Presidential Memorandum -- Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses

U.S. Environmental Protection Agency

Report prepared by:

U.S. Environmental Protection Agency, Office of Research and Development

Pursuant to the
Presidential Memorandum -- Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses, October 28, 2011

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EXECUTIVE SUMMARY

This report is in response to the Presidential Memorandum of October 28, 2011 directing agencies with federal laboratories to improve the results from their technology transfer and commercialization activities.

This report presents information on EPA's current technology programs, as well as a five-year plan for enhancing the effectiveness of these programs. The report establishes goals to increase the number and pace of effective technology transfer and commercialization activities, describes steps to streamline the collaborative research and licensing process, and highlights efforts to increase the interactions between technology transfer efforts within the Agency.

The Environmental Protection Agency (EPA) has a strong record of successful technology transfer that benefits human health, the environment, and the economy. The Federal Technology Transfer Act (FTTA) Program moves EPA-generated technology and techniques to the market and broadens the scope of EPA's research by leveraging partner research resources. These public-private collaborations can greatly increase research capacity and yield better research products.

This leveraging of private funding and external research efforts means that Agency researchers are involved in more mission-related research than would be possible absent the program. These collaborations with outside parties are also a key way for EPA scientists to collaborate with external science partners and transfer the Agency's expertise to environmental applications. Successful transfer of EPA developed technologies to the market is also evidenced through EPA licensed innovations.

EPA's FTTA Program promotes collaboration between private and federal researchers to develop and commercialize new technologies. The Federal Technology Transfer Act provides mandates and guidelines for EPA's FTTA program, and several offices and laboratories across the Agency are invested in EPA technology transfer efforts.

I. TECHNOLOGY TRANSFER AT EPA

Technology transfer is the promotion of collaboration between private and federal researchers to enhance the quality of research projects and move environmental technologies into the marketplace. Technology transfer fosters the commercialization of government funded discoveries resulting from federal laboratory research and collaborative projects with external researchers. These collaborations also serve to advance laboratory missions. Through technology transfer programs and offices, federal laboratories continually reach out to industry, academic institutions, foundations, state and local governments, and international institutions. External collaborations and partnerships with these groups leverage federal research and development (R&D) can also contribute to the economic competitiveness of the United States.

Technology transfer activities at EPA include the Federal Technology Transfer Act (FTTA) program, conducted in accordance with the FTTA of 1986 and associated legislation. EPA is enhancing research collaborations and commercialization of EPA developed technologies with regional economic sectors through a new geographic cluster initiative. EPA also fosters innovation through open innovation challenges for which we disseminate environmental problems and award small prizes for solutions, as well as solicit innovative research proposals from within EPA. EPA supports small business innovation in the environmental arena through annual small business innovative research (SBIR) awards.

These technology transfer efforts support EPA's mission of protecting human health and the environment by enhancing the quality of research through collaboration with external parties, helping to move environmental technologies into the marketplace expediently, providing opportunities and economic incentives to businesses for development of commercially viable environmental solutions.

II. EPA's CURRENT TECHNOLOGY TRANSFER EFFORTS

A. Collaborative Partnerships

EPA facilitates the transfer of its technology through partnerships with other government agencies, industry, academia, and other organizations with the overarching goal of generating U.S. commercial activity and contributing to the growth of the American economy.

A Cooperative Research and Development Agreement (CRADA) is the main vehicle for enabling these partnerships. It is often used to create a relationship between a federal agency and one or more outside partners to provide mutually advantageous leveraging of each partner's resources and technical capabilities and an opportunity for partners to expand their competencies and skills. In some cases a Materials CRADA is used when there is a minimal amount of collaborative research and an exchange of research materials is desired. When an exchange of research materials is desired with no collaboration, then a Materials Transfer Agreement (MTA) is used.

EPA also fosters collaborative partnerships and efforts worldwide. EPA actively seeks partnerships, collaboration, and cooperative activities to develop technology with dual purposes: to enable EPA to meet its mission needs and to contribute to the Nation's commercial competitiveness in global markets.

B. Licensing Patents

Licensing provides one of the chief commercialization mechanisms to create incentives for industry to further develop leading edge technologies that will be put to use contributing to environmental protection, economic growth, and competitiveness.

EPA patented technologies are available for licensing by outside parties. EPA licenses technologies primarily non-exclusively, although it does have some exclusive licenses on technologies which were co-developed with a licensee or with a CRADA partner, or in cases

where the opportunity to exclusively license a technology has been advertised through a public notice, as required by 35 USC 209. EPA typically receives royalties on its licenses.

