ABSTRACT

BRADLEY C. BLACKARD. A Technology Transfer Strategy for the National Institute of Environmental Sciences' Superfund Basic Research Program. (Under the Direction of Dr. ALVIS G. TURNER)

A technology transfer strategy has been developed for the National Institute of Environmental Health Sciences' Superfund Basic Research Program to facilitate the dissemination of information and the transfer of technology from basic to applied research and eventually commercialization. This strategy was developed by examining the evolution of U.S. technology transfer policy and its implementation by the National Institutes of Health and the U.S. Environmental Protection Agency. Various methods of technology transfer are proposed by this strategy. These include developing and managing various information databases, the disseminating of information via publication and document mailouts, sponsoring and conducting conferences and workshops, supplying supplemental funds to grantees for scale-up and demonstration research, and providing a resource of contacts for our grantees within the environmental science field for technical assistance and the development of collaborative research efforts.

KEY WORDS: Technology Transfer, Superfund, National Institute of Environmental Health Sciences, National Institutes of Health, U.S. Environmental Protection Agency

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GLOSSARY

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ADAMHA	Alcohol, Drug Abuse and Mental Health Administration
BBS	Electronic Bulletin Board
CDC	Centers for Disease Control
CERI	Centers for Environmental Research Information
CRADA	Cooperative Research and Development Agreement
CSC	Computer Sciences Corporation
DFM	Division of Financial Management
EPA	U.S. Environmental Protection Agency
ERMIS	Extramural Research Management Information System
FIE	Federal Information Exchange, Inc.
FTTA	The Federal Technology Transfer Act of 1986
GAD	Grants Administration Division
GOCO	Government Owned/Contractor Operated
GOGO	Government Owned/Government Operated
HERL	EPA's Health Effects Research Laboratory
HSRC	EPA's Hazardous Substance Research Centers
ICD	Institutes/Centers/Divisions
MeSH	Medical Subject Headings
MTA	Material Transfer Agreement
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health

GLOSSARY (cont'd)

NIST	National Institute of Standards and Technology	
NTIS	National Technology Information Service	
OCTS	Office of Computer Technology and Services	
OE	Office of Enforcement	
OGC	Office of General Council	
OIG	Office of Inspector General	
ORAM	Office of Administration, Resources, and Management	
ORD	EPA's Office of Research and Development	
ORTA	Office of Research and Technology Applications	
OSWER	EPA's Office of Solid Waste and Emergency Response	ġ
OTT	Office of Technology Transfer	
отто	Office of Technology Transfer On-line (BBS)	
PHS	Public Health Service	
SARA	The Superfund Amendments and Reauthorization Act of 1986	
SITE	Superfund Innovative Technology Evaluation Program	
TDC	Technology Development Coordinator	

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INTRODUCTION

The United States government is investing a total of \$70 billion on research and development in fiscal year 1993 (FY93). Of this total, \$25 billion is expended by Federal Laboratories, \$31 billion by industrial contractors and \$11.8 billion by universities.17 Approximately 100,000 scientists and engineers are employed by Federal Laboratories, representing about 1 out of every 6 scientists and engineers in the United States.17 This wealth of resources and knowledge represents great potential to benefit the United States' technology base. A significant part of this potential is the development of environmental technologies and the improvement of the understanding of the health effects from hazardous waste sites. "The international market for environmental goods and services is more than \$200 billion and growing at 5 percent a year. For smart U.S. companies, our Federal Laboratories can be a source of innovative technologies, giving them new opportunities and a competitive edge in the global marketplace".¹³ As a result of technology transfer, an abundance of innovative technologies can be accessed and developed within the Federal Laboratory system, contributing to the advancement of U.S. competitiveness at home and abroad.

For the purpose of this report, technology transfer is defined as the multi-faceted process through which information, data, methods, and procedures developed through research are delivered to and applied by other researchers, organizations, and individuals. This includes, but is not limited to, the formation of cooperative research and development agreements, the exchange of technical expertise, the dissemination of information and research findings through publications and computer databases, and the linking of potential research collaborators through the existing network of technology transfer personnel and resources in government and private industry.

The transfer of basic research on the health effects of hazardous waste found at Superfund sites, as well as innovative technologies designed to reduce and/or eliminate the hazards associated with these wastes, to commercial uses is important for a number of reasons. First, it is important to better understand the health effects of hazardous wastes and to develop a means of determining the level and duration of exposure. This knowledge can be used in the field to improve the process of risk assessment, provide a more accurate means of prioritizing waste sites by their hazards, and determining when a site has been remediated to a safe level. Second, by using innovative remediation technologies at a waste site, the process of cleaning up can be done more completely and usually at less cost. Finally, the economic benefits of transferring federally-funded technologies to the private sector should result in an increase in economic activity due to the large numbers of new products and methods being applied in the field as well as the benefits to tax payers of receiving more "clean-up per dollar" with their implementation.

The National Institute of Environmental Health Sciences' (NIEHS) Superfund Basic Research Program is a university-based basic research program designed to study the human health effects of hazardous substances in the environment, especially those found at uncontrolled, leaking waste disposal sites. This diverse, multidisciplinary program has the potential to make significant contributions to the three important benefits stated above. It is the purpose of this report to investigate technology transfer policy of the United States government and examine the implementation of this policy in the National Institutes of Health (NIH) and the United States Environmental Protection Agency (EPA). This investigation will be used to develop a Technology Transfer Strategy for the NIEHS Superfund Basic Research Program to help direct and prepare its grantees for the successful development of their research from basic to applied, scaleup and pre-commercial research, and eventually to commercialization.

This report begins by discussing the NIEHS Superfund Basic Research Program including its development under the four mandates set forth by Congress, its peerreviewed grant selection process, its present situation and needs as well as the anticipated future needs of this expanding program in the context of information and technology transfer.

In part II the evolution of U.S. technology transfer policy is examined to plot a course for the development of a technology transfer strategy for the NIEHS Superfund Basic Research Program.

Part III examines the technology transfer policy of the NIH. Though the policy of the NIH has traditionally been directed towards biomedical technology and does not completely address the unique multidisciplinary requirements of the Superfund Basic Research Program, the NIH may prove to be a valuable means by which to transfer biomedical technologies from the Program.

Part IV looks at the technology transfer policy of the EPA and the various

programs and strategies that are used to develop technologies for waste site remediation. Since the EPA's hazardous waste research objectives closely resemble those of the Superfund Basic Research Program, their strategy will provide useful insight into the development of a strategy for the Superfund Basic Research Program.

Part V discusses the technology transfer policy proposed for the Superfund Basic Research Program which includes various means of information transfer using electronic databases and annual mailouts; the sponsoring of conferences and workshops; and the use of granting administrative supplements to Program grantees to collaborate with other research institutions and private industry. This latter mechanism will be used specifically to assist in translating their research to field and/or commercial application. In addition, various contact resources to be used for technical assistance and/or the development of collaborative research efforts are listed.

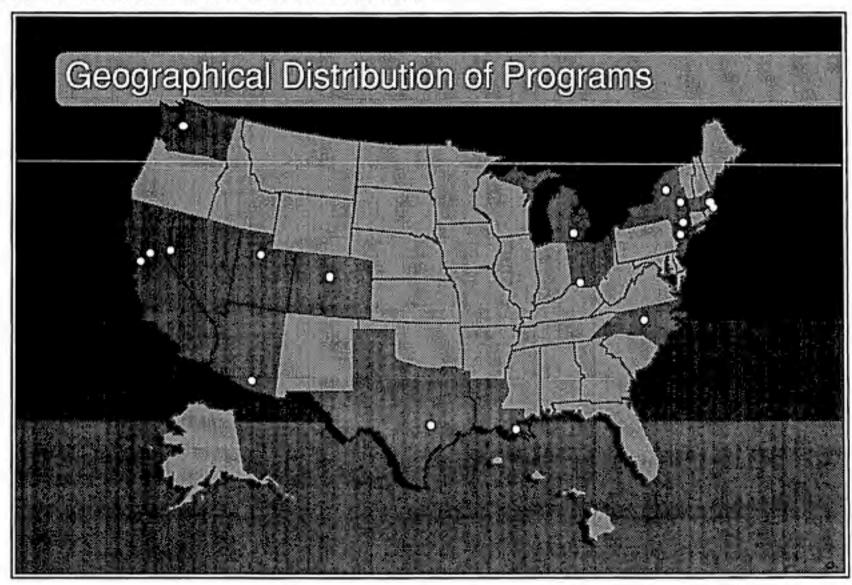
I. THE SUPERFUND BASIC RESEARCH PROGRAM

A. Overview

The Superfund Amendments and Reauthorization Act (SARA) of 1986 established a university-based program of basic research within the NIEHS, an institute of the NIH, to complement existing activities within the EPA and the Agency for Toxic Substances and Disease Registry. To accomplish this objective, the NIEHS developed the Superfund Basic Research Program, which is now in its seventh year. This Program currently provides funding to over 142 individual research projects within 18 programs at 29 universities around the United States to study the human health effects of hazardous substances in the environment, especially those found at uncontrolled, leaking waste disposal sites (see Figure I.1).

The Program's primary objectives are to expand the base of scientific knowledge, reduce the amount and toxicity of hazardous substances in the environment, and ultimately, prevent adverse human health effects. The SARA legislation mandates that the research funded by this Program should include development of (a) methods and technologies to detect hazardous substances in the environment; (b) advanced techniques for the detection, assessment and evaluation of the effects on human health of hazardous substances; (c) methods to assess the risks to human health presented by hazardous substances; and (d) basic biological, chemical and physical methods to reduce the amount and toxicity of hazardous substances in the environment.

FIGURE I.1: SUPERFUND BASIC RESEARCH PROGRAMS



In meeting these objectives, the Superfund Basic Research Program is unique in that it supports coordinated, multicomponent, interdisciplinary research programs. Sponsored research in the fields of ecology, engineering and hydrogeology (designated collectively as non-biomedical research) have been integrated into a biomedical research program core which is designed to provide a broader and more detailed body of scientific information. This information can then be used by state, local and federal agencies and by private organizations and industry in making decisions related to the management of hazardous substances. This approach encourages true collaborative efforts among researchers to address the public health concerns associated with hazardous wastes in the environment.

To achieve a sound research program that is truly integrated, applications for funding are subjected to a competitive peer-review process. This process begins with the distribution of a Request for Applications (RFA) which formally announces granting opportunities. The NIEHS staff then selects applications that respond to the specific objectives listed in the RFA. These selected applications are then reviewed and evaluated by a group of outside consultants with expertise in fields relevant to the research the NIEHS seeks to encourage. The reviewed applications and comments are then subjected to a second level of review by the National Advisory Environmental Health Sciences Council. Selection of research programs are made by NIEHS staff based on Councils' and/or the reviewers' recommendations and on the funds available.

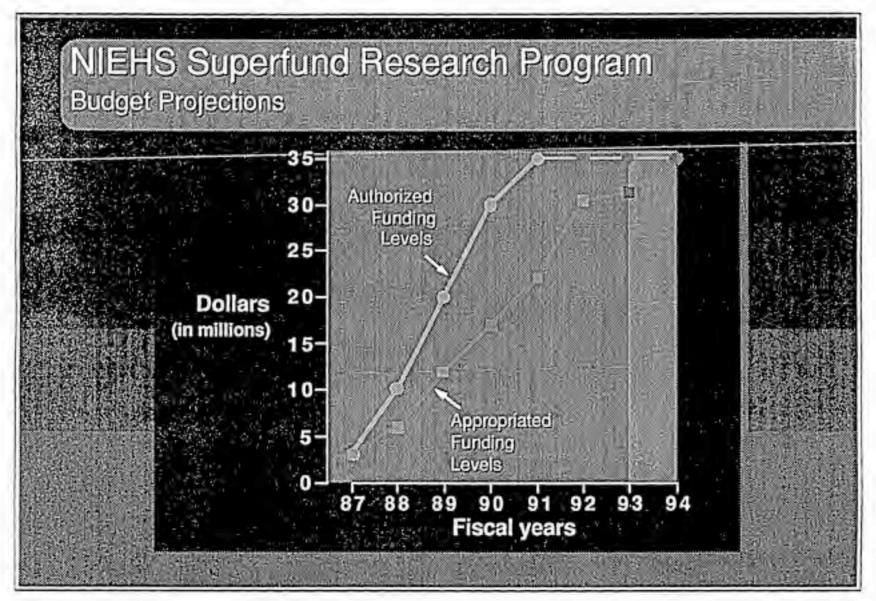
This tiered review process insures that funded research will be integrated and focused on real world problems. This is a major strength of the Program and has been

used successfully to establish support during Congressional budget testimony. Research progress is evaluated administratively on a continuing basis through the submittal of annual reports by grantees. These reports are used to monitor significant accomplishments, publications, and to update the Program database.

B. Funding History³⁴

The Superfund budget is administered by the EPA's Office of Solid Waste and Emergency Response (OSWER); however, Congress appropriates funding for the NIEHS Superfund Basic Research Program from the total Superfund budget. Funds are transferred from EPA to NIEHS via an interagency agreement. Figure I.2 shows the funding history of the Superfund Basic Research Program. This Program was originally funded at \$3 million in FY87. During the first year, only biomedical research was funded in four programs within four universities. The idea was to establish a biomedical core within these programs and phase-in non-biomedical research after two years. At \$3 million this Program represented only 0.19% of the total U.S.EPA Superfund budget.5 In FY88 the total funding level rose to \$5.915 million for these programs. A competitive renewal in FY89 brought a major expansion to the Program by adding non-biomedical research projects to the already established biomedical core. Funding escalated to \$11.9 million for 9 research programs at 12 universities. In FY90, after another competitive renewal of applications, the Program grew to \$16.9 million for 11 programs encompassing more than 110 projects at 18 universities and institutions. The funding level was increased in FY91 to \$21.915 million for the same number of programs. The

FIGURE 1.2: SUPERFUND BASIC RESEARCH PROGRAM BUDGET HISTORY



last expansion of the Program occurred in FY92 after another competitive renewal. The funding rose to \$30.615 million for 142 individual projects within 18 programs at 29 universities and institutions around the United States. Presently, the Program has been appropriated \$31.9 million for FY93 which represents 1.8% of the total EPA Superfund budget.⁵ The House of Representatives has recently approved the budget for this program at \$32.9 million for FY94 while the overall Superfund budget has been cut by \$100 million. This budget is presently in the Senate and is expected to be passed with similar funding amounts. At this level the Superfund Basic Research Program is 2.2% of the total Superfund budget.⁵

While the budget for this program has seen increases over the past years, other similar programs have not fared as well. The Health Effects Research Laboratory (HERL) of the EPA, has been forced by reductions and eventual elimination of funding to phase out its Superfund related health effects research.^{5,12} This makes the NIEHS Superfund Basic Research Program the only research of its kind being conducted by the Federal government.

C. Current Technology Transfer Needs

Before its last expansion in FY92, this Program required very little technology transfer. It consisted of compiling various program summaries, project descriptions, research highlights, annual reports and other documents requested by NIH, U.S.EPA and Congress. Since this was a basic research program very little was expected in the way of innovative and potentially commercial applications for the first few years of the Program. As the Program expanded to its present size it became necessary to develop an information database to manage the ever increasing amounts of information from 142 individual research projects. Table I.1 shows the number of projects and funding devoted to each major scientific discipline supported by this Program. This table demonstrates the diversity of research and the size and difficulty in arranging this kind of data into a comprehensible and usable format. Frequent requests were made to the Principal Investigators of the 18 programs to supply information on significant research findings, program summaries, project descriptions, listings of publications and summaries of collaborations with other federal, state and local agencies as well as private organizations and industries. This data is currently being compiled into a Superfund Basic Research Program information database so that requests for data of this type can be dealt with in a timely manner.

