

May 16, 2002

John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10235
725 17th Street, N.W.
Washington, D.C. 20503

Dear Mr. Morrall:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the March 28, 2002 Draft Report to Congress on the Costs and Benefits of Federal Regulation. FASEB is comprised of 21 societies with more than 60,000 members, making it the largest coalition of biomedical research associations in the United States. The mission of FASEB is to enhance the ability of biomedical and life scientists to improve, through their research, the health, well-being and productivity of all people.

We are joined in these comments by the Association of American Medical Colleges (AAMC), representing all 125 U.S. medical schools, over 400 teaching hospitals, and 98 academic and medical societies representing over 100,000 faculty.

The investigators and institutions represented by these two organizations manage and conduct a substantial share of the nation's publicly supported biomedical research and are stewards for the safe and responsible conduct of this research.

General Comments

We commend the Office of Management and Budget through the Office of Information and Regulatory Affairs for its commitment to approaching regulatory review in an open, transparent and analytically sound manner.

Standards for Privacy of Individually Identifiable Health Information

We are particularly appreciative of the proactive role that OIRA has taken in suggesting regulatory priorities for agency consideration. In response to suggestions solicited in OMB's draft version of last year's annual report, OIRA identified as a high priority review the Department of Health and Human Services (HHS) Standards for Privacy of Individually Identifiable Health Information. HHS has since issued guidance clarifying the requirements of this rule, has publicly committed to making regulatory changes to certain aspects of the rule and is presently considering significant modifications.

Data Dissemination Guidelines

On January 3, 2002, OIRA issued government-wide guidelines implementing Section 515 of P.L. 106-554 to enhance the quality of information that federal agencies disseminate to the public. We are pleased that OMB responded to the concerns of the academic and scientific community in revising the guidelines to explicitly recognize the objectivity of scientific information and allow research to be disseminated where “the results have been subject to formal, independent, external peer review.”

OIRA Scientific Advisory Panel

The Draft Report announces that “OIRA is in the process of forming a scientific advisory panel that will suggest initiatives to OIRA, evaluate OIRA’s ongoing activities, comment on national and international policy developments of interest to OIRA, and act as a resource and recruitment mechanism for OIRA staff.”¹ We applaud this effort to solicit input from the scientific community and we would be pleased to nominate candidates for this panel. We note that both the National Institutes of Health Regulatory Burden Advisory Group and the Department of Health and Human Services Secretary’s Advisory Committee on Regulatory Reform are charged with making recommendations on regulatory reform. It would be useful to invite at least one member of the NIH Group and at least one member of the Secretary’s Advisory Committee on Regulatory Reform to participate on the new OIRA advisory panel to share insights into what work has already been done and to coordinate future efforts.

Proposals for Reform of Regulations

Resource Conservation and Recovery Act (RCRA)

Chapter IV of the Draft Report invites recommendations from the public for the reform of Federal rules that, if adopted, would increase net qualitative and quantitative benefits to the public. We offer the following comments to the regulatory provisions of the Resource Conservation and Recovery Act (RCRA), which is administered by the Environmental Protection Agency (EPA).

The RCRA was enacted in 1976 to protect human health and the environment from the hazards posed by waste disposal. Subtitle C of RCRA establishes a system to control hazardous waste from the time of generation until its ultimate disposal. With limited exceptions, many of the hazardous waste regulations apply to academic laboratories that use chemicals, as well as to the industrial sector. However, because a laboratory setting differs dramatically from an industrial setting in the use of relatively small quantities of a large number of chemicals on a non-production basis, the RCRA regulations create difficulty for the laboratory community in the areas of interpretation, application, and compliance.²

¹ Draft Report to Congress.

² Report on Consensus Best Practices for Managing Hazardous Wastes in Academic Research Institutions October 2001, accessed April 24, 2002 at http://www.hhmi.org/research/labsafe/projects/report_congress.pdf

Our campuses report that they must contend with elaborate record keeping, detailed storage requirements for reagents that are not relevant to their everyday use, and significant costs for technician time to manage inventory, testing, and paperwork. Institutional officials emphasize that regulations ought to be appropriate to the laboratory setting. The hazards of risks involved in the use of low levels of radionuclides or toxins in academic research are significantly different from the use of these materials for industry. These concerns have been widely noted elsewhere in relation to these and other regulations.³

In recognition of these difficulties, beginning in August 1999 the Howard Hughes Medical Institute (HHMI) led a two-year collaborative initiative to “establish consensus best practices for managing hazardous wastes in academic research institutions and to demonstrate that a performance-based model can be an effective and practical approach for regulating hazardous wastes in the academic research setting.” The initiative resulted in a Report on Consensus Best Practices for Managing Hazardous Wastes in Academic Research Institutions.⁴ (See **Attachment A - Report on Consensus Best Practices**)

The House Committee on Appropriations (House Report 106-674) and the Senate Committee on Appropriations (Senate Report 106-410) supported the initiative and encouraged the Administrator of EPA to participate in it. The Committees requested a report from the EPA evaluating the initiative’s consensus best practices and the need for regulatory changes, if any, to carry out the recommendations of the initiative. In response to the Committees’ request, on March 14, 2002, EPA filed its Report to Congress, containing its evaluation of the Consensus Best Practices developed through the Howard Hughes Institute’s Project.⁵ EPA praised the HHMI Report and the participating academic research institutions for their efforts to improve hazardous waste management in their laboratories, noted that the best practices recommended by the Report addressed a wide range of issues, and most importantly encouraged academic research institutions to develop thoughtful approaches to managing their hazardous waste and instilling strong institutional commitment to environmental protection programs.⁶ (See **Attachment B – EPA Report to Congress**)

FASEB and AAMC strongly recommend that OIRA endorse the following recommendations developed by the HHMI initiative for the management of hazardous wastes in academic research:

“1. The U.S. EPA Administrator should recognize the consensus best practices developed through this initiative as a performance-based model for achieving RCRA compliance

³ See also, Abelson PH. Impact of regulations on universities. *Science*. 1995; 267: 1247, and U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science - A Technical Memorandum*, OTA-TM-SET-34. Washington, DC: U.S. Government Printing Office, February 1986.

⁴ Report on Consensus Best Practices, Executive Summary, p.5

⁵ Report to Congress Evaluating the Consensus Best Practices Developed through the Howard Hughes Medical Collaborative Hazardous Waste Management Demonstration Project and the Need for Regulatory Changes to Carry Out Project Recommendations, March 14, 2002, Office of Solid Waste, Office of Solid Waste and Emergency Response, United States Environmental Protection Agency.

⁶ Report to Congress, p. 10.11.

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and for promoting stewardship and responsibility for health, safety, and the environment in academic institutions. The Administrator should determine and initiate appropriate methods for implementing a performance-based model, using the consensus best practices developed through this initiative, for achieving RCRA compliance in academic institutions.

2. The U.S. EPA Administrator should promote conformity and consistency among the U.S. EPA regional offices and state environmental protection agencies in carrying out RCRA assistance and enforcement programs for academic institutions.

3. Academic institutions should adopt the consensus best practices developed through this initiative as a performance-based model for managing hazardous wastes in their laboratories and for achieving RCRA compliance.

4. Academic institutions should establish dialogue with their regulatory agency officials to plan cooperatively their approaches for implementing the consensus best practices developed through this collaborative initiative.”

Sincerely,



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President, FASEB

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President, AAMC

⁷ Report on Consensus Best Practices, Conclusions and Recommendations, pp.31-32.

**REPORT ON
CONSENSUS BEST PRACTICES
FOR
MANAGING HAZARDOUS WASTES IN ACADEMIC RESEARCH INSTITUTIONS**

Prepared by the
Howard Hughes Medical Institute Office of Laboratory Safety
in Collaboration with the Project's Principal Participants

October 2001

**ATTACHMENT
A**

Report on
Consensus Best Practices for
Managing Hazardous Wastes in Academic Research Institutions

October 2001

The Howard Hughes Medical Institute Office of Laboratory Safety prepared this Report in collaboration with the project's Principal Participants.

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Report on
Consensus Best Practices for
Managing Hazardous Wastes in Academic Research Institutions

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Report on
Consensus Best Practices for
Managing Hazardous Wastes in Academic Research Institutions

EXECUTIVE SUMMARY

The Howard Hughes Medical Institute (HHMI) led a two-year collaborative initiative beginning in August 1999 to establish consensus best practices for managing hazardous wastes in academic research institutions and to demonstrate that a performance-based model can be an effective and practical approach for regulating hazardous wastes in the academic research setting. The initiative partnered environmental health and safety (EH&S) professionals and biomedical research scientists from ten major academic research institutions—one from each Environmental Protection Agency (EPA) region; authorized state regulatory officials from the states of the participating institutions; and the U.S. EPA Office of Solid Waste. The institutions were Duke University Medical Center, Harvard University, Stanford University, The Rockefeller University, University of Colorado at Boulder, University of Pennsylvania, University of Texas Southwestern Medical Center, University of Washington, University of Wisconsin-Madison, and Washington University School of Medicine. A guiding principle of the initiative was a commitment to promote stewardship and responsibility for health, safety, and the environment as an integral part of the nation's biomedical research mission.

The House Committee on Appropriations (House Report 106-674) and the Senate Committee on Appropriations (Senate Report 106-410) included language in the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Bill, 2001, supporting the initiative and encouraging the Administrator of EPA to participate and provide the maximum flexibility permissible under the regulatory provisions of the Resource Conservation and Recovery Act (RCRA) in support of the initiative. The Committees requested to receive within 12 months (October 2001) a report from the EPA evaluating the initiative's consensus best practices and the need for regulatory changes, if any, to carry out the recommendations of the initiative.

The initiative responded to the continuing difficulties academic institutions are experiencing in applying the industrial-oriented RCRA regulations to the management of hazardous wastes generated in their laboratories. An objective was to develop a better regulatory approach to apply RCRA to academic institutions—one that builds upon the culture of the institutions and recognizes that laboratories differ from industrial operations in their use and handling of hazardous chemicals. Other objectives were to promote cooperation, understanding, and mutual respect among environmental protection agencies, academic institutions, and the scientific research community, and to propose a plan for implementing a performance-based approach for managing hazardous wastes in academic research institutions.

The initiative included three phases. In phase one, HHMI sponsored a workshop to introduce the initiative; to develop the project scope, objectives, criteria, and approach; and to identify the principal elements of a hazardous waste management plan for academic research institutions. Seven elements were identified: executive commitment; a management plan; responsibility and accountability; policies and procedures to minimize waste; standard operating procedures; training, education, and communication; and continual evaluation and improvement. In phase two, 14 consensus best practices for managing hazardous wastes in the academic research setting were developed. In phase three, plans for demonstrating the consensus best practices and for measuring

their effectiveness at the ten universities were developed. The demonstrations would continue for one year, concluding in October 2001; the universities would prepare comprehensive reports evaluating their demonstrations in June 2001. These evaluations served as the basis for this report.

The findings of the initiative support the views of scientists, EH&S professionals, and many regulators as reported earlier by the National Research Council and other groups, that the extant application of RCRA to laboratories is inefficient and difficult, and that a performance-based approach for the application of RCRA to laboratories is a preferred regulatory model. The initiative found a lack of conformity and consistency nationwide in the application of RCRA to academic laboratories, particularly in the range of allowable practices for making RCRA determinations. In addition, the findings of the initiative reveal that the current regulatory approach for applying RCRA to laboratories in academic institutions is a disincentive to the promotion of environmental stewardship, an objective of RCRA. A new regulatory approach for laboratories could improve RCRA effectiveness and compliance in universities, and become a catalyst to bring about commitment and action to protect human health and the environment and promote excellence in environmental stewardship within the academic research community.

The recommendations of the initiative envision a two-tiered approach for applying RCRA to universities and their laboratories. It involves the application of a performance-based model, using the consensus best practices developed in this initiative, for guiding RCRA compliance in laboratories, and the application of the current provisions of RCRA for guiding RCRA Compliance in universities at the time the universities' EH&S programs assume ownership and responsibility for laboratory waste materials and make the RCRA hazardous waste determination. The basis for this approach is the premise that the EH&S program makes the RCRA hazardous waste determination and conducts any appropriate generator treatment on behalf of the academic institution. This initiative found that four of the ten universities are successfully using this approach, with the concurrence of their state regulatory agencies, in managing their hazardous waste programs. This experience is significant because it demonstrates value in this approach as a regulatory model, and indicates that it does not compromise compliance.

There are three principal conclusions resulting from this two-year collaborative initiative.

A performance-based model that has as its core the consensus best practices developed and demonstrated through this initiative is a workable approach for effective and efficient management of hazardous waste in academic research institutions. This approach will not compromise RCRA compliance, and will promote stewardship and responsibility for health, safety, and the environment while respecting the culture of an academic institution and the unique characteristics of the laboratory setting.

Collaboratively, the EH&S professionals, scientifically trained laboratory staff, informed institutional administrators, and staff from federal and state regulatory agencies who are familiar with the laboratory and academic setting will identify safe and practical ways to improve hazardous waste management programs, and they will do this enthusiastically when the outcome promotes environmental stewardship.

The interactions between some of the universities and their corresponding state regulatory agencies provide evidence that common ground is available within RCRA to adopt both the consensus best practices and a performance-based approach for compliance. The difficulty of matching specific requirements of RCRA with the academic laboratory setting stimulated efforts to find this common ground. Four of the ten universities participating in this initiative operate their hazardous waste management programs today with the concurrence of their state regulatory officials on the premise that the EH&S professionals are the most capable for determining whether used or unused laboratory chemicals are

RCRA hazardous waste and, in this capacity, serve as the RCRA generator for overall compliance purposes. This operational practice is the cornerstone for a best practices performance-based regulatory model.

The Howard Hughes Medical Institute and the ten universities participating in this hazardous waste management initiative make the following recommendations to the U.S. EPA and to the nation's academic institutions.

1. The U.S. EPA Administrator should recognize the consensus best practices developed through this initiative as a performance-based model for achieving RCRA compliance and for promoting stewardship and responsibility for health, safety, and the environment in academic institutions. The Administrator should determine and initiate the appropriate methods for implementing a performance-based model, using the consensus best practices developed through this initiative, for achieving RCRA compliance in academic institutions.
2. The U.S. EPA Administrator should promote conformity and consistency among the U.S. EPA regional offices and state environmental protection agencies in carrying out RCRA assistance and enforcement programs for academic institutions.
3. Academic institutions should adopt the consensus best practices developed through this initiative as a performance-based model for managing hazardous wastes in their laboratories and for achieving RCRA compliance.
4. Academic institutions should establish dialogue with their regulatory agency officials to plan cooperatively their approaches for implementing the consensus best practices developed through this collaborative initiative.