C. Small Business Innovative Research (SBIR)

EPA is one of 11 federal agencies that participate in the SBIR Program established by the Small Business Innovation Development Act of 1982. The SBIR Program supports the development and commercialization of innovative technologies needed by the EPA to meet its mission of protecting human health and the environment. EPA issues annual solicitations for Phase I and Phase II research proposals from science and technology-based small businesses.

The SBIR staff solicits internal input into the solicitation categories annually in an effort to align SBIR awards with EPA needs and priority areas.

D. Environmental Technology Innovation Clusters

EPA is leveraging its research and development capability and Agency science, policy and technology programs and physical/intellectual assets to catalyze the creation of environmental technology innovation clusters through deliberate public-private partnerships. The goal of this effort is to advance environmental protection and create regional economic opportunity in tandem.

In 2010, EPA and the U.S. Small Business Administration joined forces to work with community leaders in the Cincinnati-Dayton, Ohio, Northern Kentucky and southeast Indiana region to explore the possibility of creating an environmental technology innovation cluster focused initially on commercialization of water technologies. The Federal government has supported water research and water technology development in Cincinnati for a century and has substantial research facilities and federal scientists located there. The Cincinnati regional Water Technology Innovation Cluster (WTIC) was officially launched in January of 2011 and consists of a network of small and large businesses, business incubators, investors, water utilities, manufacturers, technology developers, researchers and many others all focused on commercialization of water technologies. In its first year, the WTIC has hosted meetings to organize potential applicants to the Agency's SBIR program, assisted a number of small businesses and partnered with the WTIC on a number of events including a Water Challenges workshop. New CRADAs with regional businesses have been established.

The Agency is exploring technology commercialization/policy concepts with stakeholders in the Southern New England region, where EPA has a research Division, as part of a regional coastal water restoration and protection initiative. As EPA's work onSouthern New England Estuaries, it was recommended that the Agency convene and lead a comprehensive regional policy coordination and outreach effort to protect, enhance, and restore the coastal watersheds of southern New England. EPA will share cluster knowledge and experience and participate in on-going activities.

The Agency has also partnered with the U.S. Department of Commerce through the Economic Development Administration and other Federal Agencies in the i6 Green Challenge to support the following economic development partnerships:

-Ames, Iowa: Iowa Innovation Network i6 Green Project
-Holland, Michigan: Proof of Concept Center for Green Chemistry Scale-up
-New England: iGreen New England Partnership
-Orlando, Florida: Igniting Innovation (I2) Cleantech Acceleration Network
-Ruston, Louisiana: Louisiana Tech Proof of Concept Center
-Washington State: Washington Clean Energy Partnership Project

E. "Technology Innovation for Environmental and Economic Progress: An EPA Roadmap."

In 2011, EPA developed a document entitled, "Technology Innovation for Environmental and Economic Progress: An EPA Roadmap." In this document, EPA presents a vision for technology innovation in which EPA promotes innovation that eliminates or significantly reduces the use of toxic substances and exposure to pollutants in the environment and that also promotes growth of the American economy. The Agency seeks out prospective technological advances that have the greatest potential to help achieve multiple environmental goals. Working in partnership with EPA's diverse set of stakeholders, the Agency aims to speed the design, development and deployment of the next generation of environmental technologies.

F. Use of Challenges and Prizes

EPA's Open innovation challenges tap into the vast expertise that exists beyond the boundaries of a single organization. Congress recently passed legislation (P.L. 111-358, The America COMPETES Reauthorization Act of 2010) that authorizes the use of prizes and challenges across the federal government to spur innovation, solve tough problems, and advance core missions through a process like open innovation. Over the next year, EPA will use its prize and challenge authority to attract innovative solutions, from both the public and its own employees, to high-priority environmental protection needs. These challenges will be posted online to the public in the hope that solutions can be developed by external parties.

Scientists and engineers across EPA were invited to submit proposals for Pathfinder Innovation Projects - research projects that exemplify innovative, collaborative approaches for advancing sustainable solutions. Twelve Pathfinder awards were announced out of a total of 117 proposals that were submitted to the EPA Innovation Team in its first year (2011). Three external panels of experts were enlisted to review submissions. The proposals selected to advance as Pathfinder projects illustrate exactly the kind of diversity and creativity the Innovation Team was looking for when it called for the rapid development of a new kind of research proposal.

Lead investigators on the selected projects range from experienced, senior EPA scientists to post-doctoral researchers; a number of the projects involve collaborations across EPA

laboratories. Technologies that will be employed during the research phase of the projects range from hyperspectral imaging on the International Space Station to innovative biological treatment of drinking water contaminants. One project will explore the design of nanomaterials to facilitate their eventual decomposition in the environment, while other projects will apply cutting-edge genomics to assessment of chemical mixtures and of bacteria in water distribution systems.