D. Future Technology Transfer Needs

In the future, this Program will require a more efficient means of disseminating information as well as an innovative approach to transferring its technology from basic research to applied, scale-up and demonstration research so that it may eventually be put to work in the field. With the dissolution of the Superfund-related research being conducted by HERL, it is increasingly important for this program to fulfill the task of disseminating information and transferring basic technologies so that they can be used to effectively clean up hazardous waste sites. The proposed technology transfer strategy that must be developed is not intended to change the emphasis in the Superfund Basic TABLE I.1: PROJECTS, PROGRAMS, AND FUNDING DEVOTED TO SPECIFIC RESEARCH CATEGORIES

RESEARCH PROJECT CATEGORY *	NUMBER OF PROJECTS	NUMBER OF PROGRAMS	TOTAL FIRST YEAR FUNDING *
BIOMARKERS	35	11	\$ 5,856,567
HUMAN HEALTH EFFECTS	31	12	\$ 3,788,134
BIOREMEDIATION	30	15	\$ 3,918,289
EXPOSURE ASSESSMENT	27	12	\$ 3,716,965
ECOLOGY	27	12	\$ 3,299,496
FATE AND TRANSPORT	27	12	\$ 3,269,436
EPIDEMIOLOGY	10	6	\$ 1,414,877
ANALYTICAL CHEMISTRY	6	6	\$ 1,355,820
RISK ASSESSMENT - BIOLOGICALLY BASED	8	5	\$ 858,827
REMEDIATION - NON-BIOLOGICAL	5	4	\$ 737,859
COMBUSTION ENGINEERING	3	3	\$ 372,286
TRAINING CORES	N/A	10	\$ 1,173,909

* The above categories and costs contain overlap with some projects being in more than one category. Cores in support of research projects (with the exception of Training Cores) are not included.

Research Program from basic to applied research but rather to facilitate the dissemination of information and its application in the field. Criteria must be established to evaluate the utility of each technology developed in this Program and the most appropriate vehicle for transferring this information and technology. As this Program matures, the types of transfers needed will continue to mature as well. With a well developed and flexible strategy, the objective of this Program, to expand the base of scientific knowledge, reduce the amount and toxicity of hazardous substances in the environment and to prevent adverse human health effects, will be realized.

II. U.S. TECHNOLOGY TRANSFER POLICY

A. Introduction

In the late 1970s the United States realized that its technology policy of simply funding basic research and allowing a wealth of scientific knowledge to remain hidden behind the walls of academia and within federal laboratories was not a productive approach to enhancing its technological base or the economy. The world market was changing. Countries such as Japan and Germany were proving to be highly successful with their policies of government and industry cooperating in the development of innovative and marketable technologies. The United States, still unsurpassed in the quality and quantity of federally funded basic research, would have to develop a policy that would transfer this wealth of technology to its industries in order to remain competitive in the world market. Over the next decade, a series of Congressional Acts and Executive Orders would be signed which would change the United States' technology policy and would allow for the government and the private sector to cooperate in the development of technologies for commercial uses. Though the system is still evolving, the proverbial ball is rolling and innovative environmental technologies are being transferred from the stage of basic research to commercialization.

B. The Evolution of U.S. Technology Transfer Policy Before 1980

Before World War II the policy of the United States was to patent technologies invented within the Federal Laboratory structure and make these patents available to anyone who was interested through a non-exclusive license while the government retained the rights to the patent.^{42,26} This simple policy was adequate because a very large majority of the federally funded research and development (R&D) was performed in Federal Laboratories by government employees. The idea behind this policy was that the public had financed the research so the public should keep the rights to the research.⁴²

During World War II, the technological needs of the United States were greater than could be supplied by Federal Laboratories and their employees alone. This caused the U.S. government to begin the practice of utilizing contractors from private industry, universities and non-profit organizations to fulfill its research and development requirements. Table II.1 shows the large role that the government has played in the funding of all R&D from 1941 to 1988. This table also shows how the role of government laboratories has decreased relative to the total R&D performed in the U.S. Over the same time period the government has also contributed significantly to private research and development. Table II.2 shows this large contribution from 1941 to 1988. Comparison of Table II.1 and II.2 indicates that, of the \$60.5 billion invested by the government on R&D in FY88, \$46 billion was used to fund private research.

Throughout the time period from World War II to 1980, U.S. technology policy remained largely unchanged from its pre-war position. No "government-wide" policies or mechanisms were developed "to place the ownership of inventions made by

Total R&D	Government Funded R&D	Percent	R&D Performed by Gov't	Percent
900	370	41.1	200	22.2
1,520	1,070	70.4	430	28.3
2,870	1,610	56.1	570	19.9
6,279	3,510	55.9	905	14.1
13,730	8,746	63.7	1,726	12.6
20,439	13,040	63.8	3,093	15.1
26,134	14,892	57.0	4,079	15.6
35,213	18,109	51.4	5,354	15.2
62,594	29,453	47.1	7,632	12.2
107,757	51,668	47.9	12,945	12.0
126,115	60,500	48.0	14,500	11.5
	900 1,520 2,870 6,279 13,730 20,439 26,134 35,213 62,594 107,757	Total R&D Funded R&D 900 370 1,520 1,070 2,870 1,610 6,279 3,510 13,730 8,746 20,439 13,040 26,134 14,892 35,213 18,109 62,594 29,453 107,757 51,668	Total R&D Funded R&D Percent 900 370 41.1 1,520 1,070 70.4 2,870 1,610 56.1 6,279 3,510 55.9 13,730 8,746 63.7 20,439 13,040 63.8 26,134 14,892 57.0 35,213 18,109 51.4 62,594 29,453 47.1 107,757 51,668 47.9	Total R&DFunded R&DPercentPerformed by Gov't90037041.12001,5201,07070.44302,8701,61056.15706,2793,51055.990513,7308,74663.71,72620,43913,04063.83,09326,13414,89257.04,07935,21318,10951.45,35462,59429,45347.17,632107,75751,66847.912,945

TABLE II.1: GOVERNMENT SHARE OF FUNDING FOR ALL U.S. R&D²⁶ 16 (Amounts in Millions of Dollars)

TABLE II.2: % OF PRIVATE RESEARCH FUNDED BY THE GOVERNMENT²⁶ (Amounts in Millions of Dollars)

Year	Total Private R&D	Private R&D Funded by Government	Percent
1941	700	170	24.3
1945	1,090	640	58.7
1950	2,300	1,040	45.2
1955	5,374	2,605	48.5
1960	12,004	7,020	58.5
1965	17,346	9,947	57.3
1970	22,055	10,813	49.0
1975	29,859	12,755	42.7
1980	54,962	21,821	39.7
1985	94,812	38,723	40.8
1988	111,615	46,000	41.2

government contractors and grantees into the hands of those private parties who might best use the technology to create something productive for society" or "to license government-owned inventions to the private sector for commercialization".²⁶ Each government agency developed its own procedure for licensing technology, making the prospect of acquiring federally-owned technology for private use an extremely confusing one.²⁶ The first attempt to standardize the government patenting procedures throughout the government was by President Kennedy in 1963 with a memorandum to agency heads.²⁶ This directive gave the government the right to obtain exclusive or principal rights:

- where the purpose of the contract was to create, develop or improve products, processes or methods for commercial use by the general public or which were to be required for such use by government regulations;
- (2) where the purpose of the contract was for research concerning public health or welfare;
- (3) where the research was in the field of science or technology where the government has been the principal developer in the field; and
- (4) where the contractor operates a government-owned research or production facility or coordinates and directs the work of others.^{26,29}

Contractors were allowed to obtain principal rights in situations not falling under the above categories. Contractors were also required to report to the government on their use of the acquired technology and, if no productive attempts were made at commercializing this technology within three years, the government could "require the granting of a license to an applicant on a non-exclusive royalty-free basis".^{26,29} This directive also required the preparation of an annual report by the Federal Council for Science and Technology, in consultation with the Department of Justice, which would examine the implementation of this policy. Because this policy left the decision of the fate of technologies to the separate agencies, this directive did little to standardize the patent process. President Nixon tried again in 1971, with a "revised Statement of Government Patent Policy",²⁶ by giving more power to the heads of agencies in deciding if contractors receive principal rights. The revised policy also gave principal rights to contractors in situations where government's contribution to research is relatively small and the invention was not the primary objective of the contract.

These policies led to the development of many government-owned but unlicensed patents which were not being put to use. They had failed to transfer significant amounts of technology from basic research to commercial uses mainly due to lack of incentives for the collaboration between the government and private industry in the development of new technologies. Industry was wary when investigating a collaborative research effort with the government. There were no guarantees that returns on investment would be significant or whether a technology would be declared "for the public good" and would have to be licensed from the government. Some fundamental aspects of a capitalistic economy would have to be realized and incorporated into a technology transfer policy before the wealth of technology "owned" by the federal government could be utilized:

- technology transfer is not a hand off, but an exchange demanding significant interactions between the parties and potentially large commitments of money;
- (2) "profits", however broadly defined, are the fuel of the nation's economic engine; and
- (3) without the prospect of profits, neither party in the exchange will be motivated to participate.⁴²

Policy makers began to realize that the amount of resources being spent on R&D was not being returned to society in an effective manner and was hurting the country's productivity, as evident in the Congressional statement:

The United States can no longer afford the luxury of isolating its government laboratories from university and industry laboratories. Already endowed with the best research institutions in the world, this country is increasingly challenged in its military and economic competitiveness. The national interest demands that the Federal Laboratories collaborate with universities and industry to ensure continued advances in scientific knowledge and its translation into useful technology. The Federal Laboratories must be more responsive to national needs.²⁶

In response to these concerns, a series of Congressional acts and Executive Orders were passed during the 1980s which would shape the U.S. Technology Transfer policy of today.

C. The Evolution of U.S. Technology Transfer Policy in the 1980s

The first legislative attempt to deal with domestic technology transfer and address the concerns of the United State's waning competitiveness in the world market was the Stevenson-Wydler Technology Innovation Act of 1980.⁴³ The purpose of this act was to "improve the economic, environmental, and social well-being of the United States".⁴³ To accomplish its objective, the act proposed five major initiatives to advance the transfer of technology from Federal Laboratories to State and local government and private industry. The first of these initiatives, found in section five, was the establishment of an Office of Industrial Technology within the Department of Commerce. This Office has the responsibility of investigating technology transfer policy, its relationship to industry and the economy, and reporting to the President and Congress on the results of these studies. The second major initiative of this act, section six, establishes Centers for Industrial Technology. These Centers are affiliated with universities and/or non-profit organizations through the assistance of the Department of Commerce and the National Science Foundation. Their purpose is to enhance technological innovation by participating in cooperative activities with individuals from universities and industry, developing the generic research base, educating and training individuals in the technological innovation process, improving mechanisms for the dissemination of technological information, and utilizing the resources and expertise of the Federal Laboratories. To promote the commercialization of any inventions developed within the Centers, each Center has the option to acquire title to the invention provided that they report this to the sponsoring agency and attempt to develop the invention to commercial application within a reasonable period of time. Inventors were entitled to royalties from the invention and the Federal Government was allowed to use the technology for its own purposes.

The third major initiative of the Stevenson-Wydler Act is section nine which establishes cooperative administrative arrangements between the Department of Commerce, the National Science Foundation and eleven Departments and Agencies within the Federal government. This establishes the authority for these Departments and Agencies to participate in the funding or supplying of resources to research being conducted at the Centers.

Section eleven of the Act is the forth major initiative and perhaps the most important. This section requires each Federal Laboratory to establish an Office of

Research and Technology Applications (ORTAs) and to fund this Office with not less than 0.5% of its research and development budget. Those Laboratories which have a budget exceeding \$20 million will provide at least one full-time professional to handle the job of technology transfer. This initiative is so important because it establishes a technology transfer oriented office within each Federal Laboratory thereby adding technology transfer to the mission of these laboratories.

The last major initiative is also found in section eleven, subpart (d), which establishes a Center for the Utilization of Federal Technology within the Department of Commerce. This Center has several functions which include acting as a clearinghouse for the collection and dissemination of all federally owned or originated technology, coordinating the activities within the ORTAs, utilizing resources within the National Science Foundation and the Federal Laboratory Consortium for Technology Transfer and as a referral resource for State and local governments.

Though the Stevenson-Wydler Act made advances in the area of technology transfer by establishing ORTAs in all federal laboratories and by adding the mission of technology transfer to these laboratories, it did meet with some criticism. Many of the problems with implementing this act were a result of inadequate funding and resources. One study shows that many of the ORTAs were understaffed and were unable to carry out the objectives of the legislation. This study also questions the ability of researchers to judge the potential commercial viability of their own research.⁹ Other criticisms have been that the act was directed towards existing technologies and did not emphasize the innovation of new technologies.⁴¹

Later that same year Congress passed the Amendments to the U.S. Patent and Trademark Laws of 1980 (more commonly known as the Bayh-Doyle Act of 1980) "to use the patent system to promote the utilization of inventions arising from federally supported research or development".² Specifically, the Bayh-Doyle Act enabled small businesses and non-profit organizations to patent and retain rights to inventions resulting from federally funded R&D. This gave the much needed incentive for commercial and non-profit organizations to develop and commercialize these inventions.⁴² Even with the added incentives from the Stevenson-Wydler Act and the Bayh-Doyle Act, the process of technology development was hindered by the slow pace of patenting procedures and proved to be discouraging.³⁸

In 1983, President Reagan signed a Memorandum on Government Patent Policy which directed federal agencies to permit all government contractors to retain the rights to inventions developed under contract or cooperative agreement with the government, to the extent allowed by law.³⁰ This memorandum opened up the Bayh-Doyle Act to include essentially all government contractors, however, the problem of non-uniform patent policies in different agencies remained.⁴²

In an attempt to bring previously exempt contractors into the technology transfer process, Congress passed the Trademark Clarification Act of 1984 (or the Bayh-Doyle Amendments).⁴⁶ In Title V, section 501, of this Act, government-owned, contractoroperated (GOCO) facilities which were not involved in naval nuclear propulsion or weapons-related research and development were allowed to retain the title rights to their inventions. These GOCOs also were given the right to license their technology without going through the funding agency's licensing procedures.

In 1986, Congress amended the Stevenson-Wydler Act of 1980 by passing the Federal Technology Transfer Act (FTTA) of 1986.¹⁸ This Act was a major step towards facilitating technology transfer by establishing cooperative research and development as an objective of Federal Laboratories. Under Section 12, the director of a governmentowned, government-operated (GOGO) facility may enter into a cooperative research and development agreement (commonly referred to as a CRADA) with other Federal agencies, State and local government, industrial organizations, public and private foundations, non-profit organizations or other persons. CRADAs are a significant means by which government and other organizations can collaborate to research and develop pre-commercial inventions and ideas where the expense and risk would be too great for either to research and develop on their own. This provides incentive for private industries to look to the Federal government for ideas on new products and as a means of developing existing ideas into products. Each agency has the authority to establish its own CRADA development procedure.

