Upon arriving at EPA, Administrator Whitman commissioned a task force to identify ways to strengthen the scientific and economic bases of policies and decisions at EPA. The task force recommended that EPA scientists and engineers become more actively involved in the Agency's decision-making process, to make sure that EPA's decisions are informed by the best available scientific and technical information. As a result, the Agency has increased its support for scientific input into regulatory decisions, and the number of EPA engineers and scientists actively engaged at any one time in providing scientific input into EPA's regulations has increased substantially in the past two years.

Dr. Gilman has played an active role in shaping the Agency's Information Quality Guidelines, to ensure that all scientific and technical information disseminated by EPA meets high standards for quality. To further this objective, EPA has initiated an effort to describe the factors EPA considers when it uses scientific and technical information to inform Agency decisions. These *assessment factors* have undergone public review and will be used by all EPA programs to ensure that the Agency is using the appropriate scientific and technical information for our decisions, and that Agency decisions are clearly communicated to the public.

In another move to enhance EPA's programs' use of the best available scientific and technical information, Administrator Whitman directed increased Agency attention to EPA's Integrated Risk Information System (IRIS). IRIS, an electronic database containing information on human health effects that may result from exposure to various chemicals in the environment, is an important risk assessment tool for EPA's regulatory programs, the states, and industry. EPA is providing additional resources for updating older IRIS assessments, adding new capacity and improving the IRIS internal and external processes, including stakeholder input.

Scientific Initiatives and Committees

As Science Advisor, Dr. Gilman chairs EPA's Science Policy Council (SPC), a cross-agency committee of senior managers charged with developing policies that guide Agency decision makers in their use of scientific and technical information. In recognition of the rapid advances in the field of genomics since initial sequencing of the human genome, the SPC has developed an interim policy on the use of genomics data as supporting information for Agency assessment and regulatory purposes. Other new scientific accomplishments include guidelines for cancer risk assessment that are more science-based as well as more protective of children; a new EPA strategy that takes a preventive approach to asthma based on the reduction and control of pollutants known to cause or trigger asthma; new EPA rules that formalize and strengthen EPA's framework for federal oversight of biotechnology as applied to plant pesticides; and scientific support for Clear Skies legislation that will dramatically reduce power plant emissions of sulfur dioxide, nitrogen oxides, and mercury.

The SPC has also reconstituted the Council on Regulatory Environmental Modeling, which Administrator Whitman charged in a February 2003 memorandum to: (1) develop cross-Agency guidance on developing and using environmental models as well as on fostering greater and more consistent transparency in this area; (2) develop a publicly accessible inventory of EPA's most frequently used models; and (3) collaborate with the National Academy of Sciences to develop a report recommending best principles and practices in using environmental and human health models for decision making. Because sound decisions need to be based on sound data, EPA has established a Forum on Environmental Measurements to promote consistency and consensus within the Agency on measurement issues. Also, the SPC is leading a review of the policies and procedures of the Science Advisory Board (SAB), to prevent conflict-of-interest issues within the SAB and to avoid undue bias in the makeup of its review panels.

Strategic Science Planning

EPA is putting its science policies into action through strategic science planning. For the first time, each goal in the new EPA Strategic Plan will have a science objective. These science objectives are tied to the Agency's strategic architecture under the Government Performance and Results Act, and EPA will use the objectives to hold itself accountable for delivering relevant science in a timely manner. Another tool to enhance strategic thinking about science across the Agency is the EPA Science Inventory, which catalogs science activities conducted throughout our programs, regions, laboratories, and centers. The Agency is currently testing its new inventory as an internal agency system, and is working toward developing it into a high-quality scientific information resource for the public.

Regional Science

EPA's regional offices are on the front lines of implementing the Agency's programs, and the Administrator has taken several steps to improve scientific support to the regions and enhance the use of science in regional decisions. EPA has doubled the budget of its Regional Applied Research effort, which funds small, quick-turnaround research projects selected by the regional offices based on the potential of the research to address local problems. EPA also has established senior scientific positions in each of EPA's ten regional offices. These scientists help the regions identify scientific and engineering expertise in EPA's research laboratories and centers, and they also provide valuable input to the laboratories and centers on the scientific and technical support needs of the regions.

security

Homeland Security

On September 24, 2002, Administrator Whitman announced the formation of the EPA's Homeland Security Research Center, headquartered in Cincinnati, Ohio. The Center, as part of the Office of Research and Development, manages, coordinates and supports a wide variety of homeland security research and technical assistance efforts. Research at the Center focuses on developing methods to clean up contaminated buildings (the Safe Building Program), protecting the Nation's drinking water supply (the Water Protection Program), and improving risk assessment techniques (the Rapid Risk Assessment Program).

The Center provides the EPA with a management structure that ensures effective design and oversight of research, provides clear lines of communication, and facilitates interaction with EPA program offices and regions, other federal agencies, the private sector, and research partners. By bringing together a critical mass of research talent, the Center integrates and unifies EPA's homeland security research and provides an easily identifiable entity for communication and coordination.

Research on homeland security will develop the scientific foundations to provide decision makers with the understanding and tools necessary to prevent or manage a range of potential threats. Research and development efforts will focus on:

- Evaluating, characterizing and developing tools that can be used to detect, contain, decontaminate and manage hazardous chemical and biological materials purposefully introduced into structures, drinking water, or the environment,
- Conducting rapid risk assessments of existing or potential terrorist events (e.g., World Trade Center) to accurately characterize risks to the public and emergency response personnel in a timely manner, and
- Providing advice, guidance and scientific expertise to emergency response personnel, decision makers, and government officials on homeland security issues.

EPA's Homeland Security Research Center, motivated by the roadmap set forth in the EPA's Strategic Plan for Homeland Security, will ensure rapid and improved production, review, clearance, and distribution of EPA's homeland security research products.

workforce

Scientific Workforce

EPA is making significant progress to ensure that it has in place the scientific workforce to address the Agency's needs in the coming years. To help us educate new environmental scientists and encourage them to join EPA, the Administrator has asked for $5 million in the FY 2004 President's Budget for the Science to Achieve Results (STAR) fellowship program. In addition, the Agency has increased the number of its post-doctoral positions. The EPA Postdoctoral Program enhances the Agency's workforce by attracting quality postdoctoral scientists and engineers to its research program. A constant stream of highly trained post-docs provides a fresh perspective to EPA and assists in maintaining a cutting-edge research program. As a result of the program's success, EPA has requested an additional 20 postdoctoral positions in the FY 2004 budget. The hope is that many of these fellows and post-docs will stay with EPA to conduct scientific research for environmental protection in service to the American public.

Conclusion

Strengthening science at EPA is an ongoing effort of continuous improvement, always with an eye toward improving the scientific bases for the environmental policy decisions that impact our nation. In the past two years, we have made tremendous progress. In achieving the goal we all share of a cleaner and healthier environment, strong science is increasingly critical to informing the actions EPA takes on behalf of the American public.

For more information

Sidney Draggan, Ph.D.
Senior Science Advisor and Science Policy Advisor
to the Assistant Administrator for Research and Development
draggan.sidney@epa.gov
U. S. Environmental Protection Agency MC 8101R
1200 Pennsylvania Avenue NW
Washington, DC 20460
202-564-6658
www.epa.gov/ord

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