Report on
Consensus Best Practices for
Managing Hazardous Wastes in Academic Research Institutions

1. INTRODUCTION

The Howard Hughes Medical Institute (HHMI) led a two-year collaborative initiative to establish consensus best practices for managing hazardous wastes in academic research institutions. A goal of the initiative was to demonstrate that a performance-based model is an effective approach for regulating hazardous wastes in the academic research setting. The initiative partnered environmental health and safety (EH&S) professionals and biomedical research scientists from ten major academic research institutions—one from each Environmental Protection Agency (EPA) region; authorized state regulatory officials from the states of the participating institutions; and the U.S. EPA Office of Solid Waste.

HHMI is a scientific and philanthropic organization whose principal purpose is the direct conduct of biomedical research. Some 350 HHMI investigators carry out their research in laboratories located throughout the United States at 72 academic medical centers, universities and other scientific institutions, under long-term research collaboration agreements. It is the philosophy of the Institute that research of the highest standards occurs in laboratories where the commitment to safeguard human health and the environment is exemplary. In collaboration with the EH&S programs of the 72 host institutions, the HHMI Office of Laboratory Safety provides leadership in promoting stewardship and responsibility for health, safety, and the environment as an integral part of the nation's biomedical research mission.

Annually, HHMI sponsors a two-day conference for the directors of the EH&S programs of the 72 host institutions. The 1999 conference, *Healthy Workers—Healthful Environments—Helpful Regulations*, included a presentation by an EPA Region 1 official on the Agency's enforcement and reinvention programs. From this talk emerged the idea for a nationwide initiative to evaluate a performance-based approach for managing hazardous wastes in academic research institutions.

The HHMI Office of Laboratory Safety drafted a project scope. Key to the proposed project was the criterion that the initiative would uphold the spirit and intent of current EPA regulations. In addition, the EPA would provide the maximum flexibility permissible under the regulatory provisions of the Resource Conservation and Recovery Act of 1976 (RCRA). Since the inception of RCRA, developed with the industrial setting in mind, the academic research community has recognized that allowing sensible flexibility within the academic laboratory setting can potentially yield superior compliance while reducing regulatory burden and promote excellence in environmental stewardship.

Congressional Interest

The U.S. Congress became interested in the collaborative initiative in the summer of 2000. The House Committee on Appropriations (House Report 106-674) and the Senate Committee on Appropriations (Senate Report 106-410) included language in the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Bill, 2001, supporting the initiative's approach for development of consensus best practices for hazardous waste management in academic research laboratories, and applauding the initiative's commitment to

minimize the potential for harm to human health and the environment and to promote excellence in environmental stewardship. Both Committees encouraged the Administrator of EPA to participate in the initiative and to provide the maximum flexibility permissible under the regulatory provisions of RCRA in support of the initiative. The Committees requested to receive within 12 months a report from the EPA evaluating the consensus best practices developed through the initiative and the need for regulatory changes, if any, to carry out the recommendations of the initiative.

2. FRAMING THE RCRA ISSUE

Introduction to RCRA

The U.S. Congress enacted the Resource Conservation and Recovery Act (RCRA) in 1976 to address the problem of municipal and industrial solid waste disposal and reduction. The goals set by RCRA are:

To protect human health and the environment from the hazards posed by waste disposal.

To conserve energy and natural resources through waste recycling and recovery.

To reduce or eliminate, as expeditiously as possible, the amount of waste generated, including hazardous waste.

To manage wastes in a manner that *is* protective of human health and the environment.

Subtitle C of RCRA establishes a system to control hazardous waste from the time of generation until its ultimate disposal. The Act directs EPA to develop and promulgate criteria for identifying hazardous waste and gives the EPA Administrator the authority to develop specific requirements governing the generation, transport, treatment, storage, and disposal of hazardous waste to ensure sound and protective hazardous waste management. The EPA developed the hazardous waste regulations based largely on industrial hazardous waste activities. However, with limited exceptions, these regulations apply to academic laboratories that use chemicals, as well as to the industrial sector.

The industrial orientation of RCRA regulations creates difficulty for the laboratory community in areas of interpretation, application, and compliance. A laboratory setting is significantly different from an industrial setting and is not easily adaptable to control measures appropriate for industry. In the academic research laboratory, relatively small quantities of a large number of chemicals are in use on a non-production basis. In addition, the chemicals in use vary often depending on the frequently changing direction of a research endeavor. The potential environmental risks are of a different magnitude as well. Although the hazard inherent in a small quantity of a chemical from a laboratory is the same as the hazard inherent in a large quantity of the same chemical in an industrial process, the overall potential for harm to human health or the environment can often be less because of the smaller quantity. Further, the scientifically trained laboratory staff generally has a high level of awareness of health, safety, and environmental hazards associated with working with chemicals.

Federal Oversight of Environmental Health and Safety in Laboratories

Other federal agencies provide regulatory or advisory oversight of EH&S practices and programs in academic research laboratories including issuance of regulations and guidelines that impact waste management. These are the Occupational Safety and Health Administration (OSHA), the Department of Health and Human Services (DHHS), the Department of Transportation (DOT), the Department of Agriculture (USDA), and the Nuclear Regulatory Commission (NRC). For example, OSHA's Laboratory Standard (29 CFR 1910.1450) requires an employer to establish a Chemical Hygiene Plan (CHP). The CHP identifies standard operating procedures (SOP) for employees to follow that will protect them from the health hazards presented by hazardous chemicals in use in their laboratories. The Standard's definition for a hazardous chemical includes all materials RCRA would designate as hazardous waste. The Preamble to the Standard also provides examples of work activities that SOPs should cover including emergency response, waste disposal procedures, and spill clean-up procedures.

Similarly, DHHS, USDA, and the NRC have requirements that address the handling and disposal of laboratory waste containing human pathogens, animal pathogens, and radioactive materials, respectively. The DOT regulates the shipment of hazardous materials. The regulatory model that most of these agencies use, however, differs considerably from the traditional approach used by the EPA to develop and enforce hazardous waste regulations. For example, the NIH Guidelines for Research Involving Recombinant Molecules (66 FR 1146: January 5, 2001), presents three performance-based guidelines as disposal requirements for laboratory wastes from experiments involving the insertion of recombinant DNA molecules into a serious or lethal pathogen such as *Mycobacterium tuberculosis*.

All contaminated liquid or solid wastes are decontaminated before disposal.

Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory.

An autoclave for decontaminating laboratory wastes is available preferably within the laboratory.

An Example of a Performance-based Regulation

The OSHA Laboratory Standard is an example of a performance-based standard. The basis for this Standard was a determination by the Assistant Secretary of Labor for OSHA that laboratories typically differ from industrial operations in their use and handling of hazardous chemicals, and that an approach different from that found in OSHA's substance-specific health standards was warranted to protect workers. The Standard's definition of a laboratory reads:

"Laboratory" means a facility where the "laboratory use of hazardous chemicals" occurs. It is a workplace where relatively small quantities of hazardous chemicals are used on a non-production basis.

The Standard also characterizes a laboratory by the term "laboratory-scale." The Standard reads:

"Laboratory scale" means work with substances in which the containers used for reactions, transfers, and other handling of substances are designed to be easily and

safely manipulated by one person. "Laboratory-scale" excludes those workplaces whose function is to produce commercial quantities of materials.

To the extent possible, the Standard allows for a large measure of flexibility in compliance methods. For example, the Standard does not intend to dictate the approach that the employer may find effective in meeting the objectives of the CHP or the manner in which the employer implements the approach. (Preamble to 29 CFR Part 1910.)

Efforts to Improve RCRA Applicability to Laboratories

In a non-mandatory Appendix to the Laboratory Standard (29 CFR 1910.1450), OSHA offers guidance to laboratory employers on the development of a CHP. The recommendations came from the National Research Council's report, Prudent Practices for Handling Hazardous Chemicals in Laboratories, published in 1981. The recommendations provide an example of a performance-based standard for hazardous waste management in laboratories.

The 1981 report also noted that new regulations to control chemical waste were under development by the EPA. The regulations became effective on November 19, 1980, shortly before the report went to press. In less than six months it became clear that academic, government, and industrial laboratories were having substantial difficulties in interpreting and implementing these regulations. Over the succeeding 15 years, the National Research Council published several authoritative studies on the subject of hazardous waste management recommending that EPA change its approach to regulating laboratories.

In 1995, the National Research Council Committee on Prudent Practices for Handling, Storage, and Disposal of Chemicals published Prudent Practices in the Laboratory—Handling and Disposal of Chemicals. This report contained further recommendations that EPA change its approach to regulating laboratories. Most recommendations made in this and previous reports remain germane today. The recommendations made in 1995 by the National Research Council committee follow.

The committee recommends that regulations directed to laboratories be performance based and be structured to take into account the unique aspects and professional expertise within the laboratory.

The committee recommends that the Environmental Protection Agency extend its permit-by-rule provision to allow scientifically sound treatment of small quantities of waste generated in laboratories.

The committee recommends that the Environmental Protection Agency allow storage of small quantities of waste in laboratory facilities for periods longer than the current time limitation on storage of hazardous waste.

The committee recommends that federal, state, and local lawmakers and regulators strive for conformity and consistency in the regulations that affect laboratories.

The committee recommends that the Environmental Protection Agency allow the use of one EPA identification number for all chemical waste generated on a single campus of an educational institution. (Note: The Military Munitions Rule [40 CFR Part 260, effective August 12, 1997], generally addressed this recommendation.)

Other groups have made substantial efforts to encourage the EPA to adopt a performance-based approach for regulating academic laboratories including the National Research Council's Government-University-Industry-Research-Roundtable, the American Chemical Society, the National Institutes of Health, the National Association of College and University Business Organizations, and the American Council on Education. Studies, reports, and recommendations from these groups have a common theme: Sensible regulatory flexibility within the laboratory setting potentially can yield superior compliance while reducing the regulatory burden that results when applying an industrial oriented standard to laboratories.

EPA has recently considered some of the issues addressed by these organizations and groups. The Storage, Treatment, Transportation, and Disposal of Mixed Wastes; Final Rule (66 FR 27218: May 16, 2001; effective November 13, 2001), provides increased flexibility to generators and facilities that manage low-level mixed waste. This Rule resolves a long-standing problem for academic research institutions handling such waste in their laboratories. EPA's approval of the New England University Laboratories Project XL demonstrates the Agency's recognition that there may be value in a performance-based approach to regulating academic laboratories. In addition, the EPA regional offices have initiated several RCRA compliance assistance programs to aid universities in their efforts to achieve RCRA compliance such as Web-based guidance and regional conferences.

3. THE COLLABORATIVE INITIATIVE

Participants

The two-year collaborative initiative led by HHMI to establish consensus best practices for managing hazardous wastes in academic research institutions occurred in three phases. During each phase, the participants included the EH&S directors and hazardous waste managers from ten HHMI host institutions, each from a different EPA region. These were:

Duke University Medical Center	University of Pennsylvania
Harvard University	University of Texas Southwestern Medical Center
Stanford University	University of Washington
The Rockefeller University	University of Wisconsin-Madison
University of Colorado at Boulder	Washington University School of Medicine

Also participating were researchers from the ten HHMI host institutions; authorized state regulatory officials from the states of the host institutions; the Director and staff, Office of Solid Waste, U.S. EPA; staff of the Safety, Health and Environmental Management Division, U.S. EPA; officials from the NIH Office of Extramural Research responsible for the NIH study on regulatory burden; the Director, Office of Environmental Management, Massachusetts Institute of Technology; and the EH&S directors of the three universities involved in the New England University Laboratories Project XL.

Project Approach

In August 1999, HHMI sponsored a workshop to introduce and begin phase one. From the outset, the participants agreed that the commitment to protect human health and the environment and to promote excellence in environmental stewardship would govern all discussions. The group finalized the project scope, reached consensus on the objectives and criteria, devised an approach to

carry out the project, and identified seven principal elements of a hazardous waste management plan for academic research institutions.

Scope

To develop and carry out a broad collaborative initiative to identify and establish consensus best practices for managing hazardous wastes in major academic research institutions, and develop a proposed regulatory model for implementation at the state or federal levels.

Objectives

To develop an operational strategy for managing hazardous wastes generated in teaching and research laboratories of major academic research institutions that would (1) establish consensus best practices that are relevant to laboratory activities, practical to carry out, efficient, and cost-effective; and (2) promote excellence in environmental stewardship among students, laboratory employees and other workers, and scientists and academic leaders.

To demonstrate the efficacy of the strategy for managing hazardous laboratory wastes.

To promote cooperation, understanding, and mutual respect among environmental protection agencies, academic institutions, and the scientific research community.

To develop a plan for implementing the best practices approach for managing hazardous wastes in academic research institutions.

Criteria

Current EPA and state regulations would apply to all hazardous wastes leaving academic research institutions for treatment, storage or disposal.

Current EPA or state regulations would not constrain the development of best practices for managing on-site hazardous wastes generated in teaching and research laboratories.

The commitment to minimize the potential of harm to human health and the environment and to promote excellence in environmental stewardship would govern all discussions.

Seven Principal Elements of a Hazardous Waste Management Plan

Executive commitment	Standard operating procedures
Specific management plan	Training, education, and communication
Responsibility and accountability	Continual evaluation and improvement
Policies and procedures to minimize waste	

Phase two of the initiative began in March 2000 following a six-month period during which the ten universities independently identified best practices for managing hazardous wastes in the academic research setting. At a second workshop, using the reports prepared by the ten universities, the group reached consensus on 14 best practices.

Phase three of the initiative began in August 2000. At a third workshop, the group formalized the 14 consensus best practices, devised an implementation plan for demonstrating and measuring their effectiveness, and reviewed the maximum regulatory flexibility permissible for each. The group agreed to demonstrate and measure the effectiveness of the consensus best practices for one year beginning October 1, 2000, and ending October 1, 2001.

At the start of the demonstrations, the Director, Office of Solid Waste, U.S. EPA, wrote to all RCRA senior policy managers and branch chiefs encouraging their support of the demonstration projects. Also, at the start of the demonstrations, each university performed an extensive self-assessment of its hazardous waste management program for the 14 consensus best practices and the roughly 120 sub-elements of those practices. Each university repeated the same self-assessment at the conclusion of the demonstrations.

4. THE CONSENSUS BEST PRACTICES

The consensus best practices are not prescriptive requirements — they are guidelines that give purpose, direction, and clarity to broad functions that an academic research institution should carry out in managing the hazardous wastes produced in its laboratories. Their value is to promote stewardship and responsibility for health, safety, and the environment as a performance goal. The universities agreed that the best way to meet a performance goal is to develop institutional programs that reflect the style, culture, and nature of the laboratory activities of the individual universities. For this reason, each university could decide how to interpret and carry out the intent of the best practices. In some cases, the universities found that their current programs met the intent of one or more of the best practices and, therefore, chose not to conduct demonstration projects in those areas. However, all ten universities addressed the first best practice concerning executive commitment: Each wanted to assure strong executive commitment to their hazardous waste management program.

The 14 consensus best practices follow. The information included with each best practice clarifies intent without prescribing measures for how to develop or manage a quality hazardous waste management program.

Executive Commitment

1. The executive leadership of the institution embraces, supports, states, and carries out the commitment to protect human health and the environment and to promote excellence in environmental stewardship.