Since private industry and many non-profit organizations already had a method for rewarding innovation by recognition and monetary compensation, a similar method was developed for Federal employees to provide them with incentive to be innovative. In Section 13 of the Act, a process is established that rewards government personnel for outstanding innovations, inventions or other scientific or technological contributions of value to the United States and for exemplary activities that promote the domestic transfer of science and technology resulting in the utilization of said technology. The inventor(s) is paid at least 15% of the royalties or other income that the agency receives on account of the invention up to \$100,000 per year per person (unless a greater amount is authorized by the President). These amounts are in addition to the inventor's regular income and the payments are continued for as long as the agency receives income from the invention (even if the inventor leaves the agency).

Other amendments in this Act were the abolishment of the National Industrial Technology Board and deleting the Centers for Industrial Technology and giving their mandates to the Federal Laboratory Consortium for Technology Transfer. The Consortium's activities include training Federal Laboratory employees about the technology transfer process and determining the commercial viability of technology, providing assistance to federal agencies with technology transfer as requested, and serving as the government clearinghouse for technical assistance requests from public and private sources. To address the problem of understaffed OTRAs, the Act required that one full-time professional position devoted to technology transfer be established for every 200 full-time scientists, engineers and related technical positions instead of one full-time position for every agency with expenditures over \$20 million.

Though the FTTA of 1986 facilitated federal technology transfer, a couple of issues remained unsettled. One such issue was that agencies and firms participating in collaborative research found it difficult to protect proprietary information which resulted from the CRADA.⁹ Another issue was that the FTTA addressed GOGOs but GOCOs, like Lawrence Livermore National Laboratory, were not included due to a concern for protecting National security. Both of these issues were addressed in later legislation.

Executive Order 12591, Facilitating Access to Science and Technology, was

signed by President Reagan in 1987.¹⁶ This Order delegated authority from laboratory directors to the laboratory itself to license, assign, or waive rights to technology developed under a CRADA. In addition, the Secretary of Defense was instructed to identify technologies within the Department which have the potential for commercialization. Heads of Federal agencies were instructed to investigate the potential for developing a university research center for science, engineering and technology in the strategy and planning for future R&D programs. This Order reiterated the emphasis that the administration was placing on technology transfer and assured that Federal facilities were actively pursuing technology transfer objectives.

The Omnibus Trade and Competitiveness Act of 1988 changed the name of the National Bureau of Standards to the National Institute of Standards and Technology (NIST). In addition to the objectives of the former National Bureau of Standards, the NIST was mandated to facilitate efforts by the private sector to utilize advanced technology through cooperative agreements between government, industry, and university laboratories. The NIST was made responsible for assisting industry in technology development to improve manufacturing processes and to develop more rapid commercialization.

In the final piece of technology transfer legislation of the 1980s, the National Competitiveness Technology Transfer Act of 1989 (or the Domenici Bill)³³ opened up the GOCO facilities to provisions of the Stevenson-Wydler Technology Innovation Act of 1980 and its amendments, the FTTA of 1986, by allowing the development of CRADAs through joint work statements between the government agency and the contractor. The purpose of this act was to enhance national economic well-being by facilitating technology transfer from GOCO laboratories to the private sector and promoting the development and commercialization of marketable technologies. This Act addressed the other unresolved issue from the FTTA of 1986, namely problems experienced by contractors in maintaining confidentiality of proprietary information developed under a CRADA. Section 3133 amends the Stevenson-Wydler Act by requiring the director of a GOGO or a GOCO to not disclose any proprietary information from a CRADA for a period of five years.

D. Conclusions

This series of laws and Executive Orders laid the foundation for an efficient means to transfer technologies from the government to the private sector. The process of achieving a broad-based awareness throughout the government and private sector of the potential opportunities offered by this technology transfer structure is on-going. Technology transfer is not a one-step process. There are many possible routes for technology transfer and the diversity of processes to achieve transfer are vast and agency specific. In order to understand the implications of these legislations on agencies with a direct relevance to the Superfund Basic Research Program, the implementation of the FTTA will be examined for the NIH and the EPA. This discussion will outline the existing structure within these agencies to direct possible collaborations and interactions of the technology transfer personnel and the grantees of the Superfund Basic Research Program.

III. TECHNOLOGY TRANSFER WITHIN THE NATIONAL INSTITUTES OF HEALTH

A. Overview

The NIH is the world's largest basic biomedical research facility. The Institute is made up of twenty-one institutes, divisions, centers, and bureaus of which the NIEHS is one. Traditionally, the NIH has conducted or funded research in the biomedical sciences with the focus on improving human health and well being. Though the entire NIH spends over \$7 billion annually on extramural research programs compared to approximately \$900 million on research conducted within the Institute, or intramural programs, the FTTA Program at NIH is almost entirely focused on intramural research. The FTTA Program at NIH is responsible for assisting NIH scientists in patenting inventions, developing CRADAs between outside collaborators and NIH scientists, arranging licensing agreements, and approving Material Transfer Agreements (MTAs) for NIH technology.

The extramural program is, by its very nature, excluded from the FTTA Program's objectives. This is because researchers receiving federal funds, in whole or in part, are the owners of any inventions developed during the period of the grant.³ The government often has the right to use this invention for government purposes, but is not entitled to any royalties from commercialization. The intent of this report is to examine the technology transfer process already in place in the NIH and EPA. This knowledge

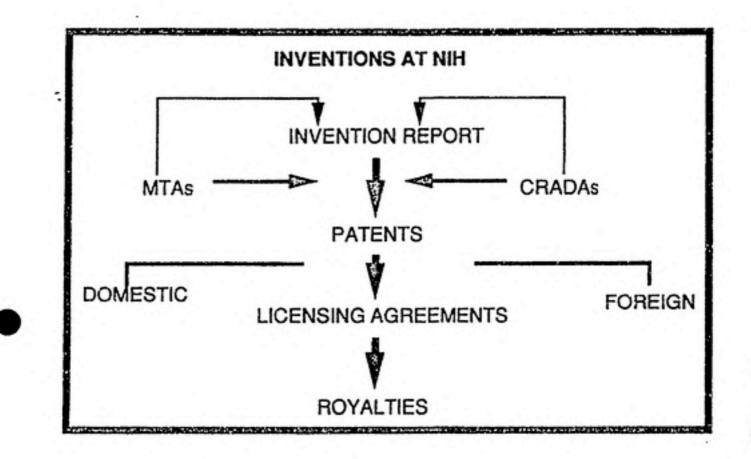
will be used as a resource and a service to guide grantees within the Program towards possible research collaborators, thereby developing their research or obtaining needed information to further their research. To this end, the FTTA process at NIH will be examined as a possible collaborator for the Superfund Basic Research Programs' biomedical scientists. Non-biomedical collaborations are more likely to be found within the EPA and related industries and will be examined in sections IV and V of this report.

The FTTA Program at NIH is guided by five general principles: "(1) awareness of its central mission as a basic biomedical research institution; (2) adoption of procedures that complement but do no unduly complicate its research efforts; (3) recognition that public health and U.S. industrial competitiveness both are served by efficient technology transfer activities; (4) decentralized technology transfer authority; and (5) the involvement of industry and academia in the review of emerging policies and draft model agreements. These general principles are evident in the...day-to-day activities of NIH's technology transfer programs."¹

Under authority of the FTTA of 1986, NIH has developed a technology transfer strategy to facilitate collaborative efforts between itself and other government agencies, universities, foundations, and industry through the use of CRADAs and patent licensing. In addition, MTAs, which share research materials and data with outside sources, have been authorized by the Public Health Service (PHS). Figure III.1 shows a schematic of the overall technology transfer process at NIH.

Scientists at NIH are encouraged to protect their research through the use of invention reports, patenting, licensing, MTAs, and CRADAs. Close interaction with the Office of Technology Transfer (OTT) will assist the scientist in deciding the method and

FIGURE III.1: TECHNOLOGY TRANSFER PROCESS AT THE NIH36



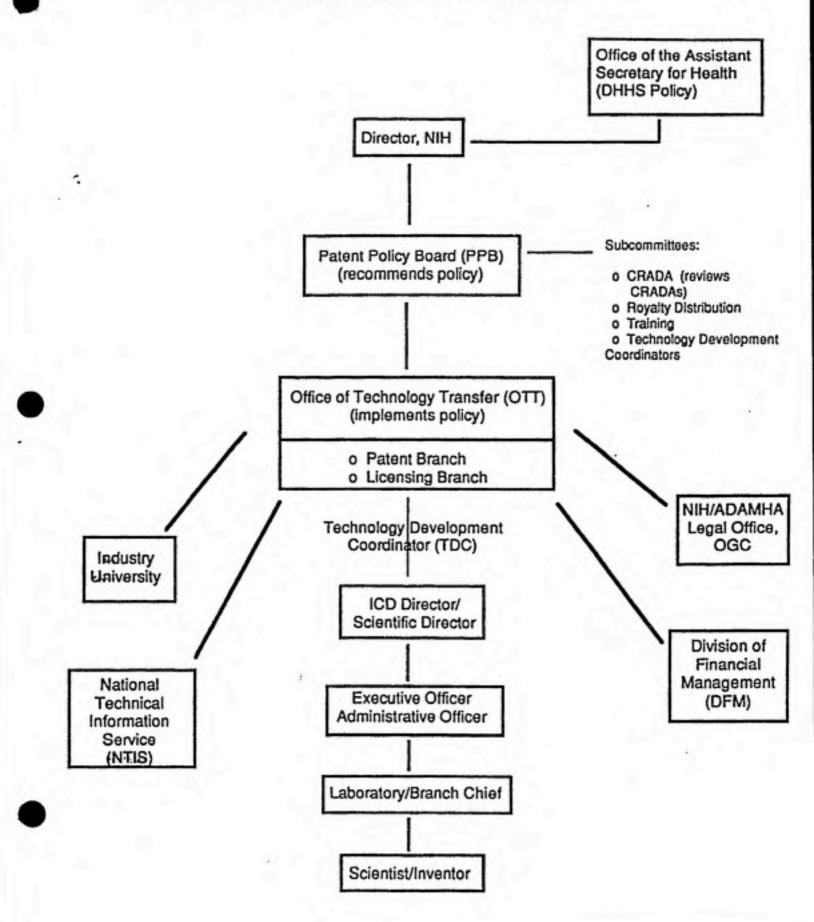
timing of invention disclosures and publications to achieve the greatest financial potential from their work. Inventions which are developed into commercial products are subject to royalty payments to the inventor. The NIH has elected to reward inventors with 25% of the first \$50,000 cumulative royalties on an invention, 20% of the second \$50,000, and 15% of the royalty income over \$100,000, up to \$100,000 in a year unless more is approved by the President. Technology transfer is viewed as an "adjunct mission" of NIH and is designed not to interfere with the Institute's mission to develop and disseminate new information related to disease and public health.^{1,36}

B. FTTA Organizational Structure

Figure III.2 shows the organizational structure of the FTTA Program. The Office of the Director (OD) is responsible for the overall administration of the FTTA at NIH. In an agreement with the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) and the Centers for Disease Control (CDC), NIH administers the FTTA for all three organizations.

The Director of NIH established the Patent Policy Board to oversee patent policy and develop the administrative framework of the FTTA Program. The Board is chaired by the Associate Director of Intramural Affairs for NIH with members representing ADAMHA, CDC, and NIH. Four subcommittees were developed under the Patent Policy Board: (1) The CRADA Subcommittee, which reviews and provides recommendations during CRADA development; (2) The Royalty Distribution Subcommittee, which reviews and recommends policy for distribution and use of royalty

FIGURE III.2: FTTA IMPLEMENTATION AT THE NIH36



incomes; (3) The Training Subcommittee, which recommends training requirements and conducts training of NIH staff to facilitate technology transfer; and (4) The Technology Development Coordinator Subcommittee, which provides a forum for Technology Development Coordinators (TDCs) to be updated on new policy and provide comments to the Patent Policy Board on technology transfer policy.

The OTT coordinates technology transfer policy and activities for NIH. Its major responsibilities are to develop policy and procedures to implement Patent Policy Board decisions, drafting CRADA and MTA models and other forms, and to patent and license inventions. Other responsibilities include:

 coordinating a data management system for all PHS inventions, patents, CRADAs, MTAs, licenses, and royalties.

 develop and maintain database of industry contacts and their area of research interests.

review CRADAs prior to Subcommittee review.

 host an annual Technology Transfer Forum where industry and government scientists and representatives are brought together to showcase research and make contacts for potential collaborations.

 publish an annual PHS Technology Transfer Directory listing names and research interests of PHS contacts.³⁶

The OTT also has three Branches devoted to specific objectives of the FTTA. The Technology Licensing Branch is responsible for marketing inventions to private biomedical companies, the Patent Branch prepares and files for U.S. patents, and the Technology Management Branch develops and maintains data and information management systems.

In addition, the OTT receives input and assistance from other sources in the

implementation of the FTTA. The Office of General Counsel (OGC) oversees the legalities of CRADAs and other agreements and also ensures that no conflicts of interest occur in the technology transfer process. The Division of Financial Management (DFM) receives and distributes royalty incomes from invention activities. The National Technology Information Service (NTIS) provides advice and instructions to the OTT through its Office of Federal Patent Licensing.

The Institutes/Centers/Divisions (ICD) of the NIH have the responsibility to implement and monitor technology transfer activities within their organizations. These include filing invention reports, negotiating CRADAs and MTAs, and distributing royalties. All technical staff within the ICDs is made aware of the FTTA process through training to ensure the proper and timely transfer of inventions. The interaction between the ICDs and the OTT is facilitated by the TDC who acts as advisor, contact, and liaison.

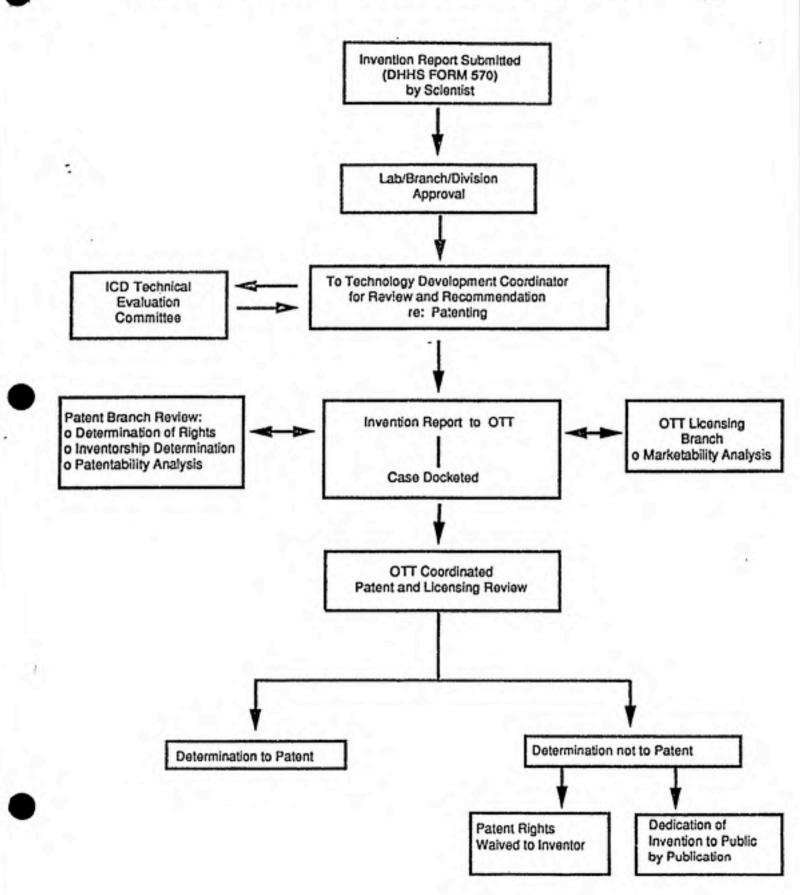
C. Invention Reports, Patent Applications, and Licensing

The major thrust of the FTTA Program within the NIH is technology transfer through the patent process which includes reporting an invention, applying for a patent, and licensing of the invention. The NIH pursues a patent for its inventions for three reasons: "(1) to provide an incentive for private industry to develop and market the invention and thus make it available to the public; (2) to provide royalty income through licensing which [NIH] can utilize in carrying out their missions and which is shared with the inventor in recognition of [their] contribution; and (3) to facilitate public benefit from non-exclusive access to taxpayer funded research without being hampered by exclusive rights of non-Government entities...*36

Figure III.3 shows the process of invention reporting. Under the terms of employment, all employees are required to report inventions to their TDCs. The TDC reviews the invention report and, in conjunction with the ICD, recommends for or against patenting. The OTT then makes the final decision on patentability. If the decision is not to patent, the rights may be waived to the inventor who may pursue patenting on their own or simply publish the results.