G. User Facilities

In recognition of the breadth and complexity of the research challenges posed by environmental issues, the EPA offers a more collaborative business model for conducting environmental research. With its valuable and highly specialized research facilities located in laboratories and research centers across the country, EPA aims to foster research partnerships with outside entities interested in addressing environmental issues by sharing research facilities and equipment through User Facility Agreements. EPA can serve as a catalyst for progress in efforts to identify, understand, and solve current and future environmental problems. User Facility Agreements allow external parties to utilize EPA's laboratories for their own research projects, so far as they align with the mission of the individual laboratory.

H. Dissemination of Research Results

EPA scientists present the results of their research all over the world through professional conferences, and publication in scientific journals. This research encompasses all aspects of EPA's regulatory and programmatic activities. Additionally, EPA develops environmental modeling tools and software programs.

III. TECH TRANSFER IN SUPPORT OF EPA'S MISSION

EPA's collaborative technology transfer efforts have helped move environmental technologies into the marketplace more quickly. This section touches on the Administrator's priorities by highlighting some examples of innovative EPA technologies developed and/or transferred through the FTTA Program. Other successful technology transfer efforts by laboratories and offices from across the Agency are summarized in Appendix B.

Taking Action on Climate Change

EPA scientists in the Office of Air and Radiation's National Vehicle and Fuel Emissions Laboratory have developed and patented an inventive and highly efficient full-series hydraulic hybrid vehicle powertrain and collaborated with external cooperators to install hybrid technology in SUVs and utility service vehicles.

Improving Air Quality

A technology developed by researchers at EPA identifies molds in homes, schools, and businesses, leading to faster analysis of illnesses associated with mold exposure. EPA's patented DNA-based process can identify and quantify more than 130 species of toxic molds and

potentially pathogenic fungi in the environment. The technology is licensed widely in the U.S. and internationally.

Assuring the Safety of Chemicals

ToxCast is a major program developed by EPA scientists as a cost-effective approach for prioritizing a large number of chemicals for toxicity testing in a short period of time. ToxCast aims to evaluate the use of in vitro assays for understanding the types of molecular and pathway perturbations caused by environmental chemicals and to build initial prioritization models of in vivo toxicity. EPA continues to expand the program with data sharing with organizations outside the Agency.

Cleaning Up Our Communities

EPA has developed a new material that can quickly, efficiently, and economically strip mercury and arsenic from industrial wastewater streams. Technology developed in the laboratory was licensed out to manufacture a product that is sold to refineries, chemical manufacturers, power plants, mining companies and other industries.

Protecting America's Waters

EPA has several efforts underway involving rapid detection of water contamination through research at EPA's National Homeland Security Research Center. Additionally, EPA's Cincinnati regional Water Technology Innovation Cluster is focused on commercialization of water technologies.

Expanding the Conversation on Environmentalism and Working for Environmental Justice

EPA has teamed up with dozens of small, economically-challenged water utilities throughout the country to conduct performance evaluation studies on over 15 different, commercially available, full scale arsenic treatment technologies, to assist in compliance with the arsenic drinking water standard.

Building Strong State and Tribal Partnerships

The Lane Regional Air Pollution Authority collaborated with scientists in EPA Region 10 to develop and patent a portable controlled air sampler that has since been incorporated into a range of monitoring efforts. This inexpensive, low-volume sampler has been used world-wide.

IV. TECHNOLOGY TRANSFER GOALS, OBJECTIVES, AND METRICS

EPA's technology transfer goal: To spur the development of cutting-edge environmental technology and to move it quickly and efficiently into widespread public use.

EPA's technology transfer objectives:

- Partnerships with external organizations on research projects to enhance the breadth and effectiveness of EPA technology development

- Effectively moving EPA developed technologies and expertise into the marketplace
- Leveraging innovative partnerships with other agencies on technology transfer for the purposes of collectively marketing government-owned technologies, establishing cooperative research projects with small businesses, and pooling our efforts for outreach to local business communities
- Engaging scientists in intellectual property protection and technology transfer at all stages of research

EPA's Current Technology Transfer Metrics

EPA uses technology transfer metrics that have been established by the Interagency Working Group on Technology Transfer for the annual report to Congress on Technology Transfer as codified at 15 USC 3710 (f). These metrics include:

A. Cooperative Research and Development Agreements (CRADAs) – traditional (CRADAs) and non-traditional (Materials CRADAs and Materials Transfer Agreements, which involve little or no collaboration respectively, but which entail an exchange of research materials).
    a. Total active in the fiscal year
    b. New, executed in the fiscal year
B. Invention disclosures and patenting
    a. New inventions disclosed in the fiscal year
    b. Patent applications filed in the fiscal year
    c. Patents issued in the fiscal year
C. Licensing (exclusive, non-exclusive, partially-exclusive)
    a. Total active in the fiscal year
    b. New, executed in the fiscal year
    c. Income bearing and non-income bearing
D. Licensing management
    a. Number of invention licenses active in the fiscal year
    b. New invention licenses, executed in the fiscal year
    c. Elapsed execution time for licenses executed in the fiscal year (average, minimum, maximum)
E. License income
    a. Total income, all invention licenses active in the fiscal year
    b. Total earned royalty income
        i. Median earned royalty income
        ii. Minimum earned royalty income
        iii. Maximum earned royalty income
        iv. Earned royalty income from top 1% of licenses
        v. Earned royalty income from top 5% of licenses
        vi. Earned royalty income from top 20% of licenses
F. Disposition of invention license income
    a. Distributed to inventors
    b. Distributed to others
G. Technology transfer highlights

The EPA FTTA Program's Proposed Metrics Structure

The proposed metrics are for the EPA FTTA program. The Agency proposes to structure the FTTA technology transfer measurement system to reflect the various definitions and metrics of technology transfer used across all Federal agencies to the extent possible. These metrics should provide information to help guide policy and operational decisions. They will be more fully developed to provide context and a basis for greater interpretation and analysis of outcomes and impacts, rather than quantitative numbers of outputs. The new metrics structure was proposed by the Interagency Working Group on Technology Transfer (IAWGTT).

1) **New Technology and Scientific Work Products**
   a) Intellectual Property including:
      (1) The number of invention disclosures prepared;
      (2) The number of patent applications filed;
      (3) The number of patents received;
      (4) The number of licenses fully-executed
         (a) royalty-bearing licenses categorized by whether they are exclusive, partially-exclusive, or non-exclusive
         (b) research licenses and other IP licenses (new and total active)
      (5) License income will be reported for intellectual property including
         (a) Breakout of earned royalties by laboratory and inventor
         (b) Other IP royalties (e.g. up front fees)
      (6) New metric of the number of licenses granted to small businesses[1]
      (7) New metric of the number of startups[2] created:
         (a) collection of data on interactions with startups;
         (b) and to develop a process to track the performance of agency-assisted companies.
      (8) Number of patents granted categorized by selected technology areas

   b) **Scientific Articles and Publications.** EPA will report on the number of scientific and engineering articles published annually as a result of the FTTA program by collecting this information through EPA's Science Inventory system (epe.gov/si). The number of citations of articles related specifically to FTTA cannot be provided, however, the Web of Science database does list articles that are deemed "high impact"

      Future Metric - The number of software programs available for download developed by Agency and the number of software programs downloaded per fiscal year by Agency. The number of software programs developed by the agency for public download is not currently a metric that EPA tracks.We will initiate a new metric in the FTTA database that will capture the number of software programs

[1] For the purpose of this report, a small business is a, privately-held, U.S., for-profit company that is not dominant in its field of operation and qualifies as a small business concern under Title 13, Code of Federal Regulations, part 121 (13 CFR 121)

[2] For the purpose of this report, a startup company is a privately-held, for-profit company operating for less than 5 years and actively seeking financing to commercialize a federal scientific work product.

developed and available for public download under future FTTA agreements. It is estimated that this enhanced feature will be available October 1, 2014.

2) **Collaborations – Public/Private Partnerships for Research and Development**
   a) **Cooperative Research and Development Agreements (CRADAs) and Other Collaborations – CRADAs** remain an important tool for collaboration between federal laboratories and other organizations and an important way to gauge cooperation. Each agency is required to maintain a record of CRADAs (15 USC 3710a(c)(5)(D))and these have been traditionally reported in the annual interagency summary report.
      i) Traditional output metrics to be retained are:
         (1) Total active CRADAs
         (2) New CRADAs executed in the fiscal year
         (3) Non-traditional CRADAs active in the fiscal year i**n**cluding Material Transfer Agreements and other important collaborations as deemed relevant by the agency
         (4) Anecdotal information on the nature, character, and successes of collaborative relationships.
      ii) In addition to existing metrics reported, the new metric of the number of CRADAs and other collaborations involving small businesses will be tracked in the FTTA database following the parameters as defined by NIST. It is estimated that this enhanced feature will be available October 1, 2014.

3) **Process Metrics – Measures of Efficiency**
   a) The amount of time that elapses from the date on which a license was requested by a licensee in writing to the date the license was executed.
   b) The amount of time that elapses from the date on which a CRADA/collaboration was requested in writing to the date the license was executed.
   c) Narrative Description providing an annual summary on the progress of streamlining administrative processes and highlights.