This commitment presumes a willingness to strive for a level of performance that exceeds basic regulatory compliance requirements. Broad performance goals are set to drive and sustain this commitment.

Executive commitment is the critical element for the success of all institutional activities that collectively promote excellence in occupational safety and health and environmental protection, including the management of hazardous wastes. The chief executive officer and all institutional governance bodies endorse the commitment. The institution provides resources sufficient to enable the implementing programs to lead the institution beyond compliance toward a level of excellence in environmental stewardship. The chief executive officer assigns responsibility and authority to senior level managers and laboratory directors for carrying out their program responsibilities. The chief executive officer also defines and assigns responsibility and accountability of all institutional employees, contractors, students, and visitors for carrying out this commitment.

The institution defines its commitment in writing, communicates the written commitment to all individuals and groups associated with the institution, and reinforces its commitment

periodically. An example statement of commitment is: “Our institution is committed to the philosophy that teaching and research are best conducted in laboratories where dedication to safety, health, and environmental stewardship is exemplary.”

Responsibility and Accountability

2. All members of the institution’s laboratories and environmental health and safety program know their roles in the institution’s chemical waste management program and understand they are accountable for their performance.

Responsibilities of individuals and groups are clear, appropriate, and relevant to their work and duties. Individuals and groups are aware of their individual and group performance expectations. The interactions between groups with responsibility are clear. Mechanisms for assuring accountability and correcting identified problems are available. Such mechanisms can include peer review, committee oversight, incentive initiatives, criteria in personnel evaluations, and procedures for reporting problems without fear of reprisal. The term members means employees, students, guests, and contract employees who work in laboratories or in the institution’s environmental health and safety program.

Policies and Procedures for Pollution Prevention

3. Policies and procedures for pollution prevention are an integral part of the institution’s chemical waste management program.

Pollution prevention is a primary goal of environmental stewardship. Pollution prevention encompasses such practices as waste minimization, recycling, and reuse. There is a high expectation that laboratory scientists with assistance from staff of the institution’s environmental health and safety program will voluntarily conduct regular project reviews to identify and implement better ways to reduce hazardous waste, including ways to reduce or eliminate chemical hazards of a protocol waste stream. Inventory procedures including periodic review of current holdings assure the purchasing of minimal chemical quantities and container sizes that are appropriate for laboratory use requirements. Procedures that allow for the voluntary transfer of unused chemicals to other laboratories that can use them are in place. Pollution prevention is a consideration in the selection and development of new research protocols. Laboratories substitute less hazardous chemicals in existing protocols and adopt micro-scale research protocols where appropriate.

Standard Operating Procedures

4. The provisions of the institution’s written Chemical Hygiene Plan apply to all practices involving the handling, containing, and storing of chemicals in laboratories.

The Chemical Hygiene Plan is a written program developed and implemented by the institution that specifies the procedures, equipment, personal protective equipment, and work practices that are capable of protecting people from the health hazards presented by hazardous chemicals used in its laboratories. The Chemical Hygiene Plan is a regulatory requirement of the Department of Labor under its Occupational Safety and Health Administration Standard on Occupational Exposures to Hazardous Chemicals in Laboratories. The Standard is applicable to all hazardous chemicals in laboratories including

used and unused chemicals that could potentially present a hazard to human health and the environment.

Institutions that write Chemical Hygiene Plans for individual laboratories provide an institutional model to assure consistent practices for handling, containing, and storing used and unused chemicals.

A State institution not under the jurisdiction of the U.S. Occupational Safety and Health Administration has a comparable written plan that describes its provisions for the protection of human health and the environment.

5. Standard operating procedures that are necessary to carry out the institution's chemical waste management program are written and readily available to members of laboratories and the institution's environmental health and safety program.

The institution incorporates the standard operating procedures for laboratories by reference as provisions of its Chemical Hygiene Plan or comparable written plan. The procedures are performance-based, clearly stated, easy to follow, specific to laboratory activities and quantities of chemicals handled, and free of extraneous material that is not relevant. The standard operating procedures for activities conducted in laboratories and in the facilities of the environmental health and safety program are based on and tailored to the specific waste management functions and responsibilities of these groups. The laboratories and environmental health and safety program jointly develop the standard operating procedures.

6. Chemical materials removed from laboratories have labels with information sufficient to inform the recipient of potential health or safety hazards, and to enable the environmental health and safety program to carry out safely and effectively the institution's chemical waste management program.

The label contains qualitative information, such as the identity of the chemicals present, and sufficient quantitative information to permit the institution's environmental health and safety program to determine the level of hazard.

7. Laboratories adapt, validate, and use laboratory protocols, where appropriate, to reduce or eliminate chemical waste.

Scientists are encouraged to adapt existing laboratory protocols and to create and validate new protocols that reduce or eliminate chemical waste and the use of hazardous chemicals in research protocols. Such initiatives offer great promise for innovative waste minimization processes.

8. The institution's environmental health and safety program collects used and unused chemicals from laboratories and transports them to on-site storage locations. The program selects options regarding reuse, recycling, consolidating, storage, volume reduction, treatment, or disposal.

The environmental health and safety program provides a timely and efficient process for responding to requests for collection of used and unused chemicals from laboratories. At the time of collection, the program verifies chemical information, assures integrity of collection containers, and communicates any discrepancies with the chemical user, laboratory director, or other available laboratory personnel. The program staff transports acceptable collection containers to on-site storage locations in secondary containment to reduce the likelihood of

release to the environment. Spill control equipment is available on vehicles used to transport collection containers between campus facilities. The inter-facility transport of collection containers is coordinated with the institution's emergency response program. Used and unused chemicals may be stored temporarily in on-site facilities under the control of the environmental health and safety program.

Environmental health and safety programs that use contractors for collection of used and unused chemicals identify chemical materials appropriate for inclusion in on-site waste minimization efforts prior to the contractor's characterization of used and unused chemicals for off-site management.

9. The institution's environmental health and safety program uses validated protocols, where appropriate, to recycle, reduce, or eliminate chemical hazards of laboratory-scale quantities of waste chemicals including bulk and consolidated materials.

The environmental health and safety program is encouraged to develop and validate protocols for recycling, reducing, or eliminating hazardous characteristics of waste chemicals collected from laboratories. Protocols will not include combustion. Compliance with the provisions of the institution's Chemical Hygiene Plan or comparable written plan assures the protection of human health and the environment when conducting these activities. Such initiatives offer great promise for innovative waste minimization processes.

10. The institution's environmental health and safety program makes the hazardous waste RCRA determination.

The environmental health and safety program may accumulate used and unused chemicals it collects from laboratories in on-site storage facilities under its control. The environmental health and safety program makes or confirms a hazardous waste RCRA determination following the institution's standard operating procedures at the time the used and unused chemicals are brought to these facilities. Once the environmental health and safety program determines a used or unused chemical is a RCRA hazardous waste, it will comply with all extant provisions of RCRA regulations for the management of hazardous waste. However, flexibility in the accumulation time limit is available to optimize waste management where there are limited treatment and disposal options, or it is necessary to minimize risk to human health and the environment.

11. The institution plans for the appropriate response to chemical emergencies in laboratories and other locations associated with the institution's chemical waste management program.

Members of laboratories know how to respond to emergencies involving hazardous chemicals handled in their laboratories. They receive information and training in the emergency procedures that the institution has established in its emergency response program relevant to work conducted in laboratories.

Training, Education, and Communication

12. The amount and complexity of training that members of laboratories and the environmental health and safety program receive correspond to the skills and knowledge required to carry out their individual responsibilities. Performance monitoring documents training effectiveness.

All training relevant to chemical waste management clearly communicates the executive commitment to protect human health and the environment and to promote excellence in environmental stewardship. Chemical waste management training is an integral part of orientation and refresher training in laboratory safety. **All** persons responsible for hazardous waste determination, RCRA waste management, and emergency response receive training consistent with applicable regulations. Appropriate members of the institution's environmental health and safety program participate in orientation training. Each visit to the laboratory by a staff member of the environmental health and safety program provides an opportunity for in-service continuing education. A continuing objective is to optimize learning methods. Innovative computer-assisted programs can provide efficient and effective training.

13. A communication system that links the executive leadership, members of laboratories, and members of the environmental health and safety program is in place to maintain awareness of and commitment to the goals and best practices of the institution's chemical waste management program.

An effective communication process helps individuals stay informed of what they need to know to do their part to maintain the quality of the chemical waste management program. Open communication where there is no fear of reprisal can accelerate the identification of problems, corrective actions, and improvements. Effective communication is vital to the success of any effort to introduce new requirements or procedures.

Program Evaluation and improvement

14. The institution's environmental health and safety program conducts carefully planned program evaluations to enhance the quality and effectiveness of the institution's chemical waste management program.

The value of a program evaluation for improving program performance is dependent on the professional skill and experience of the person conducting the evaluation. Careful studies require the selection of appropriate criteria for monitoring and documentation. Performance indicators help show measurable improvements. Environmental audits are an excellent means for evaluating program quality and effectiveness and for highlighting areas for improvements. Recommended improvements originate through effective interactions between members of laboratories, including laboratory directors, and members of the environmental health and safety program. Written reports and early feedback help the adoption of recommended improvements. Periodic evaluations allow the institution to adapt easily to changing circumstances. Environmental health and safety programs consider involving the applicable regulatory agencies as active partners in program evaluations and for sharing results of program evaluations with these agencies.

5. RESULTS AND FINDINGS OF DEMONSTRATION PROJECTS

By Consensus Best Practice

The request by Congress for a report in October 2001 evaluating the consensus best practices developed through the initiative caused the universities to shorten their demonstration period to eight months. In this eight-month period the universities made much progress. Although the

demonstration projects will continue until October 1, 2001, most of the best practices are now standard practices at the ten universities.

The following describes the results and findings of the projects that the universities undertook as part of the consensus best practices demonstrations. It does not include information describing the hazardous waste management programs the universities had in place prior to the start of this initiative, except for a few comments to add perspective. The results and findings reflect the diversity and creativity that is indicative of the potential value of a performance-based approach for managing hazardous wastes in academic research institutions.

Executive Commitment

At the beginning of the demonstration projects, Harvard University and the University of Colorado at Boulder assessed their levels of executive commitment to environmental stewardship as excellent. Both universities provide strong support with appropriate resources for their EH&S programs. At Harvard University, executive Commitment extends from the President and Deans down to each faculty and administrative group. The President's delegation of authority demonstrates a model approach for assuring subordinate leadership commitment to EH&S in academic institutions having an organizational tradition of decentralization.

Stanford University and the University of Texas southwestern Medical Center (UTSMC) assessed their levels of executive commitment as acceptable. Both universities have written statements of commitment and appropriate delegations of authority, and resources for their EH&S programs. At Stanford University, the issuance of environmental policy is under the authority of the President. In the University of Texas System, the Chancellor issues environmental policy to all University of Texas System presidents including the President of UTSMC. Stanford University and UTSMC use a committee system to guide implementation of environmental policy.

The remaining six universities made substantial progress toward enhancing their levels of executive commitment to health, safety, and environmental stewardship. Duke University's Executive Vice President issued a statement in support of environmental stewardship and plans are developing to have the Board of Trustees address this issue. The University committed new resources that enabled the EH&S program to hire an environmental engineer to develop and carry out an environmental audit program. The President of The Rockefeller University revised the University's written executive commitment statement to affirm support for excellence in environmental stewardship with regard to hazardous waste management. Plans are underway to encourage the Faculty Senate to show its support for this commitment in writing.

The universities of Pennsylvania, Washington, Wisconsin-Madison, and Washington University do not have formal statements of executive commitment to environmental stewardship, however, projects are in progress to establish these statements. The University of Pennsylvania's Health, Environment, and Safety Committee is currently reviewing a draft statement developed as part of their demonstration. The University of Washington has developed an Environmental Stewardship Task Force under the auspices of the University's Executive Vice President to develop an executive commitment policy statement and a strategy of targeted projects to attain policy goals. Recommendations will go to the University's President, Executive Vice President, and Provost. The Task Force includes faculty, administrators, and students. In addition, the University is updating existing governance documents. The University of Wisconsin-Madison is working to codify policy on health, safety, and the environment. The University's executive commitment project has raised

sensitivity to the need for written policies, even when the principles are generally accepted. At Washington University, the Associate Vice Chancellor for Medical Affairs is drafting language to be included in the University’s mission statement. The Chancellor will submit the statement to the Executive Faculty for approval this summer.

These projects raised executive leadership awareness of and interest in hazardous waste issues and the role of the universities in promoting environmental stewardship.

Responsibility and Accountability

This best practice is standard practice at the ten universities. At the beginning of the demonstrations, most universities assessed their performance as acceptable. Harvard University increased its performance level after finding that an initiative under another best practice — Effective Communication within an Organization — increased organizational and individual responsibility and accountability. During the course of the project, the University of Colorado at Boulder reassessed its performance to be at the excellent level.

At Stanford University, the EH&S staff invited several laboratories to participate in a demonstration project on a pilot basis. They briefed the laboratories on the project, asked the research staff to incorporate aspects of the consensus best practices into their daily operations, and reviewed with them the results of a University-wide baseline assessment of its hazardous waste program to ensure the results accurately reflected the conditions within the pilot laboratories. During the demonstrations, the EH&S staff provided extra resources and attention to the laboratories. A survey conducted by EH&S several months into the demonstrations showed that performance had improved considerably — to the level of excellent. Using qualitative measures of self-assessments, the EH&S staff found that the members of the pilot laboratories had a better understanding of their responsibilities, and were more knowledgeable of the practices for which they are held accountable than did their counterparts in non-pilot laboratories. Although this increase in performance may be due in part to the special care provided by the EH&S staff, the pilot laboratories reported that they were more motivated by a commitment to environmental stewardship, which guided the development of the project, than by being told to follow strictly administrative compliance activities.

STANFORD UNIVERSITY ELEMENTS OF BEST PRACTICE 2 PERFORMANCE IMPROVEMENTS IN PILOT LABORATORIES	
ELEMENT	INCREASE IN PERFORMANCE OVER BASELINE
Knowledge of hazardous characteristics	55%
Knowledge of unusual characteristics	40%
Knowledge of handling procedures	67%
Knowledge of emergency procedures	64%
Investigators convey importance of lab safety	64%
Day to day training	(-2%)
Follows up on inspections	50%

The University of Washington initiated a collaborative demonstration project, that has since become standard practice, involving auditors from its Prevention and Assessment Office and EH&S staff. The group developed a short list of possible hazardous waste deficiencies for the auditors to use during routine laboratory audits. When deficiencies are observed, the auditors encourage immediate corrective action. Where such action is not possible, the auditors notify EH&S. During

the demonstration, there were 19 deficiencies noted in audits of 37 laboratories; the laboratory staffs immediately corrected the deficiencies. This same list is included as part of a compliance evaluation form used by EH&S to note deficiencies during waste collection visits to the laboratories. When deficiencies are noted, the EH&S staff leaves the form and requests the investigator to return it within ten days indicating the corrective actions taken. The EH&S staff left compliance forms during 34 waste collection visits. All investigators returned the forms within 10 days. The EH&S staff reports no recurring deficiencies on subsequent waste collection visits; the staff credits use of the compliance forms for decreasing hazardous waste deficiencies and improving performance.