The next step in the FTTA process is the patent application as shown in Figure III.4. A patent is a legal contract that grants to the inventor exclusive rights to making, using or selling their invention for a period of 17 years. Once the decision has been made to patent, patent advisors within the OTT, in cooperation with the inventor, prepare the patent applications and file them in good faith with the U.S. Patent and Trademark Office. Due to the high costs, foreign patent applications will be carried to completion usually when a specific licensee has been determined.

Figure III.5 shows the licensing process which is the next step in the FTTA procedure. Once the patent application is filed, OTT conducts a marketability analysis and determines whether foreign patent applications are warranted. At the same time the OTT Licensing Branch is developing a licensing strategy and identifying potential licensees. Licensing may be conducted through CRADAs or on their own at the discretion of the ICD. A formal announcement must be made of the availability of a potential license which solicits applications. OTT reviews the applications, makes a



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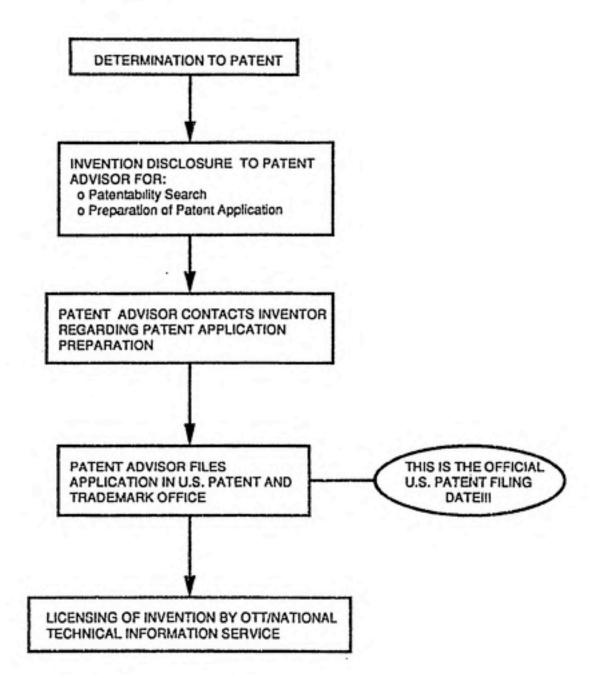
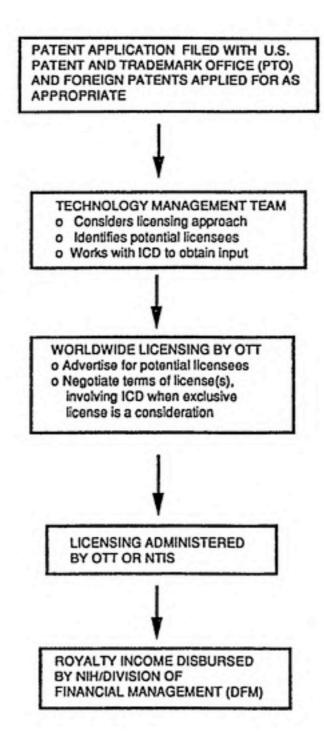


FIGURE III.5: THE LICENSING PROCESS AT THE NIH36



selection, and negotiates the terms of the license. A license can be exclusive which limits the use of the invention to a single group or entity, or non-exclusive which allows for multiple licensees. Some examples of licenses used by NIH are:

 <u>Commercial patent licenses</u> - exclusive or non-exclusive licenses which allow the commercialization of the technology.

 <u>Commercial evaluation licenses</u> - grant the non-exclusive right to make and use the technology for the purpose of evaluating its commercial potential.

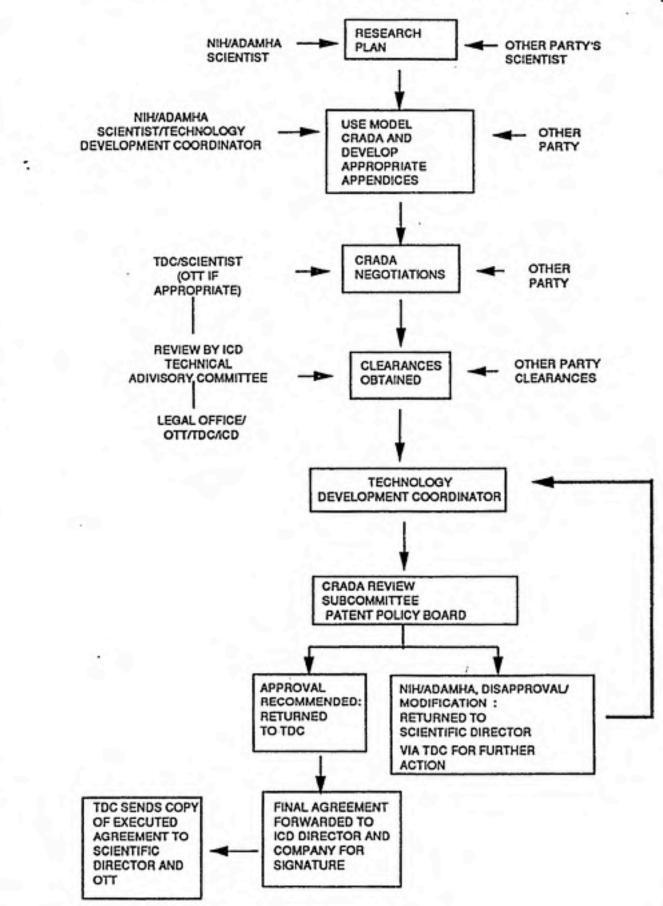
 Biological material licenses - grant the right to make, use, and/or sell commercially useful biological materials for which patent protection will not be obtained.³⁶

D. The CRADA and MTA Process

Collaborative research and exchange of materials between NIH and outside organizations are conducted through the development of CRADAs or MTAs. These agreements provide the opportunity for NIH scientists to combine resources with scientists from other government agencies, universities and industry to reach common research objectives. CRADAs are used when there is an exchange of intellectual property and/or materials through collaborative research efforts or the outside party requests the property rights to the research conducted. MTAs are used when proprietary materials and/or information is exchanged and no collaborations are planned.³⁶

Figure III.6 describes the CRADA review process at NIH. Initiation of the CRADA process usually begins with the individual scientist and an outside collaborator. The first step is for the Federal scientist and the collaborator to develop a research plan including a description of the research and each parties contribution. NIH has a model

FIGURE III.6: THE CRADA REVIEW PROCESS AT THE NIH34



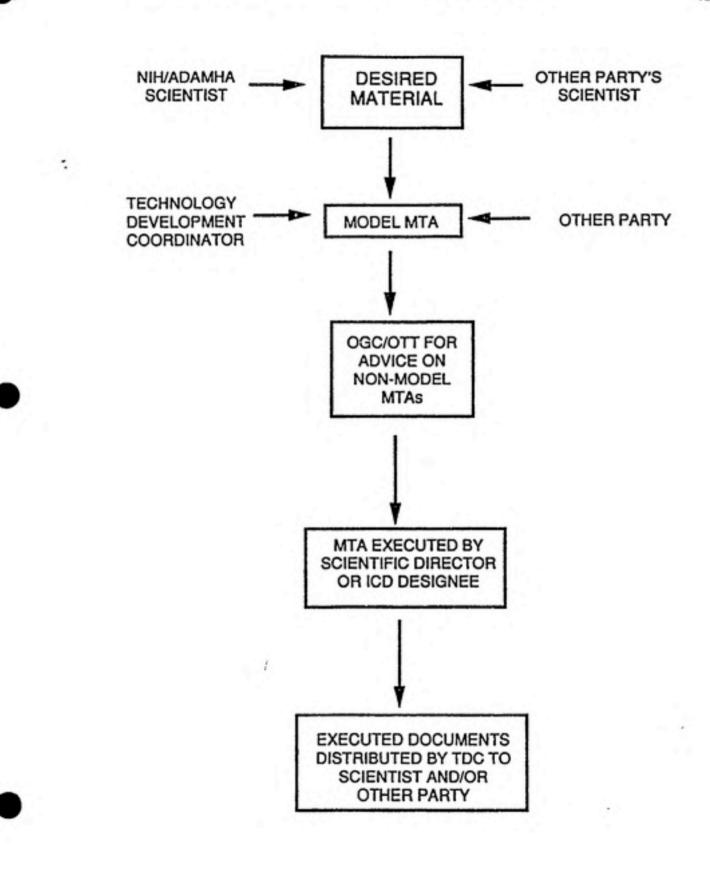
CRADA which should be used for interactions with outside parties. The TDC assists the scientist in filling out the model CRADA and forwards it to OTT and the NIH Legal Advisor. The CRADA is then sent to the CRADA Subcommittee for final approval. CRADAs that do not include licensing provisions may be approved without going to the Subcommittee for review. The Director of NIH has 30 days to approve and sign the CRADA which is then sent back to OTT for distribution to the TDC who obtains all necessary signatures from the outside party. When signed the collaborative research may begin.

Figure III.7 shows the MTA review process. MTAs provide a means of transferring research materials into or out of NIH when a non-collaborative exchange of material is desired. A model MTA has been developed by OTT to be used in the negotiation of such an agreement. Material transferred under an MTA are to be used for research purposes only and cannot be used on human subjects unless special approval is obtained. Materials can be transferred to a third party, such as a contractor, if the original party is informed and the third party agrees to the conditions of the MTA.

E. Other Technology Transfer Strategies

In addition to collaborative research and licensing of technology, technology transfer is achieved in the NIH through other means. The most visible and substantial means is through the publication of research findings. As mentioned above, the NIH is the world's largest basic biomedical research facility. The research being conducted is of vital importance to the public health of the United States as well as the world. The

FIGURE III.7: THE MTA REVIEW PROCESS AT THE NIH36



media has been a major player in making research findings of the NIH widely known. Research concerning AIDS, cancer, and heart disease are hot topics for health-related reports throughout the media.

Another means of technology transfer within NIH is the use of databases to compile and manage information on research being conducted both intramurally and extramurally. Most of the existing databases, such as the In-house Expertise Database and the Extramural Research Management Information System (ERMIS), are Institute specific with no means of access NIH-wide or publicly. This makes their use as information sources for outside sources non-existent. This limited access is due to concerns by Budget Directors and Administrators that funding amounts will be misinterpreted by the public. In addition the scientific community is concerned with their research findings being leaked to the outside without authorization. Although the major objective of the NIH is to publish research findings for the public's use, this process is controlled by NIH to protect its interests.

Two publicly accessible databases, the Public Health Service Office of Technology Transfer On-line (PHS OTTO) and Gopher, are exceptions to NIH's closed database policy. PHS OTTO is an electronic bulletin board which lists and updates a variety of technology transfer information. This information includes current CRADA listings, technologies available for licensing, research contacts within PHS, and technology transfer procedure and policy information. Gopher is a worldwide information access and retrieval program available through Internet. This program has recently been made accessible to employees of NIEHS. The Gopher program, as well as an electronic bulletin board like PHS OTTO, will be investigated as potential information systems for the Superfund Basic Research Program in section V of this report.

IV. TECHNOLOGY TRANSFER WITHIN THE U.S. ENVIRONMENTAL PROTECTION AGENCY

A. Intra-agency Technology Transfer

Technology Transfer within the U.S. EPA occurs through a variety of sources. Essentially, they may be broken down into two categories: (1) technology transfer between the various national and regional offices of the U.S. EPA, and, (2) transfer from within the U.S. EPA to the outside, including other federal, state and local agencies as well as non-profit organizations and private industry. This report is primarily interested with the second category, however, the first will be addressed briefly.

The transfer between Agency offices takes place on many levels and is designed to coordinate the approach of the Agency's overall mission, to protect human health and the environment. A detailed discussion of the structure and interworkings of this structure is beyond the scope of this report; however, a brief mention of the relationship between the Office of Research and Development (ORD), which is in charge of implementing the FTTA Program, and OSWER, which is responsible for Superfund, is in order.

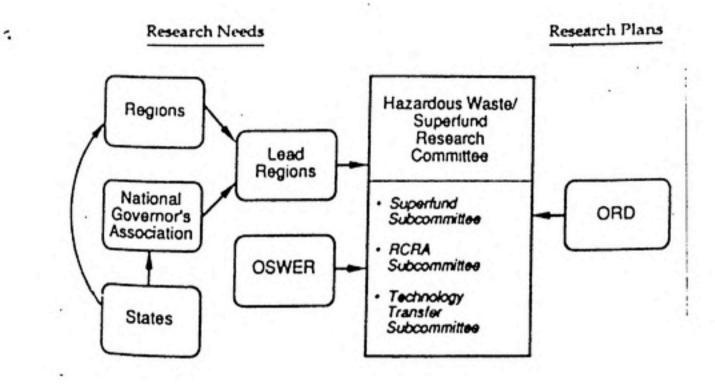
OSWER's mission is to utilize the researched, developed and demonstrated technologies from ORD and apply the best solutions available to clean-up hazardous waste sites around the United States.³⁷ To achieve an efficient exchange of research needs and the development of research plans, ORD and OSWER have formed a joint

Hazardous Waste/Superfund Research Committee (See Figure IV.1). The Committee is comprised of representatives from research, regulatory and enforcement offices, as well as from Regional offices. This Committee establishes research needs and priorities for ORD. It is "the principal cross-office organizational unit for integrating the needs and opinions of regulation developers in OSWER, regulation implementers in the Regions and states, and scientists and engineers in ORD".³⁷

With the passage of SARA in 1986, the U.S. EPA and several other agencies were given Superfund money to research health effects of waste sites and alternative technologies to clean up these sites (the NIEHS was one of the designated agencies). Because the interdependency between ORD and OSWER was emphasized with this mandate, a collective effort was made to evaluate the technology transfer needs of both Offices. In 1987 ORD and OSWER released an office-wide "Technology Transfer Strategy". This Strategy centralized the planning for technology transfer to facilitate the transfer of information and the prioritizing of strategies for transfer. While the planning and organization of technology transfer strategies is centralized, the implementation of the strategy is decentralized to streamline the process and eliminate unneeded bureaucracy.