4) **Impact Analysis**
   a)

EPA is participating in OSTP's STAR METRICS effort. Under this effort, we are working with NIH, NSF, and other agencies to better assess the impact federal science investments have on employment, knowledge generation, and health outcomes.

V. TECHNOLOGY TRANSFER DEVELOPMENT PLAN

Areas for enhancing technology transfer effectiveness:

A. Increase training to inform a greater percentage of EPA staff about technology transfer opportunities and responsibilities associated with protecting intellectual property, which will lead to an increase in the number of employee reports of invention and CRADA projects.
   a. Provide training to regional offices and laboratories.
   b. Provide training to EPA staff around the country utilizing virtual tools, such as videoconferencing and webinars.
   c. Incorporate a section on protection of intellectual property into EPA's annual ethics training, which all EPA staff must take.

B. Enhance internal database tracking system for the FTTA program
    a. An improved database, which is currently in development , will allow for improved tracking on CRADA and license funding, and an improved status tracking system for pending and active FTTA agreements. This is anticipated to be operational by October 31, 2012.
    b. An improved database will make the internal review process for CRADAs, licenses and non-disclosure agreements more efficient, thereby reducing the average time it takes to get agreements in place. In FY11 the average time to get a CRADA (including MCRADAs and MTAs) in place was 3.5 months. We anticipate enhanced efficiency of the internal review process with the revised database through improved tracking and immediate access to information regarding specific review steps. We also anticipate a reduction in overall review time by ~20%, down to an average of 3 months by 2015.
C. Joint efforts with other agencies to work on regional outreach to small businesses who could benefit from collaborative research projects with EPA or who may have an interest in licensing EPA patented technologies for their business portfolios.
D. Investigate options for coordinating patent bundling or other outreach opportunities with other government agency technology transfer programs.
E. Over the next two years, the Agency will continue to support on-going innovation cluster efforts, will form stronger partnerships with other Federal Agencies at the regional and national level to promote transfer of technologies from its laboratories to the private sector, will develop platforms for sharing of best practices and develop methods for leveraging of assets across environmental technology clusters.
F. EPA's strategy for implementing the Technology Roadmap vision includes ongoing support from internal organizations, which will commit to a portfolio of policy, regulatory, financial, and other actions that, taken together, will institutionalize and promote technology innovation along the entire continuum of technology development and deployment. Working with both internal and external partners, all functional units of the Agency will seek tangible, outcome-oriented opportunities to catalyze and support technology innovation across the range of the Agency's work.
G. Increase the number of innovative challenges posted online in search of solutions to EPA identified problem areas.
H. EPA's FTTA program will work to identify potential internal partnerships with other EPA technology transfer programs. One potential example would be the EPA SBIR Program where discussions have been held identifying possible inclusion of EPA patents into SBIR solicitations. However continued budget cuts have not allowed for expansion of the parameters of the current SBIR program.
I. EPA will retain the current policy for sharing patent licensing revenue with inventors of 35% of royalties rather than the statutory minimum of 15%.

VI. TIMELINES, MILESTONES, AND DEPLOYMENT OF NEW INITIATIVES

Training is an ongoing goal. In 2012, EPA staff have focused on reaching out to regional offices to educate them on protecting intellectual property and mechanisms for engaging in collaborative research with external parties. In the first quarter of 2012, EPA staff have provided training courses in five different locations nationwide. Working to utilize virtual communication tools such as video-conferences and webinars will be a goal of the FTTA staff for expanding the reach of its training program throughout the Agency over the next several years. As travel and funding allow, FTTA staff will continue to provide in-person training throughout the EPA laboratory system. The FTTA program has a goal of increasing the percentage of EPA staff trained in technology transfer mechanisms and protection of intellectual property by 30% (over FY11, during which 90 EPA staff were trained) by the end of 2015. The FTTA staff are working with the Agency's ethics official to incorporate information on protecting intellectual property into the required annual ethics training course for all staff. It is anticipated that this will be completed by the end of 2012.

The FTTA staff anticipate having a fully functional database system for tracking agreements by the end of 2012. This system will improve the effectiveness of budgetary reporting, trends analysis, and identification of laboratory successes over the next five years. The FTTA staff will work with EPA lab budget staff to provide training on handling of incoming FTTA funds associated with CRADAs and licenses, including dispersion of royalties. This is anticipated to occur in 2012 and 2013. The database will allow for redundancy in tracking of incoming FTTA funds to help ensure that payments are dispersed to the appropriate laboratories, offices, and individuals expediently.