Policies and Procedures for Pollution Prevention

Prior to the start of this initiative, the universities had prepared reference guides for laboratories listing opportunities for pollution prevention and waste minimization. As part of the demonstrations, many of the guides were updated and made available on the EH&S Web pages for easy access by laboratory staff. The Stanford University EH&S staff distributed information on specific practices for pollution prevention and waste minimization to their pilot laboratories. They report that the pilot laboratories were more likely to improve their chemical inventory methods, substitute less hazardous chemicals where possible, and adopt micro-scale protocols than were baseline laboratories. UTSMC is introducing a new *environmental* compliance audit program that will gather information to identify pollution prevention opportunities.

The University of Washington EH&S staff operates an excellent pollution prevention program. Developed within a five-year Pollution Prevention Plan are performance goals for treatment, recycling, surplus exchange, and hazardous materials use reduction. The EH&S staff tracks and analyzes data annually to identify high volume or high cost wastes that may offer opportunities for pollution prevention and to revise, as necessary, program goals. Promotion of the program occurs with incentives. Laboratories save approximately 60 percent in costs when purchasing recycled solvents. The surplus chemical exchange is operated free of charge. Estimates are that University laboratories participating in the program collectively saved more than \$10,000 in the year 2000. The University, under the authority granted by the Washington State Department of Ecology, also operates a "treatment by generator" program as part of its pollution prevention program. Such state authorized programs allow generators to responsibly treat wastes in tanks or containers without a RCRA permit. The University of Washington EH&S staff treats over 65,000 pounds of hazardous wastes per year.

All ten universities are expanding their silver recovery programs and accelerating efforts to eliminate the use of mercury containing thermometers in clinical and research areas. Most universities have or will implement this year a mercury thermometer exchange program. Health and safety committees and EH&S staffs are reviewing chemical requisitions and inventories to identify opportunities for pollution prevention. Redistribution programs for surplus materials are showing greater promise for intercepting these materials from laboratory waste streams.

Chemical Hygiene Plan

The federal Laboratory Standard of OSHA, which mandates a written CHP, applies to seven of the ten universities. This Standard does not apply to the University of Colorado at Boulder, UTSMC, or the University of Wisconsin-Madison, which are public institutions in non-OSHA Plan states. However, these three public universities have or are developing comparable written plans that describe provisions for protecting human health and the environment. The University of Wisconsin-

Madison EH&S staff is undertaking a project to place greater emphasis on the role of its CHP in laboratory safety and protection. The EH&S staff has shifted emphasis from development of individual laboratory plans to plans that have broader coverage such as for an academic department or an entire building. They expect this shift will increase uniformity, simplify compliance, and increase administrative involvement in environmental, health, and safety issues. The University of Colorado at Boulder and UTSMC are planning projects to evaluate and improve practices for managing hazardous chemicals on their campuses.

The EH&S staffs at The Rockefeller University and Washington University reviewed and updated their CHPs. The Rockefeller University's review concluded that this best practice offers the greatest opportunity for meaningful improvement in waste management in the laboratory because the CHP addresses the waste at the point of generation and recognizes the difference between a laboratory and an industrial setting. Further, good laboratory practices assure the safe handling of wastes in a consistent and efficient manner by appropriate staff.

The EH&S staff at the University of Pennsylvania revised its CHP to reflect changes in its chemical waste management program. This revision increased safety awareness in the laboratories, particularly with regard to hazardous waste management. The EH&S staff plans to work with the laboratories to address the human health and environmental protection issues for unique chemical waste streams generated in research. The staff believes this collaboration will foster educational opportunities and increase knowledge in safe and healthful practices.

Chemical Waste Management

Stanford University reports that members of the pilot laboratories had a better understanding of container segregation and labeling requirements, and considered pollution prevention methods more often when designing new experiments than did their colleagues in non-pilot laboratories. The close interaction between the EH&S staff and the laboratory workers established by this project contributed to this positive outcome. Members of the pilot laboratories showed only a modest interest in conducting bench top treatment; they perceive that the regulatory burden is too high.

The Rockefeller University EH&S staff reviewed the standard operating procedures of its waste management program. They revised the procedure for treatment of ethidium bromide and successfully treated 76 liters of ethidium bromide waste. The staff evaluated a neutralization program for acids and bases and concluded that the potential reduction in waste volume did not justify the use of staff resources. They also identified several improvement projects including the preparation and distribution of waste guidelines for laboratory workers, a review of waste storage practices with a goal of eliminating satellite accumulation areas within laboratories, and a training project to improve container management. An environmental audit by a consulting firm may identify other opportunities for improvements.

The University of Pennsylvania EH&S staff met with investigators, research technicians, and graduate students to review and critique the guidelines of its hazardous waste management program. Their goal was to ensure that the guidelines are current and helpful, and reflect input from the research community. The Washington University EH&S staff developed a pictorial flow chart for laboratories in need of special guidance to aid in improving their performance.

Container Labeling

Stanford University EH&S staff introduced new procedures for labeling containers in its pilot laboratories. A simplified waste label was developed and given to the pilot laboratories along with stickers designating a surplus material. The EH&S staff advised laboratory workers to manage discarded chemicals as either waste or surplus materials. There was no time limit applied to storage or accumulation of surplus materials. The staff defined waste as expired, banned, or degraded materials, and mixtures and solutions typically categorized as hazardous waste. Laboratory workers managed only waste materials as hazardous wastes. When the waste materials were received by EH&S, they were undeclared if necessary, and reclassified as surplus, retrograde, or recyclable materials. The staff used surplus, retrograde, or recyclable stickers to identify the reclassified materials. Product labels provided appropriate identification and hazard warning for materials reclassified as surplus. Upon receipt of the laboratories' surplus materials, the EH&S staff entered the materials into a chemical redistribution program or declared them a hazardous waste and managed them accordingly. The laboratory workers were responsive to the simplified labeling program and mastered the procedures with ease.

The Rockefeller University EH&S staff found through its laboratory audit program a need to improve the procedure for identifying container contents. They developed a standard label for chemical waste accumulation containers, modified the waste guidelines to require use of the label, and alerted the campus community of the changes. The staff will highlight use of the label in an intra-Web training program now in development. This summer, the staff is repeating a campus-wide educational outreach effort. Members of EH&S will meet with researchers in their laboratories, provide additional copies of the labels and updates on waste guidelines, and answer questions on waste management issues.

The University of Pennsylvania EH&S staff revised its Chemical Waste Disposal Procedures in March 2000 and internal SOPs in December 2000 to reflect changes in the storage, handling, and identification of chemical waste material in the laboratory. Large volumes of solvent wastes, for example, halogenated solvents or non-halogenated solvents, are identified as hazardous waste while inside the laboratory. The information on a color-coded tag includes the waste stream, data, and the Treatment, Storage, and Disposal Facility (TSDF) waste stream identification code for the particular waste stream. When initially placing waste into a container, it is the responsibility of the laboratory staff to attach a color-coded tag to the outside of the container. When the container is full, the staff affixes a chemical disposal label to the upper part of the container identifying the chemical compounds' corresponding percentages and principal investigator. Reagents in their original containers with legible manufacturer's labels require no additional labeling or packaging.

Laboratory Protocols to Reduce Hazard

The use of a biodegradable scintillation cocktail in place of the past traditional solvent based cocktail is an excellent example of this best practice—a laboratory protocol has been adapted to eliminate a chemical hazard. Several universities recognized the potential benefits of this best practice, but the short time allotted for the demonstrations made progress difficult. The University of Colorado at Boulder encourages laboratories to adopt post-process treatment protocols that reduce hazardous wastes. Protocols for treatments other than neutralization of clean acids and bases require approval of the EH&S program. The University of Wisconsin-Madison reports that laboratories are reluctant to incorporate hazard reduction protocols because initially they may require more time to

perform since laboratory workers are unfamiliar with the procedures. Teaching laboratories are incorporating hazard reduction protocols into procedures as part of the teaching process.

Collection, Transport, and Storage by Environmental Health and Safety

All ten universities conduct their hazardous waste management programs in accordance with this best practice and, therefore, none considered a demonstration project necessary. Seven universities report excellent performance in many elements of this best practice; three report excellent performance in most elements. Both the University of Colorado at Boulder and UTSMC have authorization under a **RCRA** Part B Permit to operate a hazardous waste TSD. The University of Wisconsin-Madison is in the final process of closure to secure its old TSD. The University built a new chemical waste facility and in the planning process determined that a RCRA Part B Permit is not advantageous. The Rockefeller University is also planning to construct a new waste management facility; the University will not apply for a RCRA Part B Permit.

Five universities reported data on the number of incidents occurring during the demonstration phase involving the collection, transport, and storage of chemical waste. One reported no incidents, three reported one incident, and one reported two incidents. No chemical waste incidents resulted in a release to the environment. All universities reported that chemical waste incidents are rare occurrences. In addition, one university noted that the majority of “unknowns” processed during this period involved clean-out of historical collections and did not originate from daily collections.

Validated Environmental Health and Safety Treatment Protocols for Volume Reduction

The University of Colorado at Boulder EH&S staff prepared procedures for laboratory workers to neutralize clean acids and bases and to dispose of the treated materials as wastewater. The staff is installing state-of-the-art equipment in its TSD to perform silver recovery, neutralization of bulk acids and bases, and organic waste ozone and ultraviolet oxidation. The University’s RCRA Part B Permit allows certain flexibility to conduct treatment that is not generally available to universities with non-permit facilities.

The University of Washington EH&S staff operates a “treatment by generator” program to treat hazardous waste on-site. The Washington State Department of Ecology allows generators of hazardous waste to treat waste in tanks or containers, without a RCRA permit, in an environmentally responsible manner to reduce the hazard or volume of hazardous waste. This treatment program treats over 65,000 pounds of hazardous wastes annually. In addition, the EH&S staff operates a solvent recycling program that distills waste solvents and markets the purified solvents to the University’s laboratories. This program saves disposal costs and reduces the laboratories’ cost of new solvents by over 60 percent.

The following table shows the results of Duke University’s current chemical waste volume reduction program. The data show a significant reduction in the use of halogenated solvents and major increases in recycling of oil, fluorescent light bulbs, and mercury. The program also redistributed through its chemical waste exchange over 1,400 pounds of usable chemicals in the year 2000. The data does not reflect solid waste that goes to a landfill and liquid waste discharged as wastewater.

DUKE UNIVERSITY
CHEMICAL WASTE VOLUME REDUCTION PROGRAM
DISPOSAL AND TREATMENT METHODS

WASTE STREAM ¹	INCINERATE		FUEL BLENDING		RECYCLE		NEUTRALIZE	
	1999	2000	1999	2000	1999	2000	1999	2000
Bulk flammable / corrosive	-	63						
Bulk halogenated solvents	7534	5993						
Bulk low solvents	1120	861						
Bulk non-halogenated solvents			11741	11044				
Bulk non-regulated solvents	2014	3954						
Bulk oil					3928	7770		
Bulk photographic fixer					2302	2307		
Bulk spill response solid material	20	1342						
Bulk xylene					2313	1865		
Fluorescent light bulbs					9739	30851		
Labpack corrosive liquid							762	681
Labpack flammable liquid	176	223						
Labpack halogenated solvents	92	-						
Labpack non-halogenated solvent	191	-						
Labpack non-regulated poisonous solid ²	-	252						
Labpack paint flammable ³	314	442						
Labpack not in file ⁴	1584	-						
Mercury					317	623		
Recyclable wastes ⁵					-	408		

¹ All the wastes are approximated in pounds

² These are incinerated or fuel blended with very little landfilled

³ Can be incinerated or mixed for fuel blending, depending on the chemical make-up

⁴ Chemical that is not in the EH&S Chemical Waste Inventory Data Base

⁵ Contains waste such as various metals, oxides and empty gas cylinders

The Duke University EH&S staff has undertaken a major project to expand the treatment capabilities of its chemical waste volume reduction program. The University entered into a Memorandum of Understanding with a process technology company to conduct a final evaluation of the cost and risk benefits of employing an innovative chemical waste treatment technology for oxidation of organic compounds in its chemical waste reduction program. The Pacific Northwest National Laboratory developed the fundamentals of the process technology, which is based on cerium electrochemistry. The North Carolina Division of Waste Management (DWM) is interested in Duke University's pursuit of this initiative. The DWM participated in the regulatory evaluation, and approved Duke University's use of this technology under the provision of the hazardous waste generator regulations.

Duke University's Nicholas School of the Environment is participating in the project. A graduate student joined the project team to study which waste streams are candidates for beneficial treatment using this technology. Current projections suggest that all bulk solvent waste and waste oil, and approximately 25 percent of the labpack waste are candidate waste streams. This represents roughly 75 percent of the waste handled in the chemical waste reduction program, excluding landfill waste and wastewater. However, the program will likely continue to recycle bulk oil and xylene, and use bulk non-halogenated solvents in fuel blending. This would make the beneficial projections approximately 30 percent, or 12,000 pounds of the consolidated waste streams. The program is also

considering introducing a new filtration technology for the treatment of ethidium bromide waste. This approach could reduce the waste volume by another 150 gallons per year.

RCRA Determination by Environmental Health and Safety

Stanford University and Washington University undertook demonstration projects for this best practice. The EH&S programs at four universities currently make the RCRA determinations; they assess their performance as excellent. Four other universities chose not to address this best practice because they perceived that their state regulatory agencies would not grant this flexibility without specific approval from the EPA.

The EH&S programs at Duke University, The Rockefeller University, University of Washington, and University of Wisconsin make RCRA determinations for waste materials collected from their laboratories with the concurrence of their state regulatory agencies. The University of Washington works closely with the Washington State Department of Ecology and receives extensive guidance in applying regulatory flexibility. The University reports that it achieves improved compliance and efficiency in following the requirements of RCRA by having its trained EH&S staff make the RCRA determinations prior to collection and by operating laboratories as satellite accumulation areas. This approach reduces errors and inconsistencies in making RCRA determinations. Laboratory personnel are able to focus their efforts on container management and hazard communication.

The laboratory staffs at Harvard University, Stanford University, UTSMC, and Washington University are responsible for making the RCRA determinations. Laboratory staffs at the University of Colorado at Boulder and the University of Pennsylvania also are responsible for making the RCRA determinations. However, the EH&S programs at these universities can change the determinations made by the laboratory staff or modify the process for making RCRA determinations. For example, at the University of Colorado at Boulder, when the laboratory staffs are unclear as to whether materials are RCRA hazardous waste, the EH&S staff makes the formal RCRA determinations. At the University of Pennsylvania, the EH&S staff makes the RCRA determinations for waste reagents that are in their original containers with intact labels.