Technology transfer was also incorporated into R&D planning by deciding from the beginning the target audience for each research project. To accomplish this, ORD and OSWER require a one-page "Technology Transfer Plan" to accompany each project proposal intended to produce technical information. This type of strategy was developed because "accomplished scientists and technical specialists do not necessarily know how

FIGURE IV.1: OSWER/ORD HAZARDOUS WASTE/SUPERFUND RESEARCH COMMITTEE³⁷



to identify and design optimal technology transfer products".³⁷ This idea of requiring research objectives to be stated before research has begun is already being utilized by the NIEHS in its peer-review process.

To prioritize technology transfer needs, the Technology Transfer Subcommittee under the Hazardous Waste/Superfund Research Committee was formed. This subcommittee ranks technology transfer needs within the U.S. EPA and advises the Committee on the allocation of resources. The "Technology Transfer Strategy" developed by both ORD and OSWER establishes close operating ties for technology transfer and efficient planning. For the purpose of collaborating with the EPA, it is important to know how these offices transfer technology and information between themselves. This knowledge can be used to direct inquiries about potential collaborations to the correct Office. This Strategy addresses requirements made by SARA but does not deal with specifications of the FTTA.

B. The FTTA Program

The provisions of the FTTA of 1986 are implemented by the FTTA Program within ORD. The FTTA Program is "designed to promote a closer, collaborative relationship between Federal government agencies and the private sector".¹⁵ This Program is aware that innovative technologies flow in both directions. To accommodate this bi-directional flow, the FTTA Program is prepared to provide technical expertise, facilities, equipment, and supplies to research projects developed outside the U.S. EPA or in a collaborative effort between the U.S. EPA and an outside party.¹⁵ For technologies developed solely within the U.S. EPA's laboratories, arrangements can be made for transfer to the outside for further development and commercialization. The most commonly used method for establishing a collaborative research effort is through the creation and signing of a CRADA. The CRADA characterizes the terms of the cooperative effort and usually describes the "provisions regarding licensing of the final product".¹⁵ However, these provisions can also be determined without a CRADA through a licensing agreement.

To promote the FTTA Program within the EPA and to reward innovative advancements of science, the EPA boasts one of the highest royalty sharing percentages, 35%, from royalty revenues received from the invention.³² The inventor may receive up to \$100,000 annually (or more with Presidential approval) above and beyond their regular salary and compensations. Co-inventors divide this amount equally among themselves or as described in provisions of a CRADA or licensing agreement. Royalties received in excess of this amount go to the laboratory where the invention originated.

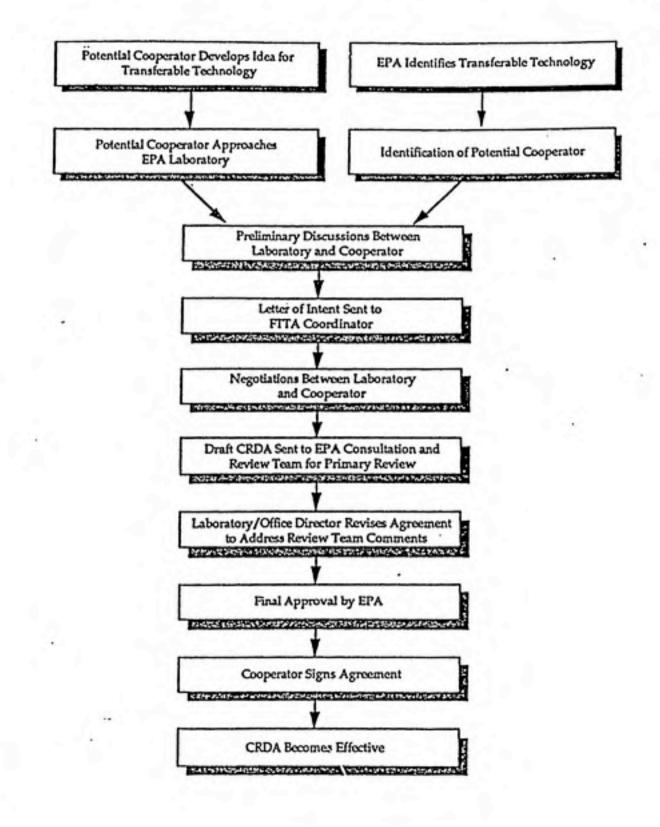
As was previously discussed, the planning for the overall Technology Transfer Strategy of the EPA was centralized to facilitate the prioritization of efforts to be implemented by the strategy. However, the actual implementation of the FTTA Program is decentralized. This means that the individual laboratories, specifically the Laboratory/Office Director, have been delegated much of the authority to represent the EPA during the CRADA and licensing process. This decentralization of authority is subject to coordination of the FTTA Program's activity "with ORD, the Office of General Counsel (OGC), the Grants Administration Division (GAD) of the Office of Administration, Resources, and Management (ORAM), the Office of Enforcement (OE), the Office of Inspector General (OIG), and others where deemed necessary".¹⁵ This coordination assures that all Offices with a potential interest are included in the FTTA process. To achieve this oversight, the Consultation and Review Team (Review Team) was developed with representatives from OGC, GAD, OIG, and OE. The Review Team "ensures that all aspects and potential ramifications of each collaborative effort are properly and thoroughly considered".¹⁵

(1) The FTTA Program CRADA Process

Cooperative agreements have been used by the EPA for years.¹⁵ The FTTA CRADAs are different than previous agreements because rights to the products developed under a CRADA are assigned to a party before work actually begins. As of May 1993, 47 CRADAs have been signed through the FTTA Program.²⁰ Figure IV.2 gives an overall schematic of the EPA's FTTA Program process through which CRADAs are developed, revised, and signed.

The technology transfer process usually begins as an interaction between an individual investigator and some outside contact or source. Whether a potential collaborator brings a technology to the EPA or an EPA scientist identifies a transferable technology and finds an outside collaborator, initial discussions are usually informal and are designed to identify mutual interest and intent to enter into a cooperative agreement. If a mutual interest is agreed upon, a letter of intent is drafted by the EPA's Laboratory Director and sent to the FTTA coordinator. This letter describes the intended

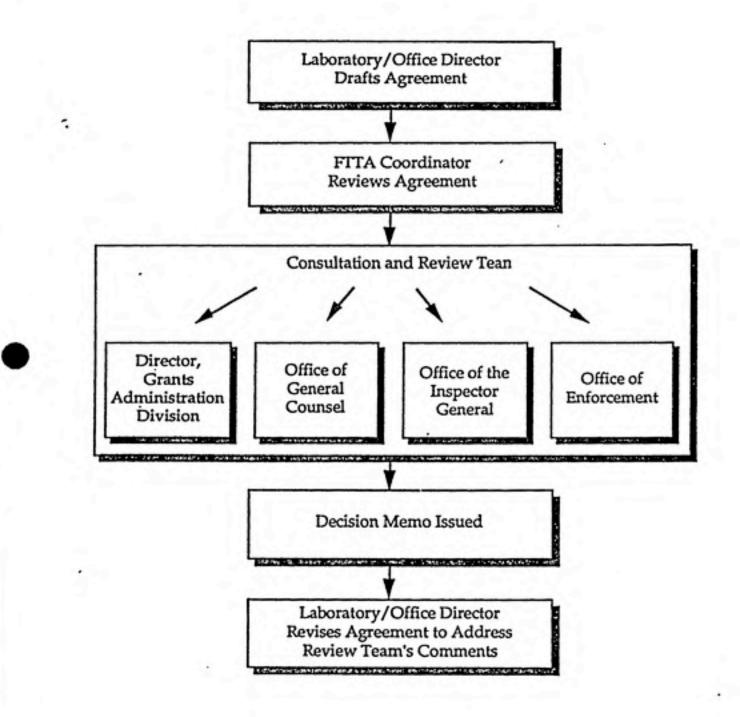
FIGURE IV.2: EPA's FTTA PROGRAM PROCESS¹⁵



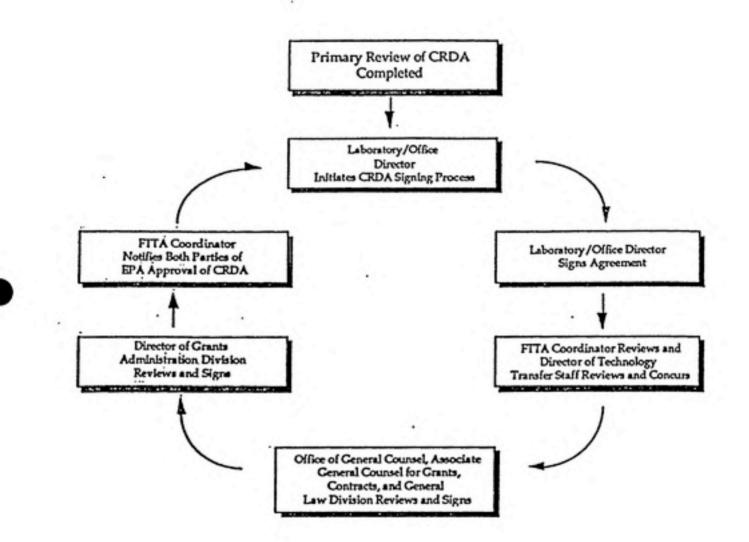
collaboration and its significance and commercial potential. All aspects of the proposal are discussed, such as, who initiated the discussions, who will be involved in the project, other outside parties working on the same technology, the expected duration of the collaboration, and proposed division of financial gains. This letter allows the FTTA coordinator and the Review Team to provide feedback to both parties and determine if this collaboration should be pursued. This initial assessment period should take two weeks to complete.

After approval of the letter, the collaborating scientists/engineer, the Laboratory Director, and the FTTA coordinator negotiate the draft agreement. The primary review process (Figure IV.3) begins with the development of the draft document and subsequently the approval of the FTTA coordinator. The approved draft is sent to members of the Review Team to begin a 30-day review period. During this review, all members of the Review Team raise questions and make comments on the draft dealing with the specific interest of the member's office.

The reviewed document is sent back to the Laboratory Director who, after addressing all the Review Teams' comments, signs the document. This begins the 15day CRADA signing period (Figure IV.4). After being signed by the FTTA coordinator, the Director of the Technology Transfer Staff, OGC, General Counsel for Grants, Contracts, and General Law Division, and the GAD, the letter is passed back to the Laboratory Director. The cooperator now signs the CRADA and the collaborative work begins.



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(2) The Licensing Agreement Process

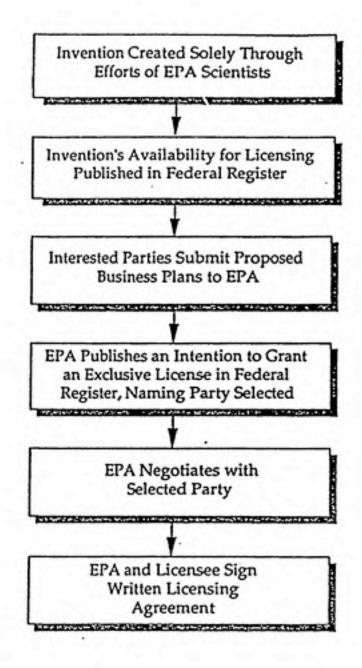
Licensing is an arrangement used by the FTTA Program to transfer the rights of an invention from one party to another. Through a licensing agreement one party is allowed to utilize or sell the intellectual property of the inventor in the market place. This procedure is common in the private sector when the inventor does not have the resources to successfully market and produce their product without licensing the invention to an organization that has sufficient resources. The goal of the FTTA Program's licensing agreements is the "development and application of environmentally-beneficial products and technologies".¹⁵ As of May 1993, seven licensing agreements have been signed through the FTTA Program.²⁰

There are three types of licenses that may be developed: (1) an exclusive license, which assigns the rights of an invention to one group or entity; (2) a non-exclusive license, which allows the assignment of rights to more than one party, and; (3) a partially exclusive license, which assigns partial rights of an invention to a party.

If the invention to be licensed is developed through collaborative research efforts between the EPA and an outside source, the agreement is usually described within a CRADA. If, however, the invention to be licensed is developed solely by an EPA laboratory, a different procedure must be followed (Figure IV.5).

Three months before an exclusive license may be granted, the EPA must announce an invention's availability in the <u>Federal Register</u>. Interested parties submit applications and the selected party is announced 60 days before the prospective signing of the license. Over this 60 day period the terms of the license are negotiated and agreed upon. The EPA and the licensee then sign the agreement to make it effective.

FIGURE IV.5: PROCESS FOR LICENSING PRE-EXISTING INVENTIONS¹⁵



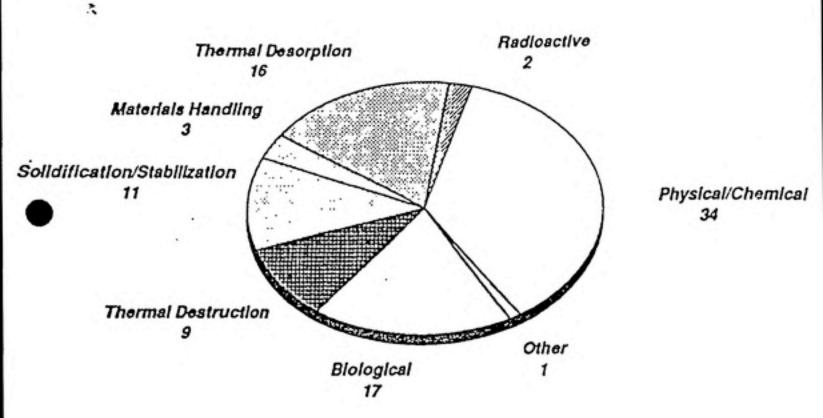
The previous sections have described EPA's internal information transfer and development of research objectives as well as the development collaborative research and licensing agreements with outside parties. The following sections describe other programs and methods utilized by the EPA to develop and transfer innovative technologies into the field.

C. The Superfund Innovative Technology Evaluation Program

SARA 1986 mandated that an "alternative or innovative treatment technology research and demonstration Program be established".¹⁴ In response to this mandate, ORD and OSWER established the Superfund Innovative Technology Evaluation (SITE) Program within the Risk Reduction Engineering Laboratory of ORD. This Program "encourages the development and implementation of (1) innovative treatment technologies for hazardous waste site remediation and (2) monitoring and measurement technologies for evaluating the nature and extent of hazardous waste site contamination".¹⁴ To accomplish this objective, the SITE Program is divided into four components; the Demonstration Program, the Emerging Technology Program, the Monitoring and Measurement Technologies Program, and the Technology Transfer Program.

The purpose of the Demonstration Program is to field-test technologies that are at the final stages of pilot-scale development or fully developed and ready to be tested at a hazardous waste site. This program compiles the cost and performance data for evaluation by potential users of the technology. Figure IV.6 shows the number of demonstrations conducted within this program from its inception in 1986 through May

FIGURE IV.6: SITE PROGRAM DEMONSTRATION TECHNOLOGIES414

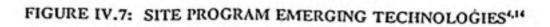


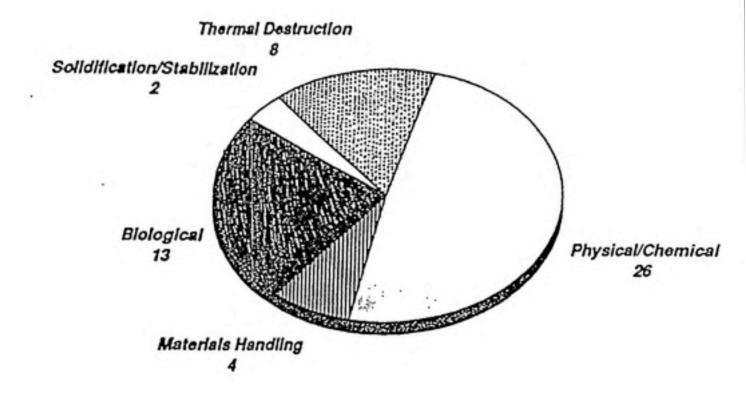
1993 broken down by treatment categories. Request for demonstrations are issued annually for participators in this program.