The EPA innovation cluster effort is currently underway. It is anticipated that in the next two years the Agency will continue to support on-going innovation cluster efforts, will form stronger partnerships with other Federal Agencies at the regional and national level to promote transfer of technologies from its laboratories to the private sector, will develop platforms for sharing of best practices and develop methods for leveraging of assets across environmental technology clusters.

By 2013, FTTA staff anticipate having efforts underway with other Federal Agencies to coordinate on the marketing of complementary patents and working together to reach out to small businesses on collaborative opportunities with government laboratories. EPA is also participating on a workgroup to develop an innovation marketplace event in Denver, CO in May 2013 to showcase EPA (and other participating agencies') technologies available for licensing in the sectors of clean energy and water treatment. Additionally, EPA is engaging in discussions with USDA in hopes of jointly marketing similar patents to external parties. It is anticipated that these discussions will continue and the EPA is hopeful that within the next five years that these efforts and perhaps other, similar efforts will result in the development of a number of cooperative research opportunities with small businesses, and the licensing of several of EPA owned patented technologies.

APPENDICES

Appendix A: Summary of Federal Technology Transfer Legislation

Appendix B: EPA Technology Transfer Highlights

Appendix A: Summary of Federal Technology Transfer Legislation

Since 1980, Congress has enacted a series of laws to promote the use of federally-developed technologies and to provide technology transfer mechanisms and incentives. Technology transfer (T2) legislation provides for activities that are the basis of federal T2 programs and includes licensing government patents; Cooperative Research and Development Agreements (CRADAs) establishing partnerships between Federal laboratories and public and private entities; cooperative agreements; grants; and consortia or regional alliances. The intent of T2 legislation and related Executive Orders is to encourage collaboration that pools resources and expertise when developing potential commercial technologies (FLC 2006). The following list is a summary of the major technology transfer laws that provide the foundation and authority for EPA's technology transfer program (FLC 2006):

The *Stevenson-Wydler Technology Innovation Act of 1980* is the first in the series of laws that define and promote federal technology transfer activities. The Act made it easier for federal laboratories to transfer technologies to non-federal parties and provides a means for outside organizations to access laboratory developments. The law requires laboratories to take an active role in technical cooperation, establishing an Office of Research and Technology Applications (ORTA) in each federal laboratory to coordinate and promote technology transfer. The law also requires that agencies set aside separate funding to support technology transfer including support for the ORTA office.

Bayh-Dole Act of 1980 (P.L. 96-517) – Amended Stevenson-Wydler Technology Innovation Act, focusing on the use of intellectual property (i.e., patents and licenses) to implement technology transfer by allowing small businesses, universities, and not-for-profit organizations to obtain title to inventions developed by them under federal funding agreements.

Federal Technology Transfer Act of 1986 (P.L. 99502) – Second major piece of technology transfer legislation focusing directly on technology transfer; established the Federal Laboratory Consortium and enabled federal laboratories to enter into Cooperative Research and Development Agreements (CRADAs) and to negotiate licenses for patented inventions made at the laboratory.

National Technology Transfer and Advancement Act of 1995 (P.L. 104-113) – NTAA amended Stevenson-Wydler to make CRADAs more attractive to federal laboratories/scientists and private industry.

Technology Transfer Commercialization Act of 2000 (P.L. 106-404)1 - Amended the Stevenson-Wydler Act to:

- Empower federal agencies to terminate licenses when licensees do not achieve practical application of inventions within a reasonable time,
- Require public comment before granting exclusive or partially exclusive licenses,
- Authorize partnership intermediaries to promote cooperation with universities,
- Require agencies to report annually on technology transfer activities, and
- Require Reports to Congress every five years on the effectiveness of Federal Technology Transfer Programs.

Appendix B: EPA Technology Transfer Highlights by EPA Laboratory

Cooperative Research and Development Agreements (CRADAs) and licenses combine government knowledge, skills, and research with business marketing and manufacturing abilities to develop and commercialize new environmental technologies. Without this important collaboration, these technologies might never reach the marketplace and achieve the intended environmental outcome. The Agency's Federal Technology Transfer Act (FTTA) Program has been successful in this regard as demonstrated in the following examples of technology transfer.