The following table summarizes the variations in RCRA determination responsibilities

EXISTING RESPONSIBILITIES FOR MAKING RCRA DETERMINATIONS		
UNIVERSITY	LABORATORY STAFF	EH&S STAFF
Duke University	No	Yes
Harvard University	Yes	No
Stanford University	Yes	Yes, for surplus reagents
The Rockefeller University	No	Yes
University of Colorado, Boulder	Yes	Can change determination
University of Pennsylvania	Yes, for large volume waste	Yes, for labpack waste
University of Texas S M Center	Yes	No
University of Washington	No	Yes
University of Wisconsin-Madison	No	Yes
Washington University	Yes	Yes, for surplus reagents

Stanford University's EH&S staff discussed their interest in conducting a demonstration project on this best practice with the California Department of Toxic Substances Control (DTSC).

The DTSC agreed to a project that allowed the EH&S staff to collect surplus materials from the pilot laboratories without the laboratory staffs making a RCRA determination. The EH&S staff made the RCRA determinations for the surplus materials collected from the pilot laboratories that were not suitable for the University's chemical redistribution program. The laboratory staff and the EH&S program found this procedure to be practical and efficient.

The Washington University's EH&S program developed its project in collaboration with the Missouri Department of Natural Resources. The demonstration project requires laboratory personnel to make initial RCRA determinations. EH&S staff makes the final determinations after the waste material is brought to its central facility. The evaluation of the project is not complete since it began toward the end on the demonstration phase.

Emergency Response

All ten universities have plans and procedures for implementing appropriate responses to emergencies including emergencies in laboratories. All report that incidents relating to the operation of their hazardous waste management programs are infrequent. For example, during the past 18 months, Duke University has experienced only one chemical waste incident in a laboratory. In addition, the University reports that of the 80 responses to chemical spills in laboratories, none resulted in a release into the environment. The ten universities agreed that this best practice did not require demonstration projects.

Training, Education, Communication

The Duke University EH&S staff revised its Web-based training modules for laboratory safety to expand emphasis on best practices. In addition, information on hazardous waste management was incorporated into a new EH&S module for graduate credit through the Nicholas School of the Environment.

Harvard University conducted three projects relating to this best practice. The EH&S staff revised the quiz found in its Web-based hazardous waste training program in response to feedback from trainees and research operational managers. The quiz now randomly selects nine questions from a group of 20 specific to laboratory hazardous waste management. This eliminates repetition and better tests the trainees' knowledge. The EH&S staff anticipates that this will yield better compliance with issues such as labeling and container management, but it is too early to determine the quantitative impact. A second project involved modifying the EH&S training database to allow users to search a department's training status for any program. One of the critical outcomes of this system is that it places the responsibility for re-training on the trainees and their departments, and not on the Harvard University EH&S staff. In addition, the staff revised its Training Requirements Guide to better assist departments in determining the individual training needs. These improvements allow EH&S to customize training programs for various groups and helps management staffs develop better training plans for their departments. In a third project, a hazardous waste module was integrated into a monthly training course that laboratory workers attend to meet their obligations for training in various EH&S disciplines. This resulted in a significant savings in time for the EH&S professionals who previously taught in hazardous waste training sessions, and eliminated confusion for trainees who were unsure about what training courses they needed.

The Stanford University EH&S staff led training sessions for the laboratory workers in its pilot laboratories tailored specifically to the health and safety issues associated with their research; the laboratory staffs appreciated the relevance of this training. The positive results of this training initiative were evident in several of the best practices including responsibility and accountability, policies and procedures for pollution prevention, chemical waste management, chemical labeling, and communication within the organization.

The University of Washington undertook a major review of its training programs and conducted several initiatives as part of this best practice. They assembled a Training Review Committee of EH&S staff, laboratory personnel, and Washington State Department of Ecology staff. The Committee reviewed existing training programs, both internal and external to the University, evaluated the effectiveness of internal programs, and identified key subjects to emphasize in future training. The group considered Web-based training and video in their review. The Committee developed an evaluation tool to obtain feedback from trainees on relevance, course presentation, and value. Several hundred incoming graduate level science students attending the University's annual laboratory safety seminar completed the evaluation. Their comments emphasized that training must be customized to the students, include examples that reflect relevant chemicals and situations, be concise, to the point, and interactive. The EH&S staff is incorporating these elements into its 2001 laboratory safety seminar that will be an interactive workshop with smaller class sizes.

In addition, the EH&S staff evaluated the capabilities of the Web for hazardous waste training. They invited 35 faculty and graduate students from two University departments to evaluate a prototype Web-based training program. The content addressed findings from the University's audit programs, common RCRA violations at academic institutions, and laboratory feedback. The staff is reviewing the evaluations to determine what content should be given emphasis,

Stanford University, The Rockefeller University^{*}, and the universities of Colorado at Boulder, Pennsylvania, Texas SMC, Washington, and Wisconsin-Madison also found Web-based training to be an effective method for increasing knowledge and awareness, and for reinforcing prudent practices in the disciplines of health, safety, and environmental protection.

Effective Communication within the Organization

The Harvard University EH&S management system has created effective communication channels within the University regarding all EH&S matters. The EH&S staff works closely with the EH&S committee structure, environmental and safety compliance officer network, laboratory safety and building manager committees, and other university contacts to provide regular, consistent forms of communications regarding EH&S matters. In addition, EH&S dedicates ample resources to the development and maintenance of its Web site which serves as an excellent means of standard and consistent communication of complex, technical, and regulatory standards to a diverse audience.

The Harvard University EH&S staff developed on its Web site several "toolkit" pages tailored to specific audiences including researchers, building managers, and students. The toolkit concept provides personnel with only that EH&S information pertinent to their operation, thus eliminating additional links that have no relevance. The laboratory toolkit, still in its pilot phase, creates one location on the EH&S Web site where laboratory personnel can get laboratory-specific EH&S information including hazardous waste resources. The EH&S staff will introduce the laboratory toolkit to the University community in the next several months.

In addition, the EH&S staff implemented an automated e-mail notification system for personnel requiring re-training, for example, annual re-training for hazardous waste. EH&S enters the names of all personnel receiving training into its Web-accessible training database. Modifications to this database have made it possible to generate automated e-mail notices to trainees requiring re-training and notices to designated department administrators for personnel overdue for re-training. Trainees receive reminder e-mail notices 30 days prior to the re-training date. Since the start of this system, several research operations managers have reported a decrease in time necessary to locate and communicate with delinquent trainees. The system allows designated "Superusers," typically department administrators and human resources staff, to run reports on their department's participation in various training requirements. They also can receive feedback on their compliance performance for re-training. Poor re-training rates may be an indication that communication barriers exist or of a need to create communication pathways.

The University of Wisconsin EH&S staff developed a "no reprisal" policy to codify its current practice. The staff is recommending that the University consider broader adoption of the policy. Washington University developed plans to conduct an annual meeting for department safety officers as a means for improving and promoting health, safety, and environmental stewardship. It is also considering a project to prepare annual reports for each department that will evaluate the department's progress in meeting the stewardship goals of the University.

All EH&S programs are employing multimedia approaches for communicating with their campus communities. There is a continuing effort to ensure essential information is current and appropriate. Several programs adapted their laboratory audits to encourage informal discussions with laboratory staff concerning health, safety, and environmental issues.

Program Evaluation and Improvement

To focus more on chemical waste management, the Duke University EH&S staff modified an existing laboratory audit program, which is an element of its CHP. The auditors now ask laboratory workers specific questions that address container management and storage as well as other aspects of the University's chemical waste management program. The following table reports the results of roughly 360 annual audits conducted in 2000 and 2001 involving 1,100 laboratories.

DUKE UNIVERSITY AUDIT RESULTS ON CHEMICAL WASTE MANAGEMENT				
YEAR	ALLREGULATED WASTES COLLECTED AND SUBMITTED TO EH&S PROGRAM	CHEMICAL WASTES LABELED APPROPRIATELY	CHEMICAL WASTES STORED APPROPRIATELY	STAFF AWARE OF SURPLUS CHEMICAL EXCHANGE
	Non-compliant 17 Percent compliant 95	Non-compliant 13 Percent compliant 95	Non-compliant 15 Percent compliant 95	Non-compliant 19 Percent compliant 94
2000	Compliant 282 Non-compliant 21 Percent compliant 93	Compliant 286 Non-compliant 20 Percent compliant 93	Compliant 290 Non-compliant 21 Percent compliant 93	Compliant 286 Non-compliant 30 Percent compliant 95

The Harvard University EH&S staff developed a hazardous waste assessment database that uses hand held computers for collecting assessment results. A hazardous waste contractor conducts monthly inspections at over 1,000 satellite accumulation areas in order to provide specific

performance data to each department. Assessment criteria consist of the most commonly cited issues for hazardous waste management—labeling and container management. Hand held technology eliminates the paper associated with many assessment programs. This system allows for fast collection and download of data to the central hazardous waste assessment database. The EH&S staff estimates that this system saves 0.5 full-time equivalents through more efficient data collection, management, and reporting. In addition, once in the database, the data is easier to analyze to identify problem areas and formulate corrective actions. Monthly reports are provided via e-mail to environmental and safety compliance officers and department managers. Detailed reports, available upon request, include assessment performance on a room-by-room basis and track each laboratory's monthly performance. This level of detail allows the environmental and safety compliance officers, laboratory directors, and others to better determine their department's weaknesses. **An** ancillary impact of these reports is that the consistency in assessment criteria has helped to focus and educate management personnel on critical management and compliance issues.

The University of Washington EH&S staff selected an evaluation team to conduct a review of its hazardous waste management program. The team consisted of the Undergraduate Director of the Chemistry Department, a research scientist with the Department of Environmental Health, two staff from the Hazardous Waste Toxics Reduction Program of the Washington State Department of Ecology, the EH&S Training Manager, and the EH&S Manager of Hazardous Materials and Waste Management. The team used a Web-based client survey to collect information. They invited 926 laboratory personnel including investigators, laboratory managers, technicians, and graduate students to participate; there was a 20 percent response. The survey indicated that most clients are satisfied with the EH&S hazardous waste management services except for the frequency of waste collections. The survey helped raise the awareness of the responders to information on the EH&S Web site about the hazardous waste management program, particularly the availability of forms and labels. The staff concluded that use of the Web could improve collection efficiencies.

All EH&S programs reported that they have existing audit programs for evaluating program quality and effectiveness and for highlighting areas for improvement. They also reported that they made significant progress toward improving their waste management programs in the short time allotted for their demonstration projects. The new initiatives and evaluation tools developed as part of this demonstration will allow progress to continue at an even greater pace.

Qualitative Assessment

At the beginning of the demonstration phase, the universities performed a qualitative assessment of their existing hazardous waste management programs. The objective was to determine the extent to which their programs carried out the spirit and intent of the consensus best practices. The self-assessments enabled the universities to select demonstration projects that would be of most benefit to their programs. It is important to note that the assessments were *not* a review of compliance performance. The goals of the consensus best practices transcend the regulatory expectations for compliance to a set of prescribed practices. The universities repeated their assessments at the end of the eight-month demonstration period. The following table reports the results of those assessments.

PROJECT PERFORMANCE ASSESSMENTS BY CONSENSUS BEST PRACTICES OCTOBER 2000 – JUNE 2001		
BEST PRACTICE	INITIAL ASSESSMENT	EIGHT-MONTH ASSESSMENT
	AVERAGE VALUE	AVERAGE VALUE
1 Executive commitment	1.6	1.9
2 Responsibility and accountability	1.7	2.1
3 Pollution prevention	1.9	2.1
4 SOP: Chemical Hygiene Plan	2.2	2.3
5 SOP: Chemical waste management	2.6	3.0
6 SOP: Container labeling	2.5	2.6
7 SOP: Laboratory protocols to reduce hazard	1.3	1.5
8 SOP: Collection, transport, and storage	3.4	3.3
9 SOP: Treatment	1.8	2.1
10 SOP: RCRA determination by EH&S	2.9	2.9
11 SOP: Emergency response	2.6	2.5
12 Training, education, and communication	1.9	2.2
13 Effective communication	1.6	2.2
14 Program evaluation and improvement	1.6	2.1

Assessment values:
1 -- Marginal performance
2 -- Acceptable performance
3 -- Excellent performance in many elements
4 -- Excellent performance in most elements
Note: One university reassessed its initial assessment of Best Practices 8 and 11 from 4 to 3 after re-evaluating its program during the eight-month demonstration period.

The assessments support two observations about the existing hazardous waste management programs of the ten universities. The first is that existing hazardous waste management practices reflect an institutional commitment to achieve regulatory compliance. The universities assessed their initial performance in the best practices that incorporate compliance functions—container labeling; collection, transport, and storage; emergency preparedness; and RCRA determination—at a high performance level and they maintained that level throughout the demonstration phase. The second observation is that efforts to promote stewardship and responsibility for health, safety, and the environment received less institutional commitment prior to this initiative than did compliance related practices. The universities assessed their initial performance in the best practices that enhance stewardship and responsibility—executive commitment, responsibility and accountability, and program evaluation and improvement—as being much lower than their performance in compliance related best practices. These best practices, however, received the greatest attention during the demonstration phase. The eight-month performance assessments show considerable progress in applying these best practices to the universities’ hazardous waste management programs.

Partnership and Collaboration

Partnership and collaboration among EH&S professionals, scientists, and officials from the state and federal environmental protection agencies are positive forces for developing consensus best practices that are relevant to the laboratory and for promoting environmental stewardship among scientists. This was evident in the results of each of the three workshops and during the demonstration phase. For example, the University of Washington reports that one of the most

valuable outcomes of this collaborative project has been their success in establishing a more cooperative relationship among researchers, regulators, university administrators, and EH&S staff. The EH&S staff recognizes this as essential to their program—it was also an underlying goal of this initiative. The EH&S staff reports that this initiative provided an opportunity to develop a partnership leading to honest dialogue with regulators about the challenges facing their University. In addition, faculty and students came to understand the significant framework that exists to promote human health and protect the environment while the campus community pursues the goals of teaching, research, and service. The staff also reports that administrative programs at the University are seeing new opportunities for increased partnerships with students and faculty in promoting future goals in conservation and environmental protection.

Another valuable outcome that resulted from Stanford University's pilot laboratories project was confirmation that scientists find performance-based initiatives developed collaboratively by EH&S staff, scientists, and regulators motivate them to think positively about environmental stewardship whereas prescriptive regulatory requirements imposed on them with little consideration of the research laboratory environment negate such thinking.

One state regulatory official participating in the initiative observed that continuing dialog on environmental regulations, both within the university, and among the university and the state and federal regulatory programs, is paramount in building trust and finding sensible approaches to meet common goals within a given regulatory structure. This dialog, it was stated, is essential in addressing environmental regulations, such as **RCRA**, that are not well suited for the one-size-fits-all approach. The official concluded that the dialog promoted by this initiative made it possible to develop and validate these best practices for managing hazardous waste in academic laboratories.