The Emerging Technology Program provides funding and technical expertise for innovative technologies at the laboratory bench-scale or the pilot-scale level. Annual Requests for Pre-proposals are solicited for inclusion in this program. Applicants are subjected to a competitive review process and are evaluated on their applicability to actual Superfund sites. Promising technologies from this program may be asked to participate in the Demonstration Program. Figure IV.7 shows the number of supported projects through May 1993, broken down by treatment category.

The Monitoring and Measurement Technologies Program assesses innovative methods for monitoring, measuring, or characterizing hazardous waste sites. These technologies are used to assess the nature and extent of the contamination and to evaluate the effectiveness of a remedial action. The selection of potential technologies is a continuous process. Technology developers are encouraged to send in data for evaluation and possibly inclusion in the program. Through May 1993 this program had competed 17 technology evaluations.⁴

The Technology Transfer Program compiles and disseminates the data generated by the Demonstration, Emerging Technology, and Monitoring and Measurement Technologies Programs. The goal of this program is to provide information on innovative technologies so that users have a wider selection from which to choose cleanup alternatives and sufficient technical data to support their choice. Access to the environmental community is gained through a variety of methods, including:





- Program-specific regional, state, and industry brochures.
- On-site Visitor's Days and demonstration videotapes.
- Project-specific fact sheets and reports.
- The SITE exhibit, displayed nationwide at conferences.
- Networking through forums, associations, regions, and states.
- Technical assistance to regions, states, and remediation cleanup contractors.¹⁴

Information on this Program is also available through the following information databases:

- Alternative Treatment Technology Information Center (ATTIC) System operator: (301) 670-6294
- Vendor Information System for Innovative Treatment Technologies (VISITT) Hotline: 1-800-245-4505¹⁴

The possibility for using the SITE Program as a means to advance technologies being developed in the Superfund Basic Research Program will be addressed in Part V of this report.

D. The Hazardous Substance Research Center Program

In 1988, the EPA established five Hazardous Substance Research Centers (HSRC) under the authority of SARA "to foster and support integrated, interdisciplinary, and collaborative efforts that advance the science and technology of hazardous substance management to benefit human and environmental health and well-being".²⁸ Through a competitive process, each of the Centers were formed by a consortium of universities focused towards a specific research objective. Assistance in choosing and monitoring research projects is given to HSRC Directors by separate scientific and technology transfer advisory committees. The members of this committee are composed of representatives from industry, academia, environmental organizations, and government

agencies. Table IV.1 summarizes the five research centers, Directors, technology transfer managers, consortium partners, and research emphasis.

The university-based Centers receive primary funding from the EPA through the Office of Exploratory Research. In addition to this resource, the Centers are required to generate additional funding from industry, universities, states, and other federal sources. Approximately 20% of each Centers' operating budget must be devoted to training and technology transfer. Technology transfer is achieved through Center-based publications which highlight research being conducted at the Centers. Other methods include training videotapes, manuals, conferences, workshops, and teacher training materials. The use of the HSRCs as research collaborators or a source to find existing waste sites for technology research will be mentioned in Section V of this report.

E. EPA Database and Information Systems

The Center for Environmental Research Information (CERI) acts as the main clearinghouse for documents and reports generated within or under contract for the offices of the EPA. Any EPA publication made available to the public since 1977, and occasionally back to 1968, can be obtained through CERI or through the ORD BBS listed below. Other EPA Programs, such as SITE and the HSRCs, also offer mailing lists which will frequently update participants about new and innovative research projects and clean-up technologies. The strategy of mailing out Programmatic information will be discussed as a NIEHS Superfund Basic Research Program strategy in section V of this report.

TABLE IV.1: U.S. EPA'S HAZARDOUS SUBSTANCE RESEARCH CENTERS

REGION, DIRECTOR (EPA REGIONS)

Northeast Region (I & II) Richard Magee, Ph.D. New Jersey Institute of Technology Newark, NJ 07102 (201) 596-3006 (201) 802-1946 FAX

Great Lakes & Mid-Atlantic Region (III & V) Walter J. Weber, Jr., Ph.D. University of Michigan Suite 181 Engineering 1-A Ann Arbor, MI 48109-2125 (313) 763-2274 (313) 763-2275 FAX

South & Southwest Region (IV & VI) Louis J. Thibodeaux, Ph.D. Louisiana State University 3418 CEBA Baton Rouge, LA 70803 (504) 388-6770 (504) 388-5990 FAX

Great Plains Basin Region (VII & VIII) Larry Erickson, Ph.D. Kansas State University Chemical Engineering Durland Hall Machattan, KS 66506 (913) 532-5584 (913) 532-7372 FAX

Western Region (IX & X) Perry McCarty, Ph.D. Stanford University Civil Engineering Stanford, CA 94305 (415) 723-4131 (415) 723-5599 FAX

TECHNOLOGY TRANSFER MANAGER

Jerry McKenna New Jersey Institute of Technology Newark, NJ 07102 (210) 596-3006 (210) 802-1946 FAX

Patricia Miller Michigan State University A127 Engineering Research Complex East Lansing, MI 48824-1326 (517) 353-9718 (517) 355-0250 FAX

John C. Nemeth, Ph.D. Georgia Tech Research Institute Environmental Science & Tech. Laboratory 042 O'Keefe Building Atlanta, GA 30332 (404) 894-3806 (404) 894-2184 FAX

Richard Hayter Kansas State University Engineering Extension 133 Ward Hall Manhattan, KS 66506 (913) 532-6026 (913) 532-6952 FAX

Kenneth J. Williamson Oregon State University Department of Civil Engineering Corvallis, OR 97331-2302 (503) 737-6836 (503) 737-3052 FAX

CONSORTIUM PARTNERS

New Jersey Institute of Technology, MIT, Princeton, Rutgers, Stevens Institute of Technology, Tufts, University of Medicine & Denistry of New Jersey

University of Michigan, Michigan State University, Howard University Bioremediation

RESEARCH EMPHASIS

Hazardous Waste

Incineration

Louisiana State University, Rice University, Georgia Tech University Contaminated Sediment and Dredged Material

Kansas State University, Montana State, Universities of Iowa, Missouri, Montana, Nebraska, and Utah Soil Renediation

Stanford University, Oregon State University

Groundwater Remediation Numerous databases, bulletin boards, and information Hotlines have also been established to provide outreach, communication, and technology transfer. Table IV.2 provides a listing and brief description of these information systems.

TABLE IV.2: U.S. EPA ENVIRONMENTAL TECHNOLOGY INFORMATION 64 SOURCES²⁰

Alternative Treatment Technology Information Center (ATTIC) - provides information on alternative and innovative hazardous waste technologies.		(301) 670-3813 (301) 670-3808
Clean-up Information Bulletin Board System (CLU-IN) - provides information of Superfund response activities and hazardous waste corrective action.	Modem: SysOp:	(301) 589-8366 (301) 589-8368
Clearinghouse for Inventories and Emmision Factors (CHIEF) - provides air pollution emission factors for criteria and toxic pollutants from stationary and area sources, as well as mobile sources.	Modem: Modem: SysOp:	(919) 541-5742 (919) 541-1447 (919) 541-5232
Hazardous Waste Ombudsman Program - provides information on hazardous and solid waste issues.		(800) 262-7937 (202) 260-9361 (202) 260-1482
Office of Research and Development Electronic Bulletin Board System (ORD BBS) - provides an on-line, text-searchable database of ORD publications and offers a message exchange, bulletins, public domain files, on-line registration for ORD meetings, and special conferences.	Modem: SysOp:	(513) 569-7610 (513) 569-7502
ORD Publications - answers phone and mail requests for ORD publications and research information.		(513) 569-7562
Pollution Prevention Information Clearinghouse (PPIC) - provides information to aid in reducing or eliminating discharges and emissions through source reduction and environmentally sound recycling. Pollution Prevention Information Exchange System (PPIES) - provides computerized access to databases and document ordering.	Modem: Clearing	(703) 506-1025 house: (703) 821-4800
Resource Conservation and Recovery Act/Superfund/UST Hotline - provides assistance in understanding EPA's regulations pursuant to RCRA, Underground Storage Tanks, Superfund/CERCLA, and Pollution Prevention/Waste Minimization.		(800) 424-9346 (703) 920-9810
Safe Drinking Water Hotline - provides information on public water supply program, policy, technical and regulatory issues.		(800) 426-4791
Small Business Ombudsman Clearinghouse/Hotline - provides information and assistance on asbestos, hazardous waste, air and water relevant to small business to enhance volutary compliance with regulation.		(703) 305-5938 (800) 368-5888
Solid Waste Information Clearinghouse and Hotline (SWICH) - collects and distributes information on solid and municipal waste systems.	Modem: (301) 585-0204 Clearinghouse: (800) 677-9424	

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V. TECHNOLOGY TRANSFER STRATEGY FOR THE SUPERFUND BASIC RESEARCH PROGRAM

A. Overview

In order for waste sites to be managed and remediated effectively, new methods and techniques must be developed to detect, assess, and monitor human health and environmental effects of toxic substances from these sites. Technology transfer is an essential step in the development and application of these innovative hazardous waste management technologies. Through the examination of the NIH and EPA technology transfer processes, it has been shown that numerous methods exist to transfer information, data, and inventions from one organization to another. Many of these methods can be incorporated into the strategy for technology transfer in the Superfund Basic Research Program. The NIH has an established FTTA Program and computer database support. Since the NIEHS is part of NIH, the resources available through the FTTA Program, such as the OTT and the NIEHS TDC, can be utilized for technical and procedural assistance. The computer support within NIH and NIEHS will be employed to establish the various Superfund Basic Research Program databases for both internal and external use. The EPA technology transfer strategy provides numerous ideas of its own, such as various electronic bulletin boards (BBS) to allow public access to a wide variety of research and technology information. The proposed strategy for the Superfund Basic Research Program will incorporate this method of information dissemination into

its database plan. In addition, the EPA's method of identifying potential technology transfer audiences with every research proposal, as mentioned in section IV, will be used to develop evaluative criteria for the distribution of Administrative supplements. Finally, the EPA's practice of distributing Program documents and research findings through massive mailing lists will be utilized by the Superfund Basic Research Program.

The Superfund Basic Research Program is designed to expand the base of scientific knowledge concerning hazardous waste management by filling gaps in existing technology. It is vital to the success of this Program, as well as to the advancement of the science of hazardous waste management, to disseminate and utilize the knowledge gained from this research. To accomplish this task, the following technology transfer strategy for the Superfund Basic Research Program is recommended. The major objective of this strategy is the dissemination of non-proprietary Programmatic and research information for use by other interested parties. This includes developing and maintaining various databases, developing and distributing Program-related documents and media productions, as well as sponsoring and conducting conferences and workshops. The second objective of this strategy is the utilization of information and inventions developed within the Program. This will include the use of Administrative Supplements to provide assistance to grantees in translating basic research findings to field applications and/or providing a resource for these researchers to find potential research collaborators in other government agencies, universities, and industry.

B. Database Development

The most efficient means available to manage the large amount of information that

has accumulated from 18 research programs encompassing 142 individual projects is through the use of an information management system or database. In order for Program personnel to have access to a wide variety of information as well as to provide information to outside parties, the following database strategies were investigated.

(1) The ERMIS Database

For internal management purposes such as writing reports or answering inquiries from NIEHS, NIH, and Congress, this Program has been involved in the development of the ERMIS database using ORACLE software. The ERMIS database has the ability to access and arrange information into an infinite number of output formats making information retrieval a timely and simple process. This database is secured for internal access only and will be used to compile various reports and documents for mailouts on a regular basis or at the request of an outside party.

Efforts are currently underway to develop areas for the storage of Medical Subject Headings (MeSH) index codes for each project. MeSH codes are used throughout the PHS to index research projects by the science within the project. It is expected that in the future a unified database will be developed for all the Institutes in the NIH, thus, the ERMIS database is incorporating MeSH terminology into its structure. Scientific codes for the non-biomedical research within the NIEHS Superfund Basic Research Program have been adapted to MeSH terminology so that this unique research Program can be included in the NIH database structure. In addition, data fields are being constructed within the ERMIS database for the storage of research highlights, program summaries, project descriptions, publication listings, and listings of collaborative research efforts between Superfund Basic Research Program grantees and other Federal, state, and local agencies, universities, and private industries. By effectively managing the information from the program, other aspects of the proposed technology transfer strategy can be conducted efficiently and with a minimum of labor input.

(2) Superfund Basic Research Program Specific Directory in the Gopher System

The Office of Computer Technology and Services (OCTS) at NIEHS and Computer Sciences Corporation (CSC), a computer support contractor for the Institute, have recently released Gopher access software to all employees of NIEHS. Gopher is a world-wide information system available through Internet. This program allows a user to search for and retrieve information stored in other computers, known as "gopher servers". Gopher's functions include accessing directories at computer sites around the world, reading and retrieving public domain documents and software, and searching numerous scientific databases. Through this program, connections can be made to universities, government agencies, and the Federal Information Exchange (FIE), Inc. The FIE has many on-line services which, through the participation of nine Federal agencies, list research opportunities and program contacts at government agencies and universities.

The Gopher program reaches a large audience and would allow this same audience access to any NIEHS directory included in the program. Therefore this Technology Transfer Strategy proposes the development of a sub-directory within the NIEHS Gopher directory to store programmatic information for public access. Preliminary inquiries into this issue have shown that this service can be provided at no charge to the Program with maintenance and support provided by the OCTS and CSC. Selected files from the ERMIS database can easily be transferred into Gopher and arranged in any structure desired. Contact numbers for persons within the Superfund Basic Research Program would be listed at the head of the directory to assist users in finding the correct person to answer any questions. Presently, OCTS and CSC personnel are testing Gopher's search capabilities. When this investigation is completed, the development of a Superfund Basic Research Program directory and the transfer of information can begin.

(3) Superfund Basic Research Program Electronic Bulletin Board

There are a couple of minor limitations of the Gopher program which can be addressed by a program-specific BBS. First, Gopher excludes those few organizations with no Internet access, and second, Gopher has no on-line, interactive communication. Though all Superfund Basic Research Program personnel can be reached through electronic mail via Internet, a BBS would provide public access to Program information and interactive communication, at specified times, including those with non-Internet capabilities. This added benefit may appear to be small but, because a BBS could be installed and maintained at a small cost, the increased access by non-internet users would be worth the expense. The Superfund Basic Research Program has access to surplus IBM computers for running the BBS software and phone lines can be added to the Program's communication contract at little or no charge. NIEHS already owns a couple of BBS programs and the cost of adding the Superfund Basic Research Program to the license is small.