National Exposure Research Laboratory (NERL)

The Office of Research and Development's NERL laboratory developed an improved drinking water method, MI Medium, that (1) simultaneously detects both total coliforms and Escherichia coli in drinking water (and other types of water samples, as well), (2) simplifies compliance monitoring, and (3) eliminates the need for repeat or serial analyses and membrane filter transfers. More importantly, by decreasing the delay in the detection of fecally contaminated drinking water, this method can provide the public with better protection from unsafe water and potential waterborne illness. The method (EPA Method 1604) is now approved by EPA for use under the Total Coliform Rule, Surface Water Treatment Rule, Ambient Water Rule, Ground Water Rule, and Long Term 2 Enhanced Surface Water Treatment Rule. Our licensees helped bring the MI method to the market, so it could be used under all of these regulations. Both the NERL laboratory and its licensees have benefited in many ways from the licensing arrangement.

National Center for Computational Toxicology (NCCT)

ToxCast™ is a major program developed by NCCT scientists as a cost-effective approach for prioritizing the toxicity testing of large numbers of chemicals in a short period of time. Using data from state-of-the-art high-throughput screening bioassays developed in the pharmaceutical industry, ToxCast™ is building computational models to forecast the potential human toxicity of chemicals. These hazard predictions will provide EPA regulatory programs with science-based information helpful in prioritizing chemicals for more detailed toxicological evaluations and lead to more efficient use of animal testing.

In 2007, NCCT announced collaborative opportunities for facilitating and expanding the development of ToxCast™ through the Agency's FTTA Program. Thus far, NCCT has executed more than 20 Materials Transfer Agreements which are expanding the high-throughput bioassay data results available on more than 300 chemicals in Phase 1 of the ToxCast™ program. All of these data will be used to derive predictive signatures based on the known toxicity of the 300 chemicals, which are primarily pesticide active ingredients that have been extensively evaluated using traditional toxicity testing. The partnerships include many private sector companies (e.g. CellzDirect, Gene Logic, Invitrogen), academic institutions (Princeton University, UNC, MIT, Michigan State University) and several international entities (BASF, MaxPlanck Institute and the National Institutes for Public Health and the Environment of The Netherlands).

The second phase of ToxCast™ will screen additional compounds representing broader chemical structure and use classes, in order to evaluate the predictive bioactivity signatures developed in

Phase 1. Most recently, NCCT has signed a CRADA with L'Oreal to provide funds for running an additional 20 chemicals (of interest to both parties) through the Phase 2 ToxCast™ assays, as well as funding a pre and post doc researcher in support of this effort.

National Health and Environmental Effects Research Laboratory (NHEERL)

NHEERL expects to continue and broaden its collaborative efforts in all arenas; federal to federal, federal to state and, federal to public. In recent times, three NHEERL scientific groups have been awarded patents for technologies and processes that were developed in the course of performing cutting edge research on environmental problems. The patents address reproductive fertility, measurement of soft tissue responses, and electromagnetic therapy. The benefits to industry arise from the development of more sensitive or novel approaches to technologies that detect and evaluate the effects of toxic agents in laboratory experiments or in the environment. Two of the groups have CRADAs in place demonstrating the interest of industry and medicine in the patents.

EPA scientists have identified a sperm protein, SP-22, that can be used in applications to evaluate, inhibit or enhance male fertility. (The use of the SP-22 gene in research and diagnostics is the subject of several issued patents and pending applications.) The applications of this protein are wide ranging and include screening for exposure to toxic pollutants, improved selection processes for animal breeding, new methods of contraception, and male fertility treatments. The invention has been tested successfully in rats, rabbits, stallions, bulls and humans and has demonstrated a proof of concept. Specifically, this invention has the potential to:

- Provide a means for predicting male fertility in animals and humans.
- Screen animals and humans for exposure to suspected endocrine disruptors for fertility.
- Select sires that are good candidates for providing sperm for artificial insemination.
- Screen human semen for fertility to improve the success of assisted reproductive techniques.
- Improve fertility in males who fail to express a sufficient amount of SP-22, formerly known as SP-16, in sperm.
- Provide a reversible male contraceptive.

National Homeland Security Research Center (NHSRC)

In collaboration with the staff of the Idaho National Laboratory (INL) in Idaho Falls, Idaho, NHSRC scientists have developed a sophisticated device for concentrating water samples for the purpose of measuring the concentration of harmful pathogenic organisms in drinking water. Traditional methods for measuring microorganisms in water require collecting a 1000 liter water sample. Sample handling, transportation, and preparation are extremely difficult, expensive, and time consuming. The collaboration between NHSRC and INL resulted in the development of a portable water concentration device that utilizes ultrafiltration membranes to concentrate water samples at the point of collection. This invention has a patent pending and there are a number of technology developers interested in commercializing the device. The FTTA Program facilitated the Inter-Institutional Agreement between EPA and INL. The program also expeditiously moved four Non-Disclosure Agreements through the system so that the EPA scientists could discuss the invention with interested technology developers.