Conformity and Consistency

This initiative found a lack of conformity and consistency nationwide in the application of RCRA to academic laboratories. These findings result, in part, from the authority RCRA gives to the states to promulgate regulations that are more stringent than federal RCRA regulations. For example, the Massachusetts Department of Environmental Protection prohibits treatment of hazardous waste except for certain emergencies and requires most recycling of hazardous waste to be a permitted activity. These types of stringent requirements discourage academic institutions from developing and adopting recycling or other waste treatment strategies recommended by EPA for managing hazardous wastes. The expense and effort required for the permit application process and the administrative requirements imposed on permitted operations are too great to justify the modest environmental benefits that are possible for a single university.

In contrast, the Washington Department of Ecology actively promotes “treatment by generator” options as a non-permitted activity. The Department of Ecology has determined that on-site treatment is a preferred waste reduction option when environmental factors are equal because “it minimizes transportation risks, limits the transfer of risk to other communities, and results in the application of appropriate, waste-specific technologies.” (Hazardous Waste and Toxics Reduction Program Technical Information Memorandum 96-412: Treatment by Generator; May 1999.)

These differences in treatment options between Massachusetts and Washington impact opportunities universities have for promoting environmental stewardship within their respective states. The University of Washington, working collaboratively with the Department of Ecology, has established a “treatment by generator” program that impacts positively the protection of health,

safety, and the environment. The three universities participating in the New England University Laboratories Project XL, two of which are in Massachusetts, had originally proposed to evaluate the environmental benefits of several treatment options as a part of their project. They chose not to do this, however, because the subject of treatment was too contentious among the project stakeholders.

Differences also exist among the EPA regional offices and state implementing agencies in areas of RCRA enforcement practices, the focus of assistance programs, and the interpretation of RCRA provisions. The most significant example is the range of allowable practices found among the universities regarding RCRA determinations (see page 19). At four of the ten universities participating in this initiative, the EH&S programs make the RCRA determinations and the laboratory staffs do not. At two of the universities, the laboratory staffs make the RCRA determinations and the EH&S programs do not. At the remaining four universities there is some leeway for sharing this responsibility between the laboratory staffs and the EH&S programs. There is value in having the EH&S staffs make the RCRA determinations because this allows them opportunities to develop waste management programs that are more efficient and effective than those developed by the EH&S programs at the universities where laboratory staffs are required to make the RCRA determinations.

Inconsistencies in required practices, however, make it difficult to establish a common understanding among scientists of the value and importance of RCRA compliance. Waste management programs at academic institutions reflect the different interpretations, guidance, and requirements of their regulatory agencies. This results in significantly different practices at the laboratory level among universities in different areas. These inconsistencies suggest to scientists that RCRA compliance requirements are often more arbitrary than sound practice. Research protocols are the same wherever conducted, requiring consistent and precise execution. However, scientists experience variations in waste handling requirements for identical research protocols frequently since it is common for scientists to move from one university to another as their careers advance. For example, a review in 1999 showed that assistant investigators at the Howard Hughes Medical Institute will move, on average, to four universities in their short careers as assistant investigators; three of these universities will be in different EPA regions.

Conformity and consistency in enforcement practices, technical guidance, and regulatory interpretations will encourage the adoption of consensus best practices. This will add value to efforts for promoting stewardship and responsibility for health, safety, and the environment.

6. DISCUSSION

Three criteria set the ground rules for the HHMI-led initiative to develop consensus best practices for managing hazardous wastes in academic research institutions and to demonstrate their value as a performance-based model for achieving RCRA compliance. The first criterion required that hazardous wastes prepared for removal from the ten participating universities would comply fully with all applicable provisions of federal EPA and state RCRA regulations. The second criterion focused the development of best practices on broad environmental performance objectives rather than prescriptive RCRA compliance requirements. The third criterion set a high standard for the initiative: Each university agreed that the commitment to minimize the potential for harm to human health and the environment and to promote excellence in environmental stewardship would be a fundamental principle of the initiative. Adherence to these criteria lends credibility to the initiative and its recommendations.

The 14 consensus best practices developed through this initiative reflect, in most part, practices currently carried out at the ten universities. The best practices are statements that give purpose, direction, and clarity to broad functions that a university should adopt when establishing programs to manage hazardous wastes produced in its laboratories. The information that accompanies the best practice statements illustrates the means used to attain the intent of the best practices; they are a composite of the types of thinking, commitment, and creative approaches used by the ten universities. The level of emphasis on any single best practice and the means used for attaining intent can vary in accordance with the style, culture, and nature of the university. This is the inherent value in a performance-based model for RCRA compliance at academic research institutions. This inherent value also could make a consensus best practices approach universally applicable to both small and large colleges and universities.

Collectively, based on their own experiences prior to beginning the demonstration phase, the ten universities recognized the value and efficacy of the 14 consensus best practices. They also had recent histories of favorable to excellent RCRA compliance. Most of the best practices demonstrations, therefore, became efforts to improve environmental awareness, processes, tools, and management systems—efforts to increase efficiency and promote environmental stewardship.

Validation of Best Practices

This discussion reviews the value found in the demonstration projects for each best practice. The best practices addressing treatment and RCRA determination receive special emphasis because they are practices for which the regulatory agencies have not established consistent policies.

Agreement to participate in this initiative was, in itself, a statement of support of the first best practice addressing executive commitment, which reads:

The executive leadership of the institution embraces, supports, states, and carries out the commitment to protect human health and the environment and to promote excellence in environmental stewardship.

This commitment strengthened during the conduct of the initiative. In September 2000, the President of HHMI wrote letters to the presidents of the ten universities reading that a goal of the initiative was “to stimulate new thinking about the role of an academic institution in promoting excellence in health, safety, and environmental stewardship as a valued part of its broad mission for teaching, research, scholarship, and service.”

Although strong executive commitment for compliance attainment was evident at the start of the initiative, six of the ten universities began to explore measures for broadening their commitment to stewardship and responsibility for health, safety, and the environment. The President from one university issued a statement promoting excellence in environmental stewardship. Five other universities are continuing their efforts to explore a role beyond compliance on issues relating to health, safety, and the environment. This is evidence that the academic community can be motivated to seek excellence in environmental health and safety beyond RCRA compliance by values unrelated to the risk of regulatory enforcement.

The best practice addressing executive commitment had a positive effect on the best practices addressing responsibility and accountability, effective communication within the organization, and program evaluation and improvement. Several universities provided additional staff and resources or

realigned program priorities to establish or augment audit processes for evaluating their multimedia environmental programs including air, water, and solid waste; to develop new tools and mechanisms to improve communications; and to provide special guidance to laboratory workers. Performance-based best practices offer many opportunities to utilize resources more effectively than do strictly compliance programs. It was evident at one university that a shift from attaining only regulatory compliance to achieving environmental goals could enhance individual responsibility and accountability. However, because of the enforcement risk, executive leadership would not condone shifting program priorities toward broad environmental performance goals when the regulatory approach demands compliance with prescriptive requirements. In addition, one university reporting greater than 95 percent compliance with waste management requirements in its laboratories would not consider changing its annual audit frequency, even though these resources could be better utilized in other areas of environmental protection. Their reason—past EPA enforcement efforts focused on absolute compliance with container management and labeling.

Best practices addressing policies and procedures for pollution prevention; chemical waste management; container labeling; collection, transport, and storage by EH&S; and emergency response specifically address extant RCRA compliance requirements. These best practices are standard practices at the ten universities. The universities' EH&S programs generally have responsibility for carrying out the universities' hazardous waste management programs. Most universities have devised labeling systems to simplify laboratory procedures and reduce compliance risks. There is a high level of performance by most of the universities in these best practices as shown by their self-assessments and regulatory compliance histories.

Demonstration projects relating to the best practice addressing training, education, and communication emphasized the value of both Web-based training and personal contact by EH&S staff in improving training and educational programs and in ensuring effective communication. Direct interactions between EH&S staff and scientists create positive results and are helpful in promoting environmental stewardship. Other demonstration projects such as those relating to compliance activities and program evaluation and improvement, also took advantage of the power and efficiencies offered by Web-based technology.

Treatment

The best practice addressing laboratory protocols to reduce hazards covers both the selection of research protocols that involve fewer or less hazardous materials and the treatment of waste in the laboratory. There is much evidence in scientific publications that scientists will adopt research protocols that reduce hazards. Micro-scale and automated research protocols result in significant reductions in the quantities of hazardous materials as compared with their predecessor protocols used a decade ago. This change resulted from scientific advancements, not from a conscious effort to develop environmentally friendly methods. Nevertheless, the rapid scientific progress achieved with efficient micro-scale methods is motivation for researchers to adopt new methods that offer the corollary benefits for environmental protection. The environmental benefits may also provide encouragement for some laboratory workers to adopt these new methods earlier.

All but one university conducts some form of treatment for certain hazardous wastes, for example, simple neutralization. Most waste treatment at the universities is done by the EH&S staff. This is the preference of several universities because when a trained staff conducts the treatment methods there is better quality control and less compliance **risk**, and there is economy in scale. There has been little motivation to do treatment in the laboratories, although several universities encourage

this practice. Laboratory workers are reluctant to treat waste because they are unfamiliar with the methods, they prefer not using their time in this way, and compliance record keeping is onerous. One demonstration project, however, found that environmental protection goals could become valuable motivators for doing waste treatment in laboratories.

The range of treatment activities varies considerably among the ten universities. One university is located in a state where a statutory provision prohibits treatment of hazardous waste except for as an emergency permitted activity. Two universities operate permitted TSDFs. Two universities have terminated use of permitted TSDFs. Regulatory complexities and costs are major reasons why universities choose not to seek or maintain authorization to establish and operate TSDFs. Two universities have authorization from their state EPA regulatory agencies for the EH&S staffs to operate “treatment by generator” programs. One of these universities is in a state that promotes “treatment by generator” programs; the other university received its authorization as part of this demonstration project.

Treatment by EH&S staffs offers much promise for waste reduction and pollution prevention. Treatment on-site reduces transportation risks, avoids transferring risks to other communities, and utilizes the most appropriate treatment technologies for specific laboratory waste streams. Using this treatment approach, however, requires that the EH&S program makes the RCRA hazardous waste determination and conducts any appropriate generator treatment on behalf of the academic institution. The potential benefit of this treatment approach is substantial. For example, if the treatment technology that is being evaluated by one university proves successful and is applied at all ten universities, approximately 740,000 pounds (370 tons) of chemical wastes (most of which is regulated hazardous waste) that is now collectively incinerated off-site could be treated on-site by the EH&S programs. This quantity of waste would represent more than 50 percent of the total annual quantities of chemical wastes generated by these universities.

RCRA Determination

The results and findings of the demonstrations show that the level of authority of a university’s EH&S program for making RCRA determinations influences the practices used in carrying out the university’s hazardous waste program. The complexities of working with the industrial-oriented RCRA regulations require EH&S programs to develop staff who are competent in the technical issues of RCRA to ensure effective and compliant operation of their hazardous waste programs. Requiring laboratory staff to acquire this level of expertise is not practical or productive.

Most of the ten universities prefer to rely on trained EH&S staff for making RCRA determinations because this increases the accuracy and reliability of the regulatory determinations. Four state agencies acknowledge that this practice adds value to a university’s hazardous waste program and endorse use of EH&S staff for making RCRA determinations. Two state agencies do not allow EH&S staff to make RCRA determinations because they are not certain that federal EPA would allow this practice. Two other state agencies were reluctant to authorize the EH&S program to make such determinations as part of their demonstration projects without specific guidance from EPA. Four state agencies allow the EH&S programs to change the RCRA determinations made by laboratory members. One EH&S program chooses to require laboratory members to label chemical waste as hazardous waste if the laboratory is unsure of the proper designation to reduce regulatory risk of an inaccurate determination. The inconsistencies in practices have come about as a result of the combined efforts of EH&S programs and state agencies to adapt an industrial-orientated standard

to the unique characteristics of the laboratory setting. In addition, the inconsistencies demonstrate the lack of conformity on this critical issue nationwide.

There are many advantages — in addition to increasing accuracy and reliability — to placing authority for making RCRA determinations within the EH&S programs. The EH&S programs would have more opportunities to develop innovative waste management strategies that are relevant to research laboratories. There would be a greater ability to plan, adopt, and use waste reduction programs. It would place the operational responsibilities for the details of RCRA compliance within the organization that has the technical expertise, training, and regulatory understanding necessary to enable the university to achieve compliance. Further, removing the complex responsibility for RCRA determinations from the laboratories would help the EH&S staff promote within the research community stewardship and responsibility for health, safety, and the environment.

Improving RCRA Applicability to Laboratories

This initiative supports the long held views of scientists, environmental health and safety professionals, and many regulators that the extant application of RCRA to laboratories is inefficient and difficult, and that a performance-based approach for the application of RCRA to laboratories is a preferred regulatory model. In addition, this initiative found that the current regulatory approach could actually constrain efforts within the academic community to promote environmental stewardship, an objective of RCRA. A new regulatory approach for laboratories could improve RCRA effectiveness and compliance in universities, and become a catalyst to bring about commitment and action for promoting stewardship and responsibility for health, safety, and environment.

This initiative envisions a two-tiered approach for applying RCRA to universities and their laboratories. It involves the application of a performance-based model, using the consensus best practices developed and demonstrated in this initiative, for guiding RCRA compliance in laboratories, and the application of the current provisions of RCRA for guiding RCRA compliance in universities at the time the universities' EH&S programs assume ownership and responsibility for laboratory waste materials and make the RCRA hazardous waste determination. The basis for this approach is the premise that the EH&S program makes the RCRA hazardous waste determination and conducts any appropriate generator treatment on behalf of the academic institution. This initiative found that four of the ten universities are successfully using this approach, with the concurrence of their state regulatory agencies, in managing their hazardous waste programs. This experience is significant because it demonstrates value in this approach as a regulatory model, and indicates that it does not compromise compliance.

Adoption by the EPA Administrator of this approach for achieving RCRA compliance in academic institutions would allow implementation of the consensus best practices performance-based model developed in this initiative. In addition, the EPA Administrator should encourage conformity and consistency nationwide in the implementation of this approach for applying RCRA to academic institutions. The Administrator should determine and initiate appropriate methods for implementing a performance-based regulatory model, using the consensus best practices developed through this initiative, for achieving RCRA compliance in academic institutions. This should proceed at an accelerated pace. The framework used by OSHA for the Laboratory Standard (29 CFR 1910.1450) is a useful model for implementing a performance-based approach.

Academic institutions that choose to adopt the consensus best practices for managing hazardous wastes in their laboratories should plan for implementation cooperatively with their state or federal regulatory officials. This initiative found that the full value of this performance-based approach is best achieved through partnership and collaboration among state and federal regulatory officials, and scientists and EH&S professionals of academic institutions.

7. CONCLUSIONS AND RECOMMENDATIONS

There are three principal conclusions resulting from this two-year collaborative initiative on consensus best practices for managing hazardous wastes in academic research institutions.