As an example of the usefulness of a BBS, the EPA established its first nationwide BBS in September 1987.³⁷ Evaluation of this BBS after the first year of operation showed its effectiveness in directing callers to the correct laboratory or office for specific subject inquiries. The Superfund Basic Research Program is not nearly the size or complexity of the EPA's organization, but a BBS can provide the same service by facilitating access to all aspects of the Program.

C. Superfund Basic Research Program Information Dissemination

The development of databases to manage information is vital to the effectiveness of this Program, however, printed documents and publications are still necessary for communicating programmatic information. An annual mailing of research highlights, a publications listing, and a technology transfer strategy update is recommended. This information will inform the user of recent research developments as well as changes and additions to the Technology Transfer Strategy. Programmatic information can be pulled directly from the ERMIS database and formatted in a manner appropriate to the intended use of the document. The Superfund Basic Research Program has compiled a very large, multidisciplinary mailing list over its seven year history making this approach effective.

The Superfund Basic Research Program has been developing documents for limited distribution since its inception. These documents have been simple Wordperfect files with no graphic displays, pictures or colors to appeal to the reader. It is recommended that more professional, appealing documents be created through the use of desk-top publishing software. This approach has not been feasible in the past because the Department of Health and Human Services has a policy which prohibits the development of such documents directly by government employees. Jobs of this type are completed through the assignment of a task to a government contractor. This is a cumbersome process which requires the development of a project proposal and a competitive bidding process to choose a contractor. With the recent 1992 Program expansion, more information is being created and there is an ever increasing need to efficiently produce high quality documents that "display" large amounts of information in a clear, concise, and easily readable format. In the past the Superfund Basic Research Program did not have the staff or mechanism to do this. To circumvent this problem the Program Administrator of the Superfund Basic Research Program has created a task for a contractor position within CSC which, in addition to scientific indexing, database management, and technology transfer objectives for the Program, will allow for the creation of documents of this quality. Because CSC has already successfully bid and received a support contract for NIEHS, the addition of this task does not require a competitive bidding process for a government contract. This should elevate the quality of Program presentations and "catch the eye" of outside parties, thereby improving the visibility of this Program.

In addition to the creation of various documents for mailout, the use of videotape media for information dissemination could be very effective. Video recordings are often made of the conferences and workshops sponsored by the Superfund Basic Research Program. A library of these videos should be maintained and copies made available for distribution for the cost of producing the copy. In addition to conference tapes, a video presentation of the Superfund Basic Research Program would be a useful, appealing way to "advertise" the Program to potential grantees and collaborators. The Hazardous Substance Research Centers recently issued a videotape of their Program which provided a thoughtful presentation of the Program as well as contacts for further information.

A complete listing of the publications and videos available for distribution should be placed in both the Gopher and the BBS systems as well as included in the annual mailouts.

D. Conferences and Workshops

The most effective way to bring together researchers from different scientific disciplines to address issues concerning the human health and environmental effects related to hazardous waste is through conferences and workshops. This strategy is successful in facilitating dialogue between scientists who would not normally work together, as well as bringing together prominent scientists from a single discipline to work together on a specific issue. The use of conferences and workshops has been a high priority for the Superfund Basic Research Program since 1990. This has been the most visible aspect of this Program and has been used successfully to address inquiries from EPA and Congress. It is suggested that the sponsoring of conferences and workshops, as well as providing travel funds to grantees to present research findings at these and other meetings, should remain a top priority. It is believed that this strategy

is an effective way to disseminate Program information, "advertise" the Program, and develop professional relationships which may lead to the advancement of science or future research collaborations.

Appendix A shows the conferences, meetings, and workshops sponsored by the Superfund Basic Research Program. This table illustrates the many scientific disciplines, research organizations, and countries that are represented at these functions.

In addition to the future conferences listed, a technology transfer conference, sponsored by the Superfund Basic Research Program, is recommended. The purpose of this conference would be to provide an opportunity for the researchers within the Program to share their findings with representatives from Federal, state, and local governments, universities, research organizations, and private industry. The agenda would include presentations by grantees who were interested in the application of their research findings to site management in the field. A conference of this type is an aggressive approach to technology transfer and has the potential to be very successful. Issues such as the protection of proprietary information, the most effective scheduling of the conference, and who to invite will require further consideration; input on these issues will be requested from grantees and technology transfer representatives in the near future and evaluated by the Program Administrator. As mentioned earlier, all conference proceedings and videotapes made of this conference would be made available to outside parties.

E. Administrative Supplements for Additional Funding to Grantees

The transfer of a technology from basic research to field demonstration requires

the input of resources. To address this requirement, the Superfund Basic Research Program has provided money to grantees at their request when additional funds were needed to advance their technology. This is not an infinite resource waiting to fund every request, but a direct means by which this Program can facilitate the transfer of technology.

To date this process has been very informal, requiring only an initial consultation between the grantee and the Program Administrator followed by a letter from the grantee requesting additional funds. It is suggested that this simple, non-bureaucratic process be continued, however, reporting requirements should be added so that supplementally funded research efforts can be recorded, observed, and reported as "products" of this Program. As was mentioned in section IV of this report, identifying research objectives and potential audiences for developed technologies is already required by both the NIEHS peer-review process and the EPA's "Technology Transfer Plan" which accompanies all EPA research proposals. This strategy will now be utilized in the Administrative supplement process. The proposed qualifying and reporting criteria are discussed below.

The initial informal consultation between grantee and Administrator will remain as before, however, the letter that follows will be required to address the following questions:

- (1) What specific objective from your original, peer-reviewed grant application will this supplemental research be developing?
- (2) How will this administrative supplement be used to build upon this original objective?
- (3) What is the potential time-frame for completion of this supplemental objective?

- (4) How will this supplemental research benefit other projects within your program thereby enhancing the inter-relatedness of the overall research effort?
- (5) What other funds will you be receiving to accomplish the supplemental research objective? List all names, addresses, and telephone numbers of organizations and contact personnel.
- (6) Have you ever received an administrative supplement from this Program before? If so, when? Provide a <u>brief</u> description of the outcome of this previous supplemental research.

These qualifying criteria will assist the Administrator in determining whether an administrative supplement is warranted and, if so, in justifying the requested supplement to the Grants Management Division of NIEHS. This information will also provide a record for the Program database so that technology developments can be followed. These records could then be retrieved from the database and used for internal reports and to answer various information inquiries. This proposed addition is simply adding a formal structure to the existing process to document criteria used to justify supplemental funding and to facilitate data entry and management in the database.

In the past, little or no effort has been made to evaluate or record the progress and success of research funded by administrative supplements. It is suggested that grantees receiving funds through this process be required to submit a progress report nine months after the original funding date. Additional progress reports will be required at the request of the Program Administrator. When the supplemental research is completed, a final report will be submitted in the same format as the progress reports. These reports will be in the form of a letter and will be required to address the following points:

(1) Is the supplemental research adhering to the original, peer-reviewed grant application objective?

- (2) <u>Briefly</u> describe the progress to date. Include any major set-backs and achievements.
- (3) What reporting mechanisms (i.e., journal publications, presentations, demonstrations) are you pursuing?

These progress reports do not add an unnecessary burden to the administrative supplement process. They allow the Program database to remain up to date and provide a means to evaluate and follow the success of technology development within this Program. Two examples of the distribution of administrative supplements are given to demonstrate how this strategy has been used.

In August 1992, Dr. Lawrence Tavlarides, a project investigator within the SUNY at Albany Program, demonstrated a laboratory scale Supercritical Extraction and Wet Oxidation process to remove PCBs from contaminated soil. In addition to the local media⁴⁴, this work also attracted the attention of the Niagara-Mohawk Power Company who was interested in developing this process to remediate PCB waste sites that they own. Niagara-Mohawk proposed a scale-up research plan where they would match funds obtained through NIEHS and Syracuse University to develop this technology. After an initial consultation between Dr. Tavlarides and the Superfund Basic Research Program Administrator, a request was made and approved for \$75,000 in September 1992 and another \$75,000 in the summer of 1993 from NIEHS. Though a few set-backs have occurred, such as disagreements about patent rights and assigning credit in the CRADA between Dr. Tavlarides and Niagara-Mohawk and obtaining an EPA permit to transport, store, and test PCB contaminated soil, a bench-scale unit is almost complete and research has begun. Interest has also been expressed by the State of New York in utilizing this technology to clean river sediment within the next two years. This collaboration is in the discussion phase.

Dr. Tavlarides' research is a good example of how administrative supplements can be used to transfer technologies out of the Program. Interest has been expressed with regard to having a resource available through which Dr. Tavlarides could be connected to other potential research collaborators and investors in the environmental science field. To provide this type of resource to the Program, various contacts are listed in Appendix B.

Another example of the use of administrative supplements is by Drs. James Hunt and Kent Udell at the University of California at Berkeley. Before the last competitive renewal in 1992, Drs. Hunt and Udell were co-investigators on a project investigating the injection of steam into contaminated soil to force contaminants from less permeable regions. One of the peer-reviewed objectives of this project was to demonstrate this technology at a waste site. In an attempt to bring all programs within the Superfund Basic Research Program onto the same funding schedule, all programs were asked to recompete in 1992 whether or not their existing funding periods had ended. This program was one that had not finished its previously approved funding period. When the Berkeley application was submitted for renewal in 1991, Drs. Hunt and Udell had split the old project into two new projects with their own objectives. After successfully competing and being renewed in 1992, they realized that the demonstration objective had been left out. They proceeded to request an administrative supplement to continue the development and demonstration of this technology. Early in the summer of 1992, these researchers were given \$138,000 to demonstrate their steam injection technology at an estimated 6,200 gallon gasoline spill at Lawrence Livermore National Laboratory. Injection began on February 4, 1993 and lasted for 35 days. The Department of Energy (DOE) had problems with acquiring funds for this demonstration and the project was shut down until May 28, 1993. Injection was resumed and continued until June 30, 1993. To date, over 6,000 of the original 6,200 gallons of gasoline have been removed from the site at a much lower cost than conventional methods such as soil excavation and treatment. A final paper on this demonstration is being prepared which will analyze cost comparisons and clean-up efficiencies. Dr. Udell expressed his support of the use of Administrative supplements to develop and transfer technologies, claiming, "This is how technology transfer should be conducted within this Program. NIEHS should provide the "seed" money to initiate the development of the technology, and other sources should collaborate to further develop the technology."47 This example shows how these supplements can be used to actually clean up an existing waste site as well as provide funds for a collaborative research effort at a National Laboratory. Contacts at various National Laboratories for joint research possibilities will be given in the next section.

G. Technology Transfer Contacts in the Environmental Field

Throughout the preparation of this report numerous contacts with technology transfer personnel at various Federal Departments, Federal Agencies, institutions, organizations, and industries have been made. Interest in the research being conducted within the Superfund Basic Research Program was very high and people were very willing to give assistance and advice. Through a number of conversations with grantees, there appears to be an interest in having access to these contacts in the environmental field. A listing of organizations and contacts that can be used to locate potential research collaborators, technical advice, and places to test technologies in actual field settings has been provided in Appendix B. A detailed discussion of the technology transfer strategies at each of these organizations is beyond the scope of this report, however, a brief description is included in the listing where appropriate. A listing of contacts will not be included in the publicly-accessible Program databases for privacy reasons but a reference will be made regarding the resources available and a contact number will be given for the Information and Technology Specialist for the Superfund Basic Research Program.

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VI. CONCLUSIONS

The study of the relationship between hazardous substances in the environment and their effects on human health is in its infancy. There are a large number of substances and mixtures that have been identified in uncontrolled hazardous waste sites, however, information on how these substances are changed as they migrate through soil, air, and water is limited. Our understanding of how these substances enter the food chain and how they may otherwise be ingested, inhaled, or absorbed by people is limited. Techniques to assess human exposure and to detect subtle or serious health effects that are clearly related to such exposures are not widely available. Basic research whose objective is to develop methods and technologies to reduce the amount and toxicity of hazardous substances in the environment requires close linkage of biological and toxicological expertise with skills in such fields as chemical engineering, microbiology, ecology, hydrogeology, and related fields. The NIEHS Superfund Basic Research Program is designed to fill the research and technology gaps which exist in the science of hazardous waste management.

This analysis has investigated and developed a technology transfer strategy for the Superfund Basic Research Program. This strategy includes the development of the ERMIS database for increased data management and retrieval, the inclusion of a Superfund Basic Research Program-specific directory in the Gopher information system, and the establishment of a Program-specific BBS for non-Internet access. In addition to information system developments, this strategy includes the increased distribution of Programmatic documents and media productions as well as the continued sponsoring of scientific conferences and workshops. To utilize the information and inventions developed within this Program, this technology transfer strategy will include the use of Administrative Supplements to provide assistance to grantees in translating basic research findings to field applications and/or providing a resource for these researchers to find potential research collaborators in other government agencies, universities, and industry.

It should be reemphasized that the purpose of this Technology Transfer Strategy is not to change the emphasis of the NIEHS Superfund Basic Research Program from basic to applied research. This Program funds basic research to expand the base of scientific knowledge which can then be used to ultimately prevent adverse human health effects from exposure to hazardous waste. It is through this basic research that inventions and/or potentially useful technologies are often developed. The proposed technology transfer strategy is designed to take advantage of this potential by assisting the researcher in the development of a technology or by distributing the technological information to potential users. As this Program matures, data and technologies from many of the original research projects are ready to be developed towards use in the field. With the elimination of Superfund-related health effects research within the EPA, more pressure is being placed on this Program to deliver basic research information and innovative technologies for development and application. It is for this reason that the development of a technology transfer strategy is both timely and essential for the continued success of this Program.