NHSRC scientists and engineers have been actively exploring new or alternative approaches for expediting the Agency's response to intentional or accidental releases of hazardous chemicals and biological organisms. The Center has submitted Employee Report of Invention for two possible patentable inventions.

The Center is routinely approached by technology vendors who are exploring ways they can adapt existing technology to meeting the nation's homeland security mission. The staff of the Decontamination and Consequence Management Division has been on the cutting edge of development of new and better ways to clean up facilities that have become contaminated with chemical, biological, and radiological materials. The Center has signed a Material Transfer Agreement with a biological decontamination technology vendor, making a piece of equipment available to the DCMD staff for testing and development of alternative methods for use of the device.

Microbiologists in the Water Infrastructure Protection Division have been researching alternatives for disinfecting drinking water that is contaminated with pathogenic microorganisms. WIPD recently signed a Material Transfer Agreement with the Centers for Disease Control and Prevention to obtain isolates of a microorganism for use in evaluating alternative methods of disinfection.

NHSRC has been and will continue to utilize the various collaborative mechanisms available through the Agency's FTTA Program. There are opportunities for NHSRC to enter into collaborative projects with other Federal agencies and departments that are actively engaged in homeland security research.

National Risk Management Research Laboratory (NRMRL)

Electrostatic Enhanced Fabric Filter (ESFF) License

Fabric Filter systems are commonly used to control particulate matter in the exhaust of power plants and other combustion processes. The Air Pollution Prevention and Control Division developed and patented the ESFF technology as a part of its R&D program to enhance the control of fine particulate matter (FPM). The ESFF incorporates a mechanism for electrostatically charging the particulate matter and the filter bags in a matter to significantly increase the collection efficiency while reducing the pressure drop across the bags. The technology was licensed to GE Energy Systems Division in 2003 and provided a 3 year royalty free commercialization period. In the last two years, the technology has been applied to 5 utility and industrial boilers. GE anticipates significant commercialization opportunities in the coming years as the requirements for FPM controls increase.

CRADA for Chlorine Dioxide Fumigation for Mold Remediation

Chlorine dioxide fumigation was used extensively for remediation of Bacillus anthracis contamination on 4 large buildings following the passage of the "anthrax letters: through the U.S. Postal System facilities. The vendor, Sabre Technical Services LLC, subsequently improved the systems for conducting the fumigation and obtained state level registrations under the FIFRA. Following the extensive mold contamination resulting from water damage associated with

hurricanes Katrina and Rita, Sabre fumigated over 200 buildings of all sizes from residences to large office buildings. They then proposed entering into a CRADA with NRMRL's Air Pollution Prevention and Control Division to conduct a systematic laboratory and field testing program which could generate data leading to a full FIFRA registration. The CRADA is being conducted in collaboration with the NHSRC's DCMD using their in house fumigation facility. The program is being coordinated with the Office of Pesticides Programs, which also provides funding, and the Office of Radiation and Indoor Air Quality. The results to date confirm the efficacy of the technology for remediating mold growth on typical indoor surfaces.

The Office of Air and Radiation, Office of Transportation and Air Quality

In April 2009, EPA and its industry partners offered a preview of a leading edge, pollution-saving truck for transferring cargo containers at the Society of Automotive Engineers World congress in Detroit, Michigan.

The special cargo mover, called a series hydraulic hybrid yard hostler, moved from the exhibition into field testing at port terminals in the United States.

EPA and its partners have applied EPA's patented series hydraulic hybrid vehicle (HHV) technology to the heavy-duty truck as part of the EPA National Clean Diesel Campaign's Clean Ports USA program.

Hostlers are large, off-road vehicles used to transfer cargo containers at marine ports, rail yards, warehouses and distribution centers. The trucks spend about half of their time idling and contribute to air pollution generated in ports throughout the world.

EPA's unique series HHV power train efficiently recovers, stores and reuses braking power while significantly reducing idling and optimizing engine operation to use less fuel and reduce air pollution. HHV technology has been demonstrated and field tested in a number of vehicles, including package delivery vehicles and reuse trucks. EPA believes this vehicle design can improve the efficiency of the yard hostler operation by 50-60 percent.

Several EPA programs, including the National Clean Diesel Campaign and its Clean Ports USA, Clean Automotive Technology, Office of International Affairs, and EPA Region 2 (New York and New Jersey) collaborated on this project. Industry technical partners include APM Terminals, Parker-Hannifin, Kalmar Industries, FEV Inc., R. H. Sheppard Co Inc., and Webasto. Additional support was provided by the Port Authority of New York and the New Jersey Department of Environmental Protection.

More information about the program and EPA technologies can be found at http://www.epa.gov/otaq/technology.