A performance-based model that has as its core the consensus best practices developed and demonstrated through this initiative is a workable approach for effective and efficient management of hazardous waste in academic research institutions. This approach will not compromise RCRA compliance, and will promote stewardship and responsibility for health, safety, and the environment while respecting the culture of an academic institution and the unique characteristics of the laboratory setting.

Collaboratively, the EH&S professionals, scientifically trained laboratory staff, informed institutional administrators, and staff from federal and state regulatory agencies who are familiar with the laboratory and academic setting will identify safe and practical ways to improve hazardous waste management programs, and they will do this enthusiastically when the outcome promotes environmental stewardship.

The interactions between some of the universities and their corresponding state regulatory agencies provide evidence that common ground is available within RCRA to adopt both the consensus best practices and a performance-based approach for compliance. The difficulty of matching specific requirements of RCRA with the academic laboratory setting stimulated efforts to find this common ground. Four of the ten universities participating in this initiative operate their hazardous waste management programs today with the concurrence of their state regulatory officials on the premise that the EH&S professionals are the most capable for determining whether used or unused laboratory chemicals are RCRA hazardous waste and, in this capacity, serve as the RCRA generator for overall compliance purposes. This operational practice is the cornerstone for a best practices performance-based regulatory model.

The Howard Hughes Medical Institute and the ten universities participating in the hazardous waste management initiative make the following recommendations to the U.S. EPA, and to the nation's academic institutions.

1. The **U.S.** EPA Administrator should recognize the consensus best practices developed through this initiative as a performance-based model for achieving RCRA compliance and for promoting stewardship and responsibility for health, safety, and the environment in academic institutions. The Administrator should determine and initiate appropriate methods for implementing a performance-based model, using the consensus best practices developed through this initiative, for achieving RCRA compliance in academic institutions.
2. The **U.S.** EPA Administrator should promote conformity and consistency among the **U.S.** EPA regional offices and state environmental protection agencies in carrying out RCRA assistance and enforcement programs for academic institutions.

3. Academic institutions should adopt the consensus best practices developed through this initiative as a performance-based model for managing hazardous wastes in their laboratories and for achieving RCRA compliance.
4. Academic institutions should establish dialogue with their regulatory agency officials to plan cooperatively their approaches for implementing the consensus best practices developed through this collaborative initiative.

REPORT TO CONGRESS

Evaluating the Consensus Best Practices Developed through the
Howard Hughes Medical Institute's
Collaborative Hazardous Waste Management Demonstration Project and the
Need for Regulatory Changes to *Carry Out* Project Recommendations

In Response to
Senate Report 106-410 and House Report 106-674
Accompanying H.R. 4635

March 2002

Office of Solid Waste
Office of Solid Waste and Emergency Response
United States Environmental Protection Agency

ATTACHMENT
B

EXECUTIVE SUMMARY

This report discusses a collaborative project initiated by the Howard Hughes Medical Institute (HHMI) to establish and evaluate a performance-based approach to management of hazardous wastes in the laboratories of academic research institutions. Participants in the project included ten academic research institutions and representatives from state and federal environmental regulatory agencies. The Environmental Protection Agency (EPA) commends HHMI, the ten participating academic research institutions, and other participants on their efforts to improve hazardous waste management in academic research laboratories through development and demonstration of a robust set of consensus best practices. EPA recognizes academic research institutions have had difficulty complying with the Resource Conservation and Recovery Act (RCRA) regulations due largely to their industry-oriented framework. Therefore, EPA supports developing effective alternatives for safely managing hazardous wastes in academic research institutions that meet standards for protection of human health and the environment. Although EPA believes that the current RCRA regulations are flexible and may allow for the implementation of the majority of the best practices developed through the project, it also believes that in some cases regulatory changes may be required. EPA also believes that the regulatory change process allows the Agency to consider views from diverse stakeholders as well as promotes national consistency. EPA plans to issue a guidance memo shortly that will address some concerns of academic institutions by clarifying existing EPA policy and how it impacts laboratory wastes and operations. At the same time EPA looks forward to working with HHMI as well as other laboratory associations, states, EPA Regions, the Occupational Safety and Health Administration, and the public to develop an approach that builds upon the consensus best practices as well as other ongoing efforts to provide labs needed flexibility while maintaining effective protection for human health and the environment. EPA expects to begin a coordinated project this spring that follows up on the recommendations of this report and integrates other ongoing work addressing related issues.

PART ONE

I. INTRODUCTION AND BACKGROUND

In 1999, the Howard Hughes Medical Institute (HHMI) initiated a collaborative project to establish and evaluate a performance-based approach to the management of hazardous wastes in the laboratories of academic research institutions. HHMI believed that such an approach coupled with regulatory flexibility could yield superior compliance and reduce burden under the hazardous waste regulations of the Resource Conservation and Recovery Act (RCRA). The HHMI collaborative project partnered environmental health and safety professionals and biomedical researchers from ten major academic research institutions and respective state regulatory officials from each of the ten regions of the U.S. Environmental Protection Agency ("EPA" or "the Agency"). The participants developed fourteen consensus best practices as guidelines to the new approach for managing hazardous wastes in academic research institutions.

During deliberations over the FY 2001 budget, both the House and Senate Committees on Appropriations included language in reports (House Report 106-674 and Senate Report 106-410) supporting the Howard Hughes Medical Institute initiative and asking that EPA provide the maximum flexibility permissible under the regulatory provisions of RCRA. Since under RCRA, states are authorized to administer and enforce a hazardous waste program in lieu of the federal program, EPA encouraged states to provide the maximum flexibility permissible under the regulations. Similarly, written guidance to RCRA Regional Program administrators encouraged support for the program. (See Attachment to Part One of this report.) Also, in response to Congressional requests, EPA has prepared this Report to Congress.

Part One of EPA's Report to Congress provides a summary of the RCRA-related challenges to academic research institutions (Section II), a summary of other initiatives that reflect or address academic research institution's concerns (Section III), a description of EPA's role in the HHMI collaborative project (Section IV), and EPA's evaluation of the consensus best practices and the need for regulatory changes to carry out initiative recommendations (Section V).

Part Two of this report contains the HHMI "Report on Consensus Best Practices for Managing Hazardous Wastes in Academic Research Institutions," October 2001. The HHMI demonstration phase report contains detailed information regarding the project and the results and findings of university-based demonstration projects, which the academic research institutions and HHMI used to evaluate implementation of the consensus best practices.

II. SUMMARY OF REGULATORY CHALLENGES

Many academic research institutions are subject to the Resource Conservation and Recovery Act (RCRA) regulations for managing hazardous wastes. These requirements are designed to protect human health and the environment from the mismanagement of hazardous wastes and establish a system to manage hazardous waste generation, transport, recycling, treatment, storage and disposal.

RCRA Overview

RCRA §3002 requires EPA to promulgate regulations applicable to generators of hazardous waste as may be necessary to protect human health and the environment. These generator regulations, codified in 40 *Code of Federal Register* Part 262, apply to all hazardous waste generators and are the primary RCRA requirements governing university hazardous waste activities. They apply to hazardous wastes managed by academic research institutions if an institution generates over 100 kilograms of non-acute hazardous waste in a calendar month or one or more kilograms of acutely hazardous waste in a calendar month. Of particular concern to regulated academic research institutions are those regulations concerning the hazardous waste determination (40 CFR 262.11), generator accumulation time (40 CFR 262.34), satellite accumulation (40 CFR 262.34(c)(1)), requirements to keep accumulation containers closed (40 CFR 262.34(a) and 265.173(a)), container labeling (40 CFR 262.34(a)(3)), manifesting shipments transported offsite (40 CFR 262.20(a) through (e)), and generator training (40 CFR 262.34 and 265.16).

RCRA-related Challenges

A number of issues have been identified by academic research institutions as presenting a challenge to waste management in their laboratories. These issues, also outlined in EPA-sponsored New England University Laboratories XL Project, are gathered from both participating and non-participating institutions and include:

Satellite Accumulation. RCRA regulations allow for the accumulation of hazardous wastes at “satellite” locations in academic research institutions (§262.34(c)). Although the requirements regarding such accumulation are minimal, they can present a logistical challenge for university academic research institutions.

For example, generators may collect up to 55 gallons of hazardous waste where the waste is initially generated with no time limitations. However, once the 55 gallon limit is reached, they are required to, within 3 days, comply with more stringent requirements for on-site hazardous waste accumulation. Typically, this means the hazardous waste will be moved to a 90-day accumulation area and will be accumulated in accordance with §262.34(a). There is no federal limit to the number of satellite accumulation areas at a facility.

Among the problems raised is the difficulty some academic research institutions experience in complying with the 3-day time frame once the quantity limit has been reached. Because the rate of waste generated in university laboratories is often unpredictable, academic research institutions say that it is difficult to predict when satellite accumulation limits may be exceeded and to arrange for removal of the waste within 3 days.

Collection of hazardous waste is also more challenging when states or academic research institutions impose more stringent requirements by reducing the volume of waste that may be accumulated or by limiting the amount waste that can be collected to one type. We also understand that some academic research institutions prefer to consolidate wastes

generated in a single building before moving the waste to a 90-day accumulation area. This may also present problems if the site is neither a satellite, nor a 90-day accumulation area.

Dual Regulation Under RCRA and Occupational Safety and Health Administration: Many academic research institutions are required to comply with OSHA regulations for the management of hazardous chemicals in the laboratory. Academic research institutions have often characterized RCRA and OSHA training requirements as duplicative, and indicate a preference for compliance with the OSHA standards for occupational exposure only, rather than both OSHA standards for managing hazardous chemicals in the laboratory as well as RCRA regulations for managing hazardous wastes. They also point to the definitional differences between RCRA and OSHA as a source of confusion.

OSHA requirements overlap with RCRA requirements in some areas. For example, OSHA regulations specify that employees must be provided with information and training in the procedures for safe removal of contaminated waste (29 CFR 1910.1450(e)(3)(viii)(B)). RCRA regulations for training require that personnel who handle hazardous waste must have training necessary to ensure safe handling of the wastes and to ensure that personnel are able to respond effectively in emergency situations. OSHA regulations, however, are not designed to protect the environment and do not specifically cover waste management except for removal. OSHA regulations also do not apply to academic research institutions in many states. States may develop and operate their own job safety and health programs that are "at least as effective as" comparable federal standards and there are 23 States and jurisdictions operating complete State plans (covering both the private sector and State and local government employees).

Decentralized Laboratory Operations: Academic research institutions commonly consist of many diverse, relatively small individual laboratory operations run by independent researchers. This distinguishes them from industrial operations that are generally more centralized and centrally controlled. Academic research institutions have said that the large number of independent waste generation points creates challenges in effectively implementing a uniform waste management program.

High Staff Turnover: The use of students and independent laboratory researchers creates a diverse population that is subject to frequent, regular turnover. This high turnover hinders the continuity of a hazardous waste management plan and the ability to systematically and efficiently train staff about RCRA-compliant handling of hazardous wastes. Academic research institutions suggest that qualified permanent Environment Health and Safety (EH&S) staff are able to more effectively manage hazardous wastes.

Waste Determination: Currently the waste determination usually occurs in the laboratory and is performed by the person performing the test, experiment, or operation. This person uses his or her knowledge to assess the nature of the materials remaining after the operation and is most familiar with the chemicals used and the chemical changes that may have occurred during the experiment or process.

Academic research institutions indicate a preference for the RCRA hazardous waste determination to be made by trained and knowledgeable EH&S staff. EH&S staff in their opinion, are aware of the potential reusability of used or opened chemicals. In some cases, they would prefer to be able to make this decision after the material has been moved from a laboratory to a central location.

Academic research institutions suggest that one drawback to making the waste determination in the laboratory is that it may be more difficult to assess the needs of the entire university for further use of certain chemicals. Academic research institutions prefer to have EH&S staff make the final hazardous waste determination because these permanent staff have campus-wide knowledge and are better able to determine that the material can be used elsewhere on campus.

Budgetary Constraints: Competing funding priorities can hinder the development and adequate support of waste management programs in individual academic research institutions or on individual laboratory research projects. Thus appropriate savings in waste management costs may result in improved waste management as well as increased funding available for research.

Inconsistency due to State Variation: Under Section 3006 of RCRA, EPA may authorize a qualified state to administer and enforce a hazardous waste program in the state in lieu of the federal program. State authorized programs may impose requirements that are more stringent or broader in scope than the federal RCRA program. As a result, there are variations in how certain requirements apply across state programs. The impacts of this variability can be magnified at academic research institutions by the relatively wide range of types of waste materials generated as well as by the relative infrequency and small volumes in which these materials are generated. Although EPA cannot mandate consistency among states, it can promote it with well-circulated guidance.

Recent RCRA Enforcement and Compliance Assistance Activities at Academic Research Institutions

Academic institutions are often similar to small cities, with many facilities and activities on their campuses such as research laboratories, auto repair facilities, power plants, wastewater treatment plants, hazardous waste management and trash disposal, asbestos management, drinking water supply, grounds maintenance and incineration. In addition, many operate medical and research facilities which create an additional set of challenges, some of which have been described in the preceding section of this report.

Because academic institutions undertake so many diverse activities, it is important that they accomplish them in a manner protective of human health and the environment. EPA is concerned about the management of hazardous waste because of the potential risk to human health and the environment and because of the proximity of these institutions to student residences and urban centers. EPA inspections of academic institutions have revealed significant noncompliance with a number of the RCRA (and other environmental) requirements. As a result, EPA has stepped up both its compliance assistance and enforcement efforts to deal with the risks to the public and the environment.

The most common RCRA violations include: failing to mark containers with the words “hazardous waste,” treating, storing or disposing of hazardous waste at a facility without a permit or interim status, disposing of potentially hazardous waste in solid waste trash bins, failure to provide and document hazardous waste training, failure to make hazardous waste determinations, and failure to inspect waste containers on a weekly basis. All of these violations can present risks to human health and the environment. Failure to label waste as hazardous increases the potential for mismanaged waste and injuries. Lack of a permit or interim status poses a danger to employees of the facility and nearby residents, and could lead to contamination of the soil, air and water. Placing incompatible wastes together in a solid waste trash bin could create fire, explosions, or dangerous gases. Failure to properly determine if a waste is hazardous could mean that it may not be handled safely on site and/or properly transported off site and disposed of in an appropriate facility.

EPA found a number of violations in academic research institutions across the country, including Massachusetts Institute of Technology, Boston University, George Washington University, the University of Hawaii, University of New Hampshire, and the University of Rhode Island. Violations ranged from improper transportation of hazardous waste between two universities to the storage of leaking chemicals in a basement over many years. One settlement resulting from such violations was worth as much as \$1.6 million. More information on recent enforcement activities can be found in the July 2000 *Enforcement Alert*, (Vol. 3, No. 7, EPA 300-N-00-012) at <http://epa.gov/oeca/ore/enfalert/vol3no7.html>.

EPA continues to offer compliance assistance to colleges and universities to help them achieve compliance with environmental laws. Some of these compliance assistance activities are summarized below.