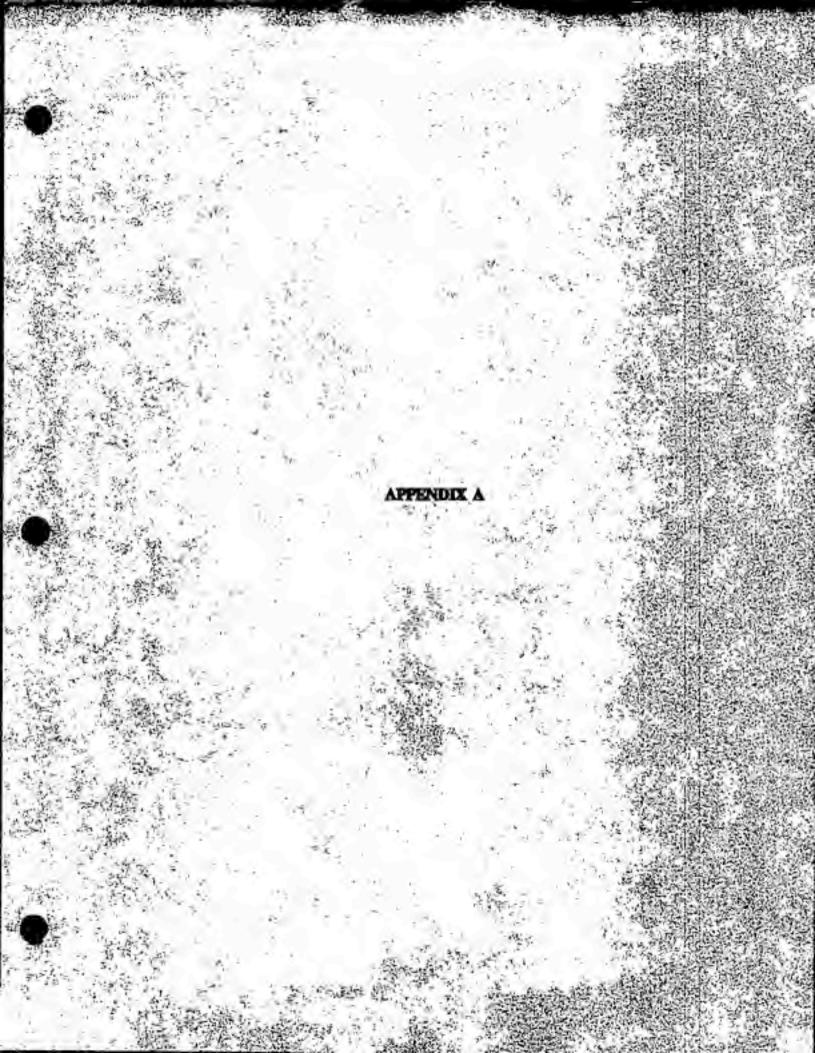
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APPENDIX A: SUPERFUND BASIC RESEARCH PROGRAM SPONSORED CONFERENCES AND WORKSHOPS

Future Conferences and Workshops

Napa Conference on Genetic and Molecular Ecotoxicology October 12-15, 1993 Yountville, California

> Sponsor(s): National Institute of Environmental Health Sciences Pew Charitable Trust University of California at Berkeley

1993 Pacific Basin Conference on Hazardous Waste Research November 8-12, 1993 Honolulu, Hawaii

> Sponsor(s): Pacific Basin Consortium for Hazardous Waste Research Carl Duisberg Gesellschaft e.V. U.S. Environmental Protection Agency United Nations Environment Programme National Institute of Environmental Health Sciences Agency for International Development U.S. Trade and Development Program World Environment Center East-West Center Argonne National Laboratory

Risk Assessment in Environmental Carcinogenesis January 17-22, 1994 Whistler, British Columbia

> Sponsor(s): American Association for Cancer Research National Cancer Institute National Institute of Environmental Health Sciences

National Conference on Pediatric Environmental Health March 16-18, 1994 Washington, D.C.

Sponsor(s): National Institute of Environmental Health Sciences

Workshop on the Sustainable Development in Urban Areas of the Americas April 1994 Santiago, Chile Sponsor(s): National Institutes of Health National Institute of Environmental Health Sciences National Institute of Standards and Technology National Science Foundation Organization of American States Embassy of Chile International University Exchange, Inc. Health Risks and Societal Costs of Hazardous Wastes April 1994 Washington, D.C. Sponsor(s): National Institute of Environmental Health Sciences International Symposium on Metals and Genetics May 24-27,1994 Toronto, Canada Sponsor(s): National Institute of Environmental Health Sciences International Association of Environmental Analytical Chemists **Risk Assessment of Complex Mixtures of PAHs** June 1994 Location TBA Sponsor(s): National Institute of Environmental Health Sciences U.S. Environmental Protection Agency Agency of Toxic Substances and Disease Registry Electrical Power Research Institute Assessment and Remediation of Hazardous Waste in Eastern Europe Summer 1994 Prague, Czech Republic National Institute of Environmental Health Sciences Sponsor(s): Czech Academy of Sciences Neurotoxicology of Hazardous Wastes Workshop 1994 Rutgers, New Jersey National Institute of Environmental Health Sciences Sponsor(s):

Environmental and Occupational Health Sciences Institute Rutgers University R.W. Johnson School of Medicine and Dentistry

Past Conferences and Workshops

Application of Molecular Biomarkers in Epidemiology February 21-22, 1990 National Institute of Environmental Health Sciences Research Triangle Park, North Carolina

Sponsor(s): National Institute of Environmental Health Sciences

Biodegradation of Hazardous Wastes April 9-10, 1990 Utah State University Logan, Utah

Sponsor(s): National Institute of Environmental Health Sciences

Assessment of Human Exposure to Chemicals from Superfund Sites June 5 and 6, 1990 Michigan State University East Lansing, Michigan

Sponsor(s): National Institute of Environmental Health Sciences

Health Effects of Combustion By-Products October 23-24, 1990 National Institutes of Health Bethesda, Maryland

> Sponsor(s): National Institute of Environmental Health Sciences National Science Foundation

1990 Pacific Basin Conference on Hazardous Waste Research November 9-17, 1990 East-West Center Honolulu, Hawaii

> Sponsor(s): Pacific Basin Consortium for Hazardous Waste Research Carl Duisberg Gesellschaft e.V. U.S. Environmental Protection Agency United Nations Environment Programme National Institute of Environmental Health Sciences Agency for International Development U.S. Trade and Development Program World Environment Center East-West Center Argonne National Laboratory

Second International Congress on Toxic Combustion By-Products: Formation and Control

March 26-29, 1991 University of Utah Salt Lake City, Utah

Sponsor(s): Coalition for Responsible Waste Incineration Department of Energy/Sandia Environmental Protection Agency Gas Research Institute National Institute of Environmental Health Sciences National Science Foundation/Advanced Combustion Engineering Research Center Southern California Edison

Utilizing Bioremediation Technologies: Difficulties and Approaches July 12-14, 1991 Henry Chauncey Conference Center Lawrenceville, New Jersey

Sponsor(s): U.S.Environmental Protection Agency New Jersey Department of Environmental Protection U.S. Navy National Institute of Environmental Health Sciences Environment Canada

1992 Pacific Basin Conference on Hazardous Waste Research April 6-10, 1992 Thailand Development Research Institute Bangkok, Thailand

> <u>Sponsor(s)</u>: Pacific Basin Consortium for Hazardous Waste Research U.S. Environmental Protection Agency United Nations Environment Programme National Institute of Environmental Health Sciences World Environment Center Carl Duisberg Gesellscgaft e.V. Australian International Development Assistance Bureau U.S. Trade and Development Program East-West Center Argonne National Laboratory

Bioaccumulation of Hydrophobic Organic Chemicals by Aquatic Organisms June 28-July 1, 1992 Landsdowne Conference Resort Leesburg, Virginia American Paper Institute Sponsor(s): American Petroleum Institute Chemical Manufacturers Association Electric Power Research Institute Institute for Evaluating Health Risks National Institute of Environmental Health Sciences U.S. Environmental Protection Agency Anaerobic Dehalogenation and Its Environmental Implications August 30-September 4, 1992 The Georgia Center Athens, Georgia Sponsor(s): Department of Energy U.S. Environmental Protection Agency General Electric National Institute of Environmental Health Sciences Thirty-First Hanford Symposium on Health and the Environment: The Development and Application of Biomarkers to the Study of Human Health Effects October 19-24, 1992 Tower Inn Richland, Washington Sponsor(s): U.S. Department of Energy Battelle, Pacific Northwest Laboratories University of Washington, Department of Environmental Health National Institute of Environmental Health Sciences Second International Meeting on the Molecular Mechanisms of Metal Toxicity and Carcinogenicity

January 10-17, 1993 Congress Center Madonna di Campiglio, Italy

Sponsor(s): National Institute of Environmental Health Sciences Nickel Producers Environmental Research Association Institute of Environmental Medicine, New York University Medical Center International Lead Zinc Research Organization

Fate, Transport and Interactions of Metals: A Joint US-Mexico Conference April 14-16, 1993 University of Arizona Tucson, Arizona

Sponsor(s): National Institute of Environmental Health Sciences Programa Universitaro de Medio Ambiente (PUMA) University of Arizona Pan American Health Organization (PAHO)

Biodegradation: Its Role in Reducing Toxicity and Exposure to Environmental Contaminants

April 26-28, 1993 National Institute of Environmental Health Sciences Research Triangle Park, North Carolina

Sponsor(s): National Institute of Environmental Health Sciences

International Congress on Human Health Effects of Hazardous Wastes May 3-6, 1993 Atlanta Marriott Marquis Hotel Atlanta, Georgia

The Agency for Toxic Substances and Disease Registry Sponsor(s): Emory University School of Public Health National Institute of Environmental Health Sciences National Institute for Occupational Safety and Health U.S. Environmental Protection Agency Association of Occupational and Environmental Clinics Carter Center of Emory University Chemical Manufacturers Association International Society for Environmental Epidemiology International Life Science Institute Association of Schools of Public Health World Health Organization United Nations Environmental Programme International Labor Organization International Society for Exposure Analysis Pan American Health Organization The Sierra Club



Third International Congress on Toxic Combustion By-Products June 14-16, 1993 Massachusetts Institute of Technology Cambridge, Massachusetts

> Sponsor(s): Coalition for Responsible Waste Incineration U.S. Environmental Protection Agency National Institute of Environmental Health Sciences U.S. Department of Energy/Sandia National Laboratory Southern California Edison National Science Foundation/ACERC Gas Research Institute Industrial Technology Research Institute, Taiwan U.S. Army Toxic and Hazardous Materials Agency Northeast Hazardous Substances Research Center

Pediatric Environmental Research Workshop June 24-25, 1993 National Institute of Environmental Health Sciences Research Triangle Park, NC

Sponsor(s): National Institute of Environmental Health Sciences



CONTACTS/RESOURCES IN THE ENVIRONMENTAL FIELD

The NIEHS Superfund Basic Research Program:

Mr. Bradley C. Blackard -	SBRP Technology and Information Specialist - (919) 541- 0431
Dr. William A. Suk -	Program Administrator - (919) 541-0797
Ms. Beth Anderson -	Program Officer - (919) 541-4481

The National Institute of Environmental Health Sciences:

Ms. Dotty Kennedy - NIEHS Technology Development Coordinator - (919) 541-1081

The National Institutes of Health:

Mr. Reid Adler -	Director, OTT - (301) 496-7057
Mr. Michael Miller -	OTT, Office System Management and Program Monitoring - (301) 496-7057
Mr. Bruce Artim -	OTT, Policy Office - (301) 496-7057
Dr. Jay Moskowitz -	NIH liaison to the Federal Laboratory Consortium - (301) 496-3152

The U.S. Environmental Protection Agency:

 <u>The FTTA Program</u>: these people are "in-the-know" with technology transfer within the EPA. Any technologies seeking a collaborative research effort with EPA should start with these people (especially Mr. Fradkin).

Mr. Michael Moore -	Technology Transfer Staff Director, ORD - (202) 260-7671
Mr. Larry Fradkin -	FTTA Program Coordinator, ORD - (513) 569-7960
Ms. Annette Gatchett -	ORD, FTTA Program - (513) 569-7697

 <u>The SITE Program</u>: will be able to transfer non-biomedical remediation technologies to this Program. The Administrators of the Program appear very interested in having NIEHS Superfund Basic Research Program technologies compete for grants under this Program.

Mr. Bob Olexsey -	Director, Superfund Technology Demonstration Division - (513) 569-7861				
Mr. John Martin -	Manager, Demonstration Program - (513) 569-7696				
Ms. Norma Lewis -	Manager, Emerging Technologies Program - (513) 569- 7665				
Mr. J. Larry Jack -	Manager, Monitoring and Measurement Technologies Program - (702) 798-2373				

3) <u>The Hazardous Substance Research Centers</u>: this Program was discussed in section IV of this report and Center contacts were listed. Through telephone conversations with the technology transfer personnel, there appears to be a great interest in the research being conducted within this Program. The HSRCs are very willing to set up collaborative research efforts and establish field-testing at sites they are using. The EPA coordinator is listed below.

Mr. Dale Manty - EPA Office of Exploratory Research - (202) 260-7445

4) The Center for Environmental Research Information: this Center serves as the clearinghouse for reports and documents generated within the EPA.

Mr. Cal Lawrence - Director, CERI - (513) 569-7391

The Federal Laboratory Consortium for Technology Transfer: this Center provides an invaluable resource of networking within the technology transfer field. Authorized under the FTTA of 1986, the FLC provides contacts for all types of research at all Federal laboratories as well as non-profit and private organizations. The FLC locator can find potential collaborators for all types of research within a short time.

Dr. Beverly Berger -	Washington, DC Representative, FLC - (202) 331-4220
Dr. Andrew Cohen -	Manager, FLC Locator - (206) 683-1005

The National Technology Transfer Center: this non-profit research coordination Center will also provide a valuable resource to connect grantees with potential research collaborators.

Mr. Lee Rivers -	Center Director - (304) 243-2455
Mr. Joe Allen -	Assistant Director - (304) 243-2455

The United States Army: The military reportedly has a massive research and development budget for hazardous waste clean-up and research. Most of this is funneled through the Army Corps of Engineers. Because of the Corps of Engineers, the Army has the lead in environmental clean-up for all service branches. Dr. Valdes, listed below, is very interested in developing collaborative research efforts from both biomedical and non-biomedical disciplines.

Dr. James J. Valdes -	Scientific Advisor for Biotechnology, U.S. Army - (301) 671-3317
Dr. Doug Gunnison -	Scientist, Corps of Engineers, Bioremediation - (601) 634- 3873
Dr. John Cullinane -	Scientists, Corps of Engineers, Bioremediation - (601) 634- 3873

The United States Department of Energy: DOE is actively pursuing innovative technologies to clean-up existing DOE waste sites. They have implemented a "30-year Plan" which is directed towards cleaning all of these sites within 30 years. The development of environmental technologies through collaborative efforts is their main strategy and they seem very willing to accept technology input from all sources. DOE sponsored Laboratories will be mentioned separately.

Dr. Clyde Frank -	Deputy Assistant Director for Technology Development, DOE - (202) 586-6382
Mr. Melvin W. Shupe -	Director, Environmental Restoration R&D Division-(202) 903-7915

U.S. Department of Commerce: this Department can provide insight to commercialization of technologies. They have a long history of working with private industry which could provide valuable experience.

Mr. Jon Paugh -

Acting Director, Office of Technology Commercialization -(202) 486-6101

National Institute of Standards and Technology: This Institute also has a long history of cooperating with private industry and could provide valuable experience about commercializing technologies.

Dr. Hratch Semerjian - Director, Chemical Science and Technology Laboratory -(301) 975-3145

<u>Argonne National Laboratory</u>: All of the National Laboratories listed below are potential research collaborators. These organizations have many hazardous waste sites which need to be remediated. Technology Directors at the Laboratories are very interested in innovative technologies to remediate these sites.

Dr. Norman Sather - Director, Energy Systems Division - (708) 252-3724

Battelle-Pacific Northwest National Laboratory:

Mr. Steven Stein -

Deputy General Manager, Battelle Environmental Management Operations - (206) 528-3302



Idaho National Engineering Laboratory:

Dr. Paul Wichlacz -	Deputy	Manager,	Waste	Technologies	Development
	Departm	ient - (208)	526-1292		
Mr. Richard Hitt, Jr		Manager, ion - (208)			d Technology

Lawrence Livermore National Laboratory:

Mr. Gibert Marguth, Jr	Program Leader, Technology Transfer Initiatives Program - (510) 422-6416					
Ms. Ann Heywood -	Program Leader, Environmental Restoration and Waste Management - (510) 422-8203					

Los Alomos National Laboratory:

Dr. James Shipley -	Director, Applied Environmental Technologies - (505) 667-
	2211
Dr. Kay Adams -	Director, Industrial Partnership Center - (505) 665-9090

Oak Ridge National Laboratory:

Dr. Anthony Malinauskas-	Director,	Waste R&D	Programs -	(615)	576-1092
				·/	

Sandia National Laboratory:

Mr. Olen Thompson - Program Manager, Technology Transfer Applications Program Office - (505) 845-9407