In November 1999, Region 1 hosted a focus group discussion for college and university environmental health and safety staff. Region 1 used the information from this dialogue to develop an integrated strategy for the college and university sector. The Region’s strategy includes 1) Basic Regulatory Compliance including an informational web page and compliance workshops, 2) Best Management Practices to provide tools to conduct audits and implement environmental management systems, and 3) Sustainability, encouraging colleges and universities currently involved in activities that go beyond compliance (i.e., green procurement, energy efficiency, etc.) to share their experiences with fellow institutions.

In 2000, Region 2 sent letters to 344 colleges and universities encouraging them to take advantage of EPA’s Audit policy providing incentives to conduct environmental audits and voluntarily discover, disclose and correct violations. The Region has combined this effort with supplemental compliance assistance mailings, including self-audit guides, and seminars. New York State also conducted compliance assistance in coordination with the Region.

Region 3 created a questionnaire for college and university presidents to determine what elements of a good environmental management system are being implemented on their campuses. Region 3 also participated in three day-long workshops hosted by Baltimore and Philadelphia universities. In June 2001, Region 3 held two workshops for colleges

and universities with hospitals.

In August 2001, Region 7 invited 400 universities to participate in a compliance workshop for colleges and universities. There were presentations on the Audit policy, waste reduction strategies, and environmental management systems.

In 2000, Region 9 invited Arizona colleges and universities to participate in a RCRA-focused Audit policy initiative. In conjunction with this effort, the Arizona Department of Environmental Quality sponsored an all-day workshop on RCRA compliance and reinforced the seriousness of follow up inspection and enforcement efforts. Region 9 also developed a compliance self-audit project that includes the University of California system. The Region invited several campuses and medical schools from the UC system to participate in a voluntary compliance self-audit program.

These Regional initiatives confirm that continued attention needs to be given to academic research institutions to improve RCRA compliance. Regions and states have worked to devise methods that improve compliance, and Best Management Practices such as those developed through the HHMI initiative provide another tool to aid in achieving compliance in academic research institutions.

III. EPA PARTICIPATION IN LABORATORY AND RELATED INITIATIVES

EPA became increasingly aware of the challenges faced by academic research institutions in complying with the hazardous waste regulations. EPA has actively participated in a number of efforts not associated with the HHMI project aimed at identifying and addressing issues of concern to academic research institutions. The initiatives described in this section include examples of ways EPA has tried to address concerns raised by academic research institutions. Concerns include requests to clarify RCRA regulations, examine performance-based approaches to managing hazardous wastes, and make it easier to move hazardous waste among buildings on university campuses. Many of these issues *are* equally evident in the HHMI project, which enables academic research institutions to focus on and understand hazardous waste management requirements, and continue to experiment with performance based-approaches to site-specific problems.

EPA Report to Congress on Management of Hazardous Waste in Educational Institutions. On April 26, 1989, EPA submitted a report to Congress entitled "Management of Hazardous Wastes from Educational Institutions." The report discussed waste management practices at educational institutions, as well as problems, and possible ways to improve the management of hazardous wastes.

NCCLS Guidelines for Clinical Laboratory Waste Management. EPA also participated in the National Committee for Clinical Laboratory Standards (NCCLS) subcommittee on Laboratory Waste to develop "Guidelines for Clinical Laboratory Waste Management." The approved Guideline was first published in 1993 and is currently available through NCCLS.

Government University Industry Research Roundtable. Beginning in 1994, EPA participated on the Government University Industry Research Roundtable, sponsored by the National Academy of Sciences, National Academy of Engineering, and Institute of Medicine. Participants in the group identified several areas of the RCRA regulations they believed needed attention, including the waste determination, treatment of hazardous wastes, reuse of chemicals, generator ID numbers, training, and expired chemicals.

New England Universities Laboratories Project XL. In June, 1998, EPA's Region I accepted the New England University Laboratories proposal as an EPA Project XL. This project was proposed by three New England universities to address many of the issues discussed in Section II of this report. On September 28, 1999 (64 *Federal Register* 52380-52396), EPA finalized the New England Universities Laboratories Project XL. This pilot project provides regulatory flexibility under RCRA for participating academic research institutions at the University of Massachusetts in Boston, Boston College, and the University of Vermont. The New England Universities (NEU) Laboratories XL Project was approved to enable academic research institutions to test the effectiveness of an integrated, flexible, performance-based system for managing hazardous wastes in academic research institutions. This XL project is designed to achieve environmental results superior to those achievable under the current RCRA system and the HHMI best practices demonstration project is in many ways consistent with the NEU Project XL. The XL pilot project has a four year time limit (to September 28, 2003) during which EPA will evaluate its success and determine whether it should be continued and/or expanded to other universities through regulatory changes.

EPA has also worked on other efforts that, although not designed specifically for labs, would address some laboratory issues. These regulatory initiatives are described below.

Hazardous Waste Manifest Exemption. In 1997, EPA finalized a rule (February 12, 1997, 62 *FR* 6621-6657) which exempts from manifest requirements shipments of hazardous waste on right-of-ways on or between contiguous properties and along the perimeter of contiguous properties controlled by the same generator. This change enables academic research institutions that are located on large parcels of land divided by public or private right-of-ways to more easily move hazardous wastes between university buildings.

Mixed Waste Rule and HWIR. On May 16, 2001, EPA finalized rules (May 16, 2001, 66 *FR* 27217) providing increased flexibility to generators and facilities that manage low-level mixed waste (LLMW) and technologically enhanced naturally occurring and/or accelerator-produced radioactive material (NARM) containing hazardous waste. LLMW is now exempt from some RCRA storage and treatment regulations, and LLMW or eligible NARM is exempt from RCRA hazardous waste transportation and disposal regulations provided they meet specified conditions. EPA and HHMI believe this rule will positively impact academic research institutions handling LLMW.

Standardized Permit. EPA is working to streamline the permit process for facilities who want to store or manage wastes they generate in tanks, containers and containment buildings. EPA published a proposed Standardized Permit Rule on October 12, 2001 (66 *FR* 52192). If finalized, this rule would simplify the permit process, shorten the time needed to process permit applications, and reduce the cost of a permit for routine permits. This change is expected to

benefit academic research institutions and others who would like to store hazardous wastes on site for longer than 90 days.

In addition to these efforts, there are a number of non-regulatory efforts designed to address concerns of academic research institutions:

Green Methods for Laboratories. EPA has been working on “Green Methods” for laboratories, which are designed to minimize the use of hazardous chemicals (such as solvents) in waste analysis procedures. This project has developed several extraction methods for organic compounds which can reduce the use of hazardous solvents 90% or more. Green Methods work is ongoing, and is published in EPA’s “SW-846” handbook of analytical methods (available on our website: <http://www.epa.gov/SW-846>).

Standard Sampling Methods for Waste Testing. EPA’s Office of Solid Waste is working with American Society for Testing Materials (ASTM) to develop standard sampling methods for waste testing. This cooperative effort has so far produced 19 consensus ASTM standards, with 13 additional standards in progress. EPA expects these ASTM sampling methods to be incorporated into EPA technical guidance documents. Our work with ASTM is part of EPA’s commitment to using industry-developed standard practices and specifications in our regulatory programs, whenever appropriate.

IV. EPA ROLE IN HHMI PROJECT

The HHMI project participants included environmental health and safety professionals and biomedical researchers from ten major academic research institutions, each in a different U.S. EPA Region, along with RCRA state regulatory officials from each of the ten Regions, the Office of Solid Waste, EPA’s Safety, Health and Environmental Management Division, and others. EPA participated as a member of the Project Steering Committee by attending meetings and contributing to discussions regarding the project. EPA also encouraged RCRA Regional program administrators to support the demonstration project as indicated in the Appropriations Report language.

EPA and state RCRA regulators participated in all three phases of the two-year HHMI collaborative initiative. During phase one, beginning in August 1999, EPA participants joined in finalizing the project scope, reached a consensus on project objectives and criteria, and identified seven principal elements of a hazardous waste management plan for academic research institutions. In phase two, beginning in early 2000, EPA participants joined in identification of fourteen best practices under the seven principal elements. Phase three ran for a twelve-month period between the Fall of 2000 and 2001. The university participants agreed to demonstrate and measure the effectiveness of the consensus best practices.

The consensus best practices and the principal elements under which they fall are listed in the HHMI Report. HHMI found that many of the best practices have become standard practice at participating academic research institutions as a result of the project. In some cases, the academic research institutions found that it was difficult to show implementation progress during

the time period of the project. None of the academic research institutions considered it necessary to develop a demonstration project for Best Practice 8, regarding the collection, transport, and storage of hazardous wastes by EH&S and for Best Practice 11, regarding developing a plan for emergency response, because they said they already conduct their programs in accordance with the practices.

V. EVALUATION OF THE HHMI CONSENSUS BEST PRACTICES AND THE NEED FOR REGULATORY CHANGES

Congress requested that EPA evaluate the consensus best practices developed through the the HHMI initiative and the need for regulatory changes to carry out the recommendations of the initiative.

The final HHMI report concluded with several recommendations regarding the management of hazardous wastes as follows:

1. “That the EPA Administrator should recognize the consensus best practices developed through this initiative as a performance-based model for achieving RCRA compliance and for promoting stewardship and responsibility for health, safety, and the environment in academic research institutions. The Administrator should determine and initiate appropriate methods for implementing a performance-based model, using the consensus best practices developed through this initiative, for achieving RCRA compliance in academic institutions.”
2. “The U.S. EPA Administrator should promote conformity and consistency among the U.S. EPA regional offices and state environmental protection agencies in carrying out RCRA assistance and enforcement programs for academic institutions.”
3. “Academic institutions should adopt the consensus best practices developed through this initiative as a performance-based model for managing hazardous wastes in their laboratories and for achieving RCRA compliance.”
4. “Academic institutions should establish dialogue with their regulatory agency officials to plan cooperatively their approaches for implementing the consensus best practices developed through this collaborative initiative.”

EPA recognizes that academic research institutions have had difficulty complying with the RCRA regulations and supports developing effective alternatives for safely managing hazardous wastes in academic research institutions that meet standards for protection of human health and the environment. EPA has supported the development of the consensus best practices under this program as well as other innovations that respond to concerns raised by academic research institutions.

EPA congratulates Howard Hughes Medical Institute and the ten participating academic

research institutions on their efforts to improve hazardous waste management in their laboratories. The ten academic research institutions reported that the initiative provided an opportunity for increased partnerships with students and faculty in promoting future goals in materials conservation and environmental protection. The ten academic research institutions also recognized the value and effectiveness of the 14 consensus best practices and described the positive impact on their programs and on the commitment to environmental protection. For example, several academic research institutions did not previously have formal statements of executive commitment to environmental stewardship, but have now begun the process of establishing these statements because of the program. EPA is pleased that the best practices have elicited positive responses from executives at the participating institutions. Executive commitment helps ensure that there is adequate support for environmental programs and that there is strong institutional commitment to environmental protection. The best practices address a wide range of issues, and encourage academic research institutions to develop thoughtful approaches to managing their hazardous waste.

EPA also understands that some states and EPA Regions have implemented initiatives of their own to address compliance issues at academic research institutions. These should also be considered, along with programs at academic research institutions that have not participated in this demonstration project, in any national effort to formalize best practices for laboratory management of hazardous wastes.

In general, EPA believes that the current RCRA regulations are flexible and may allow for the implementation of many of the best practices identified by HHMI. The consensus best practices are intended to be implemented differently by each institution depending on site-specific needs. This allows management practices to be tailored to the needs of the institution. The extent to which an application of a best practice is fully within RCRA regulations would depend upon the approach chosen to represent the best practice. In some cases, consensus best practices may be allowable under the current regulation, depending on the specific measures actually implemented by a university, and in other situations may require regulatory changes. For example, the HHMI report identifies a need for flexibility in hazardous waste accumulation time limits. Such time limits are specifically required (see, e.g., 40 CFR §262.34(a)), thus a regulatory change would likely be required to implement such a practice.

In some cases, EPA and states will need to work with academic partners to determine clearly whether a best practice would require a regulatory change. For example we will need to continue to work collaboratively to clarify how the HHMI demonstration program best practices ensure that containers will be managed to protect against spills and prevent release. EPA is aware that some academic research institutions want to leave some waste collection containers open beyond the time needed to add or remove hazardous wastes. They suggest that the current requirement that containers be kept closed except when adding or removing wastes is not always practical in the laboratory setting because commonly used containers such as beakers have an open design. If the consensus best practices would not ensure that hazardous waste containers remained closed except when adding or removing waste, an alternative to the closed container requirement would most likely require a regulatory change to consistently and unambiguously allow the practice.

Additionally, the HHMI report recommends that a university's health and safety program make the RCRA hazardous waste determination. EPA's New England Universities Laboratories Project XL (discussed in Section III) tests an approach consistent with this recommendation for its potential to provide improved environmental stewardship, but does so through a regulatory change. Depending on how this recommendation is to be implemented, however, a regulatory change may not be necessary. EPA commits to work with stakeholders *to* support the most appropriate implementation of this recommendation.

In general, EPA believes promulgation of a regulatory change to specifically address a range of academic laboratory issues is preferable because it allows the consideration of diverse viewpoints through the regulatory development and notice and comment processes, as well as provides fair notice to all concerned. A regulatory change would also allow EPA to work with HHMI, other laboratory associations, states, EPA Regions, the Occupational Safety and Health Administration, and the public to develop an approach that builds upon the consensus best practices as well as other ongoing efforts such as the New England Labs Project to provide needed flexibility and effective protection of human health and the environment. Additionally, EPA believes that a regulation is more likely to promote the national consistency that HHMI seeks from its federal and state regulators and encourages broader understanding and acceptance of an approach than would guidance or a demonstration project alone.

It should be noted that state authorized RCRA programs may impose requirements that are more stringent or broader in scope than the federal RCRA program. Thus, even where sufficient flexibility exists in the federal regulations to implement the recommended best practices, authorized states may still choose to limit such flexibility in administering their state programs. Similarly, even if EPA promulgates regulatory changes to the federal program, authorized states may choose not to adopt similar changes to their state programs. A federal rule would, however, provide leadership that encourages states to conform their regulations and adopt a consistent approach nationally.

EPA has worked to address the issues raised by academic research institutions in a variety of forums, however, we recognize that laboratories still may have difficulty after these efforts. Using the best management practices developed through this initiative can further improve the management of hazardous wastes generated in academic research institutions, however, EPA believes this would best be achieved by developing regulatory reforms that endorse best management practices and other sound alternative approaches to achieving RCRA compliance.

EPA is committed to resolving compliance problems in laboratories at academic research institutions and expects to continue working with the Howard Hughes Medical Institute and other key stakeholders to improve the RCRA program as it affects the nation's academic research institutions.

ATTACHMENT TO PART 1

October 13, 2000 Memorandum to
EPA Regional RCRA Senior Policy Managers and Branch Chiefs